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## Interactive telemedicine: effects on professional practice and health care outcomes (Review)

Flodgren G, Rachas A, Farmer AJ, Inzitari M, Shepperd S

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## [Intervention Review]

# Interactive telemedicine: effects on professional practice and health care outcomes

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## ABSTRACT

### Background

Telemedicine (TM) is the use of telecommunication systems to deliver health care at a distance. It has the potential to improve patient health outcomes, access to health care and reduce healthcare costs. As TM applications continue to evolve it is important to understand the impact TM might have on patients, healthcare professionals and the organisation of care.

### Objectives

To assess the effectiveness, acceptability and costs of interactive TM as an alternative to, or in addition to, usual care (i.e. face-to-face care, or telephone consultation).

### Search methods

We searched the Effective Practice and Organisation of Care (EPOC) Group's specialised register, CENTRAL, MEDLINE, EMBASE, five other databases and two trials registers to June 2013, together with reference checking, citation searching, handsearching and contact with study authors to identify additional studies.

### Selection criteria

We considered randomised controlled trials of interactive TM that involved direct patient-provider interaction and was delivered in addition to, or substituting for, usual care compared with usual care alone, to participants with any clinical condition. We excluded telephone only interventions and wholly automatic self-management TM interventions.

### Data collection and analysis

For each condition, we pooled outcome data that were sufficiently homogenous using fixed effect meta-analysis. We reported risk ratios (RR) and 95% confidence intervals (CI) for dichotomous outcomes, and mean differences (MD) for continuous outcomes.

### Main results

We included 93 eligible trials (N = 22,047 participants), which evaluated the effectiveness of interactive TM delivered in addition to (32% of studies), as an alternative to (57% of studies), or partly substituted for usual care (11%) as compared to usual care alone.

The included studies recruited patients with the following clinical conditions: cardiovascular disease (36), diabetes (21), respiratory conditions (9), mental health or substance abuse conditions (7), conditions requiring a specialist consultation (6), co morbidities (3), urogenital conditions (3), neurological injuries and conditions (2), gastrointestinal conditions (2), neonatal conditions requiring specialist care (2), solid organ transplantation (1), and cancer (1).

Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination. The main TM function varied depending on clinical condition, but fell typically into one of the following six categories, with some overlap: i) monitoring of a chronic condition to detect early signs of deterioration and prompt treatment and advice, (41); ii) provision of treatment or rehabilitation (12), for example the delivery of cognitive behavioural therapy, or incontinence training; iii) education and advice for self-management (23), for example nurses delivering education to patients with diabetes or providing support to parents of very low birth weight infants or to patients with home parenteral nutrition; iv) specialist consultations for diagnosis and treatment decisions (8), v) real-time assessment of clinical status, for example post-operative assessment after minor operation or follow-up after solid organ transplantation (8) vi), screening, for angina (1).

The type of data transmitted by the patient, the frequency of data transfer, (e.g. telephone, e-mail, SMS) and frequency of interactions between patient and healthcare provider varied across studies, as did the type of healthcare provider/s and healthcare system involved in delivering the intervention.

We found no difference between groups for all-cause mortality for patients with heart failure (16 studies; N = 5239; RR:0.89, 95% CI 0.76 to 1.03, P = 0.12; I<sup>2</sup> = 44%) (moderate to high certainty of evidence) at a median of six months follow-up. Admissions to hospital (11 studies; N = 4529) ranged from a decrease of 64% to an increase of 60% at median eight months follow-up (moderate certainty of evidence). We found some evidence of improved quality of life (five studies; N = 482; MD:-4.39, 95% CI -7.94 to -0.83; P < 0.02; I<sup>2</sup> = 0%) (moderate certainty of evidence) for those allocated to TM as compared with usual care at a median three months follow-up. In studies recruiting participants with diabetes (16 studies; N = 2768) we found lower glycated haemoglobin (HbA1c %) levels in those allocated to TM than in controls (MD -0.31, 95% CI -0.37 to -0.24; P < 0.00001; I<sup>2</sup> = 42%, P = 0.04) (high certainty of evidence) at a median of nine months follow-up. We found some evidence for a decrease in LDL (four studies, N = 1692; MD -12.45, 95% CI -14.23 to -10.68; P < 0.00001; I<sup>2</sup> = 0%) (moderate certainty of evidence), and blood pressure (four studies, N = 1770: MD: SBP:-4.33, 95% CI -5.30 to -3.35, P < 0.00001; I<sup>2</sup> = 17%; DBP: -2.75 95% CI -3.28 to -2.22, P < 0.00001; I<sup>2</sup> = 45% (moderate certainty evidence), in TM as compared with usual care.

Seven studies that recruited participants with different mental health and substance abuse problems, reported no differences in the effect of therapy delivered over video-conferencing, as compared to face-to-face delivery. Findings from the other studies were inconsistent; there was some evidence that monitoring via TM improved blood pressure control in participants with hypertension, and a few studies reported improved symptom scores for those with a respiratory condition. Studies recruiting participants requiring mental health services and those requiring specialist consultation for a dermatological condition reported no differences between groups.

## Authors' conclusions

The findings in our review indicate that the use of TM in the management of heart failure appears to lead to similar health outcomes as face-to-face or telephone delivery of care; there is evidence that TM can improve the control of blood glucose in those with diabetes. The cost to a health service, and acceptability by patients and healthcare professionals, is not clear due to limited data reported for these outcomes. The effectiveness of TM may depend on a number of different factors, including those related to the study population e.g. the severity of the condition and the disease trajectory of the participants, the function of the intervention e.g., if it is used for monitoring a chronic condition, or to provide access to diagnostic services, as well as the healthcare provider and healthcare system involved in delivering the intervention.

## PLAIN LANGUAGE SUMMARY

### Interactive telemedicine: effects on professional practice and healthcare outcomes

#### Background

Telemedicine uses telecommunication systems to deliver health care at a distance. This method of delivering health care may improve patient health outcomes, access to health care and reduce costs. It is important to understand the impact that care at a distance via telemedicine might have on patients, healthcare professionals and the organisation of care.

#### Review question

We assessed the effectiveness, acceptability, and costs of interactive telemedicine, delivered in addition to, or as an alternative to, usual care as compared to usual care alone.

#### Study characteristics

Researchers in The Cochrane Collaboration searched the literature up to June 2013 and found 93 eligible randomised controlled trials (N = 22,047 participants). The studies recruited participants with a number of clinical conditions: cardiovascular disease (36 studies), diabetes (21 studies), respiratory conditions (nine studies), mental health problems or substance abuse (seven studies), conditions requiring a

specialist consultation (six studies), complex co morbidities (three studies), urogenital conditions (three studies), neurological injuries and conditions (two studies), gastrointestinal conditions (two studies), neonatal conditions requiring specialist care (two studies), patients recovering after solid organ transplantation (one study) and cancer (one study).

Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination. The main telemedicine function varied depending on clinical condition, but fell typically into one of the following six categories, with some overlap: i) monitoring of a chronic condition to detect early signs of deterioration and prompt treatment and advice; ii) provision of treatment or rehabilitation, for example stroke rehabilitation; iii) education and advice for self-management; iv) specialist consultations; v) real-time assessment of clinical status, for example post-operative assessment after minor operation vi); screening for depression or angina.

### Key results

We found no difference in mortality between participants with heart failure receiving care through telemedicine, compared to those receiving health care without telemedicine. The results of the studies differed for admissions to hospital, from a relative decrease of 64% to an increase of 60%. Disease-specific quality of life was slightly improved for heart failure participants receiving telemedicine as compared to those receiving usual care only.

We found that telemedicine may improve glucose control in people with diabetes (mean difference (MD) 0.30 percentage points), but that the effect varied across studies: from a MD of -0.72 to 0.20 percentage points at a median nine months follow-up. We found some evidence for a decrease in LDL cholesterol, which is considered the 'bad' cholesterol, in participants allocated to telemedicine as compared to those allocated to usual care (MD -12.45 mg/dL). We also found a greater decrease in blood pressure in those allocated to telemedicine compared to those that were allocated to usual care.

Seven studies that recruited participants with different mental health and substance abuse problems reported no differences in the effect of therapy delivered over video-conferencing, as compared to face-to-face delivery. Findings from the other studies varied; there was some evidence that monitoring via telemedicine improved blood pressure control in participants with hypertension, and a few studies reported improvement for those with a respiratory condition. Studies recruiting participants requiring specialist consultation for a dermatological condition reported no differences between groups.

### Certainty of the evidence

We were able to summarise data from 16 studies recruiting people with heart failure (high to moderate certainty of evidence) and from 21 studies recruiting people with diabetes (high to low certainty of evidence). The results from these studies provide a good indication of the likely effect of using telemedicine to deliver health care to people with these conditions on health outcomes. The findings from the other studies are less certain, due to a relatively small number of studies recruiting participants with other clinical conditions.

## SUMMARY OF FINDINGS

### Summary of findings for the main comparison.

**Interactive telemedicine (TM) delivered in addition to, or as an alternative to, usual care (UC) compared with UC alone for people with heart failure**

**Patient or population:** people with heart failure

**Settings:** primary-, secondary-, tertiary- and community-care settings

**Intervention:** remote monitoring of chronic condition; and/or education and consultation using video-conferencing

**Comparison:** usual heart failure care

Outcomes	Intervention Effect	No and type of sites	No of studies (participants)	Certainty of the evidence (GRADE)	Comments
<b>Mortality (all-cause)</b>	RR (95% CI): 0.89 (0.76 to 1.03), P = 0.12 at a median of 6 months follow-up (range:3 to 26) see <a href="#">Analysis 1.1</a>	In 10 studies participants were recruited from hospital, and in 6 studies from a clinic. The intervention was delivered in a home setting in the 16 studies.	16 RCTs (n = 5239 )	⊕⊕⊕⊕ High	There was moderate heterogeneity ( $I^2 = 44\%$ , P = 0.03).
<b>Admission to hospital (all-cause)</b>	RRs ranged from 0.36 to 1.60. Median follow-up was 8 months (range 3 to 26 months) see <a href="#">Analysis 1.3</a>	In 6 studies participants were recruited from hospital, in 4 studies from a clinic and in 1 study from home. The intervention was delivered in a home setting in the 11 studies.	11 RCTs (n = 4529)	⊕⊕⊕⊖ <sup>1</sup> Moderate	We did not retain the meta-analysis due to a high level of statistical heterogeneity ( $I^2 = 67\%$ , P = 0.0008). We report the range of RRs.
<b>Disease-specific quality of life (QoL)</b>	MD:-4.39 [-7.94 to -0.83], P = 0.02 at a median of 3 months follow-up (range 3 to 6 months) see <a href="#">Analysis 1.2</a>	In 4 studies participants were recruited from hospital, and in 1 study from a clinic. The intervention was delivered in a home setting in the 5 studies.	5 RCTs (n = 482)	⊕⊕⊕⊖ <sup>2</sup> Moderate	Most studies used the Minnesota Living with Heart Failure (MLHF) questionnaire to assess QoL; data (when available) were pooled in a meta-analysis. Data from five studies using the MLHF could not be pooled. One study, using the Kansas City Cardiac Questionnaire, reported improvement in the TM group.

<sup>1</sup> We downgraded the certainty of the evidence due to inconsistency.

<sup>2</sup> We downgraded the evidence one step due to only 20% of studies reporting this outcome.

**CI:** Confidence interval; **MD:** mean difference; **RR:** Risk Ratio

GRADE Working Group grades of evidence

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is low.

**Moderate:** This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is moderate.

**Low:** This research provides some indication of the likely effect. However, the likelihood that it will be substantially different<sup>†</sup> is high.

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is very high.<sup>†</sup>

Substantially different = a large enough difference that it might affect a decision

## Summary of findings 2.

**Interactive telemedicine (TM) delivered in addition to, or as an alternative to, usual care (UC) compared with UC alone for people with diabetes**

**Patient or population:** adults, adolescents and children with Type 1 or Type 2 diabetes

**Settings:** primary-, secondary-, tertiary- and community-care settings

**Intervention:** remote monitoring systems for chronic condition, and/or education for self-management using video-conferencing

**Comparison:** usual diabetes care

Outcomes	Intervention effect	No and type of sites	No of studies (participants)	Certainty of the evidence (GRADE)	Comments
<b>HbA1c (%)</b>	MD (95% CI): -0.31 (-0.37 to -0.24) at median 9 months follow-up (range: 3 to 12 months) see <a href="#">Analysis 2.1</a>	In 15 studies participants were recruited from an out-patient clinic, and in 1 study from a community health centre.	16 RCTs (n = 2768)	⊕⊕⊕⊕ High	There was moderate heterogeneity ( $I^2=42\%$ ; $P=0.04$ )
<b>LDL cholesterol</b>	MD (95% CI): -12.45 (-14.23 to -10.68) mg/dL, $P<0.00001$ , at median 9-month follow-up (range: 6 to 12 months). see <a href="#">Analysis 2.2</a>	In 3 studies participants were recruited from an out-patient clinic, and in 1 from a community health centre.	4 RCTs (n = 1 692)	⊕⊕⊕⊖ <sup>1</sup> Moderate	Four out of 21 studies reported LDL data that could be pooled in a meta-analysis.
<b>Blood pressure</b>	MD (95% CI): SBP: -4.33 (-5.30 to -3.35) mmHg, $P<0.00001$ DBP: -2.75 (-3.28 to -2.22) mmHg, $P<0.00001$ at median 9-month follow-up (range: 6 to 12 months).	In 3 studies participants were recruited from an out-patient clinic, and in 1 study from a community health centre.	4 RCTs (n = 1770)	⊕⊕⊕⊖ <sup>1</sup> Moderate	Four out of 21 included studies reported blood pressure data that could be pooled in a meta-analysis.



see [Analysis 2.6](#); [Analysis 2.7](#)

<b>Disease-specific Quality of Life (QoL)</b>	Mixed effects: two studies reported a beneficial effect of TM on disease-specific QoL as compared with UC, and three studies reported no differences between groups <sup>3</sup>	In all 5 studies participants were recruited from an out-patient clinic.	5 RCTs (n = 277)	⊕⊕⊕⊕ <sup>2</sup> Low	Five out of 21 studies reported disease-specific QoL, none reported data that could be pooled in a meta-analysis.
<b>Healthcare resource use and cost</b>  (ED and urgent care visits, outpatient visits, telephone calls, consultation time; no of eye examinations)	Three studies reported no difference between groups in healthcare resource use, one study less consultation time and lower cost to the health service in the TM group and one less travel time for patients. Three studies reported a small reduction in cost to the health service, and one a small increase.	In 8 studies participants were recruited from an out-patient clinic, and in 1 study from a community health centre.	9 RCTs (n = 2208)	⊕⊕⊕⊕ <sup>3</sup> Low	Nine out of 21 studies reported on different measures of healthcare resource use and/or cost to the health service.
<b>Adverse clinical events</b>  (hypoglycaemic and hyperglycaemic events)	Six studies reported no differences between groups in the proportion of people who experienced hypoglycaemic and/or hyperglycaemic events between groups.	In all six studies participants were recruited from an out-patient clinic.	6 RCTs (n = 453)	⊕⊕⊕⊕ <sup>4</sup> Moderate	Six out of 21 studies reported on adverse events.

<sup>1</sup> We downgraded the evidence due to only 20% of included studies reporting the outcome.

<sup>2</sup> We downgraded the evidence two steps, due to inconsistency and few studies reporting this outcome.

<sup>3</sup> We downgraded the evidence two steps, due to inconsistency and small sample size.

<sup>4</sup> We downgraded the evidence one step due to only 29% of studies reporting this outcome.

**UC:** usual care; **CI:** Confidence interval; **MD:** mean difference

GRADE Working Group grades of evidence

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is low.

**Moderate:** This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is moderate.

**Low:** This research provides some indication of the likely effect. However, the likelihood that it will be substantially different<sup>†</sup> is high.

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different<sup>†</sup> is very high.<sup>†</sup>

Substantially different = a large enough difference that it might affect a decision

DBP: diastolic blood pressure; ED: emergency department; LDL: low-density lipoprotein; SBP: systolic blood pressure

## BACKGROUND

Increased access to telecommunications has been accompanied by a range of applications to deliver health care at a distance ([Bashshur 2005](#)); this is often described as telemedicine (TM). Examples include the provision of specialist consultations via video-conferencing, remote monitoring of patients with chronic conditions and the provision of clinical information for self-management. Telemedicine applications may also be linked to electronic patient records. Systems that can transmit large volumes of complex data at speed, including pictures and sound, using fixed and mobile devices, are now widespread.

### Description of the intervention

Telemedicine technology can be broadly grouped into three categories: (i) remote monitoring, (ii) store-and-forward, and (iii) interactive TM ([Casas 2010](#)). A combination of these technologies may be used and the model of care chosen will depend on organisational factors and clinical need ([Anker 2011](#)).

#### (i) Remote monitoring

Technologies, such as mobile phones, can be used to monitor the health of patients with long-term conditions by transferring clinical data. This allows the clinician, the patient, or both, to respond and adjust treatment regimens in a more immediate way than would be possible with, for example, routine clinic visits. Some TM systems may be designed with automated voice response software to give instructions to patients, others may alert health professionals and/or a patient to clinical values outside an acceptable range and, in other systems, a health professional may respond immediately.

#### (ii) Store and forward applications

These systems transmit clinical data to be analysed at a later date, and may also be used if there is intermittent connectivity. These technologies have been in use for many years, for example in dermatology, pathology, and radiology ([Arenson 2000](#); [Collins 2004](#); [Weinstein 2009](#)). Electronic images and clinical data are transmitted to a clinician remote from the participant, and stored for them to access at any time; the clinician may then return their report electronically, or have a face-to-face or telephone consultation with the patient and/or another clinician. The wide availability of e-mail and digital imaging systems for radiology and pathology has increased the use of these applications ([Anker 2011](#)).

#### (iii) Interactive telemedicine (TM) (real-time)

In these applications, clinicians and patients are able to exchange information and communicate in real-time. Clinical data might be provided from patient self-monitoring devices, digital camera or X-ray images. The consulting clinician might be in a tertiary centre or in a dedicated TM centre; the patient may be at home or in a healthcare facility.

We limited our review to studies that evaluate the use of TM in direct patient care in which the recipient is remote from the clinician and communication is interactive and occurs within an episode of care. For example, a patient transferring ECG data, using a 12-lead ECG recorder, and a healthcare professional responding by calling the patient to discuss interpretation of the data. Reviews of a broader range of TM interventions have been published in particular clinical areas, for example in patients with diabetes or asthma ([McLean 2010](#); [McLean 2011](#)). In the present review, we have

used the term *interactive telemedicine*, to include technologies in which health professionals do not necessarily respond in real-time, but do respond to the transmission of information from a patient.

### How the intervention might work

Telemedicine delivers clinical information, and permits consultation and discussion between healthcare professionals and patients regardless of where the patient is located. The aim of using TM varies with different TM applications, for example it may increase access to health care by allowing access to specialist health care that would not otherwise be possible. Patients can be monitored more often with TM and appropriate interventions delivered more quickly and effectively. Telemedicine may also support patients and their carers to be more involved in their own care. All these mechanisms might improve patient health outcomes.

### Why it is important to do this review

The use of TM has the potential to improve patient health outcomes, reduce the cost of health care, change the way health care is organised and improve access to health care. Although the technology has developed dramatically, and a large number of clinical studies are being published, there is still uncertainty about the effectiveness of TM in specific clinical situations (e.g. [Paré 2010](#); [Polisena 2009](#)), and how it should be brought into mainstream health service provision ([OECD 2010](#); [Stroetman 2010](#)).

The implementation of TM can be a challenge ([Mair 2000](#); [May 2003](#); [May 2011](#); [Nicolini 2006](#)). Problems reported in the literature include difficulty with fitting TM into routine practice (i.e. disruption of work flows), problems in the interaction between healthcare professionals, resistance to changing tasks/responsibilities, disagreements within an organisation about whether or not TM is an appropriate care delivery model, and problems related to the building, co-ordinating and sustaining of TM services in addition to the existing care delivery system ([de Bont 2008](#); [May 2003](#); [May 2011](#)). Questions also remain about the acceptability of TM by patients ([Kaplan 2008](#)), and whether the lack of visual cues may have an adverse effect on the patient-clinician interaction.

Several reviews, evaluating different types of TM technologies (and telephone consultations), have been published (e.g. [Balas 1997](#); [Bashshur 1975](#); [Hersh 2001](#); [McLean 2010](#); [McLean 2011](#); [Polisena 2009](#); [Polisena 2010](#); [Polisena 2010a](#); [Taylor 1998a](#); [Taylor 1998b](#)). One review reported improved outcomes of using TM in the delivery of cardiac rehabilitation and diabetes care ([Balas 1997](#)). One review ([Hersh 2001](#)) reported improved clinical outcomes of TM in hypertension, but conflicting evidence for the effectiveness in diabetes. One review focusing on asthma ([McLean 2010](#)) reported no differences in quality of life or in the number of emergency department (ED) visits, but a lower hospitalisation rate for patients receiving TM, compared with the control group. Two reviews ([McLean 2011](#); [Polisena 2010a](#)) reported fewer ED visits and hospitalisations in chronic obstructive pulmonary disease (COPD) patients receiving TM as compared to control, and improved quality of life ([McLean 2011](#)). Another review by Polisena and colleagues ([Polisena 2010](#)), reported decreased mortality and lower healthcare use for participants with heart failure receiving TM. One review ([Polisena 2009](#)), reported reduced number of patients admitted to

hospital and fewer hospital bed days for patients receiving home TM.

This is an update of a Cochrane Review, that included seven studies, published in 2000 (Currell 2000).

## OBJECTIVES

To assess the effectiveness, acceptability and costs of interactive telemedicine (TM), either in addition to, or as an alternative to usual care. Usual care is the provision of health care by face-to-face consultation or by telephone consultation.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) and cluster-randomised trials (cluster RCTs), that test the effectiveness of interactive telemedicine (TM). We excluded RCTs testing the feasibility of the TM technology and recruiting less than 10 participants in each study arm.

#### Types of participants

1. Patients receiving interactive TM from any qualified healthcare practitioner, compared with those receiving usual care.
2. Healthcare professionals from any discipline providing patient care through interactive TM.

#### Types of interventions

Telemedicine used in direct patient care, in which the patient is at a different location to the healthcare professional and transmits clinical information via a telecommunication technology and the healthcare professional responds. The comparison interventions include a face-to-face consultation, or telephone consultation with a qualified healthcare professional.

We excluded the following.

1. Studies that compared different technical specifications of telecommunications technologies.
2. Studies in which the use of telecommunications technology was not linked to direct patient care.
3. Studies in which the patient was not physically present at either point of care, e.g. studies evaluating the electronic transmission of X-ray images or pathology results for routine reporting for example, 'store and forward' systems with no interaction between the patient and healthcare professional.
4. Patient monitoring systems in which the patient received only an automated voice response.
5. Interventions targeted exclusively at carers.
6. Telephone only interventions as for some conditions usual follow-up care routinely includes telephone follow-up.

#### Types of outcome measures

##### Primary outcomes

1. Mortality.
2. Disease-specific and general measures of health status using validated measures (to include both clinical measures that

are used to monitor patients' response to treatment and questionnaire assessed quality of life measures).

3. Healthcare resource use.
4. Costs.

##### Secondary outcomes

Patient and healthcare professional acceptability and satisfaction measured with a validated scale.

### Search methods for identification of studies

#### Electronic searches

M.Fiander, the Cochrane Effective Practice and Organisation of Care (EPOC) group's Trials Search Co-ordinator (TSC), developed the search strategy in consultation with the review authors. The TSC searched the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews and the databases listed below for primary studies. Exact search dates for each database are included with the search strategies in Appendix 1.

#### Databases

1. EPOC Group, Specialised Register, June 2013.
2. The Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, 2013, Issue 6.
3. Health Technology Assessment Database, *The Cochrane Library*, 2013, Issue 6.
4. NHS Economic Evaluation Database, *The Cochrane Library*, 2013, Issue 6.
5. MEDLINE, 1948-, June 2013 In-Process and other non-indexed citations, OvidSP.
6. EMBASE, 1947 - June 2013, OvidSP.
7. CINAHL (Cumulative Index to Nursing and Allied Health Literature), 1980 to June 2013, EbscoHost
8. PubMed <http://www.ncbi.nlm.nih.gov/pubmed/> June 2013.

We did not apply date or language restrictions. All databases were searched from database inception.

Two methodological search filters were used to limit retrieval to appropriate study designs: the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximizing version, 2008 revision) (Lefebvre 2011) to identify randomised trials.

#### Searching other resources

##### Gray Literature

We searched the following websites: the *Institute of Health Economics* ( <http://www.ihe.ca/> ) and the *Agence d'Évaluations des Technologies et des modes d'intervention en* ( AETMIS ) using the term telemedicine and variations (accessed June 2013).

##### Trial Registries

We searched ClinicalTrials.gov, US National Institutes of Health (NIH) <http://clinicaltrials.gov/> in June 2013, with no date or language restrictions.

In addition, we also carried out the following searches.

1. Screened individual journals and conference proceedings (e.g. we handsearched the *Journal of Telemedicine and Telecare* and the *Telemedicine Journal and e-Health* from 2000 to 2009) (RC and CU).
2. Reviewed reference lists of all included studies, relevant systematic reviews and primary studies.
3. Contacted authors of relevant studies/ reviews to clarify reported published information and to seek unpublished results/data.
4. Contacted researchers with expertise relevant to the review topic/ EPOC interventions.
5. Conducted cited reference searches for all included studies in ISI Web of Knowledge.

## Data collection and analysis

### Selection of studies

Two review authors (GF, SS) and two authors of the previous version of this review (RC, CU) independently screened studies against the eligibility criteria. We directly excluded irrelevant studies not meeting the inclusion criteria and obtained the full text of possible relevant citations. At least two review authors independently assessed the eligibility of the full text studies retrieved. We resolved disagreements by discussion among the review authors. We contacted authors of original papers by e-mail to request additional data or information. In the case of no response, we sent two e-mail reminders.

### Data extraction and management

Two review authors independently extracted data from each included study using a revised version of the EPOC data collection checklist (EPOC 2013a). We resolved disagreements by discussion among the review authors. We extracted the following information: citation, study design, setting, participants, type of intervention, comparison intervention and outcomes.

### Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias of each included study using the Cochrane Risk of Bias tool (EPOC 2013b). This includes an assessment of sequence generation, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data and selective outcome reporting (Higgins 2011). We assessed the overall risk of bias of each main outcome and study (high, moderate or low risk of bias) using the approach suggested in the *Cochrane Handbook for Systematic Reviews of Interventions* (Chapter 8; Higgins 2011). For studies with low risk of bias for all key domains, or where it seemed unlikely for bias to seriously alter the results, we judged the overall risk of bias to be low. For studies where risk of bias in at least one domain was unclear, or judged to have some bias that could plausibly raise doubts about the conclusions, we considered the overall risk of bias to be unclear. Studies with a high risk of bias in at least one domain, or judged to have serious bias that decreased the certainty of the conclusions, were considered to have a high risk of bias. We resolved disagreements by discussion among the review authors.

### Measures of treatment effect

Where it was possible to combine data from different studies, we reported dichotomous outcomes as risk ratios (RR). For continuous outcomes we used mean differences (MD) to summarise the data,

and if the studies had reported an outcome in different scales we planned to use standardised mean differences (SMD). For outcomes that could not be combined, mainly due to limited reporting of data, we presented a narrative summary of the results. We presented the results for the main outcomes in 'Summary of findings' tables.

### Unit of analysis issues

If a cluster-randomised trial had been analysed as if the randomisation was performed on individuals rather than clusters, we would have calculated an approximately correct analysis, if the required information was available, on the size and number of clusters and the value of the intra-cluster correlation coefficient.

### Dealing with missing data

We attempted to contact the corresponding author by e-mail to locate missing data. We did not attempt to impute missing data.

### Assessment of heterogeneity

We assessed heterogeneity between trials by comparing the characteristics of the study populations, interventions and outcome measures; and by visual inspection of forest plots, noting where there was poor overlap of the confidence intervals and by using statistical measures: the  $\chi^2$  to test for statistical heterogeneity and the  $I^2$  level for inconsistency among trials. We considered  $I^2$  values of greater than 50% as significant heterogeneity (Higgins 2011).

### Assessment of reporting biases

We explored publication bias using funnel plots, recognising that these plots help to assess the relationship between effect size and study precision and are not necessarily indicative of publication bias.

### Data synthesis

Where possible, we pooled data (reported as (RR) using a fixed-effect meta-analysis model. We used MD when combining continuous data. We conducted a separate analysis for each distinct clinical group of patients recruited to the included RCTs (see [Subgroup analysis and investigation of heterogeneity](#)). The studies included in the main analyses (see [Data collection and analysis](#)) were, when possible, subgrouped based on type of TM reflecting the subgroups listed below. However, too few studies were included in each group, to permit a comparison between subgroups.

### Subgroup analysis and investigation of heterogeneity

We grouped studies by clinical condition: cardiovascular disease (within this group we analysed data separately for heart failure, an acute cardiac event, cardiac surgery or a cardiac procedure, hypertension and stroke); diabetes; respiratory conditions; mental health problems; and a mix of other conditions i.e. one or two trials recruiting patients with different conditions; for example, patients with co-morbidities; gastrointestinal conditions; urological conditions; which recruited a small number of participants (Total N = 3572).

### Sensitivity analysis

We did not conduct any sensitivity analyses.

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## RESULTS

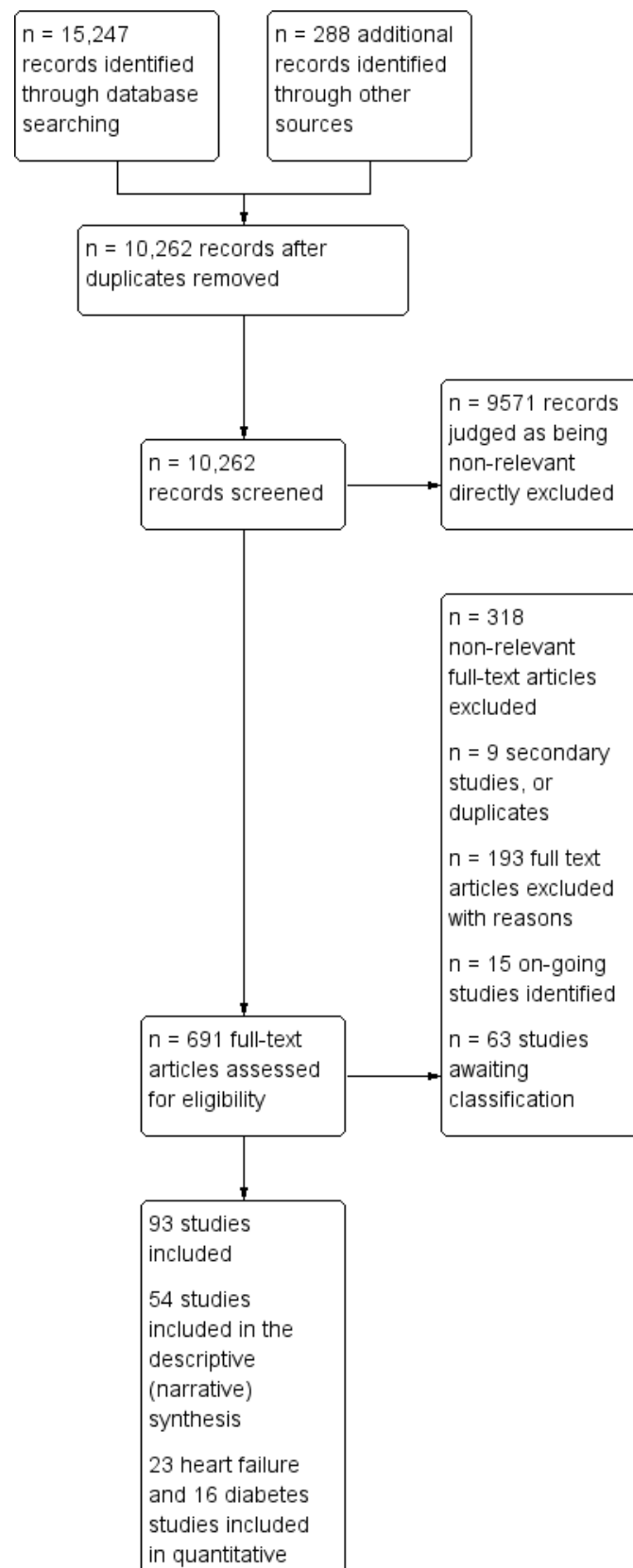
### Description of studies

We included 93 randomised controlled trials (RCTs) evaluating the effectiveness of interactive telemedicine (TM).

### Results of the search

See PRISMA study flow chart [Figure 1](#), and [Characteristics of included studies](#) table and list of [Excluded studies](#).

**Figure 1. Study flow diagram.**





**Figure 1. (Continued)**

studies included  
in quantitative  
(meta-analyses)  
synthesis

The electronic searches yielded 9974 citations after removal of duplicates. Searching other sources resulted in 288 additional citations. Of a total 10,262 citations, 9571 citations were deemed irrelevant and immediately excluded and 691 citations were considered as possibly relevant and full text retrieved. After scrutiny, 318 studies were found to be irrelevant and were excluded, nine studies were secondary or duplicates, and 193 studies excluded with reasons. Fifteen studies were classified as ongoing and 93 studies (including three of the previously included studies) were found eligible and subsequently included in the review. Sixty-three studies are listed under studies awaiting classification and will be assessed at the next review update scheduled for next year.

## Included studies

### Characteristics of the study populations and settings

See summary [Table 1](#), [Table 2](#); [Table 3](#); [Table 4](#); [Table 5](#); [Table 6](#); [Table 7](#); [Table 8](#); [Table 9](#) and [Characteristics of included studies](#) tables for details.

Thirty-six of the 93 included studies (39%) recruited participants with cardiovascular disease (N = 12, 317); 25 of these studies recruited patients with heart failure ([Antoncelli 2008](#); [Benatar 2003](#); [Bowles 2011](#); [Boyne 2012](#); [Capomolla 2004](#); [Chaudry 2010](#); [Cleland 2005](#); [Dansky 2008](#); [Dar 2009](#); [Dendale 2012](#); [Giordano 2009](#); [Goldberg 2003](#); [Jerant 2001](#); [Kashem 2008](#); [Koehler 2011](#); [Madigan 2013](#); [Mortara 2009](#); [Scherr 2009](#); [Schwarz 2008](#); [Seto 2012](#); [Soran 2008](#); [Spaeder 2006](#); [Wakefield 2008](#); [Weintraub 2010](#); [Woodend 2008](#)); five studies recruited patients (N = 4268) following an acute cardiac event, cardiac surgery or procedure ([Al Khatib 2009](#); [Chiantera 2005](#); [Crossley 2011](#); [Halimi 2008](#); [Waldmann 2008](#)); four studies recruited patients (N = 1 073) with hypertension ([Artinian 2007](#); [Madsen 2008](#); [Parati 2009](#); [Rogers 2001](#)) and two studies recruited patients (N = 260) recovering from a stroke ([Piron 2009](#); [Meyer 2008](#)).

Twenty-one of the 93 (23%) included studies evaluated TM interventions aimed at improving care for people (N = 3412) with diabetes ([Ahling 1992](#); [Biermann 2000](#); [Boaz 2009](#); [Bond 2007](#); [Charpentier 2011](#); [Chase 2003](#); [Davis 2010](#); [Izquierdo 2003](#); [Izquierdo 2009](#); [Jansa 2006](#); [Kim 2007](#); [Kwon 2003](#); [Marrero 1995](#); [McCarrier 2009](#); [McMahon 2005](#); [Ralston 2009](#); [Rodriguez-Idigoras 2009](#); [Shea 2006](#); [Stone 2010](#); [Whitlock 2000](#); [Wojcicki 2001](#)). One study ([Wojcicki 2001](#)), recruited pregnant women with Type 1 diabetes, nine participants with Type 1 diabetes ([Ahling 1992](#); [Biermann 2000](#); [Charpentier 2011](#); [Chase 2003](#); [Izquierdo 2009](#); [Jansa 2006](#); [Marrero 1995](#); [McCarrier 2009](#); [Wojcicki 2001](#)), six participants with Type 2 diabetes ([Kim 2007](#); [Kwon 2003](#); [Ralston 2009](#); [Rodriguez-Idigoras 2009](#); [Stone 2010](#); [Whitlock 2000](#)), and six participants with Type 1 and Type 2 diabetes ([Boaz 2009](#); [Bond 2007](#); [Davis 2010](#); [Izquierdo 2003](#); [McMahon 2005](#); [Shea 2006](#)). Fifteen studies recruited adults ([Boaz 2009](#); [Bond 2007](#); [Charpentier 2011](#); [Davis 2010](#); [Izquierdo 2003](#); [Kim 2007](#); [Kwon 2003](#); [McCarrier 2009](#); [McMahon 2005](#); [Ralston 2009](#); [Rodriguez-Idigoras 2009](#); [Shea 2006](#); [Stone 2010](#); [Whitlock 2000](#); [Wojcicki 2001](#)), three studies

young people ([Chase 2003](#); [Izquierdo 2009](#); [Marrero 1995](#)), and three studies both adults and adolescents ([Ahling 1992](#); [Biermann 2000](#); [Jansa 2006](#)).

Nine studies (N = 1115 participants) evaluated the use of TM for the management of respiratory disease. Five of these studies ([Chan 2007](#); [Jan 2007](#); [Rasmussen 2005](#); [Van der Meer 2010](#); [Willems 2008](#)), recruited participants with asthma (N = 825), three studies ([Koff 2009](#); [Lewis 2010](#); [Nguyen 2008](#)), participants with COPD (N = 130), and one study ([Taylor 2006](#)), recruited participants (N = 160) with obstructive sleep apnoea. Seven studies (N = 738) ([Chong 2012](#); [De Las Cuevas 2006](#); [King 2009](#); [Mitchell 2008](#); [Morland 2010](#); [Poon 2005](#); [Ruskin 2004](#)), recruited people with different mental health problems, three recruited older people (N = 209) with more than one chronic condition and who were receiving home care ([Finkelstein 2006](#); [Hopp 2006](#); [Noel 2004](#)).

Seventeen trials recruited participants (N = 4256) with a range of different conditions; these included three studies (N = 505) ([Bergmo 2009](#); [Oakley 2000](#); [Wootton 2000](#)) that recruited participants with dermatological conditions; two studies that recruited very low birth weight infants requiring specialist care (and their parents/families) (one study; N = 56, [Gray 2000](#)) and one neonates with congenital heart disease (one study; N = 59, [McCrossan 2012](#)); people visiting the emergency department (ED) with a mix of conditions (one study; N = 475, [Wong 2006](#)); participants with a spinal cord injury (one study; N = 137, [Dallolio 2008](#)); people with different neurological conditions or injuries (one study; N = 81, [Hermens 2007](#)); participants attending outpatient clinics for a specialist consultation or procedure (orthopaedics, urology, gastroenterology, otolaryngology specialists) (two studies; N = 2226, [Harrison 1999](#); [Wallace 2002](#)); participants receiving home parenteral nutrition (one study; N = 30, [Chambers 2006](#)); people with ulcerative colitis (one study; N = 47, [Cross 2012](#)); participants scheduled for elective laparoscopic or percutaneous urologic procedures (two studies; N = 326, [Ellison 2004](#); [Ellison 2007](#)); participants with urinary incontinence (one study; N = 64, [Hui 2006](#)); participants with breast, lung or colorectal cancer receiving outpatient chemotherapy (one study; N = 112, [Kearney 2009](#)); participants recovering after solid organ transplantation (one study; N = 138, [Thompson 2009](#)).

Twenty studies were conducted in primary or community care, 34 in acute hospitals, 28 in outpatient clinics, four in both acute and primary care or community settings, and in seven studies the setting was unclear.

In all but 11 studies, the patient used the TM system (mobile phone or the Internet) in his or her own home. In the other studies TM was used in an ED ([Meyer 2008](#); [Wong 2006](#)), a GP's office ([Harrison 1999](#); [Wallace 2002](#)), a local health centre ([Oakley 2000](#); [Wootton 2000](#)), a urologic clinic ([Ellison 2004](#); [Ellison 2007](#)), locations remote to the main transplantation clinic ([Thompson 2009](#)), a community centre ([Hui 2006](#)), or a school nurse office ([Izquierdo 2009](#)).



Studies were based in North America (50 in the USA, two in Canada); 35 studies in Europe (seven in Italy, three in Denmark, three in Spain, three in Germany, one in France, one in Austria, one in Norway, seven in the UK, one in Northern Ireland, two in The Netherlands, one in Belgium, one in Poland and four in more than one country), and one study in Israel, one in China, two in Hong-Kong and two in South Korea.

## Description of the intervention

### Function of telemedicine (TM)

The main TM function varied depending on the clinical condition, but fell typically into one of the following six categories, with some overlap.

#### i) Monitoring of a chronic condition to detect early signs of deterioration and prompt treatment and advice (41 studies).

In 22 studies recruiting participants with heart failure (Antonicelli 2008; Benatar 2003; Bowles 2011; Boyne 2012; Capomolla 2004; Chaudry 2010; Cleland 2005; Dansky 2008; Dendale 2012; Dar 2009; Goldberg 2003; Kashem 2008; Koehler 2011; Madigan 2013; Mortara 2009; Scherr 2009; Schwarz 2008; Seto 2012; Soran 2008; Spaeder 2006; Weintraub 2010; Woodend 2008), TM was used to monitor their condition. In three of these studies (Bowles 2011; Boyne 2012; Woodend 2008), the intervention was a combination of remote monitoring, patient assessment and self-management education, and in five studies, patient education was delivered alongside TM (Benatar 2003; Capomolla 2004; Giordano 2009; Jerant 2001; Wakefield 2008); three studies recruiting participants with hypertension (Madsen 2008; Parati 2009; Rogers 2001), nine with diabetes (Ahring 1992; Biermann 2000; Boaz 2009; Chase 2003; Kwon 2003; Marrero 1995; Rodriguez-Idigoras 2009; Stone 2010; Wojcicki 2001); and in one study, participants with obstructive sleep apnoea (Taylor 2006), were provided with support and feedback for problems experienced with continuous positive airway pressure (CPAP) use. One study recruited participants with co-morbidities receiving home health care (Noel 2004); one study (Kearney 2009), used TM to monitor symptoms for chemotherapy-related toxicity in cancer outpatients receiving chemotherapy; and one study (Cross 2012), used TM to detect signs of a worsening condition in participants with ulcerative colitis. In three studies, which recruited patients recovering after implantation of a cardiac medical device, remote monitoring was used to identify clinical or technical adverse events (Al Khatib 2009; Crossley 2011; Halimi 2008), and to evaluate the safety of early discharge (Halimi 2008).

#### ii) Provision of treatment or rehabilitation (12 studies).

Seven studies evaluated the use of TM for the delivery of psychiatric treatment or counselling to participants with mental health or substance abuse problems (Chong 2012; De Las Cuevas 2006; King 2009; Mitchell 2008; Morland 2010; Poon 2005; Ruskin 2004); one study used TM to deliver stroke rehabilitation (Piron 2009); one incontinence training (Hui 2006); two used TM to deliver rehabilitation to patients with spinal cord injury, stroke, multiple sclerosis or traumatic brain injury (Dallolio 2008; Hermens 2007); and one study, recruiting participants with diabetes (Charpentier 2011), used TM, to calculate and deliver insulin treatment.

#### iii) Education, advice for self-management, and support (23 studies).

Eleven studies recruiting participants with diabetes used TM to deliver patient education and self-management support (Bond

2007; Davis 2010; Izquierdo 2003; Izquierdo 2009; Jansa 2006; Kim 2007; McCarrier 2009; McMahon 2005; Ralston 2009; Shea 2006; Whitlock 2000), of which seven also included monitoring (Bond 2007; Jansa 2006; Kim 2007; McCarrier 2009; McMahon 2005; Ralston 2009; Shea 2006). One study recruiting participants with hypertension (Artinian 2007), five studies recruiting participants with asthma (Chan 2007; Jan 2007; Rasmussen 2005; Van der Meer 2010; Willems 2008), and three participants with COPD (Koff 2009; Lewis 2010; Nguyen 2008) used TM to assist patient's self-care, and for early detection of exacerbations. One study used TM to provide consultation to participants with co-morbidities receiving home health care (Hopp 2006), two studies that used TM to provide support to parents of neonates requiring specialist care also included real-time assessment of the baby (Gray 2000; McCrossan 2012), one study used TM to provide support to patients with home parenteral nutrition (Chambers 2006).

#### iv) Specialist consultations for diagnosis and treatment decisions (eight studies).

Three studies recruiting participants with a dermatological condition (Bergmo 2009; Oakley 2000; Wootton 2000), two studies patients with suspected stroke or patients with acute injuries who attended the ED (Meyer 2008; Wong 2006), and two studies participants with non-acute conditions visiting the GP (Harrison 1999; Wallace 2002) used TM to consult with a specialist. In two studies, extra equipment was used to enable the healthcare professional to assess computed tomography images of the brain (Meyer 2008), and radiologic images (Wong 2006). In one study, which recruited patients recovering from a cardiac event or procedure, TM was used to provide patients with the opportunity to send an ECG trace to a call-centre, and consult with a clinician in real-time (Waldmann 2008).

#### v) Real-time assessment of clinical status (eight studies).

Four studies recruiting participants with heart failure (Dansky 2008; Giordano 2009; Jerant 2001; Wakefield 2008) used TM for real-time clinical assessment, two studies participants with a urological condition (Ellison 2004; Ellison 2007), and one study participants who had a solid organ transplantation (Thompson 2009), used TM for real-time post-operative assessment. In one study recruiting patients with heart failure, the patient could send an ECG trace to a call-centre, and one study (Finkelstein 2006), used TM for real-time assessment of clinical status in patients with co-morbidities receiving home health care.

#### vi) Screening (one study).

One study used TM to screen for angina in patients recovering after cardiac event or procedure (Chiantera 2005).

### Type of Telemedicine (TM)

Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination with monitoring. The studies included in the main analyses (see Data and analyses) were, when possible, grouped by the way TM was delivered.

Remote monitoring with clinical review of patient data was used in 31 studies. Eight studies recruited participants with heart failure (Antonicelli 2008; Bowles 2011; Giordano 2009; Goldberg 2003; Kashem 2008; Koehler 2011; Madigan 2013; Soran 2008), three studies participants recovering from a cardiac event, surgery or

procedure (Al Khatib 2009; Chiantera 2005; Waldmann 2008), three studies participants with hypertension (Artinian 2007; Madsen 2008; Rogers 2001), 13 studies participants with diabetes (Ahring 1992; Biermann 2000; Bond 2007; Chase 2003; Jansa 2006; Kim 2007; Kwon 2003; McCarrier 2009; McMahon 2005; Marrero 1995; Ralston 2009; Stone 2010; Wojcicki 2001), three participants with asthma (Chan 2007; Jan 2007; Van der Meer 2010), and one study participants with obstructive sleep apnoea syndrome (Taylor 2006).

#### Remote monitoring with automatic review of data and a system for alerting the healthcare professional of out of range values

Remote monitoring with automatic review of data and a system for alerting the healthcare professional of out of range values was used in 26 studies. This included 13 studies recruiting participants with heart failure (Benatar 2003; Boyne 2012; Capomolla 2004; Chaudry 2010; Cleland 2005; Dar 2009; Dendale 2012; Mortara 2009; Scherr 2009; Schwarz 2008; Seto 2012; Spaeder 2006; Weintraub 2010), two studies patients following implantation of a cardiac medical device (Crossley 2011; Halimi 2008), one participants with hypertension (Parati 2009), three recruited participants with diabetes (Boaz 2009; Rodriguez-Idigoras 2009; Stone 2010), one with asthma (Rasmussen 2005), three with COPD (Koff 2009; Lewis 2010; Nguyen 2008), one (Noel 2004) participants with co morbidities receiving home health care, which also included disease-specific patient education modules and transferred patient data directly into an electronic database, one study recruited participants with gastrointestinal disorders (Cross 2012), and one study outpatients receiving chemotherapy (Kearney 2009).

#### Video-conferencing

Real-time video-conferencing was used in total in 36 of the included studies. Five studies recruited participants with heart failure (Bowles 2011; Dansky 2008; Jerant 2001; Wakefield 2008; Woodend 2008), five studies participants with diabetes (Davis 2010; Izquierdo 2003; Izquierdo 2009; Shea 2006; Whitlock 2000), seven studies participants requiring mental health services (Chong 2012; De Las Cuevas 2006; King 2009; Mitchell 2008; Morland 2010; Poon 2005; Ruskin 2004), two studies participants recovering from a stroke (Meyer 2008; Piron 2009), of which one (Piron 2009), was delivered with a combined virtual-reality rehabilitation application, two studies recruited participants with co-morbidities receiving home health care (Finkelstein 2006; Hopp 2006), six studies used TM to deliver a specialist consultation (Bergmo 2009; Harrison 1999; Oakley 2000; Wallace 2002; Wong 2006; Wootton 2000), two studies recruited participants after minor urological surgical procedure (Ellison 2004; Ellison 2007), and one (Hui 2006), recruited participants with urinary incontinence, two studies recruited participants with non-acute neurological injuries and conditions (Dallolio 2008; Hermens 2007), two studies recruited parents of neonates requiring specialist care (Gray 2000; McCrossan 2012), one study recruited participants recovering after solid organ transplantation (Thompson 2009). One study (Chambers 2006), which recruited participants with home parenteral nutrition, used video-phones to deliver the intervention. Note: Finkelstein 2006 had two intervention arms, of which only the arm involving video-

conferencing and remote monitoring combined was included in the review.

#### Delivery of the intervention

The intervention was delivered by nurses in 29 studies, physicians in 21 studies, psychiatrists/psychologists or psychotherapists in six studies, and by a combination of healthcare professionals in 31 studies. In six studies the intervention was delivered by other groups of healthcare professionals (physiotherapists, respiratory therapists, diabetologist and sleep medicine practitioners). For the monitoring studies, the frequency of data transfer varied from daily to every third month. The frequency of video-conference sessions ranged from one session every three weeks to two to three times per week. In 53 studies the intervention substituted for usual care, in 30 studies it was delivered in addition to usual care and in ten studies it partly substituted for usual care. The duration of the delivery of the TM interventions ranged from the length of an index visit to 26 months.

#### Outcomes

The included studies reported the following outcomes: mortality (26 studies); quality of life/health status (38 studies), functional status (eight studies), aspects of healthcare resource use, e.g. hospital admissions, ED or urgent care visits, length of hospital stay (54 studies), or practice-related outcomes e.g. time to clinical decision, correct treatment decision/diagnosis, consultation time, follow-up visits offered, discharge/transfer decisions, optimisation of medication etc. (10 studies), costs (26 studies), clinical outcomes (35 studies), effect of treatment (seven studies), medication adherence /treatment adherence and/or self-care behaviour (18 studies), satisfaction (11 studies), and adverse clinical events (23 studies). Five studies reported depression scores, two anxiety and self-efficacy scores, and one study measured social support and caregiver mastery.

#### Excluded studies

See [Characteristics of excluded studies](#).

#### Excluded studies

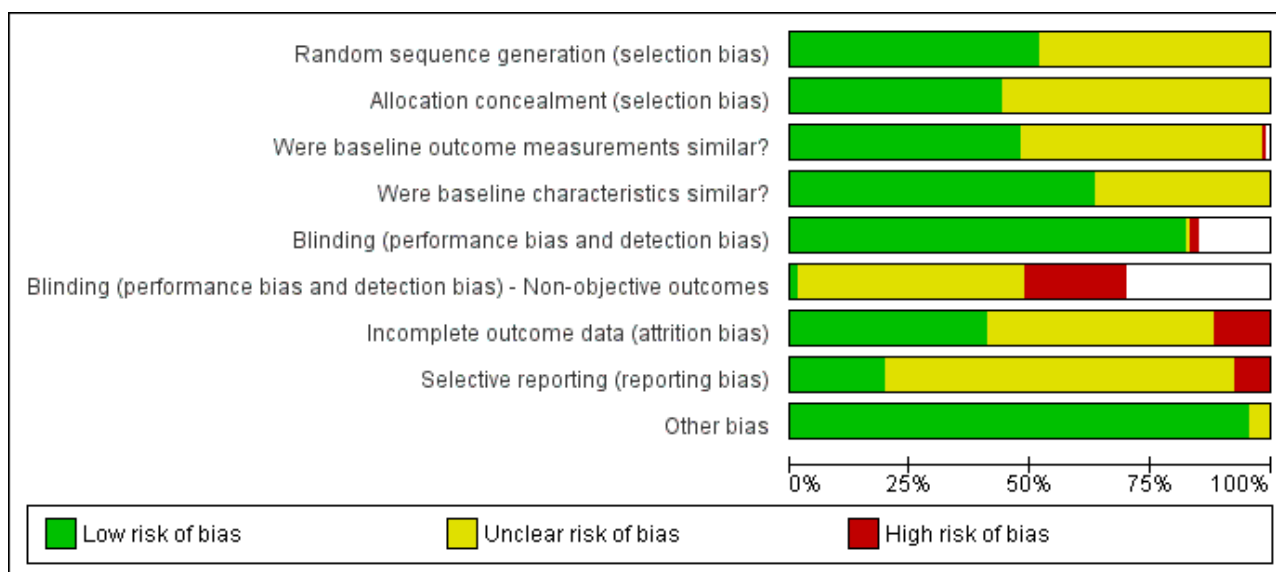
See [Characteristics of excluded studies](#).

Six hundred and ninety one studies were assessed in full text, of these 193 were excluded with reasons. The main reasons for exclusion were ineligible intervention (53 studies) (e.g. no direct patient-provider interaction), ineligible study design (48 studies), and ineligible control group (36 studies). Three of the previously included studies (Brennan 1999; Cartwright 1992; Sparks 1993) were excluded due to using a non-validated measure of self-reported outcomes and, in one study, recruiting only 20 participants (10 in each group). One previously included study (Friedman 1996) was also excluded as the intervention was an automated computerised telephone system.

#### Risk of bias in included studies

See summary of risk of bias in [Figure 2](#) and [Figure 3](#).

**Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies. White spaces in this figure represent instances where it was not possible to make a judgment regarding blinding of objective or non-objective outcomes,**



**Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study. White spaces in this figure represent instances where it was not possible to make a judgment regarding blinding of objective or non-objective outcomes,**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Were baseline outcome measurements similar?	Were baseline characteristics similar?	Blinding (performance bias and detection bias)	Blinding (performance bias and detection bias) - Non-objective outcomes	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ahring 1992	+	+	?	?	+	-	+	?	+
Al Khatib 2009	?	?	+	?	-	?	+	+	+
Antonicelli 2008	?	?	?	+	+	?	?	?	+
Artinian 2007	+	+	+	+	+		+	?	+
Benatar 2003	?	?	?	+	+	?	?	?	+
Bergmo 2009	?	?	?	?	-	-	?	?	+
Biermann 2000	?	?	+	+	+	?	?	?	+
Boaz 2009	?	?	+	+	+	?	?	?	+
Bond 2007	+	+	+	+	+	?	+	+	+
Bowles 2011	+	+	+	+	+	?	-	-	+
Boyne 2012	+	+	+	?	+	?	?	+	+
Capomolla 2004	?	?	?	+	+		?	?	+
Chambers 2006	?	?	?	?	+	?	-	?	+
Chan 2007	+	+	?	?	+	-	?	+	+
Charpentier 2011	?	?	+	?	+	?	+	?	?
Chase 2003	?	?	+	+	+	-	?	?	+
Chaudry 2010	+	+	?	+	+		?	?	+

**Figure 3. (Continued)**

Chaudry 2010	+	+	?	+	+		?	?	+
Chiantera 2005	?	?	?	?	+		?	?	?
Chong 2012	+	+	?	+	+	?	?	?	+
Cleland 2005	+	+	?	?	+		+	-	+
Cross 2012	+	+	+	?		?	-	+	+
Crossley 2011	?	?	?	+	+		-	?	+
Dallolio 2008	+	+	+	+	+	+	-	-	+
Dansky 2008	?	?	?	+	+	-	?	?	+
Dar 2009	+	+	?	+	+	?	+	?	+
Davis 2010	?	?	?	+	+		?	?	+
De Las Cuevas 2006	?	?	+	?		-	+	?	+
Dendale 2012	?	?	+	+	+		+	?	+
Ellison 2004	?	?	?	+		-	+	?	+
Ellison 2007	+	+	?	+	+	-	?	+	+
Finkelstein 2006	?	?	?	?	+	-	-	?	+
Giordano 2009	+	?	?	?	+		+	?	+
Goldberg 2003	?	?	?	+	+	?	+	?	+
Gray 2000	+	+	+	?	+	?	+	?	+
Halimi 2008	?	?	?	+	+	?	?	?	?
Harrison 1999	+	+	?	?		?	?	?	+
Hermens 2007	?	?	+	+	+		?	?	+
Hopp 2006	?	?	+	+	+	?	+	+	+
Hui 2006	+	?	+	+		-	?	?	+
Izquierdo 2003	+	+	?	?	+	?	?	?	+
Izquierdo 2009	?	?	+	?	+	?	?	+	+
Jan 2007	?	?	?	+		-	?	?	+
Jansa 2006	+	?	+	+	+	?	?	?	+
Jerant 2001	+	+	+	+	+	-	+	?	+
Kashem 2008	+	+	?	+	+	?	?	?	+
Kearney 2009	+	+	?	+		?	-	+	+
Kim 2007	+	?	+	+	+		+	?	+

**Figure 3. (Continued)**

Kim 2007	+	?	+	+	+		+	?	+
King 2009	?	?	?	+	+		-	?	+
Koehler 2011	+	+	?	+	+	?	+	+	+
Koff 2009	?	+	+	+	+	?	+	-	+
Kwon 2003	?	?	+	+	+		+	?	+
Lewis 2010	+	?	+	?	+		+	-	+
Madigan 2013	?	+	?	?	?	?	?	?	+
Madsen 2008	+	+	+	+	+	?	+	+	+
Marrero 1995	?	?	+	?	+	-	?	?	+
McCarrier 2009	+	+		+	+	?	?	?	+
McCrossan 2012	+	?	?	+	+		+	?	+
McMahon 2005	+	?	+	+	+		+	?	+
Meyer 2008	+	+	+	+	+		+	+	+
Mitchell 2008	+	+	+	?	+	?	-	?	+
Morland 2010	+	+	+	+		-	-	?	+
Mortara 2009	+	+	?	?	+		?	?	+
Nguyen 2008	+	+	+	+		?	-	?	+
Noel 2004	?	?	?	?	+	?	?	?	+
Oakley 2000	?	?	+	?	+	?	+	?	+
Parati 2009	?	?	+	+	+	?	?	?	+
Piron 2009	+	+	-	+		-	+	?	+
Poon 2005	?	?	+	?		-	?	?	?
Ralston 2009	+	+	+	+	+		+	+	+
Rasmussen 2005	?	?	+	+	+	?	?	?	+
Rodriguez-Idigoras 2009	+	+	+	+	+		+	+	+
Rogers 2001	+	+	?	?	+		+	?	+
Ruskin 2004	+	+	?	+	+	?	?	+	+
Scherr 2009	?	?	+	+	+	?	?	?	+
Schwarz 2008	?	?	?	?	+	?	+	?	+
Seto 2012	+	+	+	+	+	?	+	+	+
Shea 2006	+	+	+	+	+	?	?	+	+



**Figure 3. (Continued)**

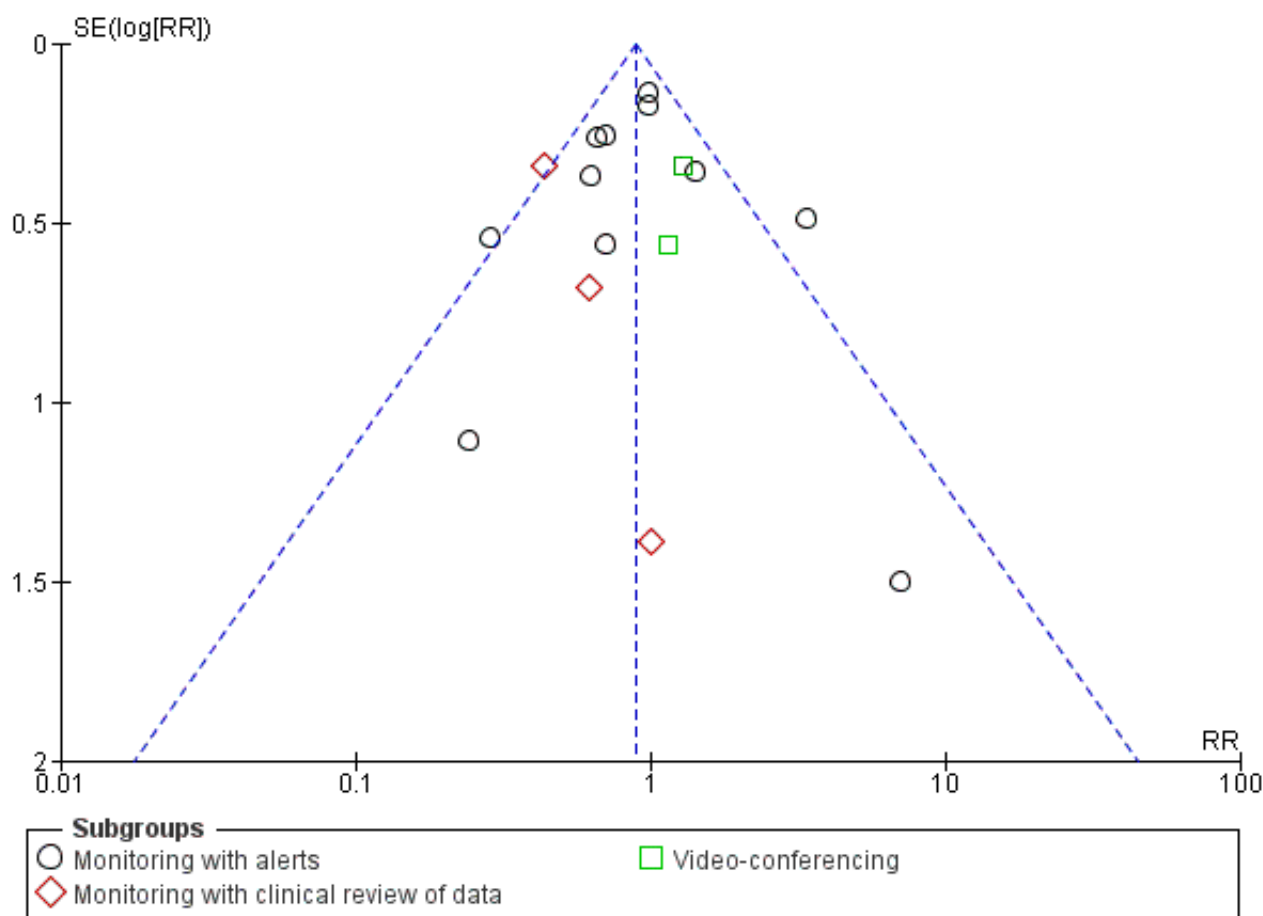
Shea 2006	+	+	+	+	+	?	?	+	+
Soran 2008	?	?	?	+	+		+	?	+
Spaeder 2006	?	?	?	+	+		?	?	+
Stone 2010	+	+	+	+	+		?	+	+
Taylor 2006	+	+	?	+	+		?	?	+
Thompson 2009	+	?	+	+		?	?	?	+
Van der Meer 2010	+	+	+	+		+	+	?	+
Wakefield 2008	?	?	?	?	+	?	?	+	+
Waldmann 2008	?	?	?	+	+		+	?	+
Wallace 2002	+	+	+	+	+	?	?	?	+
Weintraub 2010	?	?	?	?	+	?	+	?	+
Whitlock 2000	?	?	?	?	+	?	?	?	+
Willems 2008	+	?	?	?	+	+	+	+	+
Wojcicki 2001	?	?	?	?	+		?	?	+
Wong 2006	?	+	?	+	+	+	?	?	+
Woodend 2008	?	?	?	?		+	+	?	+
Wootton 2000	+	?	?	?	+		+	?	+

Risk of bias was low in 38% of studies, unclear in 41% and high in 21% of studies. No studies were judged to be at high risk of selection bias. In studies with a high risk of bias the most common source of bias was a lack of blinding in the assessment of non-objective measures of outcome (Al Khatib 2009; Cross 2012; De Las Cuevas 2006; Ellison 2004; Finkelstein 2006; Hui 2006; Jan 2007; Mitchell 2008; Morland 2010; Nguyen 2008; Piron 2009; Poon 2005; Thompson 2009; Wong 2006; Woodend 2008). Ten studies (10.6 %) were judged at high risk of bias due to inadequate follow-up (Bowles 2011; Chambers 2006; Cross 2012; Crossley 2011; Dallolio

2008; Finkelstein 2006; Kearney 2009; King 2009; Mitchell 2008; Morland 2010). The risk of reporting bias was high in seven studies (7.4%) (Bowles 2011; Cleland 2005; Dallolio 2008; Koff 2009; Lewis 2010; Stone 2010; Willems 2008).

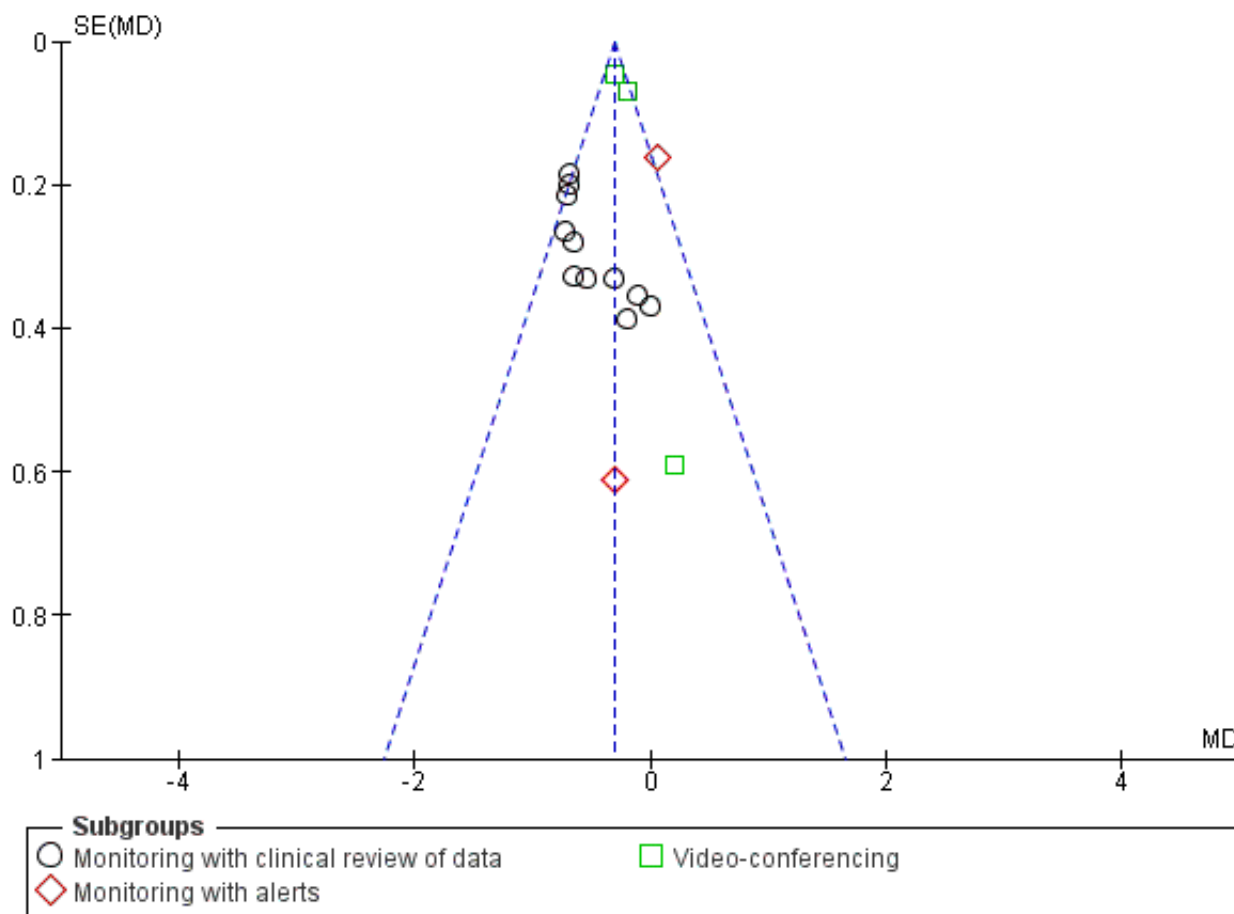
We explored publication bias using a funnel plot for one heart failure outcome, all-cause mortality (16 studies) (Figure 4); and one outcome, HbA1c (16 studies), in the studies recruiting participants with diabetes (Figure 5). There are few data points for the less precise studies; those with greater precision are evenly distributed.

**Figure 4. Funnel plot of comparison: 1 Telemedicine with and without usual care versus usual care only: Heart failure, outcome: 1.1 All-cause mortality at median 6 months follow-up.**





**Figure 5. Funnel plot of comparison: 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, outcome: 2.1 HbA1c at median 9 months follow-up.**



## Effects of interventions

See: [Summary of findings for the main comparison](#); [Summary of findings 2](#)

### Effects of telemedicine (TM) interventions targeting patients with cardiovascular disease

We report the results for the main outcomes for each clinical condition (mortality, disease-specific and general measures of health status, healthcare resource use and cost) below. Results for secondary outcomes, and when a few small studies report data for these outcomes, are described in Additional tables 10-22.

See [Summary of findings for the main comparison](#)

#### i) Heart failure

See summary of results [Table 10](#), [Table 11](#).

### Effects of interactive TM (all types) delivered in addition to, or as an alternative to, usual care versus usual care alone

#### Mortality (all-cause)

We combined data from 16 out of 25 studies (N = 6718 participants), which evaluated either remote monitoring with clinical review of data ([Antonicevili 2008](#), N = 57, [Goldberg 2003](#), N = 280, [Kashem 2008](#),

N = 48); automated review of data with alerts ([Boyne 2012](#), N = 382, [Capomolla 2004](#), N = 133, [Chaudry 2010](#), N = 1653, [Cleland 2005](#), N = 253, [Dar 2009](#), N = 182, [Dendale 2012](#), N = 160, [Giordano 2009](#), N = 460, [Koehler 2011](#), N = 710; [Seto 2012](#), N = 100, [Soran 2008](#), N = 315; [Weintraub 2010](#), N = 188); or video-conferencing ([Bowles 2011](#), N = 218, [Wakefield 2008](#), N = 101). We found no difference in all-cause mortality between TM, delivered in addition to, or as an alternative to, usual care, and usual care alone (risk ratio (RR) 0.89; 95% confidence interval (CI) 0.76 to 1.03; P = 0.12; I<sup>2</sup> = 44%; number analysed, N = 5239) at a median of six months (range three to 26 months), [Analysis 1.1](#)

Eight of these studies ([Bowles 2011](#); [Boyne 2012](#); [Capomolla 2004](#); [Chaudry 2010](#); [Dendale 2012](#); [Giordano 2009](#); [Koehler 2011](#); [Wakefield 2008](#)), evaluated the effect of TM substituting for usual care, or TM partly substituting for usual care (RR:0.93; 95% CI 0.78 to 1.10, P = 0.40; N = 3816), and eight evaluated the effect of using TM in addition to usual care. (RR:0.78, 95% CI 0.58 to 1.05, P = 0.10; N = 1423).

#### Quality of Life - disease-specific

We combined data from five of the 25 studies that assessed disease-specific quality of life (QoL) with the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Quality of life improved in the TM group, compared with control at a median of three months (range

three to six months) follow-up (mean difference (MD) -4.39, 95% CI -7.94 to -0.83,  $P = 0.02$ ; five studies,  $N = 482$ ), ([Analysis 1.2](#)). Two of the studies evaluated the effect of TM substituting for usual care, and three evaluated the effect of TM in addition to usual care, as compared with usual care alone (see [Analysis 1.2](#)). The suggested cut-off scores for the MLHFQ ([Behloul 2009](#)) are  $< 24$  good, 24 to 45 moderate,  $> 45$  poor quality of life. At follow-up, the mean score in three out of five studies in both the TM and the control group indicated low QoL, and the score in four studies indicated moderate QoL. One study ([Madigan 2013](#)), reported higher QoL (assessed with the Kansas City Cardiac Questionnaire) in TM as compared with control at 12 months (no  $P$  values or CIs for the overall score reported). Five studies ([Benatar 2003](#); [Dar 2009](#); [Goldberg 2003](#); [Weintraub 2010](#); [Woodend 2008](#)), with limited data that could not be pooled, reported no differences between groups in disease-specific QoL, general QoL, and/or self-efficacy scores (see [Table 10](#)).

### Quality of life- general

Five studies ([Antonicelli 2008](#); [Dansky 2008](#); [Dar 2009](#); [Goldberg 2003](#); [Jerant 2001](#)) reported no difference in general quality of life; all except one of these ([Jerant 2001](#)) evaluated TM in addition to usual care versus usual care.

### Admission to hospital

We combined data on all-cause hospital admissions from 11 monitoring studies ( $N = 4529$  participants) ([Antonicelli 2008](#),  $N = 57$ ; [Boyne 2012](#),  $N = 382$ ; [Chaudry 2010](#),  $N = 1653$ ; [Cleland 2005](#),  $N = 248$ ; [Dansky 2008](#),  $N = 157$ ; [Dar 2009](#),  $N = 182$ ; [Giordano 2009](#),  $N = 460$ ; [Koehler 2011](#),  $N = 710$ ; [Mortara 2009](#),  $N = 266$ ; [Madigan 2013](#),  $N = 99$ ; [Soran 2008](#),  $N = 315$ ). We did not retain this analysis due to a high level of statistical heterogeneity ( $I^2 = 67\%$ ,  $P = 0.0008$ ) (see [Analysis 1.3](#)), but have retained the forest plot. The risk ratios (RR), with a median follow-up of eight months (range three to 26 months) ranged from 0.36 to 1.60 (see [Analysis 1.3](#)). Sixteen studies reported heart failure and/or cardiovascular-related re-admission data, three of these studies ([Benatar 2003](#),  $N = 216$ ; [Capomolla 2004](#),  $N = 133$ ; [Weintraub 2010](#),  $N = 188$ ) reported a reduction in admission and 13 ([Bowles 2011](#),  $N = 218$ ; [Boyne 2012](#),  $N = 382$ ; [Dansky 2008](#),  $N = 157$ ; [Dendale 2012](#),  $N = 160$ ; [Goldberg 2003](#),  $N = 280$ ; [Jerant 2001](#),  $N = 25$ ; [Kashem 2008](#),  $N = 48$ ; [Koehler 2011](#),  $N = 710$ ; [Scherr 2009](#),  $N = 120$ ; [Schwarz 2008](#),  $N = 102$ ; [Seto 2012](#),  $N = 100$ ; [Wakefield 2008](#),  $N = 148$ ; [Woodend 2008](#),  $N = 249$ ) reported no differences between groups.

### Emergency Department (ED) and urgent care visits

We combined data on ED and urgent care visits from three studies ([Bowles 2011](#),  $N = 218$ ; [Dansky 2008](#),  $N = 157$ ; [Soran 2008](#),  $N = 315$ ); there was no difference between groups in the number of participants with at least one visit (RR 0.93 95% CI 0.74 to 1.17;  $P = 0.54$ ;  $N = 689$ ) at a median four months (range 30 days to six months) follow-up (see [Analysis 1.4](#)). We could not combine data from ten studies on ED and urgent care visits, due to differences in reporting this outcome; findings from these studies were mixed ([Capomolla 2004](#),  $N = 133$ ; [Cleland 2005](#),  $N = 426$ ; [Dar 2009](#),  $N = 182$ ; [Goldberg 2003](#),  $N = 280$ ; [Jerant 2001](#),  $N = 25$ ; [Kashem 2008](#),  $N = 48$ ; [Schwarz 2008](#),  $N = 102$ ; [Seto 2012](#),  $N = 100$ ; [Wakefield 2008](#),  $N = 148$ ; [Woodend 2008](#),  $N = 24$  (see [Analysis 1.4](#))).

### Length of hospital stay (LoS)

We combined data on LoS from five studies ([Bowles 2011](#); [Chaudry 2010](#); [Jerant 2001](#); [Koehler 2011](#); [Seto 2012](#)) and found no difference

between TM and usual care (MD -0.12; 95% CI -0.79 to 0.55,  $P = 0.73$ ;  $I^2 = 24\%$ ;  $N = 2688$ ) at a median of six months follow-up (range 30 days to median 26 months). We also combined data on heart failure-related LOS from five studies ([Bowles 2011](#); [Chaudry 2010](#); [Jerant 2001](#); [Koehler 2011](#); [Soran 2008](#)) and found no difference between groups (MD -0.16, 95% CI -0.85 to 0.53,  $P = 0.64$ ;  $I^2 = 15\%$ ;  $N = 2920$ ). Findings were mixed for the remaining ten studies ([Benatar 2003](#); [Boyne 2012](#); [Cleland 2005](#); [Dendale 2012](#); [Dar 2009](#); [Kashem 2008](#); [Mortara 2009](#); [Scherr 2009](#); [Weintraub 2010](#); [Woodend 2008](#)) (see [Analysis 1.5](#); [Analysis 1.6](#)).

### Costs

Two studies ([Benatar 2003](#);  $N = 216$ ; [Giordano 2009](#);  $N = 460$ ) of remote monitoring with automated alerts or risk stratification reported lower hospital re-admission costs for TM as compared with usual care; three studies ([Dar 2009](#);  $N = 182$ ; [Dendale 2012](#);  $N = 160$ ; [Schwarz 2008](#);  $N = 102$ ) reported no difference in total health service costs between groups. One study of TM with video-conference ([Jerant 2001](#),  $N = 25$ ) reported lower hospital re-admission costs for TM as compared with usual care.

### Satisfaction

One study ([Bowles 2011](#);  $N = 218$ ) reported higher satisfaction with care in the TM group (i.e. with the time to discharge, and knowing how to contact their nurse), but the groups were equally satisfied with the number of home care visits. However, while the aim of the study was to replace some of the face-to-face visits with virtual visits, the TM group actually received more face-to-face visits than the usual care group.

### ii) Patients recovering from cardiac event, cardiac surgery or procedure (other than implantation of cardiac medical device)

See summary of results [Table 12](#)

### Effects of real-time transmission of clinical data and real-time consultation versus usual care

#### Mortality

One study ([Waldmann 2008](#)) reported lower all-cause mortality (odds ratio (OR) 0.43, 95% CI 0.20 to 0.90;  $N = 1500$ ) in patients who, in addition to usual care, could send a 12-lead ECG trace and contact a call-centre for real-time consultation on demand, as compared with patients receiving usual care at 12 months follow-up.

#### Admission to hospital and length of stay

One study ([Waldmann 2008](#)), reported no difference in re-admission rate or LOS at 12 months follow-up between groups. A second study ([Chiantera 2005](#),  $N = 200$ ) reported a slightly lower re-hospitalisation rate during the first month after discharge, as compared with usual care.

### iii) Patients recovering from implantation or replacement of a dual chamber pacemaker or an implantable cardioverter defibrillator (ICD)

See summary of results [Table 12](#)

## Effects of TM versus usual care

### Mortality

No difference between groups was reported for all-cause mortality at 12 months with clinical review of data via TM (Al Khatib 2009, N = 151), or with automatic review of data with alerts (Crossley 2011; N = 1997).

### Quality of Life (QoL)

Two studies (Al Khatib 2009; N = 151; Halimi 2008, N = 379) reported no differences between TM and usual care in general QoL at 12 months and one month.

### Healthcare resource use and costs

Two studies (Al Khatib 2009; Crossley 2011) reported no difference between TM and usual care in hospital admissions, ED visits or unscheduled visits at 12 and 15 months follow-up. Two studies reported shorter LOS in TM as compared with control, (Crossley 2011; Halimi 2008). One study (Al Khatib 2009), reported higher mean total healthcare cost per TM patient as compared with usual care and two studies lower costs for TM (Crossley 2011; Halimi 2008).

### iv) Hypertension

See summary of results Table 13.

## Effects of TM with or without usual care versus usual care

### Blood pressure

Blood pressure measurement varied among studies at follow-up. One study (Artinian 2007; N = 387) reported a greater decrease in mean systolic blood pressure (SBP) in TM delivered in addition to usual care, as compared with usual care alone at 12 months; one study (Madsen 2008; N = 236) reported no differences in diastolic daytime and night time ambulatory blood pressure (ABPM) between groups at 6 months but did report that a greater proportion of intervention patients achieved a target BP at 6 months. One study (Rogers 2001; N = 121) reported a greater decrease in 24-hour systolic and diastolic ABPM and a greater change in mean BP in the TM group at eight weeks, as compared with control. In one monitoring study with automated review of data with alerts (Parati 2009; N = 329), the authors reported a greater proportion of TM participants achieving daytime normalisation of arterial BP as compared with control.

### Costs

One study (Parati 2009) reported no differences between groups for costs of examinations and overall cost of patient management at six months.

### v) Stroke

See summary of results Table 13.

## Effects of telemedicine (TM) interventions recruiting people with diabetes

See summary of results Table 14

## Effects of TM (all types) with and without usual care versus usual care alone

Below, we report the clinical outcomes measured by studies evaluating the effectiveness of telemedicine in monitoring the treatment response in people with diabetes,

### HbA1c

See Analysis 2.1.

We combined data on HbA1c from 16 out of 21 studies recruiting people with diabetes (number analysed, N = 2768 participants): (Biermann 2000, N = 43; Boaz 2009, N = 35; Bond 2007, N = 62; Charpentier 2011; N = 120; Chase 2003, N = 63; Davis 2010, N = 165; Izquierdo 2003, N = 37; Jansa 2006, N = 36; Kim 2007, N = 51; Kwon 2003, N = 101; McCarrier 2009, N = 77; Marrero 1995, N = 106; Ralston 2009, N = 83; Rodriguez-Idigoras 2009, N = 297; Shea 2006, N = 1355; Stone 2010, N = 137) and found lower HbA1c levels in people allocated to telemedicine than in controls (MD -0.31, 95% CI -0.37 to -0.24;  $I^2 = 42\%$ ,  $P = 0.04$ ) at a median of nine months follow-up. The variation among studies in baseline HbA1c from a mean of 7.0% to > 9% is one factor that might have contributed to the heterogeneity. In nine of these studies, TM was delivered instead of usual care (Biermann 2000; Boaz 2009; Davis 2010; Izquierdo 2003; Jansa 2006; Kim 2007; Kwon 2003; Rodriguez-Idigoras 2009; Shea 2006), in three studies, TM was delivered in addition to usual care (Bond 2007; Marrero 1995; Stone 2010), and in two studies, TM partly substituted for usual care (Charpentier 2011; Chase 2003).

Four additional studies (Ahling 1992; McMahon 2005; Ralston 2009; Wojcicki 2001), reported mixed results for HbA1c; these data could not be added to the meta-analysis due to the unit of measurement being unclear (Ahling 1992), only the change from baseline being reported (McMahon 2005; Ralston 2009), and in one study (Wojcicki 2001), a different study population (pregnant women with Type 1 diabetes) was recruited.

### Lipids

See Analysis 2.2; Analysis 2.3; Analysis 2.4; Analysis 2.5.

We pooled data on LDL (low-density lipoprotein) from four out of 21 studies (Boaz 2009, N = 35; Davis 2010, N = 165; Shea 2006, N = 1335; Stone 2010, N = 137) (number analysed, N = 1692) and found lower LDL levels for those in the TM group, as compared with control (MD -12.45, 95% CI -14.23 to -10.68 mg/dL,  $P < 0.00001$ ) at a median of six months follow-up (range three to 12 months) (see Analysis 2.3; Analysis 2.4; Analysis 2.5 for results on other lipids). Data in three studies (Izquierdo 2003; Kwon 2003; Rodriguez-Idigoras 2009), that could not be combined, reported no differences in LDL between groups.

### Blood pressure

See Analysis 2.6; Analysis 2.7.

We pooled data on blood pressure from four studies (number analysed, N = 1770), two video-conferencing studies (Davis 2010, N = 165; Shea 2006; N = 1665), one monitoring study with automatic review of data and alerts (Stone 2010, N = 137) and one study with clinical review of data (Bond 2007, N = 62). There was a larger reduction in blood pressure for those allocated to TM (with or without usual care) compared with usual care alone; systolic blood pressure (MD -4.33, 95% CI -5.30 to -3.35 mm Hg,  $P < 0.00001$ ) and

diastolic blood pressure (MD -2.75, 95% CI -3.28; -2.22 mm Hg,  $P < 0.00001$ ) at a median of nine months follow-up (range six to 12 months). One study (Izquierdo 2003), which reported no differences between groups, provided no numerical data.

### Quality of Life (QoL)

One study (Bond 2007,  $N = 62$ ) reported a beneficial effect of remote monitoring on disease-specific QoL as compared with usual care, and two studies reported no differences between groups (Jansa 2006,  $N = 40$ ; Marrero 1995,  $N = 106$ ). One study that used video-conferencing in 25 schools (Izquierdo 2009,  $N = 41$ ) reported improvements for several QoL domains in the TM group; a second study (Whitlock 2000,  $N = 28$ ) reported no differences between groups.

### Healthcare resource use and costs

Four studies reported no difference between groups in healthcare resource use (Izquierdo 2009;  $N = 41$ ; Jansa 2006;  $N = 40$ ; Marrero 1995;  $N = 106$ ; Ralston 2009;  $N = 83$ ), one study (Biermann 2000;  $N = 48$ ) reported that TM patients required less time for their consultations than controls, but that they had more contacts with their physician, and another study reported (Charpentier 2011;  $N = 120$ ) less patient time for travelling to the hospital and less waiting time for TM patients.

One study (Biermann 2002, data from Biermann 2000,  $N = 48$ ) reported lower healthcare costs per year for TM patients as compared with usual care patients, and one study (Jansa 2006,  $N = 40$ ) lower costs for TM when delivered without technical problems. Chase 2003 reported lower costs for TM as compared with face-to-face clinic visits. In one study (Boaz 2009,  $N = 35$ ), costs were increased in the usual care group due to more unscheduled visits. A cost analysis in one study (Palmas 2010, an additional report from Shea 2006), reported slightly higher mean annual Medicare payments in the TM compared with the usual care group.

### Adverse events

Six studies reported no differences in hypoglycaemic and/or hyperglycaemic events between groups. Five studies (Ahring 1992,  $N = 42$ ; Bond 2007,  $N = 62$ ; Charpentier 2011,  $N = 120$ ; McMahon 2005,  $N = 104$ ; McCarrier 2009,  $N = 77$ ), reported no differences in total number of hypoglycaemic events at a median of six months (range 12 weeks to 12 months). In one study (Biermann 2002, an additional report from Biermann 2000,  $N = 48$ ), only graphical data were provided and no between-group comparisons were reported.

### Effects of telemedicine (TM) interventions targeting patients with respiratory conditions

See summary tables Table 15.

#### i) Asthma

#### Effects of TM with and without usual care versus usual care

See summary of results Table 15

#### Clinical outcomes

Three studies that evaluated the effects of Internet-based monitoring and education (Chan 2007,  $N = 120$ ; Jan 2007,  $N = 196$ ; Van der Meer 2010,  $N = 200$ ), reported no difference between TM and usual care for lung function test scores. One study (Rasmussen 2005;  $N = 200$ ), of an Internet-based self-management

tool with automated review of data and alerts, reported a greater improvement in lung function test scores for TM participants as compared to participants receiving GP care at six months ( $P < 0.001$ ). Four studies reported no differences in asthma symptom scores between groups (Chan 2007; Jan 2007; Van der Meer 2010; Willems 2008).

### Quality of life (QoL)

Three studies (Chan 2007; Jan 2007; Van der Meer 2010), reported no differences in disease-specific QoL between patients who received an Internet-based monitoring and self-management intervention and patients who received usual care between 3 and 12 months follow-up. One study (Rasmussen 2005), reported improved QoL scores in the Internet group at five months as compared with the GP group ( $P = 0.04$ ).

### Healthcare resource use and costs

Three studies (Chan 2007,  $N = 120$ ; Van der Meer 2010,  $N = 200$ ; Willems 2008,  $N = 109$ ) reported no differences in healthcare utilisation and medication consumption between groups. One study (Rasmussen 2005,  $N = 200$ ), reported more unscheduled visits in the Internet group as compared to the GP group (3.7% versus 1.3%,  $P < 0.05$ ).

One study (Willems 2008,  $N = 109$ ) reported € 31,035/QALY (quality-adjusted life year) gained for adults and € 59,071/QALY gained for children. The probability of the programme being cost-effective compared to regular care was 85% at a ceiling ratio of € 80,000/QALY gained among the adults and 68% among the children.

#### ii) Chronic obstructive pulmonary disease (COPD)

#### Effects of remote monitoring with automated review of data with alerts versus usual care

See summary of results Table 15.

#### Clinical outcomes

One study (Nguyen 2008,  $N = 50$  adults), reported no difference in dyspnoea scores between participants receiving a web-based self-management tool (with automatic review of data and alerts) and those receiving usual care at six months.

### Quality of life (QoL)

One study (Koff 2009,  $N = 40$ ) reported that participants receiving an interactive voice-response education and monitoring system, had greater improvement in QoL, as compared to usual care at three months. One study (Nguyen 2008,  $N = 50$ ), reported no effect of the self-management intervention and usual care on disease-specific QoL, general QoL, self-reported physical functioning or self-efficacy as compared with usual care at six months.

### Healthcare resource use and costs

One study (Lewis 2010,  $N = 40$ ) compared healthcare resource use (ED visits, other visits and hospital admissions), and reported no differences between groups. One study (Koff 2009) reported no difference in total healthcare costs between groups.

#### Effects of telemedicine (TM) targeting patients with mental disorders or substance abuse

See summary of results Table 16



## Effects of real-time video-conferencing versus usual care

### Clinical outcomes

Seven studies that recruited patients with mental disorders or substance abuse (Chong 2012, N = 167; De Las Cuevas 2006 N = 140; King 2009, N = 37; Mitchell 2008, N = 128; Morland 2010, N = 125; Poon 2005, N = 22; Ruskin 2004, N = 119) reported no difference in the response to therapy delivered over video-conferencing as compared to face-to-face delivery (Table 16).

### Quality of life and patient satisfaction

Two studies (Mitchell 2008, N = 128; Ruskin 2004, N = 119) reported no difference in general health status between TM and usual care. Two studies (Mitchell 2008, N = 128; Morland 2010, N = 125), reported no differences in patient satisfaction scores between groups, while one study (Chong 2012, N = 167), reported increased satisfaction with TM care, compared with control.

### Costs

One study (Crow 2009, an additional report from Mitchell 2008, N = 128), reported lower total costs per abstinent participant for TM as compared with usual care, with the difference mostly pertaining to the travel costs of the therapist; a second study (Ruskin 2004, N = 119), reported higher costs for TM, but no differences between groups when the therapists' travel costs had been accounted for.

## Effects of telemedicine (TM) interventions targeting patients with co-morbidities receiving home care

See summary of results Table 17.

## Effects of TM (all types) versus usual care

### Mortality

One study that recruited patients with heart failure and COPD (Finkelstein 2006, N = 68), reported no difference in mortality between TM patients (video-conferencing and monitoring) and usual care, as compared to patients who received usual care only.

### Quality of life and patient satisfaction

One study (Hopp 2006, N = 37), reported a greater improvement in general mental health scores (assessed with SF-36) at six months (P = 0.04) in the TM group as compared with control, but no difference in the physical component scores or level of satisfaction in patients at high risk of hospital admission. One study (Noel 2004, N = 104), which recruited participants with heart failure, chronic lung disease and diabetes, reported no difference in general QoL, and increased satisfaction in the TM group at three and six months follow-up.

### Healthcare resource use and costs

Two studies (Hopp 2006, N = 37; Noel 2004, N = 104), reported no difference in healthcare resource utilisation between groups. One study (Finkelstein 2006), reported more patients receiving usual care being transferred to a higher level of care at six months as compared with TM group patients. This study also reported lower cost per visit in the video- and monitoring group. Noel 2004 (N = 104), which compared costs six months before the intervention and costs during the six-month intervention, reported a greater decrease in the average healthcare costs per participant in the TM group.

## Effects of telemedicine interventions targeting patients with conditions requiring a specialist consultation

See summary of results Table 18

### i) Dermatological conditions

One study (Bergmo 2009) reported no difference between specialist consultations delivered using a secure messaging system and a digital camera and consultations delivered face-to-face to children with atopic dermatitis (N = 98) and their parents, nor for physician-rated severity of the eczema, self-reported healthcare use and self-management behaviour, or family costs.

Two studies (Oakley 2000, N = 203; Wootton 2000, N = 204), reported no difference in the duration of the initial appointment between video-consultation and face-to-face consultations, and a similar proportion of follow-up appointments after the index consultation in both groups.

One study (Wootton 2000, N = 204), reported higher net societal costs for initial TM consultation than for face-to-face consultations.

### ii) Acute injuries and conditions (patients visiting the ED)

#### Mortality, morbidity and healthcare resource use

One study (Wong 2006, N = 475), reported no difference between groups in mortality for patients with emergency neurosurgical conditions receiving video-consultation and those receiving telephone consultation at six months follow-up. The same study reported high failure rate for video-consultations.

One study (Meyer 2008, N = 222), recruiting patients with a stroke, reported no difference between groups in mortality and functional outcomes at 90 days follow-up. There was no difference in the use of intravenous thrombolysis (TM: 31/111 (28%); usual care: 25/111 (23%), OR 1.3, 95% CI 0.7 to 2.5, P = 0.43) (see Table 18). There was more missing data in the usual care telephone group than in the TM group (12 % versus 3 %).

### iii) Non-acute conditions (outpatients visiting the GP)

#### Quality of life, healthcare resource use and costs

Two studies (Harrison 1999, N = 132; Wallace 2002, N = 2094), reported no difference between joint tele-consultations and face-to-face consultations on QoL, and one study (Wallace 2002), reported no differences in patient satisfaction or independence between groups at six months.

One study (Wallace 2002), reported that a greater proportion of intervention patients were offered a follow-up outpatient appointment (results from Loane 2000 with longer follow-up), and a greater number of tests and investigations were ordered for intervention patients as compared with control, while resource use in terms of additional in-and outpatients visits (contacts with GP, ED visits, number of inpatient stays, and number of day surgery and inpatient procedures) were similar. In addition, Wallace 2002 reported higher overall NHS costs at six months for the joint tele-consultations than for face-to-face outpatients consultations (the index consultation accounted for this excess), while the cost savings of patients were greater in the joint tele-consultation group.

## Effects of telemedicine (TM) interventions targeting patients with gastrointestinal conditions

See summary of results [Table 19](#).

One study ([Chambers 2006](#), N = 30) reported no difference in QoL or hospital anxiety and depression scores at six months when nurse video-phone consultations were used to provide care and support to patients with home parenteral nutrition, as compared to telephone support only. One study ([Cross 2012](#), N = 47), reported that disease activity, quality of life, and medication adherence did not differ between participants with ulcerative colitis receiving home tele management including monitoring and control group participants receiving 'best available care' at 12 months follow-up.

## Effects of telemedicine interventions targeting patients with urological conditions

See summary of results [Table 20](#)

Two studies ([Ellison 2004](#), N = 56; [Ellison 2007](#), N = 270), reported no difference in the effects of real-time video-conferencing as compared to face-to-face consultation on patient satisfaction, post-operative complication rates or in the length of hospital stay after minor urologic procedure. One study ([Hui 2006](#), N = 64), reported no difference between rehabilitation delivered over video-conferencing and face-to-face in reducing the number of incontinence episodes for participants with urinary incontinence.

## Effects of telemedicine (TM) interventions targeting patients with non-acute neurological injuries and conditions

See summary of results [Table 21](#).

Two studies ([Dallolio 2008](#), N= 137; [Hermens 2007](#), N = 81) reported on the effectiveness of real-time TM (video-conferencing, Home-Care Activity Desk) as compared to face-to-face rehabilitation training of participants with spinal cord injury ([Dallolio 2008](#)); and participants with stroke, traumatic brain injury and Multiple Sclerosis ([Hermens 2007](#)). The study by [Dallolio 2008](#), that recruited patients from four cities in three countries, reported improved arm/hand function in the Bologna part of the study, but no effects in the other two sites, and no effect on the ability of patients to perform daily tasks. No differences were reported for clinical complications or healthcare resource use. One study ([Hermens 2007](#)) reported no differences in arm-hand function between groups.

## Effects of telemedicine interventions targeting infants requiring specialist neonatal care

See summary of results [Table 22](#),

One study ([Gray 2000](#), N = 56), reported that providing parents of very low birth weight infants with a TM system for four months, which involved video-conference opportunities and an educational module, did not reduce infant's hospital stay as compared to usual care only. However, the proportion of infants who were transferred to a higher level of care at the time of discharge was lower in the TM group (0%) than in the usual care group (20%) (P < 0.05). One study ([McCossan 2012](#), N = 59), reported that using video-conference to provide additional support to parents of infants with congenital heart disease at the time of discharge, resulted in lower healthcare resource use and cost per patient during the 10-week intervention period.

## Effects of telemedicine interventions targeting other conditions

See summary of results [Table 22](#),

### *Cancer outpatients receiving chemotherapy*

One study ([Kearney 2009](#), N = 112), assessed chemotherapy-related symptoms in patients being treated for cancer and reported no difference for four out of six symptoms between those using an automated symptom alert system and usual care symptom management.

### *Solid organ transplant recipients discharged from hospital*

One study ([Thompson 2009](#), N = 138) reported no difference between using video-conferencing to provide follow-up care and depression screening, as compared to care provided to face-to-face to participants discharged from hospital after solid organ transplantation, on infections, rejections and hospital admissions (6 month follow-up only, [Leimig 2008](#), N=121), or on depression scores and hospital visits ([Thompson 2009](#)).

## DISCUSSION

This review focuses on the use of TM in direct patient care, in which the recipient is remote from the clinician, and in which a health professional responds to the clinical information transmitted via TM.

### Summary of main results

See summary of main results in [Summary of findings for the main comparison](#); [Summary of findings 2](#),.

We included 93 trials that recruited 22, 047 participants, evaluating the effectiveness of interactive telemedicine (TM) delivered in addition to (32% of included studies), as an alternative to (57% of included studies), or partly substituted for (11% of included studies) usual care, as compared to usual care alone.

The clinical conditions targeted in these trials were: cardiovascular disease (36 studies), diabetes (21 studies), respiratory conditions (nine studies), mental health or substance abuse conditions (seven studies), conditions requiring a specialist consultation (six studies), and studies covering a number of other conditions (14 studies).

Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination. The main TM function varied depending on clinical condition, but fell typically into one of the following six categories, with some overlap: i) monitoring of a chronic condition to detect early signs of deterioration and prompt treatment and advice, (41 studies); ii) provision of treatment or rehabilitation (12 studies), for example the delivery of cognitive behavioural therapy, or incontinence training; iii) education and advice for self-management (23 studies), for example nurses delivering education to patients with diabetes or providing support to parents of very low birth weight infants, or to patients with home parenteral nutrition; iv) specialist consultations for diagnosis and treatment decisions (eight studies); v) real-time assessment of clinical status, for example post-operative assessment after minor operation or follow-up after solid organ transplantation (eight studies); vi) screening, for angina (one studies).

## Health outcomes

We found 25 studies targeting participants (N = 6718) with heart failure. We pooled data on all-cause mortality from 16 out of 25 studies and found no difference between TM and usual care. There was some inconsistency among the studies, with one study (N = 182, [Dar 2009](#)), reporting a higher risk of mortality in those allocated to TM. The impact of TM on all-cause hospital admissions for participants with heart failure varied among studies from a relative decrease of 64% to an increase of 60%. Differences in the severity of heart failure at recruitment may have contributed to this variation, as some studies excluded participants receiving home care and/or participants with co-morbidities. Those receiving TM reported a greater improvement in quality of life, compared with usual care.

We included 21 trials recruiting people with diabetes. We pooled HbA1c data from 16 out of 21 studies and found a small reduction in people allocated to TM than in controls at a median of nine months follow-up. There was a moderate level of statistical heterogeneity that may be due to differences in baseline HbA1c (range 7.0% to > 9%), and that some studies required a high HbA1c as a criterion for inclusion. In addition, the different age of participants recruited to the studies (children; adolescents, adults or mixed), and the classification of diabetes (nine studies recruited participants with Type 1, six with Type 2, and six studies both Type 1 and Type 2 diabetes), may have contributed to the variation among studies. There is some evidence that LDL cholesterol (four studies; N = 1692), and blood pressure (four studies; N = 1770) improved in participants with diabetes who received TM, compared with usual care. The effects of TM on disease-specific quality of life were mixed, with five studies (N = 277) reporting this outcome.

Seven randomised controlled trials (RCTs) (N = 738; range 22 to 167 participants), recruited people with different mental health or substance abuse problems and reported no differences in treatment effect between groups, but reported cost savings related to travel. The remaining studies tested the provision of a specialist consultation via TM in populations with a range of clinical conditions, for example hypertension, asthma, COPD, dermatology, neurological injuries or conditions, emergency room visits and non-acute conditions requiring a GP consultation.

## Cost

A comparison of costs is limited due to studies costing different resources. Some studies included only the intervention cost, some hospital admissions and some healthcare, societal and personal costs in the analysis. Twenty-three of the 93 included studies reported cost data, and nine of these studies reported lower costs for those receiving TM compared with usual care. Six of these nine studies reported lower follow-up costs (intervention costs only) per patient ([Biermann 2000](#); [Chase 2003](#); [Finkelstein 2006](#); [Jansa 2006](#); [McCrossan 2012](#); [Crow 2009](#), an additional report from [Mitchell 2008](#)), and three studies reported lower hospital admission charges (at three and six months in [Benatar 2003](#); [Crossley 2011](#); [Giordano 2009](#)). Ten studies ([Al Khatib 2009](#); [Benatar 2003](#); [Boyne 2012](#); [Dar 2009](#); [Dendale 2012](#); [Halimi 2008](#); [Jerant 2001](#); [Koff 2009](#); [Parati 2009](#); [Schwarz 2008](#)) reported no differences between groups. Seven of these 10 studies reported total healthcare costs ([Al Khatib 2009](#); [Boyne 2012](#); [Dar 2009](#); [Halimi 2008](#); [Koff 2009](#); [Parati 2009](#); [Schwarz 2008](#)), and three total hospital admission charges ([Dendale 2012](#); [Jerant 2001](#); [Schwarz 2008](#)). Five studies ([Ruskin 2004](#); [Shea 2006](#); [Wallace 2002](#); [Willems 2008](#); [Wootton 2000](#)),

reported higher costs for TM, compared with usual care. In one study ([Ruskin 2004](#)), this difference disappeared when the travel costs of the psychiatrist were taken into account in the analysis. In another study ([Willems 2007](#), a report from [Willems 2008](#)), the intervention cost explained the difference in cost between the groups.

## Unintended consequences

We found no evidence of increased frequency of hospital admissions in studies recruiting patients with heart failure or diabetes when TM was used as an alternative to usual care. For studies recruiting participants with asthma, and when TM was a substitute for usual care, the frequency of asthma exacerbations, use of healthcare resources and medication was similar to the usual care group in two-thirds of the studies. One study reported more unscheduled visits and more side effects (dysphonia, candidiasis) in the TM group, compared with usual care. However, these patients had better medication adherence and disease control.

Technical difficulties, for example failure of data transmission and/or video-conferencing, were reported in only six studies. One study ([Nguyen 2008](#); N = 50) reported that technical difficulties led to a high drop-out rate (43%) in the intervention group; a second study ([Schwarz 2008](#)), reported that 20% of intervention patients were unable to begin transmission of data and another study ([Chiantera 2005](#)), reported that 10% of patients in the TM group left the study as they could not use the TM device. One study ([Crossley 2011](#)), reported failure of the TM monitoring system to send an automatic clinician alert in 246 of 575 cases (42.8%); this was because the alert was programmed to 'off' (7%) or was not reset after being previously triggered (93%). In addition, when an automatic clinician alert was triggered it resulted in a successful transmission in 180 (55%) cases, while for 149 (45%), clinical events automatic clinician alerts were triggered but not successfully transmitted. One study ([Wong 2006](#)), reported a 30% failure rate for video-consultations, which was mostly due to technical errors and logistic difficulties at the referring institution. One small study ([King 2009](#)), recruiting people attending an addiction treatment service, reported that 30% of participants experienced computer and adherence related problems.

## Overall completeness and applicability of evidence

This review is limited to TM technologies that require a healthcare professional to respond, either in real-time or with a delay, to the clinical information transmitted via TM. Other systematic reviews in this field ([Farmer 2004](#); [Inglis 2010](#); [McLean 2010](#); [McLean 2011](#); [Polisena 2009](#); [Polisena 2010](#)), have examined different types of TM interventions including telephone only, and some ([Farmer 2004](#); [Inglis 2010](#); [Polisena 2009](#); [Polisena 2010](#)) have included evidence from non-randomised studies. We did not include telephone-only interventions as this is frequently a form of standard care, nor did we include remote monitoring with algorithm-based automatic feedback only, pure self-management or educational interventions with no data transfer and no patient-provider interaction. In addition, our review was limited to RCTs.

The large volume of studies currently being published that are within the scope of our review, means we have not been able to include all studies identified in the most recent search conducted in 2013. We have listed 63 studies under [Studies awaiting classification](#), which cover the following clinical conditions: COPD

(10 studies); hypertension (seven studies); follow-up of implantable cardioverter-defibrillator (ICD) implantation (six studies); asthma (five studies); weight reduction (four studies), and a number of other conditions with just a few new potentially eligible studies. It is likely that for some of the clinical conditions (e.g. asthma, COPD, and hypertension), inclusion of these studies will make pooling of data possible.

This review includes both first- and second-generation TM systems, which involved a non-automated analysis of data and a non-immediate decision making structure and in some cases manual uploading of data by the patient (31 studies), and third- and fourth-generation TM systems, in which data are automatically uploaded and transferred and there is a system for alerting the healthcare professional of out of range values (25 studies) (classification from [Anker 2011](#)). Results from another recent TM review ([Nakamura 2013](#)) targeting people with heart failure, suggest higher effectiveness of TM in studies with a rapid response system.

TM has the potential to improve the equity, and accessibility of care, especially in areas where health care is less accessible, as often is the case in low- and middle-income countries (LMICs). Only two studies ([Ahling 1992](#); [Davis 2010](#)) investigated the effectiveness of using TM to improve access to healthcare services in rural areas, and six studies ([Artinian 2007](#); [Benatar 2003](#); [Chong 2012](#); [Dar 2009](#); [Shea 2006](#); [Soran 2008](#)) targeted patients living in underserved urban areas. However, none of these studies reported on differential effects between groups. It is worth noting that some studies excluded people who did not have a telephone line ([Antoncelli 2008](#); [Benatar 2003](#); [Goldberg 2003](#); [Hopp 2006](#); [Madigan 2013](#); [Parati 2009](#); [Stone 2010](#)), or people who did not speak English ([Gray 2000](#); [Koff 2009](#); [McCarrier 2009](#); [Ralston 2009](#); [Schwarz 2008](#); [Wallace 2002](#)). Two studies excluded people with no permanent address ([Gray 2000](#); [McCarrier 2009](#)). None of the included studies were conducted in a LMIC. More than 90 per cent of the included studies were conducted in high-income countries in North America or in Europe, and just a handful of studies in Asia and the Middle East. This may change with an increase in mobile phone coverage in LMICs ([Ronquillo 2012](#); [WHO 2011](#); [WHO 2014](#); [Zurovac 2012](#)).

While a majority of the included studies reported health outcomes as well as aspects of healthcare resource use (e.g. hospitalisations, emergency department (ED) visits, length of hospital stay (LoS) etc), only 10% of studies evaluated the effects of interventions on professional practice e.g. time to reaching a clinical decision, the correct diagnosis and treatment decision, consultation time, follow-up visits, discharge decisions, optimisation of medication etc. We report the clinical outcomes measured by studies evaluating the effectiveness of TM in monitoring the response to treatment. While it can be argued that these measures are limited, in terms of being surrogate measures, they are clinical measures that are used to monitor response to treatment. Only eleven of the included studies (11.7%) measured the satisfaction of participants with the care delivered. [Kraai 2011](#) has also reported that TM monitoring studies often omitted a measure of patient satisfaction, and when satisfaction was measured it was measured with poorly constructed questionnaires. Satisfaction, and patient acceptability are outcomes which are recommended to be included in all trials evaluating TM ([DHHSFDA 2009](#)). In addition only a quarter of included studies evaluated the cost-effectiveness of TM

as compared to usual care. This absence of data may limit the extent to which TM can be implemented as perceived high costs may be a barrier for investing in TM infrastructures in LMICs ([Wootton 2012](#)). Where possible we have reported on the key components of TM that have an impact on resource use. However, the inclusion of other types of economic evaluation is not within the scope of this review.

Only 35% of included studies reported the number of potentially eligible participants from which the study sample was recruited. Of these studies, 20% had a refusal rate of between 40% to 70%, and more than 30% of studies had a 20% to 30% refusal rate. The drop-out rate in the included studies ranged from 0% ([Bond 2007](#)) to up to 42 % in one study, due to difficulties with the technology, ([Nguyen 2008](#)). This indicates that the TM interventions may not be acceptable to some groups.

## Quality of the evidence

We judged the certainty of the evidence from studies recruiting participants with heart failure to be high for mortality, and moderate for admission to hospital, and quality of life (QoL) outcomes due to inconsistency among study findings. In studies recruiting participants with diabetes, the certainty of the evidence was high for HbA1c, moderate for LDL, blood pressure (BP) and adverse events, and low for disease-specific QoL and healthcare resource use due to inconsistency of findings among studies. For the other clinical conditions, where only a small number of studies (median 2.5; range 1 to 7) provided data on the effectiveness of TM, we judged the certainty of evidence to be moderate for the seven studies that recruited participants with a range of different mental health conditions due to limitations with the conduct of randomisation and high attrition. The findings of five out of six studies that recruited participants who required a specialist consultation for a number of different conditions (N = 3026; range 98 to 2094), were of high certainty, and one study with unblinded provider-assessed primary outcome and a small sample size provided low certainty of evidence. Eight studies recruited participants with respiratory conditions, of which the outcome data of five studies recruiting people with asthma (N = 525; range 109 to 200), were judged to be of moderate certainty due to inconsistency of findings, while results data from the three studies recruiting people with COPD (total N = 130; range 40 to 50) were downgraded to low certainty due to inconsistency of findings and imprecision (small sample sizes). For the five RCTs that targeted participants with heart disease after a clinical cardiac event or device implantation (total N = 4268; range 20 to 1997), the certainty of evidence was high in three of the studies, and downgraded to moderate in the other two due to high risk of bias. For the three studies that recruited patients with co- morbidities (total N = 209 ; range 37 to 104), the certainty of evidence was low due to inconsistency of findings and /or imprecision (small sample size) and high risk of bias. For the studies recruiting people with hypertension (four studies; total N = 2073; range 121 to 387), the certainty of evidence was judged to be moderate due to inconsistent findings.

## Potential biases in the review process

We tried to avoid publication bias by conducting an extensive search that included a large number of databases of published articles and sources of unpublished literature. Two people screened all search results to reduce the risk of missing a study for inclusion, and studies for possible inclusion were discussed by



the review authors to check that the inclusion criteria had been consistently applied.

## Agreements and disagreements with other studies or reviews

This review differs from other reviews, most of which focus on a single condition or include randomised and non-randomised evidence (for example, [Polisena 2009](#); [Polisena 2010](#)). We included studies in which TM is provided in addition to usual care, and studies in which TM is used as an alternative for usual care; other reviews have included one or the other (for example, [Marcolino 2013](#) included only studies in which TM was used in addition to usual care). Our finding of no difference in all-cause mortality between TM and usual care was also reported in a recent publication discussing the effectiveness of TM for the management of heart failure ([Anker 2011](#)), and two large trials reporting no effect ([Chaudhry 2007](#); [Koehler 2011](#)), but in disagreement with three other reviews that reported decreased mortality in participants with heart failure who received TM ([Inglis 2010](#); [Nakamura 2013](#); [Polisena 2010](#)). However, these reviews did not include the study by [Dar 2009](#), which reported an increased risk of mortality for those allocated to TM, or one or both large trials which showed no effect of TM. In addition, Nakamura and colleagues, who evaluated the effectiveness of remote patient monitoring for patients with chronic heart failure, excluded studies with fewer than 40 participants, many dropouts (not further specified), and studies published before 2003. The exclusion of small studies (<100 participants) is an approach we will use in the next update, as inclusion of a large number of small studies limits the extent to which the review can remain in date. Our results indicate no difference in the effects on all-cause re-admission to hospital between TM and control, which has also been reported by two other systematic reviews ([Clarke 2011](#); [Schmidt 2010](#)). Another Cochrane systematic review ([Inglis 2010](#)), reported a decreased re-admission rate for heart failure patients receiving TM, as compared with control. This review excluded trials which included a home visit or if clinic follow-up was for longer than four to six weeks. Our results of lower HbA1c levels in people allocated to TM than in controls are in agreement with results from two other systematic reviews ([Polisena 2009](#); [Marcolino 2013](#)). Another review ([Farmer 2004](#)), reported no difference for HbA1c between groups, but included telephone interventions, and observational and cross-over studies.

## AUTHORS' CONCLUSIONS

### Implications for practice

Telemedicine (TM) has the potential to be an effective tool for delivering more frequent and timely health care to people with chronic conditions at a distance, and for improving access to health care. While one aspect of successful implementation is the acceptability of TM by patients and practitioners, few studies included in the review directly assessed this. In addition, since only 10 of the included studies evaluated the effect of TM on practice-related outcomes, it is not possible to draw any conclusions about how the use of TM may affect professional practice. A high refusal and drop-out rate in the TM group in three of the studies suggest that in some circumstances TM was not acceptable. Reasons for participants withdrawing were associated with failure to transmit data. Few studies assessed patient satisfaction with the delivery of care. One study ([Bowles 2011](#)), which assessed patient satisfaction using a validated measure, reported higher patient

satisfaction with care in patients receiving TM, but also large losses to follow-up in the TM group as compared with usual care. Prior to establishing a TM service, an assessment of barriers may facilitate successful implementation ([Bashshur 2005](#)). Providing training to both providers and patients in how to manage the equipment, and the development of user-friendly TM systems, may also improve implementation. With the increasing ownership and use of mobile technologies, such as mobile phones, Smartphones and ultra-portable computers, these issues may become less important. The cost of implementing TM, compared with usual care, was only reported in 25% of included studies and no studies assessed how TM might alter the structure of health service delivery and payment. Summarising the cost of TM, compared with usual care, in any meaningful way was limited by each study attributing costs to different resources. In addition to the cost of the TM equipment, the costs of hospital admissions and costs to the patients and their families should also be accounted for. Cost savings associated with travel were commonly reported in studies using TM for remote consultations.

Fourteen studies recruiting participants with heart failure reported no increase in hospital admissions associated with using TM as an alternative to usual care. However, few of the studies included in this review reported data on unintended consequences and further evidence is required from implementation studies. With the function of some of the more outdated technologies being transferred to newer mobile devices, the implementation of these types of healthcare delivery systems is becoming more widespread. This increase in coverage is being accompanied by an increase in the number of different ways mobile technologies are being applied to deliver health care ([Free 2013](#)).

### Implications for research

A major barrier to conducting research in this area is that the rapidly evolving technology of TM is out of step with the time it takes to conduct research. New applications are being developed and applied in different settings and in areas with different healthcare needs. However, despite this caveat, the number of randomised controlled trials being conducted in this area is encouraging, though it would be more efficient if a few large trials were funded rather than a large number of small trials. Future research should build on the current evidence and aim to use the same standardised measures for outcomes that are important to patients, for example measures of disease-specific quality of life, self-care and satisfaction. Trials should aim to recruit clinically homogenous and well-defined populations to provide specific guidance for decision-makers. The inclusion criteria between studies recruiting participants with a similar condition varied, with some studies using previous hospitalisation as a proxy for the severity of the condition and others used standardised measures of clinical severity. Additional details of the type of care delivered in both intervention and control group would better support implementation. The evidence base for the cost-effectiveness of TM monitoring strategies to improve outcomes or reduce the need of face-to-face consultations is limited, future research should plan to address this by designing cost-effectiveness studies alongside studies of effectiveness. Pragmatic studies over multiple sites are also needed to show that individual site set-up costs are low enough to make the overall strategy cost-effective. Evidence on the acceptability to both patients and health professionals is also limited, future studies should attempt to capture patients views

and assess how TM fits within a local health system. Finally, the reporting of data can be improved to allow data to be combined from different studies.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Ahring 1992

Methods

**Study design:** RCT

**Inclusion criteria:** age 15 to 65 years, with insulin-dependent diabetes, HbA1c > 7, who owned a touch-tone telephone.

**Exclusion criteria:** NA

**Method of patient recruitment:** Patients referred from two endocrine clinics were consecutively chosen by one of the investigators, who did not know them.

**Study sample calculation:** NA



**Ahring 1992** (Continued)

**Data collection:** When entering the study and at the end of each 6-week period, all patients attended clinic, had blood drawn to determine HbA1c levels, and had their weight measured.

**Unit of analysis issues:** (yes/no): no

Participants

**Total no of eligible patients:** not stated (around 90% of patients to whom the study was explained entered the study)

**No of patients randomised to groups:** n = 42; Intervention: n = 22; Usual care: n = 20

**No of patients lost to follow-up:** n = 4; 2 patients from each group.

**Patient baseline characteristics:**

a) Clinical condition: diabetes treated by insulin

b) Age (years), mean, SD (range): Intervention: 41.6 ± 16.9 years (range 17-64 years); Usual care: 41.2 ± 13.9 years (range 20-65 years)

c) Gender: 22 females and 20 males

d) Ethnicity: NA

e) Severity of condition: NA

f) Major co-morbidities: NA

Condition specific characteristics:

Duration of diabetes, mean (SD): Intervention group: 11.93 ± 11.43 years; Usual care: 11.19 ± 4.51 years

Body weight, mean kg: 77.8 kg (range 49.5 to 114.0 kg) both groups taken together)

**Setting** (hospital/community/residential care): two endocrine clinics at a Health Science Centre

**Location** (rural/urban etc.): Newfoundland, rural area

**Country:** Canada

Interventions

**Study objective:** to assess whether the use of telephone modems for the transmission of self-monitored blood glucose improves diabetes control in a rural area

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** All patients were asked to perform five blood glucose determinations/day (before breakfast, before lunch, afternoon, before dinner, and at bedtime) twice/week. The modem group then transferred their data over the phone once a week. The data-link allows data to be collected in an assisted (manual) or unassisted (automatic) mode. All data collections in this study were done in an assisted mode because the telephone lines went through the hospital switchboard, which means that one of the investigators had to answer the phone. At the first visit, the patients in the intervention group were instructed on how to use the equipment.

**Type of technology and its application:**

For the modem group Glucometer M (Miles, Elkart, IN) was used together with a telephone modem, which allows the data stored in the glucometer to be transferred over telephone lines to a computer. Glucofacts Data Management (Miles) software was used for all computer tasks. It includes the data-collecting program Data-Link and the data-processing program Glucofacts. In the control group, 18 patients used Glucometer M, 2 patients used Glucometer II (Miles), which is very similar to Glucometer M in terms of operation and range of readings.

**Did the patient receive education about their condition?** Yes, through the diabetes centre

**Frequency of patient data transfer:** weekly

**Ahring 1992** (Continued)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** weekly (12 in total)

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The investigators.
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): after the receipt of data
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to adjust insulin dosage or food intake if necessary.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** NA

**Duration of intervention:** 12 weeks.

**Comparison intervention** (e.g. face-to-face, telephone, none): patients taking results of measurements to routine clinic visit at 0, 6, and 12 weeks.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> <li>• Random blood glucose</li> <li>• Number of hypoglycaemic episodes</li> <li>• Weight</li> <li>• Satisfaction of patients, carers and healthcare professionals (experimental group only)</li> </ul> <p><b>Follow-up time:</b> 12 weeks from start of intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> NA</p> <p><b>Sources of funding:</b> NA</p> <p><b>Conflicts of interest:</b> NA</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>p.971, Col.2, Para 4</p> <p>QUOTE:</p> <p>"Stratified blocked randomization was used to divide the patients into two groups at baseline to assure an even distribution between the study groups. The patients were randomly assigned to a control or modem (experimental) group."</p>
Allocation concealment (selection bias)	Low risk	See quote above.
Were baseline outcome measurements similar?	Unclear risk	No differences reported.
Were baseline characteristics similar?	Unclear risk	<p>see. p.972, Col.1, Para2</p> <p>QUOTE:</p> <p>"Of the few participant characteristics reported there were no differences."</p>

## Ahring 1992 (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: HbA1c, random blood glucose, weight</b>  The healthcare professional could not be blinded to the allocation of patients, and neither could the patient. However, HbA1c, random blood glucose and weight are objective outcomes.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	<b>Outcome group: no of hypoglycaemic events</b>  The participants and the personnel could not be blinded to the group allocation. The outcome (number of hypoglycaemic events) was patient-reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Four patients dropped out of the study, two from each group.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not identified.
Other bias	Low risk	No evidence of other risk of bias.

## Al Khatib 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> 18 years of age or older, participants had an implantable cardiac device with hospital follow-up planned, a landline telephone, and were able to provide informed consent.</p> <p><b>Exclusion criteria:</b> none stated</p> <p><b>Method of patient recruitment:</b> Patients were identified from the population of patients seen in any device clinic at Duke University Medical Center.</p> <p><b>Study sample calculation:</b> no information</p> <p><b>Data collection:</b> All patients randomised to the remote monitoring system were contacted via telephone at 6 months to collect data on cardiac problems, implantable cardioverter defibrillator (ICD)-related issues, medications, quality of life, and their satisfaction with their ICD care. All patients filled out a QOL and patient satisfaction questionnaire at baseline, 6 months (done via telephone for patients randomised to the remote monitoring arm), and 12 months after enrolment. All data obtained were based on patients' self-report.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> unclear, but n= 174 patients screened</p> <p><b>No of patients (randomised) to groups:</b> n = 151; Intervention: n = 76; Control: n = 75</p> <p><b>No of patients lost to follow-up:</b> n = 1 patient was lost to follow-up; four patients withdrew from the study (one for lack of transportation to clinic, one for a language barrier, and two were moved to a nursing home). Two patients crossed over from remote monitoring to quarterly clinic visits.</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: cardiac patients with an ICD</p> <p>b) Age (years): Intervention: 63 (54,70); Control: 63 (54, 72)</p> <p>c) Gender, male sex (%); Intervention: 72%; Control: 73%</p> <p>d) Ethnicity, white race (%): Intervention: 62%; Control: 64%</p>

**Al Khatib 2009** (Continued)

e) Severity of condition:

New York Heart Association (NYHA) class II or III, ischaemic cardiomyopathy, and ejection fraction (EF)  $\leq$  35%: Intervention: 57; Control: 60

NYHA class II or III, non-ischaemic cardiomyopathy, and EF  $\leq$  35%: Intervention: 33; Control: 30

NYHA class III or IV, EF  $\leq$  35%, QRS  $\geq$  120 ms: Intervention: 13; Control: 16;

f) Major co-morbidities:

Hypertension (%): Intervention: 71; Control: 65

Diabetes (%): Intervention: 37; Control: 35

Renal insufficiency (%): Intervention: 16; Control: 14

End-stage renal disease on dialysis (%): Intervention: 4; Control: 1;

Pulmonary disease (%): Intervention: 20; Control: 16

Cerebrovascular disease (%): Intervention: 5; Control: 14;

g) Condition specific characteristics: ICD (%): Intervention: 83%; Control: 80%

Mean time from device implantation to enrolment (years): Intervention:  $1.5 \pm 1.4$ ; Control:  $1.4 \pm 1.3$ ;

Coronary artery disease (CAD), NSVT, LVEF  $\leq$  40%, inducible sustained VT: Intervention: 7; Control: 6;

**Setting** (hospital/community/residential care): one University Medical Centre

**Location** (rural/urban etc.): urban (Durham, NC)

**Country:** USA

Interventions

**Study objective:** to determine whether remote monitoring of patients with ICDs improves patient outcomes compared with quarterly device interrogations in clinic

**Type of TM /mode of delivery** (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.): remote monitoring

**Delivery of the intervention:** Patients were taught how to use the remote monitor during their clinic visit. They were advised to keep a log of dates of and reasons for admissions to the hospital, emergency room visits, and electro-physiology clinic visits. They were asked to use the remote monitoring system every 3 months, and they were seen in the device clinic at 12 months and at any time for device-related issues.

**Type of technology and its application:** remote monitoring of ICDs using the Medtronic CareLink transmission monitor.

**Frequency of patient data transfer (monitoring studies only):** every three months

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** one telephone contact at 6 months and one follow-up clinic visit at 12 months

**Clinician response to receipt of data:**

a) Who contacts the patient?: The physician

b) Method of patient contact (e.g. e-mail, automated feedback, telephone): unclear

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): transmitted data were reviewed within two business days and patients were only contacted if further evaluation was needed. Emergent cases were reviewed as soon as the transmission was received.

## Al Khatib 2009 (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):unclear

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians

**Duration of intervention:** 12 months

**Comparison intervention:** quarterly clinical interrogations of device

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• Cardiovascular hospitalisations</li><li>• ED room visits for a cardiac cause</li><li>• Unscheduled visits to the electrophysiology clinic for a device-related issue at 1 year.</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Use of evidence-based medications</li><li>• Health Related Quality of Life(assessed with the EURO QoL thermometer)</li><li>• Patient satisfaction (unclear if assessed with validated tool)</li><li>• Costs of device implantation, clinic visits, remote monitoring/device interrogation, travel to the clinic, loss of work time not part of the analysis due to the elderly population recruited.</li></ul> <p><b>Follow-up time:</b> 12 months from start of intervention</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b>Funding was received from the same company that produces the technical equipment (Medtronic)</p> <p><b>Conflict of interest:</b> The lead author receives research funding and speaking fees from Medtronic and research funding from Biotronik. Dr. Piccini receives research funding from Merck (through an ACCF grant) and from Boston Scientific. The remaining authors declared no conflicts of interest.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	<p>p.546, Col 1, Para 2</p> <p>QUOTE:</p> <p>"Random group assignment was accomplished via sealed envelopes delivered to the clinic at the inception of the study."</p>
Allocation concealment (selection bias)	Unclear risk	<p>p.546, Col 1, Para 2</p> <p>QUOTE:</p> <p>"Random group assignment was accomplished via sealed envelopes delivered to the clinic at the inception of the study".</p>
Were baseline outcome measurements similar?	Low risk	<p>p.548, Col 1,Para 4-5</p> <p>QUOTE</p> <p>"Data on ICD detection and therapy at baseline and during follow-up are presented in Table 2. No differences were reported.</p>
Were baseline characteristics similar?	Unclear risk	<p>p.547, Col 2, Para 1</p> <p>QUOTE:</p>



## Al Khatib 2009 (Continued)

All baseline characteristics were evenly distributed between the 2 groups except for more patients receiving an ACE inhibitor at baseline.		
Blinding (performance bias and detection bias) Objective outcomes	High risk	<b>Outcome group: healthcare resource use, use of evidence based medication (both patient-reported)</b>  The participants and the personnel could not be blinded to the group allocation. Patient-reported outcomes at high risk.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Patient-reported outcomes assessed with a standardised questionnaire (HRQOL) at unclear risk.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A similar number of patients in the intervention (n = 70) and the control group (n = 69) was still in the study at 12 months follow-up. However, some outcome data were missing due to patients' failure to transmit data.  p.547,Col 2, Para 1  QUOTE:  "Excluding patients who died, withdrew from the study, or crossed-over from remote monitoring to quarterly clinic visits, six patients failed to transmit data at 3 months, one patient failed to transmit data at 6 months, and two patients failed to transmit data at 9 months."
Selective reporting (reporting bias)	Low risk	Results for all outcomes described in the trial protocol are presented in the paper.
Other bias	Low risk	No evidence of other risk of bias.

## Antonicelli 2008

### Methods

### Study design: RCT

**Inclusion criteria:** chronic heart failure signs and symptoms such as dyspnoea and peripheral or pulmonary oedema requiring diuretic administration (NYHA class II –IV); evidence of pulmonary congestion on chest x-rays, ejection fraction (EF) by cardiac ultrasonography < 40% as an index of systolic dysfunction, combined or not with a left ventricular filling pattern supporting the presence of diastolic dysfunction, according to the American College of Cardiology/American Heart Association Guidelines for chronic heart failure. Patients with New York Heart Association class II and III who had an EF fraction of > 40 % and evidence of diastolic LV dysfunction were also included in the study

**Exclusion criteria:** lack of co-operation and/or reliable family assistance at home, severe dementia or debilitating psychiatric disorders, inability to access a home telephone line, end-stage heart failure requiring regular inotropic drug infusions, cachexia, chronic renal failure requiring dialysis treatment and unstable angina

**Method of patient recruitment:** Hospitalised patients with heart failure were consecutively recruited from an ageing research hospital

**Study sample calculation:** minimum number 55 required for primary endpoint with a power of 80% and an error of 0.05 (two tailed test). The study power was > 95% for almost all the variables with the exception of differences in EF (power 79%) and in number of patients treated with ACE inhibitors (power 88%).

**Data collection:** participants in the intervention group were contacted by telephone at least once a week by the heart failure team, to collect information of symptoms and adherence to prescribed treatment as well as blood pressure, heart rate, body weight and 24 hours urine output on the previous day.

**Antonicelli 2008** (Continued)

A weekly ECG transmission was also required. Participants in the control group were contacted monthly by telephone to collect data on new hospital admissions, cardiovascular complications and death.

**Unit of analysis issues:** (yes/no): no

Participants	<p><b>Total no of eligible patients:</b> n = 96 participants were considered for inclusion, 39 were not included due to different reasons</p> <p><b>No of patients randomised to groups:</b> n = 57; Intervention: n = 28; Control: n = 29</p> <p><b>No of patients lost to follow-up:</b> no information</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: patients discharged after hospitalisation for worsening heart failure condition</p> <p>b) Age; years (SD): Intervention: 77 (8); Control: 79 (6)</p> <p>c) Gender, men/women (n, %); Intervention: 16/12 (57/43%); Control: 19/10 (66/35%)</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition:</p> <p>New York Heart Association class, n (%)</p> <p>Class II: Intervention:15 (54%); Control:18 (62%)</p> <p>Class III: Intervention:12 (43%); Control: 9 (31%)</p> <p>Class IV: Intervention:1 (4%); Control: 2 (7%)</p> <p>Ejection fraction, % (SD): Intervention: 35 (6); Control: 37(7)</p> <p>f) Major co-morbidities: no information</p> <p><b>Setting:</b> (hospital/community/residential care): one (the Italian National Research Centre on Ageing) hospital</p> <p><b>Location:</b> (rural/urban etc): urban (Ancona, central Italy)</p> <p><b>Country:</b> Italy</p>
Interventions	<p><b>Study objective:</b> to determine whether the addition of tele-monitoring in follow-up care for older patients with chronic heart failure improves outcomes as compared to standard follow-up care</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> remote monitoring + UC</p> <p><b>Delivery of intervention:</b> no description of how the TM system was used by the patients or by providers</p> <p><b>Type of technology and its application:</b> the patients were required to measure their home blood pressure daily using a transtelephonic ECG recording device (Card Guard CG-7100 12-lead device, Card Guard Scientific Survival Ltd, Israel), which was being obtained weekly and checked.</p> <p><b>Did the patient receive education about their condition?</b> Patients and caregivers underwent a training course during the hospitalisation period, to apply the home study protocol and to ensure the correct use of the equipment.</p> <p><b>Frequency of patient data transfer (monitoring studies only):</b> weekly ECG transmissions</p> <p><b>Planned/scheduled number of TM contacts between patient and healthcare personnel:</b> weekly</p> <p><b>Clinician response to receipt of data:</b></p> <p>a) Who contacts the patient?: CHF team member (specialist physician)</p>

## Antonicelli 2008 (Continued)

- b) Method of patient contact (e.g. e-mail, automated feedback, telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): weekly
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): changing treatment, clinic visits and admission to hospital

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** clinical heart specialists; both groups were managed by the same CHF team

**Duration of intervention:** 12 months

**Comparison intervention:** Participants in the control group were regularly seen in the heart failure outpatient clinic every four months, additional visits being performed whenever required by changes in clinical status (at least 4 clinic visits, and 12 telephone calls). Control participants underwent a course aimed at explaining the importance of adherence to therapeutic prescriptions as well as maintaining a suitable lifestyle.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Mortality</li><li>• Hospitalisation</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>• Compliance with drug regimen</li><li>• QOL (assessed with the SF-36)</li><li>• Costs (not reported)</li></ul> <b>Follow-up time:</b> 12 months from start of intervention	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> grants from the Italian Ministry of Health <b>Conflicts of interest:</b> no information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	No differences were reported
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: mortality, hospitalisation</b>  The healthcare professional could not be blinded to the group allocation, neither could the patients. However, the primary outcomes were objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: QOL, compliance with drug regimen and health perception scores.</b>

## Antonicelli 2008 (Continued)

		No information on whether or not the outcome assessor was blinded. The patient was not blinded to the intervention which may have affected the patient-reported outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not identified. In the abstract the authors say they will report cost outcomes, but no cost outcomes were reported.
Other bias	Low risk	No evidence of other risk of bias

## Artinian 2007

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> ≥18 years of age; SBP ≥140 mm Hg or DBP ≥90 mm Hg, unless self-identified as having diabetes or with a history of chronic kidney disease, then SBP ≥130 mm Hg or DBP ≥80 mm Hg; access to a land-based telephone in own residence (owned or rented); oriented to person, time, and place; English speaking; and intent to remain in Detroit for the next year.</p> <p><b>Exclusion criteria:</b> arm circumference &gt;17.5 inches; history of dementia, mental illness, terminal cancer, advanced liver disease, or haemodialysis; and self-reported illicit drug use or alcohol abuse as measured by the CAGE (Cut, Annoyed, Guilty, Eye-opener) questions (Buchsbaum, Buchanan, Centor, Schnoll, &amp; Lawton, 1991).</p> <p><b>Method of patient recruitment:</b> African Americans with hypertension were recruited through free blood pressure (BP) screenings offered at community centres, thrift stores, drug stores, and grocery stores located on the east side of Detroit. Because the classification of BP is based on at least the average of two or more properly measured, seated BP readings on each of two or more visits, participants were screened for study eligibility three times. The first screening was used to determine if they met the BP inclusion criterion. The second screening, about a week later, was used to determine if individuals met all other eligibility criteria, including the BP criterion. Individuals were screened a third time immediately prior to the baseline interview to verify continued uncontrolled BP.</p> <p><b>Study sample calculation:</b> no information</p> <p><b>Data collection:</b> Data were collected through two hours structured interviews and brief physical exam. Blood pressure was measured after a 5 min rest. Data were collected at baseline and 3-, 6- and 12-month follow-up.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 462 (n = 63 refused to participate; n = 12 were unable to contact)</p> <p><b>No of patients randomised to groups:</b> n = 387; Intervention: n = 194; Control: n = 193</p> <p><b>No of patients lost to follow-up:</b> N = 27 in the intervention group and n = 23 in control group were lost at 12-month follow-up</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: hypertension</p> <p>b) Age, M ± SD (years): Intervention: 59.1 ± 13.0; Control: 60.2 ± 12.3, t = 0.88 (ns)</p> <p>c) Gender, female sex no (%); Intervention: 114 (59); Control: 135 (70)</p> <p>d) Ethnicity: African Americans 100%</p>

**Artinian 2007** (Continued)

e) Severity of condition:

Mean number of antihypertension medications taken 7.87

0 medications: Intervention: 54 (34.4); Control: 60 (39.2)

1 medication; Intervention: 57 (36.3); Control: 57 (37.3)

2 medications: Intervention: 29 (18.5); Control: 29 (19.0)

3 medications: Intervention: 14 (8.9); Control: 6 (3.9)

4 medications: Intervention: 3 (1.9); Control: 1 (0.7)

SBP, mmHg: Intervention: 156.8 (19.6); Control: 155.9 (19.2)

DBP, mmHg: Intervention: 89.5 (14.0); Control: 88.4 (13.0)

f) Major co-morbidities: Self-reported diabetes: Intervention: 50 (25.8); Control: 50 (25.9)

**Setting** (hospital/community/residential care): community centres, thrift stores, drug stores, and grocery

**Location** (rural/urban etc.): urban (Detroit)

**Country:** USA

**Interventions**

**Study objective:** To test the hypothesis that individuals who participate in usual care (UC) plus BP tele-monitoring will have a greater reduction in BP from baseline to 12-month follow-up than would individuals who receive UC only.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring + UC

**Delivery of the intervention:** During a prescheduled appointment, the intervention nurse delivered the BP monitor and tele-monitoring link device (device that links BP monitor to the telephone) to the participant's home. At the time of the home visit, an intervention nurse taught participants how to self-monitor BP in accordance with The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-VII) guidelines (Chobanian et al., 2003), set up the home TM system, demonstrated the system, had participants practice using the BP monitor, and answered questions. The intervention nurse returned to the participant's home within 24 to 48 hours of the initial home visit for a follow-up demonstration and to answer additional questions. Between baseline and 12-month follow-up participants were asked to measure their BP three times a week in the morning before they had taken any antihypertension medication. From the digital reading on the automated BP monitor, participants knew their BP reading after each BP measurement. TM participants were also asked to telephonically send their BP readings to the intervention nurse and their care providers once a week during the first 3 months of the study, then once a month between the 4 and 12 month follow-up. Once the intervention nurses received the BP reports, they telephoned each participant to provide feedback in relation to the target goals and to provide tele-counselling about lifestyle modification and medication adherence in accordance with JNC-VII guidelines. Initially, tele-counselling calls were more frequent to assist participants to learn hypertension self-care behaviours and incorporate them into their daily routine or to establish them as habit; calls were gradually reduced during the follow-up period. Call attempts were made at varying times of the day and on varying days, including weekend days. For each week, five call attempts were made before the call was considered missed.

**Type of technology and its application:** The TM equipment was a LifeLink Monitoring, Inc. (Bearsville, NY). Participants connected their BP monitors to a BPLink Communicator (the Link) and pressed a single button to send stored readings. The Link, which connected to the participant's telephone, automatically dialled a toll-free number and connected to a server at LifeLink's headquarters. The server uploaded the stored readings, computed average BPs that could be compared with the target goal pressure, and formatted reports that were sent to the primary care providers and principal investigator by e-mail or fax. The target goal was set at 135/85 mm Hg because persons with an average BP more than 135/85 mm Hg measured at home are generally considered to be hypertensive (Chobanian et al., 2003).



**Artinian 2007** (Continued)

**Did the patient receive education about their condition?** Participants received an AHA pamphlet, Silent Stalker: Our Guide to High Blood Pressure, that identifies causes of HBP, describes how it is diagnosed, and suggests strategies to reduce risk and control HBP.

**Frequency of patient data transfer (monitoring studies only):** once a week during the first 3 months of the study, then once a month between the 4- and 12-month follow-up.

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** weekly between baseline and 3-month follow-up, monthly between 4 and 6 months, and then once at 8 months (a total of 16).

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The intervention nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): once the intervention nurses received the BP reports, they telephoned each participant.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to provide feedback in relation to the target goals and to provide tele-counselling about lifestyle modification and medication adherence in accordance with JNC-VII guidelines.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** specially trained nurses

**Duration of intervention:** 8 months

**Comparison intervention:** Enhanced UC for participants included visits to their primary care provider (PCP) scheduled at intervals requested by the PCP and influenced by the participant's level of adherence to keeping appointments. Participants who did not have a PCP were provided with a list of locations where they could obtain a PCP and free or low-cost health care. Participants who could not afford their medications were enrolled in a pharmacy assistance program.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Blood pressure</li> </ul> <p><b>Follow-up time:</b> 12 months after the start of the intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> This study was supported in part by a grant from National Institute of Nursing Research and National Institutes of Health: Grant No. RO1 NR 7682, 2001Y2006.</p> <p><b>Conflict of interest:</b> None stated</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>see p.515, Col 1, Para 1</p> <p>QUOTE:</p> <p>" Sequentially numbered computer-generated randomization assignments were determined prior to the start of data collection, but participants were not notified of the group assignment until after baseline data were collected. To keep data collectors blinded to group assignment, the study's project manager informed participants of their group assignment by mail or telephone within a week of their baseline interview. Data collectors were trained not to ask participants about group assignment and to ask participants not to reveal their assignment to them. Randomization was done individually within each data col-</p>

## Artinian 2007 (Continued)

		lection site to ensure balancing for sites and to ensure that all sites had a fair opportunity to try both interventions."
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Low risk	see quote below
Were baseline characteristics similar?	Low risk	see. p.317, Col 1, Para 4  QUOTE:  "There were no demographic or health characteristic differences between the two study groups, except gender and household density.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: blood pressure</b>  The healthcare professional delivering the intervention could not be blinded to the patient assignments, and nor could the patients. However, the main outcome (blood pressure) was objective and the data collectors blinded, and therefore the risk of bias low.  p.515, Col 1, Para 1  QUOTE:  "To keep data collectors blinded to group assignment, the study's project manager informed participants of their group assignment by mail or telephone within a week of their baseline interview. Data collectors were trained not to ask participants about group assignment and to ask participants not to reveal their assignment to them."
Incomplete outcome data (attrition bias) All outcomes	Low risk	N = 27/194 (14%) in the intervention group and n = 23/193 (12%) in control group were lost at 12-month follow-up. Analysis based on intention to treat.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not identified.
Other bias	Low risk	No evidence of other risk of bias.

## Benatar 2003

Methods	<b>Study design:</b> RCT	
	<p><b>Inclusion criteria:</b> included at least one of the following: (1) documented diagnosis of heart failure (HF) as determined by means of radiographic evidence of pulmonary congestion; (2) documented New York Heart Association classification III or IV; (3) HF symptoms of dyspnoea and oedema that responded to diuresis; and (4) echocardiographic evidence suggestive of HF. Heart failure was defined as an ejection fraction (EF) of 40% or less for systolic dysfunction, or impairment in one or more indices of ventricular filling with a corresponding clinical picture for diastolic dysfunction, in accordance with the American College of Cardiology/American Heart Association guidelines for chronic HF.</p> <p><b>Exclusion criteria:</b> (1) unstable angina, (2) renal failure, (3) severe dementia or another debilitating psychiatric disorder, (4) end-stage HF requiring regular inotropic infusions, (5) anticipated survival of less than 6 months, (6) planned discharge to a long-term care facility, (7) current use of illicit drugs, (8) participation in another HF research protocol within the last past 6 months, (9) scheduled HF specific home health nursing, and/or (10) lack of an operational home telephone line.</p>	

**Benatar 2003** (Continued)

**Method of patient recruitment:** patients admitted to the UIC and WSVA medical centres between April 1997 and July 2000 with a diagnosis of HF and meeting the inclusion criteria were asked to participate.

**Study sample calculation:**no

**Data collection:** Outcomes were measured at the end of the intervention period. Additional outcomes were measured at 6 and 12 months. Hospitalisation charges were calculated for each admission according to discharge summary data and totaled for each group. No information on how outcomes were assessed.

**Unit of analysis issues:** (yes/no): no

Participants

**Total no of eligible patients:** n = 272 hospitalised patients were identified during our time frame with a diagnosis of HF, n = 56 of these patients were excluded due to different reasons. No eligible patient refused participation.

**No of patients randomised to groups:** n = 216; Intervention: n = 108; Control: n = 108.

The patients entered the study 1 to 3 weeks after hospital discharge.

**No of patients lost to follow-up:** All randomised patients completed at least 3 months of the study.

**Patient baseline characteristics:**

a) Clinical condition: HF

b) Age, mean  $\pm$  SD, years: Intervention: 62.9  $\pm$  13.2; Control: 63.2  $\pm$  12.6

c. Gender, female sex ,no (%): Intervention: 69 (63.9); Control: 67 (62.0)

d) Ethnicity, African American, no (%): Intervention: 90 (83.3); Control: 96 (88.9)

e) Severity of condition:

NYHA class, mean  $\pm$  SD : Intervention: 3.13  $\pm$  0.27; Control: 3.12  $\pm$  0.25

LVEF, mean $\pm$ SD, %: Intervention: 38.05  $\pm$  13.7; Control: 38.83  $\pm$  13.97

f). Major co-morbidities: Diabetes: Intervention: 39 (36.1%) ; Control:11.0 (10.2%) , P < 0.001.

Hypertension and Coronary heart disease (no differences between groups)

Condition specific characteristics:

There were no differences in treatments/medications between groups.

**Setting** (hospital/community/residential care): the UIC and WSVA medical centres, three home health-care agencies

**Location** (rural/urban etc.): urban

**Country:** USA

Interventions

**Study objective:** to compare outcomes for patients whose home care is provided by nurse tele-management or home nurse visits

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (frequent surveillance for timely actions; assessment, medication therapy, education)

**Deelivery of the intervention:** Patients used transtelephonic home monitoring devices to measure their weight, blood pressure, heart rate, and oxygen saturation. These data were transmitted daily to a secure Internet site. The tele-management model incorporates an advanced practice nurse (APN) who works collaboratively with a cardiology fellow and a cardiology attending physician. Medical plans are developed by the physicians and implemented by the APN. Clinical goals for tele-management are set as desired physiological ranges for blood pressure, heart rate, weight, and laboratory values specified

## Benatar 2003 (Continued)

to each patient's individual medical plan; the APN evaluates the objective data transmitted by the patient; conducts telephone assessments, titrates medication therapy, and conducts patient education as needed to achieve the goal of the medical plan.

**Type of technology and its application:** The home monitor is a small, lightweight device (64X152X89 mm, 680 g) that automatically notifies patients to obtain their vital signs (blood pressure, heart rate, arterial oxygen saturation, and weight). The tele-management hardware and software were developed and purchased from AvidCare Corporation (Milwaukee, Wis). Alarm parameters were established according to each patient's baseline condition, as deemed appropriate by the medical director and the APN. The home monitor was attached in parallel to the patient's telephone line and transmitted the acquired physiological data to a central on-line server, which can be accessed by the care givers using a secure Internet connection. In addition, the server automatically transmits physiological alarms along with the time, date of the alarm, and patient home telephone number to an alphanumeric pager. The pager and a cellular phone allow for timely response relative to any aberrant data. Any patient data that exceed their specific physiological parameters are sent as alarms to the receiving alphanumeric pager. Additional patient data and a complete electronic health file can also be accessed and reviewed from the same Internet site.

**Did the patient receive education about their condition?** Education was one part of the intervention.

**Frequency of patient data transfer (monitoring studies only):** Daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** No information

**Clinician response to receipt of data:**

- a) Who contacts the patient?: An APN
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): 'timely response to any aberrant data'
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): conducts telephone assessments, titrates medication therapy; conducts patient education.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** an APN working collaboratively with a cardiologist physician and a cardiologist fellow (nurses from three homecare agencies delivered the care in the control group and a single tele-monitoring APN delivered the TM intervention)

**Duration of intervention:** 3 months

**Comparison intervention:** Three home healthcare agencies provided care for the usual care group (home nurse visits), all of which followed a specific HF program with clinical pathways based on the American Health Care and Policy Research clinical HF guidelines and used special cardiac nurses. Visit frequency was based on the following template: 3 visits during the first week, 2 visits during the second and third weeks, 1 visit during the fourth and fifth week, and further visits on an as needed basis. The first 4 visits included detailed discussions involving diet, symptom recognition, and compliance with medication regimens. The remaining visits included assessment of the patient's symptoms and vital signs with physician notification, if deemed necessary. From 9 to 12 home visits were made, depending on the need defined in each agency-specific clinical pathway. Visit frequency was similar in all three groups, and was based on the following template: 3 visits during the first week; 2 visits during the second and third weeks, one visit during the fourth and fifth weeks, and further visits on an as-needed basis.

## Outcomes

### Primary outcomes:

- Re-admission due to heart failure
- Length of stay (LoS)
- Hospitalisation charges
- Self-efficacy (assessed with the Heart Failure Self Efficacy Scale 30) at 3 months

### Benatar 2003 (Continued)

- QOL (assessed using the Minnesota Living with Hear Failure questionnaire; the Quality of Life Index-Cardiac version; Hospital Anxiety and Depression scale) at 3 months

**Follow-up time:** at 3, 6 and 12 months after randomisation

Notes	<p><b>Ethical approval and informed written consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> grants from the US National Institutes of Health</p> <p><b>Conflict of interest:</b> no information</p>
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#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	There were no baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	see p.349, Col 2, Para 2 no differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p><b>Outcome group: re-admissions, LoS, hospitalisation charges</b></p> <p>The healthcare professional could not be blinded to the patient allocation, and neither could the patient. However, objective outcomes are at low risk of bias.</p>
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<p><b>Outcome group: self-efficacy and QOL</b></p> <p>The participating patients and personnel could not be blinded to the group allocation. This may have affected the patient-reported outcomes.</p>
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>p.349, Col 1, Para 2</p> <p>QUOTE:</p> <p>"All randomised patients completed at least 3 months of the study". The number of patients remaining in the study at 6 and 12 months was not reported.</p>
Selective reporting (reporting bias)	Unclear risk	Trial protocol not identified.
Other bias	Low risk	No evidence of other risk of bias.

### Bergmo 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Children with medium to severe atopic dermatitis</p> <p><b>Exclusion criteria:</b> Not reported</p> <p><b>Method of patient recruitment:</b> Parents were asked for permission to participate in the trial during the initial consultation.</p>
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**Bergmo 2009** (Continued)

**Study sample calculation:** Not reported

**Data collection:** Questionnaires at baseline and 12 months follow-up, and through logging messages.

**Unit of analysis issues:** (yes/no): no

Participants

**Total no of eligible patients:** unclear (a total of n = 131 children and parents. unclear number of patients from a second clinic (Hammerfest Hospital))

**No of patients randomised to groups:** n = 98, intervention: n = 50; control: n = 48

**No of patients lost to follow-up:** 74.5% of participants completed follow-up

**Patient baseline characteristics:**

a) Clinical condition: children with medium to severe atopic dermatitis

b) Age: intervention: 4.6 (3.7–5.5) years; control: 5.3 (4.3–6.3) years

c) Gender, female sex number (%); intervention: 26 (52); control: 28 (58)

d) Ethnicity: not reported

e) Severity of condition: Scoring Atopic Dermatitis (SCORAD): intervention: 22.3 (19.1–25.6); control: 22.3 (18.7–25.8)

f) Major co-morbidities: not reported

g) Other treatments received: complementary therapies used by the children's parents.

**Setting** (hospital/community/residential care): one university hospital Paediatric and Dermatology clinic (or Hammerfest Hospital) clinic in north Norway (secondary care)

**Location** (rural/urban etc.): Hammerfest

**Country:** Norway

Interventions

**Study objective:** To analyse how web-based consultations for parents of children with atopic dermatitis effect self-management behaviour, health outcome, health resource use and family costs.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** Web-based consultations

**Delivery of intervention:** The parents sent digital photographs of the affected area, together with supplementary information, to classify and rate the extent and severity of eczema and to consult a paediatric dermatologist for treatment advice. The dermatologist responded in 24 hours, or during the next working day, to provide advice using web-based messaging.

**Type of technology and its application:** A secure web-based messaging/consultation system.

**Did the patients receive education about their condition?** Both intervention and control group received education.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The dermatology resident.

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): secure web-based messaging.

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): within 24 hours or next day (delayed).

## Bergmo 2009 (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): advice on how to handle the condition.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** one dermatology resident (or specialist nurse if the resident was not available).

**Duration of intervention:** 12 months.

**Comparison intervention:** The control group received standard treatment without TM access to specialist care. They were encouraged to seek treatment through traditional means such as general practitioner (GP) visits and hospital care

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Severity score of atopic dermatitis</li><li>Resource use (self-reported GP visits etc.)</li><li>Family costs (self-reported)</li></ul> <b>Follow-up time:</b> 12 months from baseline	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> Helse Nord <b>Conflict of interest:</b> None stated.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	p.317, Col.1, Para.2  QUOTE:  "..the children were consecutively randomized into two groups, using the simple randomization method with shuffled envelopes (48 to the control group and 50 to the intervention group).The parents then received information in a letter about group allocation"  Comment: unclear if the envelopes were opaque
Allocation concealment (selection bias)	Unclear risk	See quote and comment above
Were baseline outcome measurements similar?	Unclear risk	No information.
Were baseline characteristics similar?	Unclear risk	p.318, Col.1, Para.2  QUOTE:  Differences between groups include parents age (younger in the intervention group) and urban residency (more in the intervention group lived in an urban setting).
Blinding (performance bias and detection bias) Objective outcomes	High risk	<b>Outcome group: resource use and costs (patient-reported)</b>  Neither the healthcare professional or patient could not be blinded to the intervention. All outcomes were patient-reported.

## Bergmo 2009 (Continued)

Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	<b>Outcome group: severity score (physician-rated)</b>  Neither the healthcare professional or patient could not be blinded to the intervention; the outcome was assessed by unblinded physician..
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.318, Col.1, Para.1  QUOTE:  "Participants with missing data were excluded from the specific analyses." 74.5% completed follow-up.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

## Biermann 2000

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients receiving intensified insulin therapy with a minimum of 4 insulin injections daily, separation of basal and meal-related insulin and a predefined target range for pre-prandial blood glucose. Patients received a structured diabetes education programme, self-monitoring of blood glucose values before each insulin injection and calculation of insulin dose by carbohydrates to be ingested and actual blood glucose value.</p> <p><b>Exclusion criteria:</b> None stated.</p> <p><b>Method of patient recruitment:</b> Not reported.</p> <p><b>Study sample calculation:</b> The sample size was calculated assuming a difference in glycosylated haemoglobin (HbA1c) of 1%, a SD of 1.5%, a type 1 error of 0.05 (95% CI) and a type 2 error of 0.1.</p> <p><b>Data collection:</b> Laboratory controls and metabolic assessment were scheduled every 2 months for safety reasons.. Consultation times were taken from the patients chart records and all other times were recorded by questionnaire.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> Not reported.</p> <p><b>No of patients randomised to groups:</b> n = 48; intervention: n = 30; control: n = 18</p> <p><b>No of patients lost to follow-up:</b> n = 3 in the Intervention group and n = 2 in the control group</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: diabetes (insulin treated)</li> <li>b) Age: Intervention: 30.5 ± 11 years; Control: 30.0 ± 8.6 years</li> <li>c) Gender: no information</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition:</li> </ul> <p>Unstable metabolic control: Intervention: 9 patients; Control: 3 patients</p> <p>Duration of diabetes: Intervention: 10.9 years; Control: 8.1 years</p>

## Biermann 2000 (Continued)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one diabetes centre.

**Location** (rural/urban etc.): unclear

**Country:** Germany

### Interventions

**Study objective:** not explicitly stated.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring.

**Delivery of intervention:** every 1 to 3 weeks the patients transmitted data and every 2 to 4 weeks the nurse contacted the patients to advise on their insulin dose. Additional consultations, were scheduled on demand. For urgent consultations, patients were able to contact the centre via a 24-hour voice recorder system and a consultation with the physician was established the following day. Telecare patients were asked to transmit their blood glucose values before each personal visit or telephone consultation, or, because of limited storage capacity of the blood glucose-meters, at least every 2 weeks.

**Type of technology and its application:** a tele-medical system for transmission of self-monitoring blood glucose values from the patients' home to the diabetes centre with a combined modem-interface is described. Data are processed by PC and advice is given by telephone. Patients received a modem preprogrammed with their ID and the telephone number of the diabetes centre for automatic dialling. They determined their blood glucose-values by using memory meters, and storing these values with their respective date and time on a blood glucose-meter with a storage capacity of 120 values (Precision QID Abbott/mediSense). The meter could be connected to the preprogrammed modem, which automatically uploaded the data via the analogue telephone system to the diabetes centre. At the diabetes centre data were displayed and stored by a customised software (Precision Link Plus, Abbott, mediSense). Advice for proper dose was given by telephone.

**Did the patients receive education about their condition?** Yes

**Frequency of patient data transfer (monitoring studies only):** every 1 to 3 weeks

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** every 2 to 4 weeks

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): every 2 to 4 weeks (no alarms) depending on the extent of specific problems, or the day after if urgent
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): advice for proper insulin dose adjustment.

**Providers (e.g. number, profession, training, ethnicity etc. if relevant):** physicians.

**Duration of intervention:** 4 to 8 months.

**Comparison intervention:** personal visits in the control group were performed on average once a month.

### Outcomes

**Primary outcomes:**

- HBA1c
- Patient time expenditure
- Physician time expenditure
- Costs (no data reported)
- Number of hypoglycaemic events (data presented in graphs only)

**Biermann 2000** (Continued)

**Follow-up time:** 4 months after randomisation (8 months for a smaller group of patients if blood glucose was not under control).

Notes

**Ethical approval and informed consent obtained (yes/no):** Not reported.

**Sources of funding:** MediSense/Abbott Co., Wiesbaden, Germany

**Conflict of interest:** Not reported.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation was carried out by lots with a chance of 2:1 in favour of telecare.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Low risk	p.5, Col.2, Para.1  QUOTE:  "The differences in the frequency of hypoglycaemia are random due to the wide dispersion of these values and the relatively small sample size."
Were baseline characteristics similar?	Low risk	p.5, Col.2, Para.1  QUOTE:  "Data indicates fairly good matching of the patients between the two groups."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: HbA1c</b>  The healthcare professional could not be blinded to the intervention, and neither could the patient. However, as an objective measure of outcome this was judged at low risk of bias.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: time expenditure</b>  The healthcare professional could not be blinded to the intervention, and neither could the patient. Non-objective outcomes (self-reported time expenditure) judged at unclear risk.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	N = 3 in the intervention group and n = 2 in the control group were lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Boaz 2009**

Methods

**Study design:** RCT



## Boaz 2009 (Continued)

**Inclusion criteria:** 18 years of age and older, who monitored blood glucose with a glucometer more than six times daily at least 2 times per week and more than 3 times daily the rest of the week.

**Exclusion criteria:** diagnosis of concomitant illness including advanced or active cardiovascular disease, neurologic, psychiatric illness or any terminal illness. Patients participating in any other study could not concurrently participate in this study.

**Method of patient recruitment:** study participants were drawn from among insulin-treated patients with Type I and Type II diabetes treated at the E.Wolfson Medical Center (Holon, Israel) ambulatory diabetes clinic.

**Study sample calculation:** post hoc power calculation reported; the authors state that the study is underpowered to detect differences in clinical endpoints.

**Data collection:** the metabolic parameters were assessed and the QOL questionnaire administered at baseline and at the 6-month follow-up point

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** not reported.

**No of patients randomised to groups:** n = 35; intervention: n = 18; control: n = 17

**No of patients lost to follow-up:** not reported.

**Patient baseline characteristics:**

a) Condition: insulin treated diabetes Type I and Type II )

b) Age: Intervention: 63 ± 10 years; Control: 63 ± 15 years

c) Gender: female sex no (%); intervention: 10 (59); control: 12 (67)

d) Ethnicity: no information

e) Severity of condition: no information

f) Major co-morbidities: no information

Condition specific characteristics:

HbA1c(%): intervention: 8.4 ± 1.4; control: 9.3 ± 1.6

Weight, kg: intervention: 78 ± 11; control: 77 ± 12

**Setting** (hospital/community/residential care): one hospital medical centre

**Location:** urban (Holon, Tel-Aviv area)

**Country:** Israel

### Interventions

**Study objective:** to assess impact of remote monitoring (TM) versus conventional monitoring of patients with diabetes on quality of life, treatment satisfaction and markers of metabolic control during a 6-month follow-up period.

**Type of TM/ mode of delivery (e.g. video conferencing, remote monitoring with healthcare professional responding to transferred data and alerts, etc) :** remote monitoring

**Delivery of the intervention:** real-time blood glucose data were transmitted to the diabetes clinic from the patient's home. If the values deviated from normal the patient was contacted by a specialist nurse over the phone to provide advice, and the nurse also alerted the patient's physician. In non-urgent cases, patients in the TM group were free to contact the diabetes clinic by phone as needed. Both groups received training on the use of the glucometer. In the TM group, patients also received instructions on how to utilise the monitoring system.

## Boaz 2009 (Continued)

**Type of technology and its application:** the TM group glucometers were fitted with a transmitter that automatically transferred data via Medicgate, a receiver that also transmits data to the information server. Information was transferred in real-time directly to a computerised medical file. Additionally, results of the glucose measures were simultaneously shown both on the patient's glucometer display and on the diabetes clinic's computer screen. Access to these data was via Internet. For each patient, a range of acceptable glucose values was individually set, and values less than or exceeding the range (from 50 to 280 mg/dL for most patients) triggered an audio alarm at the diabetes clinic computer and generated a text message to the cellular phone of the caregiver, a specialised diabetes nurse (certified by the Ministry of Health to provide medical advice regarding titration of insulin dose, oral medications etc.).

**Did the patient receive education about their condition?** No information

**Frequency of patient data transfer (monitoring studies only):** unclear

**Planned/scheduled number of TM contacts between patient and healthcare provider:** unclear

**Clinician response to receipt of data:**

- a) Who contacts the patient?: A specialised diabetes nurse
- b) Method of patient contact (e.g. e-mail, telephone, automated feedback): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): provide medical advice regarding titration of insulin dose, oral medications etc., and also notified the diabetes care physician.

**Providers (e.g. number, profession, training):** one specialist nurse

**Duration of intervention:** 6 months

**Comparison intervention:** participants in the conventional monitoring group used their usual glucometers and were free to contact clinic personnel by telephone or visit their outpatient clinic or emergency care unit if they felt glucose values deviated from desired levels. Otherwise, they were scheduled to visit the diabetes clinic every 3 months.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• HbA1C</li><li>• Other metabolic markers</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Quality of life (questionnaire name not reported, measured disease symptoms, subjective psychological experience of disease, perceived control, need of family assistance)</li><li>• Patient satisfaction (unclear if assessed with validated tool)</li></ul> <p><b>Follow-up time:</b> 6 months after start of intervention</p>	
Notes	<p><b>Ethic approval and informed consent obtained:</b> yes</p> <p><b>Sources of funding:</b> equipment was provided by Medic4all, Israel. However, no financial association exists or was provided by the company for this project or for any other project with which these researchers are associated.</p> <p><b>Conflict of interests:</b> no conflict of interest for any of the authors.</p>	
<b>Risk of bias</b>		
Bias	Authors' judgement	Support for judgement

## Boaz 2009 (Continued)

Random sequence generation (selection bias)	Unclear risk	see p.182, Col 1, Para 2  QUOTE:  "Subjects were randomised to TM or conventional monitoring,"
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Low risk	see p.183, Col 1, Para 2  QUOTE:  "The groups were similar with the exception of HbA1c, which was markedly higher in the control group."  "Table 2 presents baseline quality of life measures by monitoring group. Again the groups were similar in terms of symptoms, hypo- and hyperglycaemic event rates, and subjective experience of disease." Comment: HbA1c was adjusted for baseline differences.
Were baseline characteristics similar?	Low risk	see p.183, Col 1, Para 2  QUOTE:  "Demographic and baseline metabolic characteristics of the study population are presented in Table 1. The groups were similar with the exception of HbA1c, which was markedly higher in the control group."
Blinding (performance bias and detection bias) - Objective outcomes	Low risk	<b>Outcome group: metabolic parameters</b>  The health professionals could not be blinded to the group allocation, and neither could the patients. However, objective outcomes judged at low risk.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: clinical events, symptom free, quality of life, satisfaction</b>  The participants and personnel could not be blinded to the group allocation, which may have affected the non-objective patient-reported outcomes. High risk for patient-reported outcomes, and unclear for those assessed by a standardised quality of life questionnaire.
Incomplete outcome data (attrition bias) - All outcomes	Unclear risk	Not reported.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Bond 2007

Methods	<b>Study design:</b> RCT	
	<b>Inclusion criteria:</b> age 60 years or older, having been diagnosed with diabetes (Type 1 or Type 2) for at least 1 year, living independently in the community, and oral fluency in English. No prior computer experience was required. Individuals were eligible regardless of entry HbA1c level.	

## Bond 2007 (Continued)

**Exclusion criteria:** moderate or severe cognitive, visual, or physical impairment or the presence of severe comorbid disease (end-stage renal disease, blindness, terminal cancer).

**Method of patient recruitment:** participants were enrolled through the University of Washington Diabetes Center, Puget Sound Health System, and local diabetes fairs held in the greater Seattle area. Flyers, provider referral or letters sent to potential participants from members of the Washington State Diabetes Registry. Eligibility was screened by telephone prior to the baseline examination. Eligible participants were contacted by mail and telephone and invited to attend the baseline examination, where consent was obtained.

**Study sample calculation:** 62 participants (including a 15% attrition rate), based on a 0.5 correlation between the pre-intervention/post-intervention scores, would provide for an intervention control comparison of the magnitude demonstrated in the literature to detect a moderate effect size of 0.55 with an 80% power.

**Data collection:** A home visit performed by a trained research assistant/phlebotomist was done at baseline and 6 months post-intervention using a single-use home HbA1c testing kit, a blood pressure device with various-size cuffs, and a calibrated scale.

**Unit of analysis issues:** no

### Participants

**Total no of eligible patients:** n = 62

**No of patients randomised to groups:** n = 62; intervention: n = 31; control: n = 31

**No of patients lost to follow-up:** no losses to follow-up

**Patient baseline characteristics:**

a) Clinical condition: diabetes (Type 1 or Type 2)

b) Age, mean years: intervention: 66.2 (5.7); control: 68.2 (6.2)

c) Gender, % female sex: intervention: 42%; control: 48%

d) Ethnicity, Caucasian: intervention: 87%; control: 86%

e) Severity of condition:

Years with diabetes:(mean): intervention: 16.1 (10.5); control: 17.8 (11.7)

BL HbA1c (%): intervention: 7.1 (0.18); control: 7.1 (0.20)

BL Blood pressure (mm Hg)

Systolic intervention: 132 (2.5); control: 132 (2.8)

Diastolic intervention: 76 (1.2); control: 74 (1.3)

HDL cholesterol (mg/dL): intervention: 43 (2.5); control: 43 (2.9)

Total cholesterol (mg/dL): intervention: 174 (5.7); control: 176 (6.5)

Weight (pounds): intervention: 200 (6.4); control: 207 (7.4)

f) Major co-morbidities: no information.

**Setting** (hospital/community/residential care): one diabetes (hospital) clinic.

**Location** (rural/urban etc.): unclear.

**Country:** USA.

### Interventions

**Study objective:** to investigate the impact of a 6-month web-based intervention on the physical outcomes associated with diabetes management in older adults.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (web-based intervention; additional to usual care).

## Bond 2007 (Continued)

**Delivery of the intervention:** a program designed to be delivered via the Internet to improve the participants' diabetes self-management by using behavioural and motivational strategies and cues to modify perceptions of self-efficacy and personal beliefs regarding the ability to affect the progress of the disease and change personal behaviour. Additional strategies included instruction in disease management, diet, and exercise, and the introduction of interventions to deal with the physical and emotional demands of the disease. The active intervention served as an adjunct to usual care provided by each participant's provider. The interaction between the study nurse and active intervention participants occurred using both synchronous communication (instant messaging and chat) and asynchronous communication (e-mail and a bulletin board). In addition, participants accessed a study web-site ([www.diabetes-takecharge.org](http://www.diabetes-takecharge.org)) to enter their blood sugar readings, exercise programs, weight changes, blood pressure, and medication data. The study nurse accessed participants' logs to monitor changes in their self-management patterns. As part of the intervention, the study nurse contacted the participant via e-mail or through instant messenger and/or chat when there were changes in blood sugar patterns that needed problem-solving to resolve. The weekly online educational discussion group treatment component was delivered by the principal investigator through a weekly online or e-mail communication.

**Type of technology and its application:** no additional details.

**Did the patient receive education about their condition?** Yes, as a part of the intervention.

**Frequency of patient data transfer (monitoring studies only):** not reported.

**Planned /scheduled no of TM contacts between patient and healthcare professional:** none.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse.
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): direct chat/messaging or e-mail.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): not reported.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): problem-solving, self-management education.

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** a nurse.

**Comparison intervention:** participants in the control group received their standard diabetes care from their provider. No educational or training materials associated with the intervention were provided to the control group. Participants in the control group had access to educational materials/classes provided by their health provider through traditional face-to-face classroom methods and/or via the Internet.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> <li>• Blood pressure</li> <li>• Weight</li> <li>• Cholesterol, and high-density lipoprotein (HDL) levels</li> <li>• QoL (assessed with the The Problem Areas in Diabetes Scale (PAID scale)</li> <li>• Depression (assessed with the Center for Epidemiological Studies Depression Scale (CES-D scale)</li> <li>• Social support (assessed with the Diabetes Support Scale)</li> <li>• Self-efficacy (assessed with the DES scale (Diabetes Empowerment Scale)</li> </ul> <p><b>Follow-up time:</b> 6 months after randomisation (but a 12 month follow-up was described in the trial protocol).</p>
Notes	<p><b>Ethics committee approval and informed consent obtained (yes/no):</b> yes.</p>



## Bond 2007 (Continued)

**Sources of funding:** grant K01 NR08506-03 from the National Institute of Nursing Research.

**Conflict of interest:** None stated.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were assigned to intervention or control groups based on a stratified randomisation, managed by an institutional biostatistician who was external to the project (information retrieved from authors).
Allocation concealment (selection bias)	Low risk	Prior to the step of randomisation disclosure to the participant, the recruitment and interventionist team members were blinded to the randomised assignment (information retrieved from authors).
Were baseline outcome measurements similar?	Low risk	The intervention and control groups did not differ with respect to baseline demographic and clinical characteristics (Tables 2 and 3).
Were baseline characteristics similar?	Low risk	The intervention and control groups did not differ with respect to baseline demographic and clinical characteristics (Tables 2 and 3).
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: HbA1c, BP, cholesterol, and weight.</b> All physiological outcomes were objective and the personnel conducting these examinations were blinded to intervention status and were not involved in supporting the technical aspects of the intervention, or in delivering diabetes case management services.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: quality of life, depression, social support and self-efficacy</b> (assessed with validated instruments). Patient-reported outcomes may be at risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although there were some variations in participation in the intervention, there was no loss to follow-up for the primary outcome.
Selective reporting (reporting bias)	Low risk	According to the trial protocol the plan was to measure and report results for multiple measures within three different domains: 1) physical (glycosylated haemoglobin [HbA1C], weight, and lipid levels); 2) behavioural (monitoring blood glucose levels, feet inspections, diet, and exercise frequency), and 3) psychosocial (depression, quality of life, social support, and adjustment to diabetes). Results for the behavioural measures were not reported in Bond 2007 or in Bond 2010, but in a paper from 2008, in which preliminary results were reported.
Other bias	Low risk	No evidence of other risk of bias.

## Bowles 2011

### Methods

**Study design:** RCT

**Inclusion criteria:** English speakers; mentally competent as determined by the Mini Cog test [33, 34]; weighed less than 450 pounds (scale maximum); had a land line telephone; were able to see, hear, place a cuff on their arm, and stand on a scale to weigh themselves; and were referred to, and accepted home care services.

**Bowles 2011** (Continued)

**Exclusion criteria:** Patients in another heart failure (HF) clinical trial, on dialysis, on the heart transplant list, with cancer as a primary diagnosis, or in a disease management programme.

**Method of patient recruitment:** not reported; recruitment took place between March 2006 and November 2009.

**Study sample calculation:** sample size calculation based on home care agency reported 60-day re-admission rates of 37% at the time of study planning. Unpublished pilot work and experience in other studies indicated that the re-admission rate may decrease to 19% using tele-health [35, 36]. The anticipated difference between groups was 19% with  $\alpha = 0.05$  yielding power of 0.80. This would require a sample size of 90 per group (or 180 total participants). To account for the anticipated effect of a 20% attrition rate, we targeted 108 participants per group for a total of 216 participants.

**Data collection:** Information about re-admissions, ED use, and length of stay was also collected from the hospital administrative database and medical records department.

**Unit of analysis issues:** (yes/no): no

Participants

**Total no of eligible patients:**  $n = 475$ , of which 257 refused to participate (54.21%).

**No of patients randomised to groups:**  $n = 218$ ; intervention:  $n = 102$ ; control:  $n = 116$ .

**No of patients lost to follow-up:** six patients in each group died during the study, 31 of 102 (30.1%) TM participants withdrew from the study as compared with 18 of 116 (15.5%) randomised to usual care. One intervention patient was excluded due to transplantation.

**Patient baseline characteristics:**

a) Clinical condition: heart failure

b) Age (years), mean, SD: TM: 71.3 (10.2); usual care 73.5 (9.6)

c) Gender, male number (%): TM:36 (35.6); usual care:39 (33.6)

d) Ethnicity: white, number (%): TM:33 (32.7); usual care:39 (33.6); African-Caribbean number (%): TM:66 (65.3); usual care:75 (64.7)

e) Severity of condition: symptoms well controlled with current therapy number (%): TM:0 (0); usual care:2 (1.8)

Symptoms controlled with difficulty, affecting daily functioning; patient needs ongoing monitoring: TM:52; (51.5); usual care: 72 (63.2)

Symptoms poorly controlled, patient needs frequent adjustments in treatment and dose monitoring: TM:40 (39.6); usual care:30 (26.3)

Symptoms poorly controlled, history of re-hospitalisation: TM: 9 (8.9); usual care: 10 (8.8)

HF (months): TM:60.7 (67.7); usual care: 61.5 (71.6) (usual care: data for one patient missing)

f) Major co-morbidities:

Co-morbid Conditions: TM: 6.8 (4.0),  $n = 101$ ; usual care: 6.0 (4.0),  $n = 116$

g) Other treatment:concomitant medications: TM: 11.3 (4.6),  $n = 95$ ; usual care: 10.0 (3.4),  $n = 113$

**Setting** (hospital/community/residential care): one (not-for-profit) Home Health Care Agency (HHCA)

**Location** (rural/urban etc.): Philadelphia

**Country:** USA

Interventions

**Study objective:** to assess the clinical effectiveness, access to, and satisfaction with care using a Tele-homecare substitution Intervention.

## Bowles 2011 (Continued)

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring+ video-conferencing (partly substituting usual home care)

**Delivery of intervention:** nurses taught the patients and their caregivers how to operate the equipment and reviewed the study goals. Patients were taught to use the devices daily by 11 am and a tele-health nurse at the agency monitored the data daily for out of range readings. According to the protocol, the tele-homecare nurse was to make at least four video visits with the patient in addition to their daily monitoring. Video visits were considered important for teaching, and to replace personal contact as home visits were decreased. The homecare nurses conducted the in-person home visits and four tele-homecare nurses monitored the data and conducted the video visits. The tele-homecare nurses notified the home visiting nurses and/or patient via phone or voicemail if readings were out of normal range to obtain changes in the treatment plan or confirm the accuracy of the transmission with another reading (i.e., blood pressure) or assessment of other symptoms. The tele-homecare nurses and visiting nurses collaborated on the plan of care and determined when to notify a physician of symptoms or changes in the measures.

**Type of technology and its application:** The tele-health equipment was based on patient need. e.g., if they had diabetes or chronic obstructive pulmonary disease in addition to HF, they received a glucometer and pulse oximeter, respectively. All patients received a video phone, blood pressure cuff, and a weight scale. The devices were wireless for easy placement throughout the home and transmitted data via a hub automatically every day that connected to the Internet via a telephone line.

**Did the patient receive education about their condition?** Yes, as part of the intervention.

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** at least 4 video-visits (one weekly for week 2,3 and 6, two weekly for week 4 and 5); the type and number of visits were guided by a standardised study protocol

**Clinician response to receipt of data:**

- a) Who contacts the patient?: Nurses.
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): phone or voice-mail.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): reviewed daily (unclear if this was also during weekends).
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): changes in the treatment plan, or confirm the accuracy with another reading, notify physician if judged needed.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses.

**Duration of intervention:** at least one period of home health care (60 days) and some patients received a second period of home care.

**Comparison intervention (e.g. face-to-face,telephone, none):** usual home care consisted of at least five intermittent in-person skilled visits by a registered nurse over a 60-day episode to assess, teach, and case manage the patient's care.

## Outcomes

### Primary outcomes:

- All cause and HF re-admissions,
- Hospital days
- Time to re-admission or death

### Secondary outcomes:

- Access to care,

## Bowles 2011 (Continued)

- ED use
- Satisfaction with care (using a validated tool designed specifically for home healthcare patients)

**Follow-up time:** 30- 60 days (the TM equipment was removed at the end of the home care period (i.e., around 60 days). Secondary outcomes assessed at up to 180 days. TM patients had a longer home healthcare period than usual care patients, and they more often received a second period of home care. Only 30 day data are included in the results and analysis.

### Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** the National Institute of Nursing Research, NRO1-008923.

**Conflicts of interest:** not reported.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.2, Col.2, Para 2  QUOTE:  “Enrolled patients were randomized by the project manager using an allocation spreadsheet prepared by the statistician using a randomly permuted blocks algorithm to insure equal distribution between the two groups.”
Allocation concealment (selection bias)	Low risk	See quote above
Were baseline outcome measurements similar?	Low risk	No difference between groups in the number of hospitalisations in the 12-month period preceding the study.
Were baseline characteristics similar?	Low risk	Tele-homecare patients were taking more medications than control patients, and tended to be younger. All analyses were adjusted for these factors.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: healthcare utilisation</b> (length of time until first re-hospitalisation or death, number of all-cause and HF related hospitalisations, hospital days and ED visits, and access to care). Objective outcomes retrieved from medical records.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group:</b> patient satisfaction with care. The participants could not be blinded to the intervention. However, a validated tool was used during interview assessed satisfaction (assessor blinded). Note: only satisfaction with home care was assessed, and not TM per se.
Incomplete outcome data (attrition bias) All outcomes	High risk	31 of 102 (30.1%) TM participants withdrew from the study as compared with 18 of 116 (15.5%) randomised to usual care. 36 % of intervention group did not receive the intervention.
Selective reporting (reporting bias)	High risk	Results for a number of outcomes listed in the study protocol are not accounted for in the full text i.e. self-care, health status, quality of life, and cost effectiveness.
Other bias	Low risk	No other risk of bias identified.

## Boyne 2012

### Methods

**Study design:** RCT (multicentre)

**Interactive telemedicine: effects on professional practice and health care outcomes (Review)**

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## Boyne 2012 (Continued)

**Inclusion criteria:** patients with heart failure (HF) in New York Heart Association class II–IV were included. HF was defined as at least one episode of fluid retention requiring diuretics, either with an echocardiographic LVEF  $\leq 40\%$  or a preserved ejection fraction (EF) with diastolic dysfunction. Further inclusion criteria were age  $\geq 18$  years, capable of providing informed consent, and being treated by a HF nurse together with a cardiologist.

**Exclusion criteria:** patients were excluded if operating the Health-Buddy system was physically or cognitively impracticable or when their expected life span was  $< 1$  year. A prior admission for HF was not a prerequisite for inclusion

**Method of patient recruitment:** patients were screened and approached about participation during their planned visit to our HF clinics.

**Study sample calculation:** to detect a 50% reduction from 25% to 12.5% in HF-related hospitalisations with a two-sided 5% significance, a power of 0.80, and 10% loss to follow-up, a sample size of 195 patients per group was required.

**Data collection:** an independent expert committee, blinded to study arm assignment, adjudicated HF-related hospitalisations and deaths. Hospitalisations were identified during follow-up visits and by reviewing medical records. Data on hospitalisation and mortality were collected by research nurses not involved in the patient care.

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** 870 patients were screened; 488 patients refused to participate or were ineligible.

**No of patients randomised to groups:**  $n = 382$ ; intervention:  $n = 197$ ; control:  $n = 185$

**No of patients lost to follow-up:** 31 participants in the TM group and 20 in the control group discontinued

#### Patient baseline characteristics:

a) Clinical condition: heart failure

b) Age (years), mean, SD: TM:  $71.0 \pm 11.9$ ; usual care:  $71.9 \pm 10.5$

c) Gender, male number (%): TM: 115 (58); usual care: 111 (60)

d) Ethnicity: NA

e) Severity of condition:

History of HF, months: TM: 19 (6–41); usual care: 17 (6–40)

New York Heart Association (NYHA) classification/n (%): NYHA II : TM: 110 (56); usual care: 109 (59); NYHA III : TM: 79 (40); usual care: 74 (40); NYHA IV: TM: 8 (4); usual care: 2 (1)

LVEF (%): TM: 36 (28–50); usual care: 35 (26–42)

Pacemaker: TM: 59 (29.9); usual care: 53 (28.6)

f) Major co-morbidities

Charlson index: TM: 2 (2–3); usual care: 2 (1–3)

g) Medication therapy: no differences between groups.

**Setting** (hospital/community/residential care): 3 hospitals.

**Location** (rural/urban etc.): NA.

**Country:** The Netherlands.



## Boyne 2012 (Continued)

### Interventions

**Study objective:** to test the hypothesis that tele-monitoring reduces HF hospitalisations during one-year follow-up.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (partly substituting usual care; two of four follow-up visits were skipped)

**Delivery of intervention:** responses to health Buddy questions were also transferred into risk profiles (low, medium, high) and positive answers for symptoms triggered immediate responses by the HF nurse. The process was led by a HF nurse and a nurse assistant. The nurse assistant took care of educational and general high risks, such as persistent lack of adherence or symptoms of depression.

**Type of technology and its application:** a device, with a liquid crystal display and four keys, connected to a land line phone. Automatic transfer of vital signs was not part of the system. Heart rate and blood pressure for both groups were collected during regular face-to-face contacts. Daily pre-set dialogues were communicated about symptoms, knowledge, and behaviour, being answered by touching one of the keys and sent to a server and to the nurses' desktop. Incorrect answers to a knowledge or behaviour issue were automatically corrected by the device and were visible in the display. After the basal set of dialogues during the first 3 months patients were allocated to the best fitting sets: 17 (9%) were re-allocated to the same set, 29 (15%) to sets emphasising symptoms, 64 (23%) to the education set, and 89 (45%) to a maintenance programme.

**Did the patient receive education about their condition?** Yes, as part of the intervention.

**Frequency of patient data transfer:** daily.

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none.

#### Clinician response to receipt of data:

- Who contacts the patient?: The HF nurse (a nurse assistant handled signs of depression and persistent lack of adherence).
- Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): immediate responses to alerts (on weekdays).
- Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** HF nurse and a nurse assistant

**Duration of intervention:** 12 months.

**Comparison intervention (e.g. face-to-face, telephone, none):** nurse-led usual care was given according to the latest European Society of Cardiology (ESC) guidelines, oral and written educational information and psychosocial support as needed.

### Outcomes

#### Primary outcomes:

- Time to first HF hospitalisation, i.e. at least one overnight stay for a new episode or progression of fluid retention, with insufficient response to adjustment of oral medication, needing in-hospital intravenous treatment
- Costs and cost-effectiveness (reported in Boyne 2013)

#### Secondary outcomes

- Combined endpoint of HF admission and all-cause mortality
- Number of re-admissions for HF
- All-cause hospitalisations,
- Days in hospital for HF, cardiovascular (i.e. related to treatment or diagnostics of cardiac disease, or HF-related) reasons.

## Boyne 2012 (Continued)

- Other-cause hospitalisations (i.e. not related to HF or cardiovascular reasons).
- Mortality.
- Number of visits to the HF clinic.
- Disease-specific knowledge (assessed with the Dutch Heart Failure Knowledge Scale).
- Self-care (assessed with the European Heart Failure Self-Care Behavior Scale (EHFSCB).
- Self-efficacy (assessed with the Barnason Efficacy Expectation Scale).
- Adherence (assessed with the Heart Failure Compliance Scale), the 4 last outcomes which were reported in Boyne 2014, were assessed through 4 postal questionnaires.

**Follow-up time:** 12 months after randomisation.

### Notes

**Ethical approval and informed consent obtained (yes/no):**yes.

**Sources of funding:** The Province of Limburg in The Netherlands; the Annadal Foundation Maastricht, Astra Zeneca [an unrestricted grant]; the Rescar Foundation Maastricht, The Netherlands.

**Conflicts of interest:** none declared.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.792, Col1, Para.4  "...were enrolled and assigned to a study arm, using a computer-generated randomisation procedure, with stratification per centre."
Allocation concealment (selection bias)	Low risk	p.792 Col.2 Para.2  "blinded endpoint evaluation, conducted at three hospitals in The Netherlands. Investigators and study personnel (except for data entry officers) were unaware of the treatment group results until database closure"
Were baseline outcome measurements similar?	Low risk	Most patient-reported outcomes were similar, and those that were not were adjusted for in the analysis.
Were baseline characteristics similar?	Unclear risk	p.795,Col.1, Para.3  QUOTE:  "Study arms were balanced regarding baseline characteristics, except for predominance of atrial fibrillation in the intervention group."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: healthcare resource use and mortality</b> (time to first hospitalisation;re-admissions for HF and all-cause admissions;days in hospital;no of visits to HF clinic). Objective outcomes and therefore low risk of bias.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: patient-reported outcomes</b> (knowledge, self-care, self-efficacy, and adherence)  Outcomes based on patient self-report but assessed using validated questionnaires may be susceptible to bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31 of 185 participants (16.7%) in usual care group and 20 of 197 participants (10.2%) in the usual care group discontinued the study.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol are reported, but in three different papers.

## Boyne 2012 (Continued)

Other bias	Low risk	No other risk of bias identified.
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## Capomolla 2004

### Methods

#### Study design: RCT

**Inclusion criteria:** patients with heart failure (HF) referred between June 2000 and June 2001 were screened for eligibility to participate in the intervention based on cognitive and logistic criteria.

**Exclusion criteria:** patients with unstable angina, atrial fibrillation, a pacemaker or automatic defibrillator, renal failure, end-stage heart failure requiring intravenous support, planned discharge to an out-patient HF care facility and finally those with a very low probability of survival were excluded.(i.e. very ill patients were excluded).

**Method of patient recruitment:** Patients with HF referred between June 2000 and June 2001 were screened (clinical and functional examination) for eligibility to participate in the intervention and were randomised at discharge.

**Study sample calculation:** not reported.

**Data collection:** not reported.

**Unit of analysis issues: (yes/no):** no

### Participants

**Total no of patients:** n = 133 patients were eligible

**No of patients randomised to groups:** n = 133; intervention: n = 67; control: n = 66

**No of patients lost to follow-up:** 12 out of 67 (18%) patients recruited to tele-monitoring system did not contact the service and were considered drop-outs.

#### Patients baseline characteristics:

a) Clinical condition: heart failure

b) Age: intervention: 57 ± 10 years; control: 57 ± 10 years

c) Gender, male/female; intervention: 62/5; control: 55/11

d) Ethnicity: not reported.

e) Severity of condition: New York Heart Association II/III-IV All: 89/44; Intervention: 45/22 ; Control: 44/22

f) Major co-morbidities: not reported.

**Setting** (hospital/community/residential care): one HF unit, one day-hospital.

**Location:** unclear (Montescano region).

**Country:** Italy,

### Interventions

**Study objective:** to evaluate the outcomes of a comprehensive tele-management system in comparison to the usual program of care after discharge from a HF unit.

**Type of TM/ mode of delivery (e.g. vide- conferencing, remote monitoring with healthcare professional responding to alerts etc.):** remote monitoring of chronic condition (substituting for usual care).

**Delivery of the intervention:** the home tele-monitoring service implemented a case disease HF management program. In order to send the vital signs to the medical staff, patients in the tele-monitoring group used their touch pad of their phone, after dialling a toll-free number. Each parameter was entered in a reply to a question asked by a recorded voice and confirmation was requested for each. Be-

## Capomolla 2004 (Continued)

fore entering data, the patient was requested to give her/his identification code of the study. The overall procedure was managed by an interactive voice response (IVR) system, *hence data transmission did not require operator support*. Each patient was also allowed to contact the medical staff at any time by leaving a message in an answering machine integrated in the IVR system, asking for advice and/or help. If at least one parameter was out of range, a 'range alarm' was automatically triggered, similarly, if at least one parameter showed abnormal change, a 'stability alarm' was automatically triggered. Abnormal values typically elicited intervention in the form of phone call to the patient at home.

**Type of technology and its application:** each message was saved in digital form, thus becoming an integral part of the dataset generated for each patient during the study. The overall management of vital signs and voice messages was carried out by a dedicated software package (IMAC, Biomedical, Engineering Unit, Montescano). At the time of enrolment into the study; the software generated a personalised timetable for planned periodic transmissions of vital signs and provided the patient with a copy. The daily tele-monitoring activities typically began by listening to the vocal messages and taking the appropriate action (not real-time sent messages). The software then identified those patients that had not transferred their vital signs, as expected by their timetable. These patients were contacted by phone. Attention was given to received transmissions containing abnormal vital signs (store-and-forward). A list of these patients was automatically created by the software package on the basis of i) one or more parameters being outside the accepted individual range of variation and or ii) the rate or change of one or more parameters exceeding pre-set values. Both the acceptable range of variation and rate of change of vital signs were entered into the management software by the attending physician before follow-up commenced. Each patient had his/her personalised settings according to clinical status and functional examinations.

**Did the patients receive education about their condition?** The patients received educational materials, including cardiac failure book, tele-monitoring service booklet, daily computerised medications plan, pillboxes with scheduling time, summary sheets of domestic and physical activities.

**Frequency of data transfer (monitoring studies only):** patients accessed the service on 294 occasions: 246 of these were accesses with transmission of vital signs and symptoms and 48 were calls to the 24-hour answering machine. A personalised timetable for periodic access to the tele-monitoring service was determined according to the patient's risk class: low risk patients every 60 days, medium risk patients every 30 days and high risk patients every 15 days.

**Planned/scheduled number of TM contacts between patient and health care personnel:** at least monthly, and In case of a receipt of a voice message or an alarm a nurse and/or a physician contacted the patients by phone.

### Clinician response to receipt of data

- a) Who contacts the patient?: Nurses and/or physicians contact the patients at least monthly, and In case of a receipt of a voice message or an alarm.
- b) Method of patient contact (e.g. e-mail, telephone, automated feedback etc): telephone.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the patient could be contacted to perform counselling or triage, for integration or changes in the therapy, to require further examinations, or to manage unexpected access.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** the staff of the tele-management intervention was the same which operated the day-Hospital and consisted of two cardiologists, and two nurses with consolidated experience.

**Duration of the intervention:** 12 months

**Comparison intervention** (e.g. face-to-face, telephone, none): the patients in the usual care group returned to the community and were followed up by a primary care physician with the support of a cardiologist..

## Outcomes

### Primary outcome:

## Capomolla 2004 (Continued)

- Combined event rate (re-hospitalisation, emergency room access and total mortality)

### Secondary outcomes:

- Compliance to the tele-management care process (patients enrolled who subsequently transmitted data)
- Compliance to home tele-monitoring (accesses made according to timetable/feasible accesses ratio)

**Follow-up time:** 10 ± 6 months of follow-up (median 11 months)

Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> no information</p> <p><b>Sources of funding:</b> Ministero della Salute funds (ICS 030.4/RF99.102).</p> <p><b>Conflicts of interest:</b> no information</p>
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### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>No information.</p> <p>p.F92, Col 2, Para 1</p> <p>Quote: "At discharge patients were randomised to receive UC or enter the home tele-monitoring management program run by the tele-monitoring service of the HFU."</p>
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcomes.
Were baseline characteristics similar?	Low risk	<p>p.F94, Col.2, Para.1</p> <p>No differences were reported.</p>
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p><b>Outcome group:combined event rate (re-hospitalisations, ED room access, total mortality)</b></p> <p>The healthcare professional could not be blinded to the group allocation (the same staff delivered the intervention), and neither were the patients. The primary outcome measure was objective.</p>
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>p.F94, Col.2, Para.2</p> <p>QUOTE:</p> <p>"Twelve out of 67 (18%) patients recruited to tele-monitoring system did not contact the service and were considered drop-outs."</p>
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Chambers 2006

Methods	<p><b>Study design:</b> multi-centre RCT</p> <p><b>Inclusion criteria:</b> consenting newly discharged patients on home parental nutrition (HPN), and referred to the HPN provider company Calea UK Ltd</p> <p><b>Exclusion criteria:</b> patients not referred to the HPN provider company Calea UK Ltd.</p> <p><b>Method of patient recruitment:</b> HPN patients at nine UK centres were approached before discharge and interviewed by a member of their nutrition team. Information sheets and consent forms were provided. On agreement, the consent form was faxed to the trial co-ordinator, who then randomised patients within 24 hours.</p> <p><b>Study sample calculation:</b> the numbers per group required to demonstrate a difference of 20 (alpha = 0:05, power = 80%) in the SF36 score between groups over time) was physical functioning 22 (15), physical role 47 (30), bodily pain 23 (15), general health 17 (11), vitality (VT) 18 (12), social functioning 21 (14), emotional role 44 (28), and mental health 14 (9).</p> <p><b>Data collection:</b> questionnaire data collection was by telephone by a trial co-ordinator who was not involved with the patients' care. The trial co-ordinator visited each hospital to obtain full medical records.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients in groups:</b> n = 30; intervention: n = 15; control: n = 15</p> <p><b>No of patients lost to follow-up:</b> n = 16, unclear how these were divided between groups. Reasons for HPN being discontinued (n) were death (n = 7), bowel adaption (n = 8) and n = 1 participant was lost to follow-up.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: home parenteral nutrition (HPN)</li> <li>b) Age, mean (range): intervention: 42.1 (29–62); control: 37.5 (22–59)</li> <li>c) Gender, male/female: intervention: 8/7; control: 5/10</li> <li>d) Ethnicity: no information.</li> <li>e) Severity of condition: no information.</li> <li>f) Major co-morbidities: no information.</li> </ul> <p>Length of index hospital admission, days (SD): intervention: 75 (44); control: 60 (30).</p> <p><b>Setting</b> (hospital/community/residential care): 9 UK HPN centres.</p> <p><b>Location</b> (rural/urban etc.): unclear.</p> <p><b>Country:</b> UK.</p>
Interventions	<p><b>Study objective:</b> to compare longitudinal trends in quality of life in patients after starting HPN and who received specialist support by telephone from a nutrition nurse, with those in contact via TM.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> videophone (support/consultation).</p> <p><b>Delivery of the intervention:</b> after the line had been installed, a video-phone was delivered to the patient who was given a tutorial on how to use the equipment.</p> <p><b>Type of technology and its application:</b> video-phone, no further information provided.</p> <p><b>Did the patient receive education about their condition?:</b> Not reported.</p> <p><b>Frequency of patient data transfer (monitoring studies only):</b> N/A.</p>



## Chambers 2006 (Continued)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** weekly for the first month; fortnightly for the next month, once monthly for the next 4 months, and at least once every 3 months for the remainder of the study.

### Clinician response to receipt of data:

- a) Who contacts the patient?: N/A
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a nurse specialist.

**Duration of intervention:** 12 months.

**Comparison intervention:** patients not receiving TM received standard care and follow-up according to his/her centre's usual protocol, with telephone links with the nutrition nurse specialist (NNS): weekly for the first month, fortnightly for the next month, once monthly for the next 4 months, and at least once every 3 months for the remainder of the study.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• Quality of Life (assessed by the SF-36 instrument and EQ5D).</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Outpatient re-attendances.</li><li>• Re-admissions.</li><li>• Hospital anxiety and depression (Hospital Anxiety and Depression scale, HADS).</li><li>• Number of central lines required.</li></ul> <p><b>Follow-up time:</b> 12 months from start of intervention.</p>	
Notes	<p><b>Ethical approval and written informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Calea UK Ltd., an HPN provider.</p> <p><b>Conflicts of interest:</b> No information reported. Patients referred to the funding company could be included in the study.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	p.507, Col1, Para 4  QUOTE:  " Centre-specific blocks of four randomisations were applied."
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Unclear risk	p.508, Table 3  No differences reported.
Were baseline characteristics similar?	Unclear risk	p.508, Table 1

## Chambers 2006 (Continued)

No differences reported.

Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p><b>Outcome group:re-admissions, re-attendance and number of central lines replaced</b></p> <p>The healthcare professionals delivering the intervention could not be blinded to group assignment, and neither could the patients. However, objective measures of outcomes were used.</p> <p>p.507, Col.1, last paragraph, and Col.2, Para.1</p> <p>QUOTE:</p> <p>"The trial coordinator visited each hospital, to obtain full medical records."</p>
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<p><b>Outcome group:QoL and Hospital Anxiety and Depression</b></p> <p>The participants and personnel could not be blinded to group assignment, which may have affected outcomes self-reported by patients.</p> <p>p.507, Col.1, last paragraph, and Col.2, Para.1</p> <p>QUOTE:</p> <p>"Questionnaire data collection was by telephone by a trial coordinator not involved with the patients' care."</p>
Incomplete outcome data (attrition bias) All outcomes	High risk	Only 14 patients out of 30 enrolled remained in the study at 12-month follow-up. Unclear how these patients were divided between groups.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Chan 2007

Methods

**Study design:** RCT

**Inclusion criteria:**dependent of active duty or retired US military personnel, 6 to 17 years of age, not moving from Oahu for 12 months after entry into the study, ability to receive cable modem connections in the home, willing to learn to record and to send inhaler technique and peak flow data 2 times per week, willing to attend asthma education follow-up visits either in person or electronically (virtually) at 2-week, 6-week, 3-month, and 6-month intervals after initiation into the study, willing to complete satisfaction and education surveys at the end of the study period, and willing to sign informed written consent forms.

**Exclusion criteria:** no information.

**Method of patient recruitment:** children with persistent asthma were solicited for enrolment into the study via telephone (with permission from their primary care provider) and on presentation to the paediatric clinic for an asthma visit, from a population of 40,000 military dependent children on the island of Oahu.

**Study sample calculation:** a minimal sample size of 45 patients in each group enabled detection of an effect size of 20% at an level of .05, with 84% statistical power. This sample size of 45 patients in each group would also allow detection of a difference in group means with an effect size of 30%, using a 2-tailed t test, at an level of .05, with 80% statistical power.

**Chan 2007** (Continued)

**Data collection:** the measures of disease control included lung function tests (spirometry performed at intake and study exit), peak flow (percentage of personal best), patient and caregiver paediatric asthma quality of life questionnaires (analysed at intake and study exit), utilisation of services (emergency department visits, hospitalisations, and unscheduled acute visits because of asthma, from our centralised medical chart database and case manager records), rescue therapy use ( $\beta$ -receptor agonist use and refills and use of oral prednisone rescue therapy, from computerised pharmacy records), symptom control (diary symptom score), and asthma knowledge retention. Patient and case manager participation time was also recorded.

**Unit of analysis issues:** no

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**Participants**

**Total no of eligible patients:** n = 127 patients were screened for eligibility. Of these, 7 were excluded because they were not able to meet the residency requirement of 1 year or their families were not interested in participating.

**No of patients randomised to groups:** n = 120; Intervention: n = 60; Control: n = 60

**No of patients lost to follow-up:** 20 patients were lost to follow-up; intervention: 7 discontinued (non adherence) and 8 moved; control: 4 discontinued (non-adherence) and 1 moved.

**Patient baseline characteristics:**

a) Clinical condition: asthma

b) Age, mean years: intervention: 10.23 (3.1); control: 9.03.(3.0)

c) Gender, male sex: intervention: 37; control: 38

d) Ethnicity: no information

e) Severity of condition:

Mild persistent asthma: intervention:7; control: 15

Moderate asthma: intervention:41; control:40

Severe asthma: intervention:12; control: 5

Baseline FVC, mean  $\pm$  SD, % predicted: intervention: 103.7  $\pm$  17.4; control:104.5  $\pm$  15.4

Baseline FEV1, mean  $\pm$  SD, % predicted: intervention: 104.1  $\pm$  19.9; control: 96.8  $\pm$  13.04

Baseline FEF 25–75, mean  $\pm$  SD, % predicted: intervention: 83.8  $\pm$  25.6 control: 84.3  $\pm$  23.5

f) Major co-morbidities: not reported.

**Setting** (hospital/community/residential care): one asthma clinic

**Location** (rural/urban etc.): not reported.

**Country:** USA

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**Interventions**

**Study objective:** to determine whether home asthma tele-monitoring with store-and-forward technology improved outcomes, compared with in-person, office-based visits.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of the intervention:** the virtual group received 3 in-person visits, at 0, 26, and 52 weeks, and the remainder were virtual visits. Virtual visits included asthma education, a video recording of peak flow meter and inhaler use forwarded to the website, daily asthma diaries, and communication with the case manager electronically via the website. Digital videos of the patients using inhaled medication and the peak flow meter were recorded and loaded to the website on a predetermined schedule, according to the protocol. A detailed asthma symptom diary and quality of life survey were included on

## Chan 2007 (Continued)

the website. Patients and families were instructed regarding the submission of daily symptom diary entries. This diary information was entered electronically, directly to the website.

**Type of technology and its application:** a home computer system, camera, and Internet access. On-site in-home instruction was provided by technical experts on equipment use and website capabilities and use. Each patient received the same models of computer and computer equipment, as well as broadband Internet access. Patients and their parents were taught how to use the equipment and how to record and to submit videos by using a computer-mounted digital video camera, to capture the patient's peak flow meter and inhaler technique. A customised educational and monitoring website was developed, which allowed for secure socket layer interactive asthma education that followed the same curriculum as the office-based asthma education. The site also provided secure e-mail contact between patients and case managers, as well as the capability for digital video uploads.

**Did the patient receive education about their condition?** Yes, but the case manager and an educational website.

**Frequency of patient data transfer (monitoring studies only):** patients sent videos of inhalation technique 2 times per week for 6 weeks and then once-weekly thereafter; and completed electronic symptom diaries daily.

**Planned /scheduled no of TM contacts between patient and healthcare professional:** 2 times per week for 6 weeks and then once-weekly.

### **Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient? The case manager
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail (to provide feedback on inhalation technique); unclear if feedback was provided on symptom scores
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): 2 times per week for 6 weeks and then once-weekly thereafter
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): feedback on technique; unclear how the case manager 'intervened'. The case manager recommended an appointment with the study paediatrician and case manager for patients in either group if one was needed for closer observation or intervention, as determined through telephone or e-mail communication.

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** study paediatrician and case manager

**Duration of intervention:** 12 months

**Comparison intervention:** office-based group patients received all of their information in person at the paediatric clinic. The study paediatrician and case manager for all scheduled physician visits. Both groups had 24-hour/7-day access to their case manager through the Internet (virtual group) and/or telephone (virtual and office-based groups). Patients in both groups were contacted (by telephone for the office-based group and by e-mail for the virtual group) by the case manager 2 times per week for 6 weeks and once per week thereafter, to review the asthma action and home management plans, to assess the symptom diary, to remind the patient to perform and to record peak flow measurements daily in the diary, to remind the patient to complete symptom diary information every day, to answer questions, and to intervene if needed. All patients were able to contact the case manager 24 hours per day, 7 days per week, to obtain an unscheduled "sick" office visit with the paediatrician and the case manager as needed, in addition to their scheduled protocol visits.

## Outcomes

### **Primary outcomes:**

- Therapeutic and diagnostic adherence
- Disease control (quality of life, lung function, utilisation of services, rescue therapy, symptom control, patient education, and patient satisfaction)

**Follow-up time:** 12 months after randomisation

## Chan 2007 (Continued)

Notes

**Ethic's committee approval and informed consent obtained (yes/no):** yes

**Sources of funding:** a grant from the US Army Medical Research Acquisition Activity

**Conflict of interest:** no information

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.570, Col.2, Para.3  QUOTE:  "Patients underwent block randomization with a table of random numbers and were enrolled in either the "virtual" group (60 subjects) or the office-based group (60 subjects)."
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Unclear risk	No differences between groups for baseline lung function outcomes. Other baseline measures of outcomes not reported.
Were baseline characteristics similar?	Unclear risk	Patients in the office-based group were slightly younger, and more had mild persistent asthma.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Objective outcomes: healthcare resource use, lung function tests; rescue medication</b>  The participants could not be blinded to the group allocation, and neither could the healthcare professional delivering the intervention. However, objective measures of outcomes were used.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	<b>Outcome group:</b> patient-reported outcomes (quality of life, symptom scores)  The participants could not be blinded to the group allocation, and neither could the healthcare professional delivering the intervention. Unclear risk for questionnaire assessed quality of life, and high risk for self-reported symptom scores.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	In total: n = 20 patients (16.7%) were lost to follow-up; intervention: 7 discontinued (non adherence) and 8 moved; control: 4 discontinued (non-adherence) and 1 moved. All were included in the analysis.
Selective reporting (reporting bias)	Low risk	Results for all outcomes mentioned in the trial protocol were reported in the full text paper.
Other bias	Low risk	No evidence of other risk of bias.

## Charpentier 2011

Methods

**Study design:** RCT (3-armed)

**Inclusion criteria:** over 18 years old with type 1 diabetes for at least 1 year, and treated with a basal bolus insulin regimen for at least 6 months, either with multiple daily injections or with a pump. They were eligible for the study if their last HbA1c values during the year before and at entry of the study were > 8.0%.

**Charpentier 2011** (Continued)

**Exclusion criteria:** participation in a diabetes educational program within 3 months before the study or a clinical condition requiring the patient to receive follow-up more frequently than the quarterly visits scheduled.

**Method of patient recruitment:** N/A

**Study sample calculation:** to detect a 0.7% difference in HbA1c at month 6 (with a baseline mean 6 HbA1c SD of  $9.0 \pm 1.2\%$ ), 48 participants were needed in each group (80% power;  $\alpha < 0.05$ ).

**Data collection:** N/A

**Unit of analysis issues:** (yes/no): no

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Participants

**Total no of eligible patients:** N/A

**No of patients randomised to groups:** n = 120; intervention (Diabeo + telephone consultations) n = 59; usual care n = 61. Note: a third intervention group (Diabeo without telephone consultation, n=60) was not included in this review.

**No of patients lost to follow-up:** n = 3, two from the intervention and one from the usual care group were excluded from analysis due to missing data/no visit.

**Patient baseline characteristics:**

- a) Clinical condition: diabetes type 1
- b) Age (years), mean, (SD): TM: 31.6 (12.5); usual care: 36.8 (14.1)
- c) Gender: male, TM: 22 (37.3%); usual care: 21 (34.4%)
- d) Ethnicity: not reported.
- e) Severity of condition:
  - Retinopathy: TM: 12/56 (21.4%); usual care: 17/58 (29.3%)
  - Nephropathy: TM: 7 (11.9%); usual care: 4/58 (6.9%)
  - Clinical neuropathy: TM: 7 (11.9%); usual care: 9/59 (15.3%)
  - Insulin pump: TM: 36.7% (22); usual care: 36.1% (22)
  - HbA1c at baseline: TM: 9.11 (1.14); usual care: 8.91 (0.90)
  - Duration of diabetes, years, mean (SD): TM: 14.7 (9.1); usual care: 16.9 (10.5)
  - Body mass index (BMI) kg/m<sup>2</sup>: TM: 25.8 (5.0); usual care: 25.1 (6.8)
- f) Major co-morbidities: N/A (young population)
- g) Education: more than 50 % of participants had received higher education.

**Setting** (hospital/community/residential care): 17 hospitals

**Location** (rural/urban etc.): N/A

**Country:** France

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Interventions

**Study objective:** to demonstrate that Diabeo software combined with TM enabled individualised insulin dose adjustments and improved HbA1c in patients with poorly controlled type 1 diabetes.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (substituting usual care)



**Charpentier 2011** (Continued)

**Delivery of intervention:** Participants received a smart phone with the Diabeo software. Tele consultations by telephone call were planned every 2 weeks. Participant self-monitoring plasma glucose (SMPG), diet, and insulin treatment data were automatically uploaded by the smart phone to a secure website, where they were available to investigators at any time, including during the tele-consultations. Tele-consultations were conducted with both patients and doctors in front of their computers or smart phone, which displayed the previous weeks data and focused on insulin dose adjustments and motivational support. Data were collected in an electronic case-report form.

**Type of technology and its application:** Diabeo software is a bolus calculator with validated algorithms, taking into account SMPG level before meals, carbohydrate counts, and planned physical activity. Parameters personally tailored for adjustment of prandial and basal insulin dose were entered into the system for each patient. If fasting or postprandial SMBG do not meet target levels, the system can suggest adjustments for carbohydrate ratio, long-acting insulin analogue dose, or pump basal rates.

**Did the patient receive education about their condition?** N/A

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** every two weeks

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The doctor
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): every two weeks
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): insulin dose adjustments and motivational support

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** doctors

**Duration of intervention:** 6 months.

**Comparison intervention** (e.g. face-to-face, telephone, none): participants in the usual care group had no electronic logbook but kept their paper logbook and were asked to attend two follow-up visits at the hospital, after 3 and 6 months.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• HbA1c levels</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Change in the HbA1c level from baseline to end point</li> <li>• Proportion of patients reaching the HbA1c target of &lt; 7.5%</li> <li>• Change in SMPG frequency</li> <li>• Change in QoL (determined by assessment of satisfaction using DQOL questionnaire (no data were provided in the paper) and the Diabetes Health Profile questionnaire)</li> <li>• Time spent by investigators conducting face-to-face visits or tele consultations, and by the participants coming for hospital visit</li> <li>• Major hypoglycaemia episodes (defined as requiring third party assistance)</li> <li>• Minor hypoglycaemia episodes (defined as symptomatic, non-severe hypoglycaemia self reported by the patient)</li> </ul> <p><b>Follow-up time:</b> 6 months from recruitment</p>
Notes	<p>NB: HBA1C refers to glycated haemoglobin; SMPG refers to self-monitored plasma glucose</p> <p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p>

## Charpentier 2011 (Continued)

**Sources of funding:** Voluntis provided the Diabeo software, and Orange (Paris, France) provided the smart phone and telephone lines; Sanofi-aventis (Bridgewater, NJ) and CERITD funded the study. CERITD is a non-profit clinical translation research centre located in Corbeil Hospital (Corbeil-Essonnes, France).

**Conflicts of interest:** Dr Charpentier has, since 2007 been an investigator, consultant or speaker for Astra-Zeneca, Bayer, Boehringer, Eli Lilly, Johnson & Johnson, Medtronic, Merck Serono, Merck Sharp Dome, Novartis, Novo Nordisk, Pfizer, Roche, **Sanofi-Aventis**, Siemens and Takeda. Prof. Benhamou has received grants for his institution from **CERITD** and is a member of the boards of MSD Chibret, Roche, and Diagnostics. He has received payment for the development of educational presentations including speakers' office services for Eli Lilly, Novo Nordisk, Novartis, MSD-Chibret, **Sanofi-Aventis**, and Roche. He has had travel and accommodation expenses covered or reimbursed by Novartis, Abbott and Eli Lilly.

Dr Borot has received grants for her institution from **CERITD**. She has received honoraria from Takeda, Aventis and VitalAire and has had travel and accommodation expenses covered or reimbursed by Novartis, Eli Lilly, **Aventis** and Servier. Dr Schaepelynck-Belcar has received grants and support in kind, such as writing, the provision of medicines or equipment or administrative support for her institution from **CERITD**. Dr Franc is a member of the Board of Roche Diagnostics, consultant for Novonordisk and speaker for **Sanofi-Aventis**, GSK, Novonordisk, Abbott, Eli Lilly, Novartis and Takeda. Dr Chaillous has received grants for her institution from Astra-Zeneca, **CERITD**, Lilly, Novo-Nordisk, Merck Serono, Pfizer, **Sanofi-Aventis**, and Schering-Plough. She has received honoraria from Novo Nordisk, Pfizer, and **Sanofi-Aventis** and payment for the development of educational presentations including speakers' office services, for Bristol-Myers-Squibb, Glaxo-Smith-Kline, Menarini, Novo-Nordisk, **Sanofi-Aventis**, and Servier. She has had travel and accommodation expenses covered or reimbursed by Abbott, Bristol-Myers-Squibb, Eli Lilly, Merck, Medtronic, Novo-Nordisk, Pfizer, Roche Diagnostics, **Sanofi-Aventis**, and Servier.

Dr Leguerrier has received honoraria from Astra Zeneca, BMS, **Sanofi Aventis**, GSK, Novo-Nordisk, Eli Lilly and Novartis. She has received payment for the development of educational presentations including speakers' office services, for Astra-Zeneca, Novo-Nordisk, Eli Lilly, **Sanofi Aventis**, BMS and Novartis. Dr Monier Pudar has been a consultant for Becton Dickinson, Eli Lilly, Novartis, Novo-Nordisk, and **Sanofi-Aventis**. She has been paid for manuscript preparation for Becton Dickinson, and for the development of educational presentations including speakers' office services for Eli Lilly, GSK, Johnson & Johnson, Novartis, Novo-Nordisk, **Sanofi-Aventis**, and Takeda. She has had travel and accommodation expenses covered or reimbursed by Eli Lilly, Novartis, Novo-Nordisk, Roche Diagnostic, Sanofi-Aventis and Takeda. Dr Moreau has received grants for his institution from CERITD. He has been a consultant for Abbott, GlaxoSmithKline, Merck-Serono, Novo-Nordisk, Pfizer, and Sanofi-Aventis. He has also provided expert advice to Servier and has received payment for the development of educational presentations including speakers' office services for GlaxoSmithKline, Novo-Nordisk, and Sanofi-Aventis. He has had travel and accommodation expenses covered or reimbursed by Bristol-Myers Squibb, Eli Lilly and Servier. Dr Winiszewski has received honoraria from Merck Serono, MSD, Sanofi Aventis and Urgo. Dr Vambergue has received grants for her institution from CERITD. Dr Millot has received honoraria from Sanofi-Aventis, Pfizer, Eli Lilly, Novo-Nordisk, GlaxoSmithKline, Takeda, Bristol-Myers Squibb, Novartis, AstraZeneca and Merck Sharp & Dohme. He has had travel and accommodation expenses covered or reimbursed by Eli Lilly, Novartis and Novo-Nordisk. Dr Reffet received payment for the development of educational presentations including speakers' office services from Sanofi-Aventis. Dr Quesada is employed by the University Hospital of Grenoble and has received payment for manuscript preparation, for writing or reviewing manuscripts, and for fees for participation in review activities, such as data monitoring boards, statistical analysis, endpoint committees, and similar. Dr Clergeot has received grants for his institution from CERITD. Prof. Halimi has received grants for his institution from CERITD and is a member of the boards of Novartis, Sankyo, GSK, Boehringer-Ingelheim, Roche Pharma and Roche Diagnostics. He has received grants for his institution from MSD Chibret and honoraria from Boehringer-Ingelheim. He has received payment for the development of educational presentations, including speakers' office services from Eli Lilly, Novo Nordisk, Novartis, MSD-Chibret, Sanofi Aventis, Roche Pharma, Roche Diagnostics, Takeda, Servier and Johnson & Johnson. He has had travel and accommodation expenses reimbursed by Abbott, Novartis, Servier and Sanofi Aventis. Dr Ronsin has received grants for her institution from CERITD. She was a speaker for Novo Nordisk in 2009.

Dr Renard is a consultant for Roche Diagnostics, Novo Nordisk France, Novo Nordisk, Disetronic Medical Systems and Sanofi Aventis. He has received honoraria from Lilly-France, Medtronic and Novartis, and payment for the development of educational presentations including speakers' office services, from

## Charpentier 2011 (Continued)

Sanofi Aventis and Eli Lilly. He has had travel and accommodation expenses covered or reimbursed by Eli Lilly, Novo Nordisk, Novartis, Takeda and Abbott. Prof. Thivolet is for a member of the boards of Medtronic, Novo Nordisk and Sanofi Aventis, and a consultant for Roche Diagnostics and MSD. He has had travel and accommodation expenses covered or reimbursed by Sanofi Aventis, Abbott and Lilly Laboratories. Dr Bosson is employed by the University Hospital of Grenoble and his institution has received payment for manuscript preparation, for writing or reviewing manuscripts, and fees for participation in review activities, such as data monitoring boards, statistical analysis, end-point committees, and similar. His institution has had travel/accommodation expenses covered or reimbursed. Prof. Penfornis has received grants for his institution from CERITD. He is a member of the boards of AstraZeneca, Bristol-Myers Squibb, Novartis, Novo Nordisk and Sanofi Aventis and is a consultant for Novo Nordisk. He has received gifts for his institution from Eli Lilly, Merck Sharp & Dohme, Novo Nordisk and Sanofi Aventis and grants for his institution from Sanofi Aventis. He has received payment for the development of educational presentations including speakers' office services from Abbott, Eli Lilly, Medtronic, Merck-Serono, Merck Sharp & Dohme, Novartis, Novo Nordisk, Pfizer, Sanofi Aventis and Takeda. His institution has received payment for the development of educational presentations including speakers' office services from Bristol-Myers Squibb, Merck Sharp & Dohme, Sanofi Aventis and Takeda. He has had travel and accommodation expenses covered or reimbursed by Abbott, AstraZeneca, Boehringer-Ingelheim Pharmaceutical, Eli Lilly, GlaxoSmithKline, Medtronic, Merck-Serono, Merck Sharp & Dohme, Novartis, Novo Nordisk, Sanofi Aventis, Servier and Takeda.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.334, Col.2, Para.3  QUOTE:  "Randomization was carried out using a Web-based system." Comment: No information on how this was done or by whom.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	HbA1c and quality of life at baseline appeared slightly higher in the intervention group, adjustments were made for these factors in the ANCOVA.
Were baseline characteristics similar?	Unclear risk	Patients in the intervention group appeared to be slightly younger, and to have a lower mean duration of diabetes. Results were adjusted for age and HbA1 at baseline.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Outcome: HbA1c is an objective measure of outcome.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Satisfaction was the only domain of the quality of life questionnaire reported by the authors, no numerical data were provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 3 participants were lost to follow-up, two from the intervention group and one from the UC group. For 11 patients, surrogate data were used: missing values were replaced either by HbA1c measurements taken at month 6 in a private laboratory, provided the upper normal range limit was < 6.0% (n = 6). If no result was available at month 6, HbA1c measures at month 3 were used (n = 5). Missing data by group were not reported.
Selective reporting (reporting bias)	Unclear risk	Results for most of the outcomes listed in the trial protocol were reported in the paper (except mean of blood glucose values 14 days prior to inclusion and at 6-month follow-up; blood-glucose profiles (blood glucose measured at 8

## Charpentier 2011 (Continued)

prespecified timepoints per day) and the number of patients continuing to use the TM system in routine care).

Other bias	Unclear risk	All authors have an affiliation with Sanofi-Aventis, the developer and seller of the Diabeo system. The authors provided no data on the patients' use or non-use of the system.
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## Chase 2003

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> people aged 15–20 years who were diagnosed with Type 1 diabetes for at least 1 year and with an HbA1c value of 7.0–13.0% and a haematocrit of 20% to 55% at screening were included. Patients were included only if they took at least two insulin injections per day or used pump therapy and were willing to perform at least two blood glucose tests per day.</p> <p><b>Exclusion criteria:</b> patients were excluded if they had any significant diseases other than diabetes or plans to become pregnant during the next 6 months. Use of illegal drugs, surgery planned in the next 6 months, or being a ward of the state were also exclusion criteria.</p> <p><b>Method of patient recruitment:</b> volunteers were recruited from a paediatric and young adult diabetes clinic in Denver, Colorado.</p> <p><b>Study sample calculation:</b> not reported.</p> <p><b>Data collection:</b> HbA1c levels were determined at 0 and 6 months, and the number of high and low blood glucose levels and adverse events were tracked. Clinic visit costs, patient expenses, and health-care provider times were tracked for cost analysis for both groups.</p> <p><b>Unit of analysis issues:</b> no</p>
Participants	<p><b>Total no of eligible patients:</b> not reported.</p> <p><b>No of patients randomised to groups:</b> n = 70; intervention: n = 35; usual care: n = 35</p> <p><b>No of patients lost to follow-up:</b> n = 7 participants in total were lost to follow-up: n = 5 from intervention group and n = 2 from the usual care group.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: Type 1 diabetes.</li> <li>b) Age, mean years: intervention: 17.4 (1.7); usual care: 17.2 (1.5)</li> <li>c) Gender, male/female sex: intervention: 14/16; usual care: 16/17</li> <li>d) Ethnicity: Caucasian and Hispanic</li> <li>e) Severity of condition:</li> </ul> <p>Duration of diabetes, years (mean): intervention: 8.4 (4.6); usual care: 7.4 (3.1)</p> <p>BL HbA1c: intervention: 9.0 (1.2); usual care: 8.9 (1.1)</p> <ul style="list-style-type: none"> <li>f) Major co-morbidities: not reported</li> </ul> <p><b>Setting</b> (hospital/community/residential care): one diabetes clinic</p> <p><b>Location</b> (rural/urban etc.): not reported.</p> <p><b>Country:</b> USA</p>

## Chase 2003 (Continued)

### Interventions

**Study objective:** To determine whether modem technology allows for effective management of Type 1 diabetes when used in lieu of a clinic visit.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (intervention replacing one of three face-to-face visits)

**Delivery of the intervention:** The modem group had two clinic visits, at 0 and 6 months, and electronically transmitted blood glucose information to the clinic approximately every 2 weeks during the 6-month period. A healthcare provider, either a registered nurse (for 33 patients) or a doctor (for 2 patients), was assigned to each of the 35 modem patients for the 6-month period. The healthcare provider reviewed each transmission and called the patient to both discuss the information transmitted and make treatment changes as needed

**Type of technology and its application:** Acculink modem, not further described

**Did the patient receive education about their condition?** Not reported

**Frequency of patient data transfer (monitoring studies only):** every 2 weeks

**Planned /scheduled no of TM contacts between patient and healthcare professional:** not reported

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: A specialist nurse (33 patients), or a doctor (2 patients)
- b) Method of patient contact (e.g. e-mail, telephone. automated feedback(yes/no): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): every 2 weeks
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to discuss the data and make medication adjustments

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** specialist nurse or doctor

**Duration of the intervention:** 6 months

**Comparison intervention:** the usual care group had three clinic visits during the 6-month period at 0, 3, and 6 months, with the option to telephone or fax blood glucose results to the clinic as desired by the patient or recommended by the physician.

### Outcomes

**Primary outcomes:**

- HbA1c
- Hypoglycaemic and hyperglycaemic events
- Costs

**Follow-up time:** 6 months after randomisation

### Notes

**Ethic's committee approval and informed consent obtained:** informed consent was obtained but unclear if ethical approval was obtained

**Sources of funding:** Roche Diagnostics; Grant M01-RR00069; the General Clinical Research Centers Program, National Centers for Research Resources, National Institutes of Health (Bethesda, MD); and the Children's Diabetes Foundation (Denver, CO).

**Conflict of interest:** not reported

### Risk of bias

#### Bias

#### Authors' judgement

#### Support for judgement

### Chase 2003 (Continued)

Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Were baseline outcome measurements similar?	Low risk	There were no statistically significant differences ( $P > 0.05$ ) between the usual care and modem groups.
Were baseline characteristics similar?	Low risk	There were no statistically significant differences ( $P > 0.05$ ) between the usual care and modem groups.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The main outcome (HbA1c) was objective. The incidence of mild-to-moderate hypoglycaemia was determined from the patient meter downloads during each clinic visit.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	Patient-reported outcomes at high risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Five patients (14.2%) from the intervention group and 2 (5.7%) from the usual care group were lost to follow-up. There was no difference in the discontinuation rate.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not identified.
Other bias	Low risk	No evidence of other risk of bias.

### Chaudry 2010

#### Methods

**Study design:** RCT (multicentre)

**Inclusion criteria:** hospitalised for heart failure (HF) in the previous 30 days.

**Exclusion criteria:** residence in a long-term nursing home; inability to participate in the study protocol for any reason, including a low expected probability of survival for the next 6 months owing to conditions other than HF; inability to stand on a scale; severe cognitive impairment; and a planned hospitalisation for a procedure.

**Method of patient recruitment:** patients were enrolled from 2006 through 2009 at 33 cardiology practices across the United States (see the Supplementary Appendix, available at NEJM.org). Site co-ordinators identified patients hospitalised for HF in the previous 30 days.

**Study sample calculation:** the study was designed to have a power of 80% ( $\alpha 0.05$ ) to detect a 15% relative reduction in the primary end point in the tele-monitoring group as compared with the usual-care group.

**Data collection:** patients were also interviewed within 2 weeks after enrolment (which was considered to be the baseline), and 3 and 6 months after enrolment, by staff at the co-ordinating centre who were unaware of the treatment assignments. During these telephone interviews, information was collected about the quality of life, satisfaction with care, and use of medications. At 6 months, site co-ordinators at each clinical-practice site reviewed the office and hospital medical records to ascertain readmissions. They also contacted patients and their primary care providers to inquire about re-admissions. Discharge summaries, other chart documentation, or both were obtained for all re-admissions.

**Unit of analysis issues:** (yes/no): no



**Chaudry 2010** (Continued)

Participants

**Total no of eligible patients:** n = 5069 patients were assessed for eligibility, of which 2442 were ineligible, and 964 (19%) declined participation

**No of patients randomised to groups:** n = 1653; intervention: n = 826; control: n = 827

**No of patients lost to follow-up:** n = 119 patients never activated the system, but all are included in the analysis

**Patient baseline characteristics:**

a) Clinical condition: heart failure (HF)

b) Age (years), median, IQR: TM: 61 (51–73); usual care: 61 (51–73)

c) Gender, female sex, no. (%) : TM: 359 (43.5); usual care: 336 (40.6)

d) Ethnicity:

White: TM: 413 (50.1); usual care: 402 (48.6)

Black: TM: 314 (38.0); usual care: 330 (39.9)

e) Severity of condition:

NYHA class — no. (%)

I: TM: 48 (5.8); usual care: 52 (6.3)

II: TM: 301 (36.4); usual care: 306 (37.0)

III : TM: 416 (50.4); usual care: 423 (51.1)

IV: TM: 61 (7.4); usual care: 46 (5.6)

Left ventricular ejection fraction < 40% (%): TM: 572/806 (71.0); usual care: 563/802 (70.2)

f) Major co-morbidities:

Chronic kidney disease — no./total no. (%): TM: 370/814 (45.5); usual care: 378/813 (46.5)

COPD — no. (%): TM: 169 (20.5); usual care: 177 (21.4)

Diabetes mellitus — no. (%): TM: 394 (47.7); usual care: 378 (45.7)

Hypertension — no. (%): TM: 632 (76.5); usual care: 639 (77.3)

Coronary artery disease — no. (%): TM: 432 (52.3); usual care: 403 (48.7)

g) Medications; no (%):

ACE inhibitor or ARB: TM: 549 (66.5); usual care: 557 (67.4)

Beta-blocker: TM: 668 (80.9); usual care: 641 (77.5)

Loop diuretic: TM: 646 (78.2); usual care: 646 (78.1)

Digoxin: TM: 214 (25.9); usual care: 198 (23.9)

Aldosterone-receptor antagonist: TM: 266 (32.2); usual care: 277 (33.5)

**Setting** (hospital/community/residential care): 33 cardiology practices across the USA

**Location** (rural/urban etc.): not reported

**Country:** USA

Interventions

**Study objective:** to investigate if tele-monitoring improves outcomes for patients with HF.

**Chaudry 2010** (Continued)

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring with alerts (used as an alternative to usual care)

**Delivery of intervention:** the TM group was instructed to make daily, toll-free calls to the system. During each call, patients heard a series of questions about general health and HF symptoms, and they entered responses using the telephone keypad. Every 30 days, validated screening questions for symptoms of depression were also included. Information from the tele-monitoring system was downloaded daily to a secure Internet site and was reviewed every weekday (except on holidays) by site co-ordinators. All questions had predetermined responses that triggered "variances" to flag clinicians' attention (see description of variance triggers [http://www.nejm.org/doi/suppl/10.1056/NEJMoa1010029/suppl\\_file/nejmoa1010029\\_appendix.pdf](http://www.nejm.org/doi/suppl/10.1056/NEJMoa1010029/suppl_file/nejmoa1010029_appendix.pdf)). The protocol required the sites to contact any patient whose response generated variances and document their management of the variances. To maximize adherence to tele-monitoring, patients were told that their information would be reviewed by the clinicians responsible for managing their HF. If patients did not use the system for two consecutive days, they received a system-generated reminder call; after that, they were contacted by site staff to encourage participation.

**Type of technology and its application:** tele monitoring was performed with the use of a commercial system, Tel-Assurance (Pharos Innovations).

**Did the patient receive education about their condition?** All participants received education.

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The clinical sites (clinicians)
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): not clear, probably telephone.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): reviewed every weekday; contact made in the case of a variance trigger
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): details not reported.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** clinicians

**Duration of intervention:** 6 months

**Comparison intervention (e.g. face-to-face, telephone, none):** participants assigned to usual care are treated by the attending physician in the usual manner and in accordance with the American College of Cardiology/American Heart Association Guidelines for the management of HF. These Guidelines are discussed with the physicians prior to enrolment.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Re-admission for any reason</li> <li>• Death from any cause within 180 days after enrolment.</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Hospitalisation for heart failure</li> <li>• Number of days in the hospital</li> <li>• Number of hospitalisations.</li> </ul> <p><b>Follow-up time:</b> 6 months</p>
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes

## Chaudry 2010 (Continued)

**Sources of funding:** National Heart, Lung and Blood Institute (5 R01 HL080228).

**Conflicts of interest:** none declared.

**Reimbursement:** study participants were not compensated for participation, sites receive \$300 for each patient enrolled in UC and \$900 for each patient enrolled in tele-monitoring. The higher reimbursement for participants assigned to the intervention reflects the greater effort required by sites, specifically to monitor daily responses and to follow up on variances. Additionally, any costs incurred by sites related to obtaining IRB approval are reimbursed.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.3, Para.2  "Patients were randomly assigned to receive usual care or undergo tele-monitoring, according to a sequence of computer-generated random numbers, with stratification on the basis of the study site."
Allocation concealment (selection bias)	Low risk	The sequence is unknown to the attending cardiologists and nurses.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.5, Col.1, Para 1  "Baseline characteristics of the patients were similar between the two groups (Table 1)."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective outcomes (resource use and mortality) are at low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	119 of 826 participants in TM group (14.4%) did not activate the system.
Selective reporting (reporting bias)	Unclear risk	Results for all primary outcomes listed in the trial protocol are reported in the full text.
Other bias	Low risk	No other risk of bias identified.

## Chiantera 2005

### Methods

**Study design:** RCT

**Inclusion criteria:** patients with recent acute coronary syndrome discharged from hospital

**Exclusion criteria:** the presence of a bundle branch block or a permanent pacemaker.

**Method of patient recruitment:** not reported

**Study sample calculation:** not reported

**Data collection:** not reported

**Unit of analysis issues:** (yes/no): no

## Chiantera 2005 (Continued)

### Participants

**Total no of eligible patients:** not reported

**No of patients randomised to groups:** n = 200; intervention: n = 99; control: n = 101

**No of patients lost to follow-up:** n = 10 (10%) intervention patients left the study at the end of the first month due to their inability to use the device

**Patient baseline characteristics:**

a) Clinical condition: recent acute coronary syndrome

b) Age, mean years (SD): 61 (12)

c) Gender, male/female: 161/39

d) Ethnicity: not reported

e) Severity of condition:

Risk score: intervention:16.6 (SD12.8); control: 15.9 (SD 12.4)

f) Major co-morbidities: not reported

**Setting** (hospital/community/residential care): one coronary care unit

**Location** (rural/urban etc.): not reported

**Country:** Italy

### Interventions

**Study objective:** to compare tele-cardiology with usual care in a prospective, controlled study, carried out in patients discharged after recent acute coronary syndrome, in the assessment of symptoms of angina.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** monitoring (assessment of angina)

**Delivery of intervention:** patients were taught to send a 12-lead ECG spontaneously for symptoms (tele-assistance) and/or every week as scheduled (tele-monitoring) for 4 weeks.

**Type of technology and its application:** a portable device by means of which a 12 -lead ECG could be recorded and transmitted to a service centre by telephone (fixed or mobile).

**Did the patient receive education about their condition?:** Not reported

**Frequency of patient data transfer (monitoring studies only):** at least once weekly

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** not reported

**Clinician response to receipt of data:**

a) Who contacts the patient?: Unclear

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): unclear

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the nursing staff and the cardiologist issued a medical report and eventually proceeded to an interactive consultation with the patient.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nursing staff and a cardiologist

**Duration of intervention:** 4 weeks

## Chiantera 2005 (Continued)

**Comparison intervention:** usual care patients underwent a control visit 15 and 30 days after discharge.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>• Early hospital re-admission</li> <li>• Occurrence of angina</li> </ul> <p><b>Follow-up time:</b> one month after randomisation</p>
Notes	<p><b>Ethical approval and informed consent obtained:</b> not reported</p> <p><b>Sources of funding:</b> not reported</p> <p><b>Conflicts of interest:</b> not reported</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Were baseline outcome measurements similar?	Unclear risk	Not reported
Were baseline characteristics similar?	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Low risk of bias for re-admission.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	n = 10 (10%) patients dropped out from the intervention group because they could not use the equipment.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Unclear risk	Short trial report limited assessment of bias.

## Chong 2012

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Hispanics (self-identified) attending the health centre, who scored 10 or more (= moderate depression) on the Personal Health Questionnaire 9 (PHQ-9) and with a diagnosis of major depression disorder based on the Mini International Neuropsychiatric Interview (MINI)</p> <p><b>Exclusion criteria:</b> 1) diagnosis of bipolar affective disorder, schizophrenia, schizoaffective disorder, dementia, or current substance dependence based on the MINI or had any concurrent DSM-IV Axis I disorder that required inpatient or crisis residential treatment at the time of screening; (2) manifested signs or symptoms of serious medical or neurological illness – for complications; 3) serious medical ill-</p>
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**Chong 2012** (Continued)

ness that might explain depressive symptoms; 4) active suicidal or homicidal ideation; 5) pregnant/lactating; 6) unable to give informed consent.

**Method of patient recruitment:** through annual registration, advertisements/signs, and provider referral. Providers at the health centre were periodically reminded of the study's inclusion and exclusion criteria.

**Study sample calculation:** not reported

**Data collection:** administrative data, the total number of possible visits was made up of the number of times they were "no shows" for the appointment and the number of times they completed the appointment.

**Unit of analysis issues:** (yes/no): no

**Participants**

**Total no of eligible patients:** n = 182 invited, 4 refused, 11 ineligible) - 171 (unclear what happened with four people)

**No of patients randomised to groups:** n = 167; Intervention: n = 80; usual care: n = 87

**No of patients lost to follow-up:** a total of 15 individuals never returned to the clinic (usual care: n = 6 and TM: n = 9), and 5 patients (3 usual care and 2 TM) actively dropped out of the study.

**Patient baseline characteristics:**

- a) Clinical condition: major depression
- b) Age, mean (SD): intervention: 42.8 (12.0); usual care: 43.2 (11.9)
- c) Gender, male no: intervention: 7/80; usual care: 12/87
- d) Ethnicity, Hispanic or of Mexican origin: 100%
- e) Severity of condition: moderate depression at least (PHQ 10 or more)
- f) Major co-morbidities: over 50% of participants did not have a chronic illness.

**Setting** (hospital/community/residential care): one community health centre in Tucson, Arizona that serves low-income uninsured and underinsured individuals; over 90% of patients pay on a sliding fee scale

**Location** (rural/urban etc.): Tucson (urban)

**Country:** USA

**Interventions**

**Study objective:** To assess the feasibility and acceptability of tele-psychiatry for low-income Hispanic patients with major depression.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (using a using webcam and an online virtual meeting program)

**Delivery of intervention:** prior to beginning the session, the psychiatrist at his or her office at the University of Arizona sent the URL to the project recruiter at the health centre to enter the virtual room. The connection was checked for video and audio qualities before the patient entered the TM consulting room. During the session, the psychiatrist and the patient sat in front of their computers and webcams to talk. If the psychiatrist needed to communicate with the project recruiter during or at the end of the session, the psychiatrist would communicate through the telephone. Webcam patients could also access the mental health specialist if such an event was considered appropriate by the psychiatrist. Each psychiatrist or mental health specialist had his or her own caseload. Although the psychiatrists did not discuss treatment as usual (TAU) patients with the health centre providers, they were available as a resource regarding pharmacotherapy.



**Chong 2012** (Continued)

**Type of technology and its application:** the psychiatrist used the Macromedia Breeze Manager Web application to create a virtual meeting room that can be entered using a software-generated URL specific to that meeting.

**Did the patients receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** once a month for 6 months (1 hour for intake, and six 30-minute follow-ups)

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** two Hispanic psychiatrists (both Mexican Americans fluent in English and Spanish, one male, one female) provided tele-psychiatry services to the patients.

**Duration of intervention:** 6 months

**Comparison intervention:** Those assigned to usual care were told that their health centre provider would be responsible for their mental health needs. Health centre providers were notified through the patients' electronic medical record.TAU at the health centre included having one of several in-house mental health specialists to whom the providers could refer patients if needed. Appointments for the mental health specialists at the health centre tended to be for 1 hour.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• Depression severity (assessed with the PHQ-9)</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• No of days lost (not going to work or to school, self-reported outcome)</li><li>• No of unproductive days (went to work but productivity was reduced, self-reported outcome)</li><li>• Acceptability of tele-psychiatry (intervention group only)</li><li>• Resource use (appointment keeping, data from registers)</li><li>• Antidepressant use (self-reported outcome)</li></ul> <p><b>Follow-up time:</b> 6 months after randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> the Robert Wood Johnson Foundation through its Finding Answers Program (April 2008–April 2009).</p> <p><b>Conflict of interest:</b> No competing financial interests exist.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.298, Col.1, Para.5  QUOTE:

## Chong 2012 (Continued)

"Randomization was achieved using a computer-generated list."		
Allocation concealment (selection bias)	Low risk	p.298, Col.1, Para.5  QUOTE:  "The assignment was unknown to both the recruiter and the patient until the patient had undergone informed consent procedures and eligibility screening."
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.300, Col.1, Para.1  QUOTE:  "No significant differences were found between the TAU and WEB patients at baseline."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective outcome: resource use, consultations obtained from registers.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The project recruiter (Spanish-English bilingual Mexican American) conducted data collection. Valid measure of depression severity was used.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	All patients were followed up (in person or through the telephone), regardless of whether or not they accessed services, unless they refused to participate in the study follow-up. The follow-up rate was above 80% at the 3- and 6-month follow-up periods. A total of 15 individuals did not return to the clinic (6 TAU and 9 WEB), and 5 patients (3 TAU and 2 WEB) actively dropped out of the study.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Cleland 2005

Methods	<b>Study design:</b> 3-armed multicentre RCT  <b>Inclusion criteria:</b> a hospital admission due to or complicated by worsening heart failure (HF) lasting 48 hours within the last six weeks; to have persisting symptoms of HF, a LVEF < 40%, an LV end-diastolic dimension 30 mm/m (height); and to be receiving furosemide at a dose 40 mg/day or equivalent (e.g., 1 mg of bumetanide or 10 mg of torasemide). In addition to these criteria, patients had to have at least one of the following markers of a further increase in risk: an unplanned cardiovascular admission lasting 48 hours within the previous 2 years, an LVEF < 25%, or treatment with furosemide at a dose of 100 mg/day or equivalent.  <b>Exclusion criteria:</b> patients younger than 18 years of age; who were deemed unable to comply with home tele-monitoring; or who were awaiting revascularisation, cardiac re-synchronisation, or heart transplantation.  <b>Method of patient recruitment:</b> each hospital provided a secondary care function to their local community from which patients were recruited.	
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## Cleland 2005 (Continued)

**Study sample calculation:** no

**Data collection:** N/A

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** not reported

**No of patients randomised to groups:** n = 253: Intervention (tele-monitoring); n = 168; Usual care: n = 85. Note: a third study arm (nurse telephone support, n = 173) was not included in this review.

**No of patients lost to follow-up:** Intervention: n = 3 (1.8%); Usual care: none, and n = 12 declined to comply with regular tele-monitoring (over a median follow-up of 484 days)

#### Patient baseline characteristics:

a) Clinical condition: heart failure (HF)

b) Age, mean (SD): TM: 67(13) years; usual care: 68(10) years

c) Gender, female sex (%) ; TM: 20 %; usual care: 18 %

d) Ethnicity- NA

e) Severity of condition:

NYHA I : Intervention: 34 (22%); Usual care:14 (18%)

NYHA II: Intervention: 71 (46%); Usual care:28 (36%)

NYHA III: Intervention:33 (23%); Usual care: 33 (42%)

NYHA IV: Intervention:13 (8%) ; Usual care:3 (4%)

Mean LVEF was 25% (SD,8)

f) Major co-morbidities:

Previous myocardial infarction: TM:94 (56%); Usual care:57 (67%)

**Setting** (hospital/community/residential care): 12 main and 4 satellite hospitals (acute care)

**Location** (rural/urban etc.): unclear

**Country:** Germany, the Netherlands, the UK

### Interventions

**Study objective:** to identify whether home tele-monitoring (HTM) improves outcomes compared with nurse telephone support and usual care for patients with HF who are at high risk of hospitalisation or death

**Type of TM/ mode of delivery (e.g.video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring of chronic condition (substituting usual care)

**Type of technology and its application:** the equipment consisted of low-profile, electronic, weighing scales, an automated sphygmomanometer, and a single-lead electrocardiogram using wrist-band electrodes. Each device contained a short-range radio-transmitter that allowed it to communicate automatically with a hub connected to the patient's conventional telephone line and, thereby, automatically to a central web server and then via secure Intranet connections to a workstation at each investigator site. Data were encrypted during transmission to ensure patient confidentiality.

**Delivery of the intervention:** after randomisation (median 12 days; upper quartile 24 days), a service engineer visited the patient's home to install the equipment. The nurses and medical staff learned how to use the technology as the study progressed. Patients assigned randomly to home tele-monitoring received instructions on how to use the tele-monitoring equipment, and nurse telephone support was offered as for the NTS group. Patients were asked to make a set of measurements every day before

## Cleland 2005 (Continued)

breakfast and before their evening meal, after emptying their bladders, while, wearing light clothing, no shoes and before the next dose of medication. Thus, the patient's weight, blood pressure, heart rate and rhythm were monitored and transferred twice daily. Values greater than or less than preset limits were notified automatically to the study nurses, who then reviewed the information and took action either directly for any short-term advice or through the primary care physician if long-term changes in therapy were required. Nurses could scan patient data manually to identify any trends that they considered as requiring action. Study personnel were primarily responsible for implementation of the management plan in patients assigned randomly to HTM. The primary care physician and the investigator were kept informed of all contacts.

**Did the patient receive education about their condition?** All patients were given an individualised written management plan by the investigator that described what pharmacologic treatment they should receive, in what order, and how it should be monitored. All patients required a loop diuretic according to the study entry criteria. The management plan focused on treatment of LV systolic dysfunction with appropriate doses of angiotensin-converting enzyme (ACE) inhibitors and beta-blockers and, if severe symptoms persisted, spironolactone according to regional guidelines. Digoxin and anticoagulants were recommended for patients in atrial fibrillation. Patients who could not tolerate or who had contraindications to the aforementioned medication were permitted in the study provided an explanation was given.

**Frequency of patient data transfer:** twice daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** TM: unclear number of contacts, NTS: monthly telephone calls; usual care: clinic visits every four months

### Clinician response to receipt of data:

a Who contacts the patient?: The nurse

b) Method of patient contact (e.g. e-mail, automated feedback, telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): directly or after consultation with the physician

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the study nurses, who reviewed the information, took action either directly for any short-term advice or through the primary care physician if long-term changes in therapy were required. Nurses also could scan patient data manually to identify any trends that they considered as requiring action.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses, physicians

**Duration of intervention:** unclear

**Comparison intervention:** the patient's management plan was sent to the patient's primary care physician, who was asked to implement it. Where the usual organisation of care involved nurse specialist titration of drugs, this was allowed. Patient's were assessed at a research clinic every four months to assess intervening history, symptoms and signs, renal function, and serum electrolytes. Contact with the research team was discouraged between visits.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Days lost because of death or hospitalisation in acute medical/surgical beds for any reason</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Days in hospital</li> <li>Mortality</li> <li>Medication use according to patients management plan</li> </ul> <p><b>Follow-up time:</b> 240 days (reduced from planned 450 days after interim analysis)</p>
Notes	<p><b>Ethical approval and written informed consent obtained (yes/no):</b> yes</p>

## Cleland 2005 (Continued)

**Sources of funding:** the European Union's Trans European Network (TEN) Telecom programme, provided most of the financial support for clinical investigators, data collection, and analysis, and Philips Medical Systems provided information technology systems, tele-monitoring solutions, and support engineers and contributed to investigator-site staff costs.

**Conflicts of interest:** not reported.

**Note:** recruitment to the study stopped after 426 patients at the request of the statistician due to a difference in mortality rates between UC and the other groups, and because it was unlikely that the primary end point would be reached.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	see p.1656, Col 1, Para 2  QUOTE: "After acquiring consent, patients' baseline data were recorded and sent to an independent statistical group (i.e., Institute for Medical Informatics and Biostatistics, Basel). Random permuted blocks for each center was used to allocate patients to treatment groups. The block size was kept confidential and was varied to avoid investigators predicting which management group would be next to be allocated."
Allocation concealment (selection bias)	Low risk	p.1656, Col 1, Para 2  QUOTE: "The block size was kept confidential and was varied to avoid investigators predicting which management group would be next to be allocated."
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Unclear risk	No information.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: days lost because of death or hospitalisation</b>  The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, objective putcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	7.1 % (12 patients) discontinued in the TM group, as compared to none in the usual care group. Analyses were conducted by intention-to-treat.
Selective reporting (reporting bias)	High risk	Results for many outcomes listed in the trial protocol were reported in the paper, but not the Best Medical Therapy score, quality of life or economic efficiency and resource use.
Other bias	Low risk	No other risk of bias identified.

## Cross 2012

### Methods

**Study design:** RCT

**Inclusion criteria:** adult patients with ulcerative colitis receiving usual care

**Exclusion criteria:** none stated.

## Cross 2012 (Continued)

**Method of patient recruitment:** all adult patients with ulcerative colitis from the University of Maryland, Baltimore and the gastroenterology clinic at the Veterans Affairs Maryland Health Care System in Baltimore were sent a letter inviting them to participate in the study. Patients were also invited to participate at the time of clinic visits.

**Study sample calculation:** sample size calculations were performed for each primary outcome measure. All sample size estimates were performed assuming a Type 1 error rate of 5%, a Type 2 error rate of 20%, and an attrition rate of 10%. Assuming a standard deviation of 39.4 in Seo Index scores, a standard deviation of 34 in IBDQ scores, and a baseline adherence rate of 50% in the best available care arm, we had sufficient power with a sample size of 84 participants to detect a 35-point difference in Seo scores, a 32-point difference in IBDQ scores, and a 30% difference in adherence rates. SeoIndex is used to assess clinical disease activity.

**Data collection:** all participants underwent visits every 4 months for one year. Study questionnaires and blood draws for measurement of albumin, sedimentation rate, and haemoglobin were done at each study visit.

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** n = 167 patients assessed for eligibility (n = 119 were excluded: of which n = 5 not meeting the inclusion criteria; n = 113 refused participation; n = 1 other reason)

**No of patients randomised to groups:** n = 47; Intervention: n = 25 Usual care: n = 22

**No of patients lost to follow-up:** 3 patients in each group withdrew after baseline visit and did not receive the allocated intervention; one patient in the usual care group and 8 patients in the intervention group discontinued.

#### Patient baseline characteristics:

a) Clinical condition: ulcerative colitis

b) Age: intervention: 41.7 ± 13.9 years; usual care: 40.3 ± 14.4 years

c) Gender, female sex no (%): intervention: 15 (60); usual care: 15 (68)

d) Ethnicity, white no (%): intervention: 16 (64); usual care: 15 (68)

e) Disease extent:

Proctitis/Left: intervention: 12 (48); usual care: 10 (45)

Sided pancolitis: Intervention: 113 (52); usual care: 2 (55)

f) Medications:

Steroid use: intervention: 3 (12); usual care: 2 (9)

Immunosuppressant use: intervention: 14 (56); usual care: 6 (27)

Infliximab use: intervention: 7 (28); usual care: 7 (32)

g) Major co-morbidities: N/A

**Setting** (hospital/community/residential care): one gastroenterology clinic of the Veterans Affairs Health Care System

**Location** (rural/urban etc.): Baltimore, urban

**Country:** USA

### Interventions

**Study objective:** to evaluate a home tele-management system for UC (UC HAT) on disease activity, quality of life (QoL), and adherence compared to best available care in a randomised, controlled trial.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** monitoring and education



## Cross 2012 (Continued)

**Delivery of intervention:** participants answer questions regarding symptoms, side effects, adherence, and receive disease-specific education using the home unit. The home unit automatically transmits the results to the decision support server after each self-testing session through an active telephone line; for participants without an active telephone line, a cell phone is provided to transmit self-testing results over a secure wireless network in a similar manner. Data transmitted from the participant's home are de-identified and encrypted. The web portal provides an interface for the collected participant data. The web-based care management portal is used to set up customised clinical alerts and action plans. Updated action plans are automatically transmitted to participant home units. If certain clinical conditions are met, e-mail alerts are sent to the nurse coordinator. The co-ordinator reviews the information and if necessary consults the medical provider and the participant for management changes.

**Type of technology and its application:** UC HAT is comprised of a home unit, a decision support server and a web-based clinician portal. The UC HAT home unit consists of a net book computer and an electronic weight scale.

**Did the patients receive education about their condition?** An educational curriculum was developed for patients from materials provided by the Crohn's and Colitis Foundation of America.

**Frequency of patient data transfer (monitoring studies only):** weekly

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse co-ordinator
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): not reported, if certain clinical conditions are met, e-mail alerts are sent to the nurse co-ordinator.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the co-ordinator reviews the information and if necessary consults the medical provider and the participant for management changes.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 12 months

**Comparison intervention:** the standard of care for participants in this study is modelled on the standard of care at the institution, and is based on current evidence-based guidelines including comprehensive assessment, a guideline-concordant therapy plan, scheduled and as needed clinic visits, scheduled and as needed telephone calls, and administration of educational fact sheets about disease-specific topics when appropriate. We also provided the usual care group with all currently available educational fact sheets from the Crohn's and Colitis Foundation at the time of group allocation, and individualised written action plans at the time of group assignment without reinforcement. We termed the care given in the control intervention group as best available care (BAC).

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Clinical disease activity (assessed using the Seo index)</li> <li>• Disease specific quality of life (assessed using the IBD questionnaire (IBDQ))</li> <li>• Medication adherence (assessed using the Morisky Medication Adherence Score)</li> </ul> <p><b>Other outcomes:</b></p> <ul style="list-style-type: none"> <li>• Adherence</li> </ul> <p><b>Follow-up time:</b> 12 months after the randomisation</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p>

## Cross 2012 (Continued)

**Sources of funding:** the Broad Medical Research Program (BRMP-0190), University of Maryland General Clinical Research Center Grant (M01 RR 16500), General Clinical Research Centers Program, National Center for Research Resources (NCRR), NIH, and the Baltimore Education and Research Foundation.

**Conflict of interest:** none reported.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.3, Col.1, Para 2  QUOTE:  "Assignment to the experimental intervention was made using a random permuted block design with randomly varied block sizes; randomisation was stratified within baseline disease activity strata (disease in remission vs. active disease)."
Allocation concealment (selection bias)	Low risk	p.3, Col.1, Para 2  QUOTE:  "Group assignment was concealed and was not revealed to the patient or the research team members until after all baseline data were collected."
Were baseline outcome measurements similar?	Low risk	Seo index scores and adherence scores were similar in the two groups, while IBDQ scores were significantly higher at baseline in the control group, 190.8+/-24.2 compared to 171.6+/-30.1 in UC HAT (P = 0.02). The analyses were adjusted for baseline differences.
Were baseline characteristics similar?	Unclear risk	p.65, Col.1, Para.5  There were no differences between the study groups, except that 27% (n = 6) of participants in the control group used immune suppressants compared to 56% (n = 14) in UC HAT.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: clinical disease activity, QoL and medication adherence</b> (assessed with standardised, validated tools)  p.3, Col.1, Para 2  QUOTE:  "Research staff at study visits was blinded to treatment allocation of research participants for subsequent visits." The participants however could not be blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Three patients in each group did not receive the intervention. Eight patients (32%) in the intervention group discontinued (unknown reasons) compared with one patient (4.5%) in the control group.  p.65, Col.1, Para.4  QUOTE:  "There were no differences between trial completers and participants that withdrew except that trials completers had less extensive colitis." Intention to treat analysis used.

## Cross 2012 (Continued)

Selective reporting (reporting bias)	Low risk	Trial protocol found. Results for all outcomes listed in the protocol were reported in the paper.
Other bias	Low risk	No evidence of other risk of bias.

## Crossley 2011

Methods	<p><b>Study design:</b> multicentre RCT</p> <p><b>Inclusion criteria:</b> adult patients who had an implanted a Medtronic (Minneapolis, Minnesota) wireless Implantable cardioverter-defibrillator (ICDs) and cardiac resynchronisation therapy with defibrillation (CRT-D) system utilising the Medtronic CareLink Network.who were being able and willing to replace regularly scheduled in-office follow-ups with remote follow-ups; and being able to attend all required follow-up visits.</p> <p><b>Exclusion criteria:</b> permanent atrial fibrillation (AF) (constant AF for which there were no plans to attempt to restore sinus rhythm); chronic warfarin therapy; having had a previous ICD, CRT device, or pacemaker; being 18 years of age; and having a life expectancy 15 months.</p> <p><b>Method of patient recruitment:</b> no information</p> <p><b>Study sample calculation:</b>The statistical software package PASS 2005 (NCSS, Kaysville,UT) was used to generate the sample size requirement with the following inputs: <math>\alpha = .05</math>, power = 80%, in-office arm mean time =25 days, in-office arm SD = 27.8 days, remote arm mean time =3 days, remote arm SD = 1 day.</p> <p><b>Data collection:</b> no information</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n=1980 adult patients</p> <p><b>No of patients randomised to groups:</b> n = 1997; intervention: n = 1014; control: n = 983</p> <p><b>No of patients lost to follow-up:</b> n=17 participants were excluded from the analysis the following reasons: permanent AF (n =2), not implanted with a required study device (n = 9), previous defibrillator or pacemaker (n = 3), unwillingness to conduct CareLink follow-up visits (n = 2), and inability to attend all required follow-up visits (n = 1).</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: patients with recent acute coronary syndrome discharged from hospital</p> <p>b) Age, years (SD): intervention: 65.2 (12.4); control: 64.9 (11.9)</p> <p>c) Gender, male sex: intervention:70.5%; control: 71.7%</p> <p>d) Ethnicity: not reported</p> <p>e) Severity of condition:</p> <p>New York Heart Association class</p> <p>No heart failure: intervention: 5.3%; control:6.7%</p> <p>Class I : intervention:3.9%; control:4.7%</p> <p>Class II: intervention: 40.9%; control:39.5%</p> <p>Class III: intervention: 48.5%; control:47.5%</p> <p>Class IV: intervention: 1.5%; control: 1.5%</p>

**Crossley 2011** (Continued)

LVEF, % (SD) intervention: 28.6(10.0); control: 29.2 (10.3)

f) Major co-morbidities:

Hypertension: intervention: 74.2%; control: 76.9%

**Setting** (hospital/community/residential care): 136 clinical sites

**Location** (rural/urban etc.): not reported

**Country:** USA

Interventions

**Study objective:** to determine the impact of wireless remote monitoring with automatic clinician alerts on the time from clinical events to clinical decisions and on health care utilisation.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** monitoring (with automatic alerts) and advanced diagnostics

**Delivery of intervention:** The latest defibrillators have wireless technology that can automatically transmit data from a patient's defibrillator to the home monitor and central server without any patient action. The transmissions include regularly scheduled checks and automatic clinician alerts in response to clinical events. The patients must activate an initial monitor setup. In addition, patients who are away from their monitor for extended periods of time reduce the ability of automatic clinician alerts to transmit.

**Type of technology and its application:** A Medtronic (Minneapolis, Minnesota) wireless ICD or CRT-D system utilising the Medtronic CareLink Network.

**Did the patient receive education about their condition?** Not reported

**Frequency of patient data transfer (monitoring studies only):** automatic alerts

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** all patients had study visits at 1, 3, 6, 9, 12, and 15 months post-implant. Patients in the remote arm had their in-office visits at 3, 6, 9, and 12 months replaced with remote visits, including a remote device transmission.

**Clinician response to receipt of data:**

a) Who contacts the patient?: Unclear

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): unclear

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): once the system was activated, a successful transmission led to a clinician viewing the data within 1.5 days 70% of the time.

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): echocardiogram, ECG, change in oral medication, device interrogation, device testing, system modification, blood test, chest x-ray, cardioversion, Transesophageal Echocardiography

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** clinicians

**Duration of intervention:** 15 months

**Comparison intervention:** usual (office) care

**Frequency/number of contacts between control patient and healthcare personnel:** All patients had study visits at 1, 3, 6, 9, 12, and 15 months post-implant.

Outcomes

**Primary outcome:**

- Time from clinical event to clinical decision

**Secondary outcomes:**

## Crossley 2011 (Continued)

- Rates of cardiovascular health care utilisation (related hospitalisations; ED visits, office visits)
- Length of hospital stay (LoS)
- Costs

### Process outcome

- Actions taken

**Follow-up time:** 15 months from start of the intervention

### Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** this study was supported by Medtronic Inc.

**Conflict of interest:** Dr. Crossley is a consultant for Medtronic, Boston Scientific, and Cardiac Control systems; receives lecturing income from Medtronic, Boston Scientific, and Sanofi; and receives research support from Medtronic, Boston Scientific, and St. Jude Medical. Dr. Boyle serves on an advisory board for Medtronic. Dr. Vitense and Ms. Chang are employed by Medtronic. Dr. Mead receives consulting fees and honoraria from Medtronic, Proteus Biomedical, EBR Systems, and InnerPulse; has equity interests in Proteus Biomedical, EBR Systems, InnerPulse, and iRhythm; and serves as officer and director for iRhythm.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The randomisation process was described in the protocol, see below.  "Patients will be randomized in a 1:1 manner to remote monitoring or in-office care. Randomization will be stratified by device group within each center. For each center, a separate randomization sequence will be generated for CRT-D and ICD patients."
Allocation concealment (selection bias)	Unclear risk	The allocation concealment was described in the protocol: "sites will be provided with envelopes containing the randomization assignment to open after successful implant of a study-eligible device."  Comment: It is unclear whether envelopes were opaque
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcomes.
Were baseline characteristics similar?	Low risk	p.1184, Col.1, last para. and Col.2, Para.1  QUOTE:  "The remote and in-office arm patients had similar demographic data (Table 2)"
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: time to clinical event to clinical decision, healthcare resource use</b>  The healthcare professional delivering the intervention could not be blinded to the group allocation, and neither could the patient. The primary outcome (time to clinical decision), was defined as the time from device detection of a clinical event to a decision being made in response to the event, as reported by the clinician or as evidenced by device data obtained at interrogation.
Incomplete outcome data (attrition bias) All outcomes	High risk	See p.1184, Col 2, Para 2  Analysis was restricted to 140 /575 clinical events that triggered an alert.

## Crossley 2011 (Continued)

Automatic clinician alerts were triggered but not successfully transmitted for 149 (45%) clinical events, mainly because the home monitor was not set up and initiated to send out transmissions. Of the 180 successfully transmitted events, 40 were not viewed before clinical decision.

Other outcomes: healthcare use, LoS, healthcare economics

“All patients in the analysis cohort were included in this analysis”=low risk

Selective reporting (reporting bias)	Unclear risk	Results for some of the outcomes listed in the trial protocol were not reported in the full text paper (e.g. patient well-being, burden of in-office visits, heart failure status, state anxiety, trait anxiety, distance travelled, patient experience, hours absent from work).
Other bias	Low risk	No other risk of bias identified.

## Dallolio 2008

Methods	<p><b>Study design:</b> multicentre RCT</p> <p><b>Inclusion criteria:</b> adult patients with spinal cord injury (SCI) discharged for the first time from the spinal cord unit to their homes (Belgium and Italy) or to their homes or another facility (UK). Inclusion criteria were (1) having non-progressive, complete, or incomplete SCI with lesion level at C4-L2, (2) living within the catchment area of the spinal cord unit (UK, Belgium) or being willing to travel to the spinal cord unit with their caregiver for 2 ambulatory follow-up visits (Italy) at months 2 and 6 after discharge, (3) age 18 years or older and willingness to participate with their caregivers (informed consent signed by the patient and the principal caregiver), and (4) having suitable home (nursing home, hospital) facilities to install broadband lines and video-conference equipment.</p> <p><b>Exclusion criteria:</b> enrolled participants were excluded if: (1) the patient withdrew from the trial for any reason before the end of the trial period either by declaring voluntary withdrawal or by not participating in more than 2 consecutive scheduled TM sessions, or (2) the patient was readmitted to the spinal cord unit or another hospital for a period lasting more than 2 weeks.</p> <p><b>Study sample calculation:</b> a sample size of 90 participants a treatment group (i.e., 30 TM and 30 controls a site [Salisbury and Stanmore were combined to form 1 site] for a total of 180 participants) was determined by setting alpha at 0.05 and power at 80%.</p> <p><b>Method of patient recruitment:</b> participants were recruited at 4 spinal cord units between November 2003 and February 2006. All patients were assessed by trained clinicians 10 days before discharge and eligible patients were randomised to treatment group 8 days before discharge from hospital.</p> <p><b>Data collection:</b> disability was assessed at the follow-up visits by independent evaluators not involved in the treatment of patients. Complications were assessed by spinal cord unit physicians who were not involved in the clinical care of those patients at months 2 and 6 (1 week) on the occasion of a scheduled follow-up visit to the spinal cord unit or during an outpatient visit of spinal cord unit personnel to a patient's home or nursing home or general hospital.</p> <p><b>Unit of analysis issues:</b> no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 249 eligible patients with SCI, of which n = 57 refused to participate and n = 55 were excluded of other reasons</p> <p><b>No of patients randomised to groups:</b> n = 137; intervention: n = 69; control: n = 68; n = 7 patients in the intervention group and n = 3 in the control group did not receive the allocated intervention.</p> <p><b>No of patients lost to follow-up:</b> n = 1 patient in the intervention group and n = 3 patients in the control group were lost to follow-up, and n = 8 patients in the intervention group and n = 1 in the control group discontinued intervention due to different reasons.</p>



## Dallolio 2008 (Continued)

**Patient baseline characteristics:** (Bologna: n = 59; Brussels: n = 17, Salisbury/Stammore: n = 51)

a) Clinical condition: spinal cord injury (SCI)

b) Age: 40 years (range, 18–85 years)

c) Gender, male sex: 107 (84.2%)

d) Ethnicity: not reported

e) Severity of condition:

Tetraplegia (%): Bologna: 24 (40.68); Brussels: 3 (17.65); Salisbury/Stammore: 20 (39.22)

Paraplegia (%): Bologna: 35 (59.32); Brussels: 14 (83.35); Salisbury/Stammore: 28 (54.90)

Spinal Cord Independence measure (SCIM II) score at discharge: Bologna: 52.59 ± 17.96; Brussels: 63.11 ± 23.96; Salisbury/Stammore: 46.9 ± 23.34

Functional Independent Measure (FIM) score at discharge: Bologna: 88.28 ± 24.77; Brussels: 94.76 ± 34.50; Salisbury/Stammore: 87.19 ± 26.40

Median LOS in the spinal cord unit (days): Bologna: 186.5; Brussels: 224.5; Salisbury/Stammore: 230

f) Major co-morbidities: not reported

**Setting** (hospital/community/residential care): 4 spinal cord units, the patients' homes (Belgium and Italy), the patients' homes or another facility (UK (Duke of Cornwall Spinal Treatment Centre, Salisbury, and the London Spinal Injuries Unit of Royal National Orthopaedic Hospital, Stanmore))

**Location** (rural/urban etc.): urban (Brussels, Bologna, UK (Stanmore and Salisbury))

**Country:** Belgium, Italy and the UK

## Interventions

**Study objective:** to compare the outcomes of standard care at 6 months postdischarge with those of TM in patients with SCI, in terms of functioning, disability, number and type of complications and satisfaction with care.

**Type of TM/mode of delivery (e.g. videoconferencing, remote monitoring with the healthcare professional responding to alerts etc):** videoconferencing (+ usual care)

**Delivery of the intervention:** in addition to usual care, patients in TM group received 1 TM session every week during the first 2 months (for a total of 8 sessions) followed by 9 TM bi-monthly sessions. Sessions lasted approximately 45 minutes and were of 2 types: type 1 sessions involved at least 1 medical doctor and 1 nurse, and type 2 sessions involved a physiotherapist and/or 1 occupational therapist. Type 1 session consisted of a structured interview to collect signs and symptoms usually assessed in the clinical routine. The following items were investigated: any type of acute complaint, signs of new pressure ulcers, episodes of fever, bladder and bowel function, signs of urinary tract infections, pulmonary complications and autonomic dysreflexia, and symptoms of depression or anxiety. During the TM video-conference, patients and their caregivers also had the opportunity to share views and concerns as well as to receive professional advice. At the end of the TM session physicians and nurses formulated specific recommendations to address medical and psychologic problems to be passed by caregivers on to the therapists or the general practitioners responsible for the care of the patients. In some cases, general practitioners attended the TM sessions to be updated on the patient's progress. During type 2 sessions, therapists assessed a number of functional parameters related to mobility (i.e., sitting up, sitting in bed) and other skills (i.e., handwriting, use of telephone) by means of a structured interview. Specific recommendations were given to address issues related to patient mobility such as transfer from bed to wheelchair, use of aids, prostheses, and use of remote controls for electronic devices in the immediate surroundings (i.e., to turn on/off lights, to open doors).

**Type of technology and its application:** the platform was composed of the following items: 1 central unit (set-top box), 1 webcam, 1 microphone with noise and echo cancellation, 1 remote controller, 1 universal serial bus electronic security key, 1 audio/video television connection cable and the related Syndicat des Constructeurs d'Appareils Radiorécepteurs et Téléviseurs (SCART) adapter, 1 power ca-

## Dallolio 2008 (Continued)

ble, 2 audio interconnection cables, 1 untwisted cable to connect to the integrated services digital network socket or to the asymmetric digital subscriber line modem, and 1 system reference manual. The video-conferencing platform was powered by software specifically designed to allow operation by people with limited manual skills and to allow the sending and storage of video messages.

**Did the patient receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** in addition to usual care, patients in TM group received 1 TM session every week during the first 2 months (for a total of 8 sessions) followed by 9 TM bimonthly sessions.

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians, nurses, physiotherapists, occupational therapists.

**Duration of intervention:** 6 months

**Comparison intervention:** Standard care only, unclear what standard care consisted of.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• Functional status (assessed using the FIM scale and the SCIM II scale)</li><li>• Clinical complications (assessed through interview and patient diaries)</li><li>• Patient satisfaction (assessed with non-validated questionnaire)</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Medications prescribed</li><li>• Number and length of any re-admissions to the spinal cord unit</li><li>• Number and length of emergency admissions to other hospitals</li></ul> <p><b>Follow-up time:</b> 6 months after the start of the intervention</p>	
Notes	<p><b>Ethical approval and written informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> the European Commission’s Framework V Programme.</p> <p><b>Conflicts of interest:</b> no commercial party declared a direct financial interest.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>see p.2333, Col 2, Para 5</p> <p>QUOTE:</p> <p>"The study was a multicenter randomized controlled trial. A computerized randomization sequence was generated for each research center."</p>

**Dallolio 2008** (Continued)

Allocation concealment (selection bias)	Low risk	see p.2333, Col 2, Para 5  QUOTE:  "The randomisation list was kept by the scientific coordinator of the project."
Were baseline outcome measurements similar?	Low risk	p.2335, Col.1, Para.1  QUOTE:  "..the disability levels at discharge of subjects in the TM and control groups were comparable."
Were baseline characteristics similar?	Low risk	p.2335, Col.1, Para.1  QUOTE:  "The demographic characteristics and the disability levels at discharge of subjects in the TM and control groups were comparable."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<b>Outcome group: healthcare resource use, medications prescribed</b>  The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, health resource use and medications prescribed are objective outcome measures.
Blinding (performance bias and detection bias) - Non-objective outcomes	Low risk	<b>Outcome group: functional status (assessed by observation), clinical complications, patient satisfaction</b>  The participating patients and personnel could not be blinded to the group allocation, which may affect self-reported outcomes.  p.2334, Col 1, under 'Outcomes'  QUOTE:  "Patients were assessed by trained clinicians 10 days before discharge (before randomisation) and 6 months after discharge" by staff not involved in the study or the care of patients and "Complications were assessed by spinal cord unit physicians who were not involved in the clinical care of those patients."
Incomplete outcome data (attrition bias) All outcomes	High risk	114 of 137 (83.2%) randomised patients remained in the study at follow-up. However, there was a large amount of missing data for the clinical outcomes studied.  see p.2337, Table 2 Clinical outcomes, and discussion p.2340, Para.1  QUOTE:  "Second, the amount of missing data on clinical outcomes affects the external validity of our study and makes it difficult to draw a valid conclusion about the difference between the 2 treatments. Thus, our results, suggesting no significant differences in clinical complications between the 2 treatment groups warrant replication in further studies."
Selective reporting (reporting bias)	High risk	Results for two of the outcomes listed in the protocol are not presented in the full text paper (i.e. QOL, and costs).
Other bias	Low risk	No evidence of other risk of bias.

## Dansky 2008

Methods	<p><b>Study design:</b> multicentre RCT</p> <p><b>Inclusion criteria:</b> all patients with primary or secondary diagnoses of heart failure (HF) and ability to communicate in conversational English were eligible to participate. During the admission visit, the home health nurse documented that the patient was cognitively intact, able to see and hear the equipment, and had a phone line in the home.</p> <p><b>Exclusion criteria:</b> none reported.</p> <p><b>Method of patient recruitment:</b> the study sample was drawn from a pool of patients admitted to the 10 participating home health agencies (HHAs) for skilled home care</p> <p><b>Study sample calculation:</b> an effect size of 0.2 would require a sample size of 394 to achieve statistical power of 0.80; final sample size was 284 at Time 3.</p> <p><b>Data collection:</b> three research assistants who were blinded to the study group collected patient data via a telephone interview at each data point. The research assistants were all graduate students in health services and trained to use the instruments in the study. Health services utilisation data were collected at 60 and 120 days from the patient's medical record at the HHA. In addition, the research assistant asked the patient, during the telephone interviews, if any ED visits or hospitalisations had occurred. This self report was verified by a review of the hospital records for the appropriate time period.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients randomised to groups:</b> n = 157; Intervention (monitor and video): n = 45 ; control: n = 112. Note: a third intervention group (monitor only, n=127) was not included in this review.</p> <p><b>No of patients lost to follow-up:</b> not reported</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: heart failure (HF)</li> <li>b) Age: 77.0 (9.83), no differences between groups</li> <li>c) Gender: not reported</li> <li>d) Ethnicity: not reported</li> <li>e) Severity of condition: not reported</li> <li>f) Major co-morbidities: not reported</li> </ul> <p><b>Setting</b> (hospital/community/residential care): 10 HHA's</p> <p><b>Location</b> (rural/urban etc.): unclear</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b> To determine the effects of tele-homecare on hospitalisation, ED use, mortality, and symptoms related to sodium and fluid intake, medication use, and physical activity.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> remote monitoring (monitor and video group and monitor only group; the latter not included in this review)</p> <p><b>Delivery of intervention:</b> patients in the treatment groups received a tele-homecare system for the duration of their home health services, to be used in conjunction with usual home health care.</p> <p><b>Monitor and video group:</b></p>

## Dansky 2008 (Continued)

The two-way system (Aviva) adds a video camera and digital stethoscope to the monitoring device, permitting two-way synchronous interaction between nurse and patient. Monitoring sessions are scheduled by the home care nurse according to the patient's condition and care plan, usually two to three times per week. Patients can use the system as often as they wish to monitor their condition, but for the model used in this study, the data were stored offline, and later transmitted to the nurse during the synchronous

connection. During this live connection, the nurse reviewed all data downloaded from the patient's independent use of the equipment and discussed the results with the patient. The nurse also used the digital stethoscope to listen to the patient's heart and lungs. Vital signs, blood sugar, or pulse oximetry readings were collected as ordered by the physician. The nurse used the audio and video to interact with the patient to discuss symptoms, diet, medications, and physical activity. Regardless of the type of system being used, a central station at the HHA tracks and displays data for analysis by the home health nurses and physicians. If a patient's clinical measurements fall outside of preset parameters, alarms enable immediate detection of problems. The central station also is designed to flag late or missing measurements to alert clinicians to a potential problem. An authorised clinician can access the patient's medical record data in the database viewing vital signs data and still images. Access to the electronic medical record is restricted to users who are on the internal network and who have authorized user names and passwords. Communications among the central station, network server, and electronic medical record database are encrypted for privacy. The systems in this study were not programmed to provide health instruction or educational material. There was no control on what type of TM system the participants received because the intervention was dependent on the system used by the HHA.

**Type of technology and its application:** the system operated over telephone lines via a standard modem, linking a central station at the HHA to remote units in homes or other settings (a two-way synchronous monitoring system). The HHA determined the type of system used.

**Did the patient receive education about their condition?** each patient in the study received a packet of information on heart failure which provided basic facts on the disease, guidelines on self-management, and specific instructions on when to notify his or her home care nurse or personal physician.

**Frequency of patient data transfer (monitoring studies only):** two-way monitoring system, two to three times per week

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** two-way system with contacts 2 to 3 times per week

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): one-way monitoring: the nurse reviewing the data could call the patient or the homecare nurse if values deviated from normal; two-way monitoring: the nurse reviews and discusses the data with the patient during the video-call, and discusses also symptoms, diet, medications and physical activity.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 120 days

**Comparison intervention:** patients in the control groups received routine home visits only.

### Outcomes

#### Primary outcomes:

- Hospitalisation
- ED use
- Mortality
- Symptoms related to sodium and fluid intake
- Medication use

## Dansky 2008 (Continued)

- Physical activity

**Follow-up time:** 120 days from start of intervention

### Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Robert Wood Johnson Foundation through the Health E-Technologies Initiatives.

**Conflict of interest:** Not reported.

**Note:** one of the interventions arms was not included in the review, the one-way monitoring system which allowed a patient to take his or her own measurements (e.g., blood pressure, pulse, weight) through peripheral devices and transmit the readings to the HHA. The one-way monitoring systems used in the study were either the HomMed Health Monitor or the ViTel Net system. The one-way systems are used independently by the patient and are typically programmed to be used every day at a predetermined time.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	See p.185, Col 1, Para 2  QUOTE:  "The project manager at each HHA randomly assigned the patient to the intervention or control group, using a sealed, opaque envelope technique."
Allocation concealment (selection bias)	Unclear risk	No information about whether the envelopes were sequentially numbered etc.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Low risk	p.187, end of page and p.190, Para.1  QUOTE:  "None of the demographic or clinical characteristics were found to be different for the groups at baseline."
Blinding (performance bias and detection bias) - Objective outcomes	Low risk	<b>Outcome group:</b> mortality, health care use  Judged as low risk for mortality, and healthcare resource use which was collected from medical records.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	<b>Outcome group:</b> patient-reported outcomes (physical activity, medication use and symptoms)  The participating patients could not be blinded to the group allocation.  p.187, Para.1  QUOTE:  "Three research assistants who were blinded to the study group collected patient data via a telephone interview at each data point. The research assistants were all graduate students in health services and trained to use the instruments in the study."
Incomplete outcome data (attrition bias)	Unclear risk	Not reported.



## Dansky 2008 (Continued)

### All outcomes

Selective reporting (reporting bias)	Unclear risk	According to the trial protocol the study would evaluate knowledge, self-management, and health status. Neither knowledge, nor health status were reported in the paper; health resource use which was not listed in the trial protocol is reported.
Other bias	Low risk	No other risk of bias identified.

## Dar 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> patients aged over 18 years with a primary diagnosis of heart failure (HF) and deemed fit for discharge by their medical team, had a home telephone line, lived within the catchment population of the recruiting hospitals, and were classified as class II–IV New York Heart Association at the time of discharge</p> <p><b>Exclusion criteria:</b> patients were not recruited if they had cognitive impairment sufficient to interfere with their use of the tele-monitoring equipment.</p> <p><b>Method of patients recruitment:</b> all patients admitted to hospital with a diagnosis of HF as defined by the European Society of Cardiology criteria (either a new diagnosis or an acute decompensation of chronic HF) were screened for eligibility. Patients were recruited between July 2006 and August 2007.</p> <p><b>Study sample calculation:</b> a sample size of 300 was calculated for risk of all-cause rehospitalisation of 50% for usual care and 36% in the tele-monitoring arm over a 6-month period, with 80% power and alpha 0.05; a 30% relative reduction in the risk of rehospitalisation with tele-monitoring was considered clinically meaningful.</p> <p><b>Data collection:</b> details of hospital admissions, hospital visits, and telephone contacts with the HF nurses were collected using hospital records, supplemented by the patient diaries. At 3 and 6 months after randomisation, quality of life questionnaires were posted to patients and a stamped addressed envelope was provided. Primary care physicians were also contacted at these time points for details of the medication history and primary care contacts made over the follow-up period.</p> <p><b>Unit of analysis issues:</b> no</p>
Participants	<p><b>Total no of eligible patients:</b> unclear, n = 456 patients were assessed for eligibility and 182 (40%) patients consented to inclusion in the study</p> <p><b>No of patients randomised to groups:</b> n = 182; intervention: n = 91; control: n = 91. N = 7 in the TM group did not receive the intervention (four withdrew and three died before the start of the intervention); n = 2 did not receive usual care (one withdrew and one died before home visit)</p> <p><b>No of patients lost to follow-up:</b> intervention: n = 6 patients died between the installation and 90 days and n = 8 died between 90 and 180 days; control: n = 4 died between home visit and 90 days, and none thereafter</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: heart failure (HF)</li> <li>b) Age, mean (SD): intervention: 70 (12.8) years; control: 72 (10.4) years</li> <li>c) Gender, female sex number (%); intervention: 29 (32); control: 32 (35)</li> <li>d) Ethnicity, south Asian, n (%); intervention: 18 (20); control: 19 (21)</li> <li>e) Severity of condition: all patients had New York Heart Association class II–IV. Note: no information on the NYHA class by group.</li> </ul>

**Dar 2009** (Continued)

Normal LVEF>40% (available for 168/182 patients), number (%): intervention: 33/85 (39); control:33/83 (40)

f) Major co-morbidities: chronic renal failure (69%), hypertension (61%), and previous myocardial infarction (48%).

g) Heart failure history

New diagnosis of HF, number (%): intervention: 37 (41); control:44 (48)

One HF admission in preceding year, number (%): intervention: 16 (18); control:15 (16)

> 1 HF admission in preceding year, number (%): intervention: 7 (8); control:5 (5)

**Setting** (hospital/community/residential care): three large acute care hospitals

**Location** (rural/urban etc.): urban, multi-ethnic North West London

**Country:** UK

Interventions

**Study objective:** to determine if home tele-monitoring of the signs and symptoms of typical HF patients recently discharged from hospital could reduce the risk of all-cause re-hospitalisation, when compared with usual specialist care alone, and at what costs

**Type of TM/mode of delivery (e.g.video-conferencing, remote monitoring with the healthcare professional responding to alerts etc.):** remote monitoring

**Type of technology and its application:** the equipment included an electronic weighing scale, automated blood pressure cuff, pulse oximeter, and a control box which was connected to the domestic phone line.

**Delivery of the intervention:** in addition to usual care, patients in the intervention group had tele-monitoring equipment installed in their home, during an initial nurse home visit, to monitor signs and symptoms. Each morning the patient followed the verbal instructions from the monitor to weigh themselves and use the equipment to record their blood pressure, heart rate, and oxygen saturation. They then answered four questions related to symptoms indicative of HF de-compensation (breathlessness, orthopnoea, dizziness, ankle swelling) by pressing buttons marked 'yes' or 'no' in response to the questions from the monitor. All the readings were encrypted and then transmitted via a dedicated telephone line to the base station in each of the hospitals. The transmitted data were reviewed on a daily basis (Monday to Friday) by a heart failure nurse. Any variation of these vital signs from predefined parameters triggered an alert suggesting clinical deterioration and resulted in a telephone call for further patient assessment. (Note: It was unclear if the predefined criteria for alerting the healthcare professional of a worsening condition were individually tailored to each patient, or if the same criteria were used for all intervention participants.) This then led to one of four possible responses. An initial home visit was made to patients in both arms of the study by the study nurse. At this visit patients received advice on self monitoring of heart failure.

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned contacts; contacts only in case values deviated from normal

**Clinician response to receipt of data:**

a) Who contacts the patient?: HF nurse

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): immediately in case of an alert

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): life-style advice, advice regarding medication, recommendation to contact primary care, or early review in secondary care.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** HF nurse and cardiologist, physician with special interest in HF

Dar 2009 (Continued)

**Duration of intervention:** 6 months

**Comparison intervention:** all patients received usual care. Each of the three sites provided a HF service that included at least one cardiologist or a physician with a specialist interest in HF, and at least one HF specialist nurse. Each hospital provided regular clinic review by the HF team and telephone support was available during normal working hours, Monday to Friday. The clinic review provided life-style advice and optimisation of HF medication. The frequency of clinical follow-up was at the discretion of the HF team.

## Outcomes

### Primary outcomes:

- Days alive and out of hospital

### Secondary outcomes:

- Number and duration (LoS) of HF related hospitalisations
- Number of clinic visits
- HRQOL
- Direct health service costs (tele-monitoring equipment cost, hospital re-admission costs, drug costs, primary care visit costs, secondary care visit costs, and hospital transport costs)

**Follow-up time:** 3 and 6 months after randomisation

## Notes

**Ethical approval and written informed consent obtained:** yes

**Sources of funding:** Honeywell HomMed provided the funds to perform this study and the tele-monitoring equipment used, via a research contract agreement with Imperial College London. The design, conduct, analysis, and manuscript have not been influenced by Honeywell HomMed or any of its employees.

**Conflicts of interest:** none declared

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	see p.320, Col 2, Para 4  QUOTE:  "After fully informed consent was obtained from an eligible patient, third party randomization was undertaken using computer generated random blocks of random size, with patients randomized in a 1:1 ratio to TM or usual care. Randomization was stratified by hospital site."
Allocation concealment (selection bias)	Low risk	see p.320, Col 2, Para 4  QUOTE:  "Both the recruiting nurse and the patient were therefore unaware of the group allocation until after consent was obtained."
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	see p.321, Col 2, under the subheading 'Baseline characteristics'  QUOTE:  "The baseline characteristics of the two groups were similar (Table 1)".

## Dar 2009 (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	Outcome group: days alive and out of hospital, health resource use, costs  The health professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, the outcomes were objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: HRQoL</b>  The participants and the personnel could not be blinded to the group allocation, which may have affected the patient reported outcomes. Questionnaires were posted to the patients.
Incomplete outcome data (attrition bias) All outcomes	Low risk	p.322, Figure 2  A similar number of patients in the intervention and control group completed 90 days follow-up (n = 83 vs. n = 88) and 180 days follow-up (n = 74 vs. n = 79). Analysis based on intention-to-treat,
Selective reporting (reporting bias)	Unclear risk	Results for a couple of the outcomes listed in the trial protocol were not reported in the paper (anxiety and depression, drug optimisation as measured by medication prescription, and drug utilisation).
Other bias	Low risk	No evidence of other risk of bias

## Davis 2010

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Glycated haemoglobin (GHb) &gt; 7%, age &gt; 35 years, seen within the last year at the community health centre, a clinical diagnosis of diabetes, and being able and willing to participate in a 1-year clinical trial.</p> <p><b>Exclusion criteria:</b> BMI 25 kg/m<sup>2</sup> (based on self-reported height and weight), pregnancy, acute or chronic illness that prevented safe participation in the study.</p> <p><b>Method of patient recruitment:</b> recruitment between April 2005 to October 2006. A billing data extraction yielded 1984 patients with diabetes, and 43.8% were eligible at medical record review. Telephone contact was attempted and, of those eligible and interested, n = 165 completed two in-person screening visits and were randomized.</p> <p><b>Study sample calculation:</b> sample size of 200 was calculated, based on a power of 0.8, an of 0.05 and an effect size of 0.5% change in GHb as the primary outcome, with detectable clinically relevant changes in secondary outcomes and allowing for 30% loss to follow-up.</p> <p><b>Data collection:</b> participants were given a gift card for each completed visit. The licensed practical nurse (LPN) was trained to collect data in a standardised way before the start of recruitment. Retraining took place prior to each subsequent data collection period, and direct observation of the LPN occurred during all active data collection periods.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 869 (unclear if this is the number screened)</p> <p><b>No of patients in groups:</b> n = 165: intervention: n = 85; usual care: n = 80</p> <p><b>No of patients lost to follow-up:</b> retention rates at 6 and 12 months were 91% and 82%,</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: diabetes (Type 1 and Type 2)</p>

**Davis 2010** (Continued)

b) Age, mean (SD): intervention: 59.9 ± 9.4; usual care: 59.2 ± 9.3

Weight, mean (SD): intervention: 101.3 ± 21.7 Kg; usual care: 96.6 ± 22.3

c) Gender, % females: intervention: 72.9%; usual care: 76.3%

d) Ethnicity- race%: intervention: 75.3% African-American/other, 24.7% Non-Hispanic/white; usual care: 72.5% African American/other; 27.5% Non-Hispanic/White

e) Severity of condition:

Duration of diabetes (years): intervention: 8.5 (6.6); usual care: 10.3 (8.1)

Oral medication & insulin(%): intervention: 32.5%; usual care: 29.1%

BMI (kg/m<sup>2</sup>): intervention: 37.1 ± 8.1; usual care: 35.9 ± 7.6

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): three community health centers members of CareSouth Carolina, a federally qualified health centre

**Location** (rural/urban etc.): rural (Northeast south Carolina)

**Country:** USA

Interventions

**Study objective:** to evaluate a remote comprehensive diabetes self-management education (DSME) intervention administered by a dietitian and nurse diabetes educator (certified diabetes educator [CDE]) designed to improve adherence to American Diabetes Association (ADA) guidelines, which included the availability of a remote retinal assessment.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (education)

**Delivery of the intervention:** Diabetes TeleCare was a 12-month DSME intervention with 13 sessions, 3 individual and 10 group. Two sessions (one individual and one group) were held in the first month for an intervention "jump start." Three group sessions were conducted in-person; all others were conducted by interactive video-conferencing by the self-management education team (a nurse/CDE and a dietitian) who were at the academic health centre while the participants were at the primary-care clinic. Make-up sessions were conducted on the telephone. Given the remote location of the clinic sites, a licensed practical nurse (LPN) was hired to co-ordinate in-person administrative functions at the clinic sites, to serve as a "hands-on" assistant for the self-management team during intervention sessions, and to perform standardised data collection. Additionally, intervention participants were offered retinal imaging in the primary-care setting when they were due for their annual eye exam. This was optional, as some participants preferred to seek an eye exam by their eye care provider.

**Type of technology and its application:** tele-health strategies, including interactive video-conferencing, telephone (both cellular and land lines), fax line, and a tele-health-enabled retinal camera, were used in the setting of a community health centre. The telemedicine retinal screening program involved use of a non mydriatic retinal camera (Digiscope-EyeTel Imaging, Columbia, MD) located in a rural, federally-funded primary care practice. The LPN was trained to pharmacologically dilate the pupil of each eye (1% tropicamide, one drop) and conduct the exam. Electronically stored retinal images were sent after hours via fax line to a remote reading centre. An ophthalmologist located at the university setting distant from the primary care practice site evaluated the retinal photograph and consulted with the patient using real-time video-conferencing. Reading services were contracted, which included a quality-control process for standardisation over time. Referrals for any retinal abnormality or un-gradable images were scheduled with the nearest ophthalmologist (50 miles away), and transportation was provided at no charge.

**Did the patient receive education about their condition?** Education was the focus of the intervention.

**Frequency of patient data transfer (monitoring studies only):** N/A

Davis 2010 (Continued)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 13 sessions.

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a dietitian and nurse/ certified diabetes educator (CDE).

**Duration of intervention:** 12 months

**Comparison intervention:** usual care consisted of one 20-min diabetes education session, using American Diabetes Association (ADA) materials, conducted individually at the time of randomization by the LPN. No other education/support for diabetes was given. However, access to existing services at the community health centers continued, including a diabetes collaborative (sponsored by the Bureau of Primary Health Care/Health Resources and Services Administration), care managers available for education/goal setting, and a nurse practitioner to help patients with the highest GHb levels. The control group received an ongoing educational program administered by a certified health educator.

Outcomes	<b>Primary outcome:</b> <ul style="list-style-type: none"><li>• HbA1c</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>• LDL cholesterol</li><li>• Albumin-to-creatinine ratio</li><li>• Number of eye examinations (reported also in two conference abstracts by Davis form 2003)</li></ul> <b>Follow-up time:</b> 6 and 12 months from start of the intervention	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> NIH/NIDDK R18DK067312 to R.M.D. <b>Conflict of interest:</b> none reported.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Unclear risk	No comparisons of the baseline outcomes measures were reported.
Were baseline characteristics similar?	Low risk	p.1714, table 2 The baseline characteristics were similar.



**Davis 2010** (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective measures of outcome: HbA1c, LDL, albumin to creatinine ratio, number of eye examinations.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.1716, Col.1, Para.3  QUOTE:  "Retention rates at 6 and 12 months were 90.9 and 82.4%, respectively, and were attributed to factors such as reminder telephone calls and mailings and is described fully elsewhere."  Comment : Unclear how the losses to follow-up were divided between groups.
Selective reporting (reporting bias)	Unclear risk	Cost-effectiveness, cost-utility and weight that were outcomes listed in the trial protocol were not reported here (but BMI).
Other bias	Low risk	No evidence of other risk of bias.

**De Las Cuevas 2006**

Methods	<b>Study design:</b> RCT  <b>Inclusion criteria:</b> not reported  <b>Exclusion criteria:</b> not reported  <b>Method of patient recruitment:</b> outpatients were recruited from the Community Mental Health Centre of San Sebastian de la Gomera, in the Canary Island.  <b>Study sample calculation:</b> not reported  <b>Data collection:</b> the same psychiatrist administered the interviews and assessed the outcomes for both groups.  <b>Unit of analysis issues:</b> no
Participants	<b>Total no of eligible patients:</b> n = 140  <b>No of patients randomised to groups:</b> n = 140; Intervention: n = 70 ; usual care: n = 70  <b>No of patients lost to follow-up:</b> n = 4 patients dropped out prematurely from the intervention group and n = 6 from the usual care group.  <b>Patient baseline characteristics:</b> a) Clinical condition: mental health condition b) Age: <25 years: intervention: 12 (17.1); usual care: 13 (18.6) 25–45 years: intervention: 37 (52.9); usual care: 33 (47.1) 45–65 years: intervention: 16 (22.9); usual care: 21 (30) >65 years: intervention: 5 (7.1); usual care: 3 (4.3) c) Gender, male sex: intervention: 22 (31.4); usual care: 25 (35.7) d) Ethnicity: not reported

**De Las Cuevas 2006** (Continued)

e) Severity of condition:

Clinical Global Impressions (CGI) scale, severity of illness, no (%)

Moderately ill: intervention: 8 (11.4); usual care: 5 (7.1)

Markedly ill: intervention: 61 (87.1); usual care: 65 (92.9)

Severely ill: intervention: 1 (1.4); usual care: 0 (0)

f) Major co-morbidities: not reported

g) Diagnoses

ICD-10:

Mental and behavioural disorders due to psychoactive substance abuse: intervention: 5 (7.1); usual care: 6 (8.5)

Schizophrenia, schizotypal, and delusional disorders: intervention: 5 (7.1); usual care: 6 (8.5)

Mood (affective) disorders: intervention: 23 (32.9); usual care: 25 (35.7)

Neurotic, stress-related and somatoform disorders: intervention: 31 (44.3); usual care: 25 (35.7)

Disorders of the adult personality and behaviour: intervention: 6 (8.6); usual care: 8 (11.4)

**Setting** (hospital/community/residential care): one Community Mental Health Centre (of San Sebastian de la Gomera) and one University hospital (the University Hospital de la Candelaria in Santa Cruz)

**Location** (rural/urban etc.): Canary Islands

**Country:** Spain

Interventions

**Study objective:** to evaluate the efficacy of tele psychiatry through video conference in the treatment of mental disorders by comparing to face-to-face conventional (F2FC) treatment.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (treatment/consultation)

**Delivery of the intervention:** the tele-psychiatry treatment was conducted by video-conference between the University Hospital de la Candelaria in Santa Cruz de Tenerife (psychiatrist's location) and the Mental Healthcare Centre of San Sebastian de la Gomera. Face-to-face treatment takes place at the Mental Healthcare Centre of San Sebastian de la Gomera, in the same tele-psychiatry room. Treatment was the same in both alternatives and involves at least eight sessions lasting 30 minutes over the 24-week study period. Additional treatment sessions take place if clinically indicated. The treatment consists of pertinent psychotropic medication plus cognitive-behavioural treatment and psychological evaluation concerning the disease, medications, and side effects.

**Type of technology and its application:** Tele-psychiatry consultations use commercial videoconferencing equipment (Viewstation 512, Polycom; Slough, Berks, UK) providing high-quality enhanced video at 30 frames per second (fps) at 384 to 768 kilobits per second (Kbps) and full-duplex digital audio with noise suppression and echo cancellation.

**Did the patient receive education about their condition?** Not reported

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned /scheduled no of TM contacts between patient and healthcare professional:** eight consultations (video or face-to-face) lasting 30 minutes

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

## De Las Cuevas 2006 (Continued)

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** the same psychiatrist diagnosed and treated all the patients.

**Duration of intervention:** 24 weeks

**Comparison intervention:** the patients in the usual care group received the face-to-face treatment in the same tele-psychiatry room at the Mental Healthcare Centre. Treatment was the same in both alternatives and involved at least 8 sessions lasting 30 minutes over the 24-week study period. The treatment consisted of psychotropic medication plus cognitive-behavioural treatment and psychological evaluation concerning the disease, medications and side effects.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Change in psychiatric test scores (severity of illness)</li> </ul> <p><b>Follow-up time:</b> 24 weeks from randomisation</p>
Notes	<p><b>Ethic's committee approval and informed consent obtained:</b> unclear</p> <p><b>Sources of funding:</b> this study is part of the ISLANDS Research Project (Integrated System for Long distance psychiatric Assistance and Non-conventional Distributed health Services) funded by the European Union (Quality of Life and Management of Living Resources, Contract Number: QLRT-2001-01637).</p> <p><b>Conflict of interest:</b> not reported.</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Low risk	see p.5, Table.2  Patient outcomes were measured prior to the intervention and were similar in both groups.
Were baseline characteristics similar?	Unclear risk	Fewer moderately ill participants and fewer who could read and write in the usual care group as compared with in the intervention group. Differences also in the number of participants with some ICD-10 diagnoses (F4, and F6) between groups.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	Outcome: severity of illness  The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. The same psychiatrist diagnosed and treated all the patients that were recruited and administered the interviews and assessed the outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data was unlikely to bias the results. see p.1, under abstract

## De Las Cuevas 2006 (Continued)

QUOTE: "Only 4 patients dropped out prematurely from the study in VCTP and 6 in F2FC." in total 10/140 (7%) dropped out.

Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias

## Dendale 2012

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> eligible if hospitalised for fluid overload due to heart failure (HF) requiring an increase or initiation of diuretic treatment. All patients had to be treated with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor antagonist, and with a beta-blocker in the absence of contraindications. Only patients with a sufficient cognitive function to understand the aims of the study and to perform the recordings of body weight, blood pressure, and heart rate.</p> <p><b>Exclusion criteria:</b> reversible forms of acute HF (acute ischaemia, myocarditis, etc.), HF due to severe aortic stenosis, previous residency in a nursing home, inclusion in a cardiac rehabilitation programme on discharge, creatinine clearance <math>\geq 15</math> mL/min, planned dialysis in the next 6 months, planned biventricular pacemaker or cardiac surgery, life expectancy of <math>&lt;1</math> year due to other diseases, severe pulmonary obstructive disease (GOLD III), and/or significant mental or cognitive problems interfering with the daily measurements or intake of medication.</p> <p><b>Method of patient recruitment:</b> patients were approached during hospital admission between April 2008 and June 2010.</p> <p><b>Study sample calculation:</b> based on a 38% reduction in all-cause mortality, (Clarke et al) with alpha 0.05, power 0.80, and effect size of 0.30, a sample of 133 was required. With an anticipated drop-out of 20% a sample of 160 participants were required.</p> <p><b>Data collection:</b> the data were collected by a data manager not involved in patient care, and not stationed in one of the participating hospitals.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 166, of which 4 patients and 2 GPs declined to participate</p> <p><b>No of patients randomised to groups:</b> Total n = 160; Intervention: n = 80; Control: n = 80 (calculated from tables)</p> <p><b>No of patients lost to follow-up:</b> n = 4 (2%) TM participants prematurely dropped out of this study because of a lack of motivation</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: heart failure (HF)</li> <li>b) Age (years), mean, (SD): TM: 75.9 (9.6); usual care: 75.6 (9.8)</li> <li>c) Gender (male) no (%): TM: 50 (62%); usual care: 54 (67%)</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition:</li> </ul> <p>Heart rhythm (sinus rhythm): TM: 45 (56%); usual care: 45 (56%)</p> <p>Hospitalisations before inclusion: TM: 1.7 (2.5); usual care: 1.4 (1.7)</p>

## Dendale 2012 (Continued)

Body weight (kg):TM: 77 (17); usual care: 75 (16)

Blood pressure

Systolic (mmHg):TM: 125 (23); usual care: 124 (23)

Diastolic (mmHg):TM: 73 (12); usual care: 70 (12)

Heart rate (b.p.m.):TM: 72 (15); usual care: 75 (16)

NYHA class:TM: 3.0 (0.5); usual care: 3.0 (0.5)

LVEF (%):TM: 34.9 (15.0); usual care: 35.9 (15.1)

NT-proBNP (pg/mL) on discharge:TM: 4994 (6836); usual care:6818 (7456)

6 min walking test (m):TM: 273 (123); usual care: 288 (114)

**Setting** (hospital/community/residential care): 7 hospitals

**Location** (rural/urban etc.): not reported

**Country:** Belgium

### Interventions

**Study objective:** to investigate whether intensive follow-up of patients through a tele-monitoring facilitated collaboration between general practitioners (GPs) and a HF clinic could reduce mortality and re-hospitalisation rate.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring with alerts (partly substituting usual care)

**Delivery of intervention:** on the day of hospital discharge, TM patients were instructed how to use an electronic body weight scale, a blood pressure monitoring device, and a cell phone. The TM group measured body weight, blood pressure, and heart rate at a fixed hour and on a daily basis with electronic devices that transferred the data automatically to an online database. E-mail alerts were sent to the GP and HF clinic to intervene when pre-defined limits were exceeded. The GP was left free to contact the patient even in the absence of any alerts. The GP and the HF specialist were asked to enter all changes in medication into an online website database. The website also allowed the GP to ask the HF specialist questions concerning the patient, and the specialist could advise the GP.

**Type of technology and its application:** the scale and sphygmomanometer were connected by Bluetooth to a dedicated cell phone, which automatically forwarded the results to the central computer. Prespecified alert limits were determined: for body weight (+2 kg from discharge body weight), systolic blood pressure [140 mmHg (upper limit) and 90 mmHg (lower limit)], and heart rate [90 b.p.m (upper limit) and 50 b.p.m (lower limit)]. When recordings of body weight, systolic blood pressure, and/or heart rate fell outside these limits for two consecutive days, the GP and HF clinic were alerted by automatic e-mail, containing a graph of the evolution of the parameter that caused the alert. At that moment, per protocol, the GP was asked to visit or contact the patient and to adapt the treatment, if he/she felt necessary. The HF nurse contacted the patient by telephone 1–3 days after the alert to verify whether the intervention was effective. When on two consecutive days no measurements were received by the central computer, a 'frequency alert' was generated. This alert was followed up by the call centre of the provider. Patients were called by phone to stimulate them to make the recordings, or to help them in the case of malfunction. A regular feedback of these interventions was sent to the investigators.

**Did the patient receive education about their condition?** all participants and close relatives received a standard education course concerning HF of approximately 1 hour duration by the HF nurse before discharge.

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

## Dendale 2012 (Continued)

**Clinician response to receipt of data:**

- a) Who contacts the patient?: GP and nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): face-to-face visit and/or telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): GP action at the time of the alert; nurse contacted patient within 1-3 days
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): per protocol, the GP was asked to visit or contact the patient and to adapt the treatment, if s/he felt necessary

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses, GPs and cardiologists

**Duration of intervention:** 6 months

**Comparison intervention** (e.g. face-to-face, telephone, none): the patients in the usual care group were followed up by their GP who could refer the patients to their cardiologist if needed.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>All-cause mortality.</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Days lost to death, hospitalisation, or dialysis</li> <li>Number of hospitalisations</li> <li>Costs</li> </ul> <p><b>Follow-up time:</b> 6 months from recruitment</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Belgian Government Health Insurance Institute (Rijksinstituut voor Ziekte en Invaliditeitsverzekering); Leo Pharma (the determination of plasma NT-proBNP)</p> <p><b>Conflicts of interest:</b> None declared.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>page 334, Col.1, Para.4</p> <p>QUOTE:</p> <p>"patients were block randomised by sealed envelopes to 6 months of intense follow-up facilitated by tele-monitoring (TM) or usual care".</p> <p>Every hospital received envelopes containing an equal allocation for tele-monitoring and usual care control (additional information from authors)</p>
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Low risk	Similar number of hospitalisations before intervention.
Were baseline characteristics similar?	Low risk	Similar baseline characteristics. See p.335, Table 1



**Dendale 2012** (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	Data were collected by a data manager not involved in patient care, and not stationed in one of the participating hospitals: mortality, days lost to death, hospitalisation, or dialysis, number of hospitalisations.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Four participants were lost from the intervention group and none from the control group. Analysis based on intention-to-treat.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found
Other bias	Low risk	No other risk of bias identified.

**Ellison 2004**

Methods	<p><b>Study design:</b> 3-armed RCT</p> <p><b>Inclusion criteria:</b> individuals older than 18 years, able to understand and read English, and scheduled for a minimally invasive surgical procedure with an expected hospital stay of less than 72 hours. Patients undergoing the following laparoscopic procedures were considered eligible: donor nephrectomy, adrenalectomy, radical nephrectomy, partial nephrectomy, retroperitoneal lymph node dissection, and pyeloplasty. In addition, patients undergoing percutaneous procedures for kidney stone removal and treatment of upper tract urothelial cancers were considered eligible.</p> <p><b>Exclusion criteria:</b> patients unable to provide consent or those who did not wish to participate were not included in the study. One patient refused to participate.</p> <p><b>Method of patient recruitment:</b> after clinical evaluation and a shared decision to treat the condition with a minimally invasive surgical procedure, the research coordinator approached each patient independently. The study was discussed and the patient given the opportunity to consent to involvement.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> the patients filled in the questionnaires that were sent to their homes 2 weeks after discharge.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 86</p> <p><b>No of patients randomised to groups:</b> n = 56; robotic tele-rounds: n = 27; standard rounds: n = 29. Note: a third intervention group (tele-rounds, n=29) was not included in this review.</p> <p><b>No of patients lost to follow-up:</b> none</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: minimally invasive surgical procedure.</li> <li>b) Age (y): robotic tele-rounds: 58.8; tele-rounds: 49.7; standard rounds: 57.0</li> <li>c) Gender, male (%): robotic tele-rounds: 58; tele-rounds: 57; standard rounds: 59</li> <li>d) Ethnicity: not reported</li> <li>e) Severity of condition:</li> </ul> <p>Cancer: robotic tele-rounds: 22; tele-rounds: 19; standard rounds: 19</p> <ul style="list-style-type: none"> <li>f) Major co-morbidities: not reported.</li> </ul> <p><b>Setting</b> (hospital/community/residential care): in-patient setting, post-operative care.</p>

**Ellison 2004** (Continued)

**Location** (rural/urban etc.): not reported.

**Country:** USA.

## Interventions

**Study objective:** to assess the impact of introducing remote video-conferencing during the immediate post-operative period (tele-rounds) on patient-reported satisfaction with their hospitalisation.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (tele-rounding)

**Delivery of intervention:** the intervention was delivered on the first post-operative day. All patients were seen and examined twice daily by the fellow and resident surgical team. Tele-rounding patients were seen once at the bedside by the attending, and then again by the attending using the web-based video conferencing system during usual resident afternoon rounds. The video-conferencing system was brought to the patient's room, where the vital signs and fluid measurement from the nursing flow sheet were relayed. The attending, from a geographically remote office, then conversed with the patient for 3 to 5 minutes and visually examined the incisions and drain effluent. Alterations in post-operative management were relayed to the resident or nursing staff, and the encounter concluded.

**Type of technology and its application:**

**Tele-rounding equipment:**

The web-based video-conferencing system used for the tele-rounding group comprised commercially available computer components. The unit brought to the patient room included a laptop computer with an 866 MHz CPU, a unidirectional microphone, digital camera, PCMI card using 108.11b wireless technology, Cisco wireless access point, and Microsoft NetMeeting software. The base unit for the attending surgeon consisted of the same peripheral configuration attached to a desktop computer in the academic urology offices. Patient confidentiality was maintained by encrypting the data before transmitting it over a secure wireless Internet link.

**Robotic tele-rounding equipment:**

The robotic tele-rounding system used similar web-based telecommunications, but the unit was mounted on a remotely controlled service robot (In Touch Health). This robot was driven into the patient room by a remote workstation. A joystick interface was used to steer the robot and operate the zoom, pan tilt, and focus functions of the camera.

**Did the patient receive education about their condition?** not reported.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** Robotic tele-rounding: participants were seen at the bedside by the attending on the first post-operative day. A resident accompanied the service robot on subsequent days. An identical tele-rounding encounter then occurred between the attending and patient. Tele-rounding: daily attending level bedside visits plus afternoon tele-rounds.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient? N/A
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** attending physician.

**Duration of intervention:** estimated length of stay after the minor surgical procedure was circa 72 hours, and each round lasted 3 to 5 minutes.

## Ellison 2004 (Continued)

**Comparison intervention:** patients randomised to standard rounds were seen once daily by the attending. All attending rounds lasted 3 to 5 minutes.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Patient satisfaction with post-operative care measured by a 23-item questionnaire to allow patients to rate various aspects of their hospital care; the instrument was field tested on a set of 10 patients during the technical development phase of this project.</li> </ul> <p><b>Follow-up time:</b> 2 weeks after discharge.</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> a research training grant from the Robert Wood Johnson Foundation.</p> <p><b>Conflict of interest:</b> Dr Kavoussi is on the scientific advisory board of In-Touch Health and has an equity interest (In-Touch Health provided the robotic tele-rounding system).</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcome reported.
Were baseline characteristics similar?	Low risk	Patients in the tele-rounds group were younger than in the two other groups but data adjusted for age.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professionals delivering the intervention could not be blinded to the group assignment, and neither could the patient. Outcomes related to satisfaction with care are highly subjective; the absence of blinding is likely to have generated a performance bias which in turn may have affected the patient satisfaction.
Incomplete outcome data (attrition bias) All outcomes	Low risk	100% of participants responded after three mailings of the questionnaire. Missing data not reported.
Selective reporting (reporting bias)	Unclear risk	No trial protocol found. Crude and adjusted odds ratios (OR) comparing robotic tele-rounds with control are not provided.
Other bias	Low risk	No other risk of bias identified.

## Ellison 2007

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> patients undergoing the following laparoscopic procedures were offered participation: nephrectomy, partial nephrectomy, nephroureterectomy, retroperitoneal lymph node dissection, partial ureterectomy, and radical prostatectomy. Patients had an expected hospital stay of 24 to 72 hours.</p>
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**Ellison 2007** (Continued)

**Exclusion criteria:** eligible patients who were unable to provide consent or who did not want to participate in the study received the standard of care provided at each institution.

**Method of patient recruitment:** patients scheduled for minor urologic surgical procedures were offered participation in the study.

**Study sample calculation:** the expected rate of complications (major and minor) after a laparoscopic urologic procedure was 16.0%. On the basis of the power calculation, 270 patients (135 in each arm) were required in order to detect a 1% difference in complications at the 0.05 level and the 0.80 level.

**Data collection:** identification of complications was recorded prospectively. Usual resident-level bedside rounds were maintained throughout the study. The resident team and the attending surgeon independently recorded events.

**Unit of analysis issues:** (yes/no): no

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**Participants**

**Total no of eligible patients:** n = 280 (10 patients refused to participate)

**No of patients randomised to groups:** n = 270; intervention: n = 134; control: n = 136

**No of patients lost to follow-up:** according to % in table 2: attrition of 19.4% in the intervention group and 17.9% in the control group.

**Patient baseline characteristics:**

a) Clinical condition: patients post minor urologic surgical procedures

b) Age, mean years: tele-rounds: 53.6; standard rounds: 54.3

c) Gender, male sex, % tele-rounds: 62.0; standard rounds: 60.0

d) Ethnicity: not reported

e) Severity of condition:

Surgical distribution (%)

Upper urinary tract resection: tele-rounds: 63.9; standard rounds: 59.3

Upper urinary tract reconstruction: tele-rounds: 6.5; standard rounds: 15.0

Radical prostatectomy: tele-rounds: 29.6; standard rounds: 25.7

f) Major co-morbidities: N/A

**Setting** (hospital/community/residential care): three academic institutions

**Location** (rural/urban etc.): the University of California Davis Medical Center, Johns Hopkins Hospital, and Sentara Health

**Country:** USA

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**Interventions**

**Study objective:** to determine if robotic tele-rounds match the performance of standard bedside rounds after urologic surgical procedures in terms of morbidity.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (robotic rounding).

**Delivery of intervention:** consenting patients received the standard perioperative and immediate post-operative care. All the patients were managed with a rapid recovery protocol, which included a liquid diet beginning 12 hours after surgery with immediate advancement as tolerated; complete blood cell counts and measurement of serum electrolyte, blood urea nitrogen, and creatinine levels in the recovery room and each morning until hospital discharge; and usual nursing data recorded during each shift (including oral temperature, blood pressure, pulse, respiratory rate, fluid intake, fluid output, and pain scale score). Once transferred to the patient floor, all the patients communicated with their attending physician on a daily basis. The visit, either at the bedside or via tele-rounds, followed a set script. The visit was conducted between the patient and the attending physician without other staff present. The focus of the visit was a review of objective data (vital signs, fluid balances, and laboratory

**Ellison 2007** (Continued)

values) and subjective data (cursory abdominal examination if at the bedside and evaluation of drain effluent) and a discussion of the anticipated goals for the day. Visit duration was timed. Tele-rounding concluded with either hospital discharge or identification of a major post-operative complication.

**Type of technology and its application:** the tele-rounding robot is a 60-inch-tall wheel-driven device. The robot consists of the motor base unit, a central processing unit (Pentium III; Intel, Santa Clara, California), a high definition digital camera, a flat-screen monitor, and a microphone. Data to and from the robot is transferred over a high speed wireless network and is integrated with proprietary software. The physician connects remotely to the robot via a base station. The base station consists of a Pentium III desktop computer, a high-definition digital camera, a flat-screen monitor, a microphone, and a joystick controller. Each institution used identical technology.

**Did the patient receive education about their condition?** N/A

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** daily tele-rounding only by the attending surgeon.

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient? N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** attending surgeons

**Duration of intervention:** each tele-round 3-5 min. "Visit duration was timed" but the result is not given

**Comparison intervention:** daily bedside rounding by the attending surgeon.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>Morbidity (major, and minor)</li> </ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"> <li>Patient satisfaction with care</li> <li>Length of stay (LoS)</li> </ul> <b>Follow-up time:</b> none	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> not reported. <b>Conflict of interest:</b> not reported; in Ellison 2004: "Dr Kavoussi is on the scientific advisory board of In-Touch Health and has an equity interest (In-Touch Health provided the robotic tele-rounding system)." <b>Risk of bias</b>	
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A stratified block scheme was used for randomisation."

## Ellison 2007 (Continued)

Allocation concealment (selection bias)	Low risk	see above
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	No differences in demographic and operative measures.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Low risk for objective measures of outcome.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professional delivering the intervention could not be blinded to the group allocation. The absence of blinding may have increased the risk of performance bias and reporting of fewer complications and increased patient satisfaction. The definitions of major and minor complications are not objective, as they involve surgeon's judgement to transfer the patient or to delay discharge.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	A loss to follow-up of 19.4% (tele-rounds) and 17.9% (usual consultation).
Selective reporting (reporting bias)	Low risk	Results for the one outcome listed in the protocol (post-operative morbidity) were reported in the full text paper.
Other bias	Low risk	No other risk of bias identified.

## Finkelstein 2006

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> (1) eligible to receive skilled home nursing care for either congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), or chronic wound care (CWC); (2) physically and cognitively able to use the equipment, or have a supportive care partner who could do so; and (3) living in a technically functional home environment. A functional home environment is a home with sufficient space for the equipment to be set up and remain in one place, a telephone and television, close proximity of telephone line to television, adequate lighting, and manageable clutter.</p> <p><b>Exclusion criteria:</b> not reported.</p> <p><b>Method of patient recruitment:</b> participants were drawn from the pool of patients recently discharged from a hospital or those on a Home Health Care (HHC) maintenance level program receiving a reduced number of nurse home visits each month.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> morbidity was evaluated in terms of changes in the knowledge, behaviour and status scales of the Omaha Assessment Tool. All participants were followed throughout their HHC episode and for up to 6 months after discharge from HHC to track their need for different levels of care.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients randomised to groups:</b> n = 68; numbers in each group not reported.</p> <p><b>No of patients lost to follow-up:</b> n = 15 (22%)</p>



**Finkelstein 2006** (Continued)

**Patient baseline characteristics:**

- a) Clinical condition: CHF, COPD and wound care patients receiving home care
- b) Age, yrs: 74.3 years (with an age range of 60–96 years)
- c) Gender, female/male: video + usual care: 8/6 males; video + monitoring+usual care: 9/11; Control: 9/10
- d) Ethnicity: not reported.
- e) Severity of condition: not reported.
- f) Major co-morbidities: not reported.

**Setting** (primary care/secondary care): one hospital

**Location** (rural/urban etc.): four rural and urban HHC agencies

**Country:** USA

Interventions

**Study objective:** to evaluate patient outcomes, cost, and satisfaction with HHC delivered by TM or traditional means for patients receiving skilled nursing care at home

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing and video-conferencing + monitoring

**Delivery of intervention:** the nurses initiated virtual visits by telephoning the participant; the participant answered the call to proceed with the virtual visit. The nurse controlled audio and video adjustments at both sites. The nurse entered all standard medical charting data for TeleHomeCare into the CareFacts™ Clinical Information System. The set-top box in the participant's home had a built-in browser for Internet access. Accounts were set up for all video and monitoring participants by our Internet service provider industry partner. A toll-free access number was provided to simplify the process. Participants also had access to a simple web-based messaging system that provided the opportunity to communicate with the nursing personnel at their homecare agency. Customized web pages were designed to accommodate some of the special needs of the typical elderly participant by using large, easy-to-read text, simple colours and well marked and explained links to other pages of interest plus. For the home-based physiologic monitoring an electronic diary was used to report monitored measurements and symptom information.

**Type of technology and its application:** the systems deployed in the participant's home consisted of a set-top box (ViaTV VC55, 8x8 Inc., Santa Cruz, CA) connected to the participant's television set and telephone line. A lightweight, variable focus eyeball camera (VC73105T, Philips Electronics, New York, NY) was placed on the box. It had a 6-foot tether for easy positioning so that the camera, and not the participant could be moved to transmit real-time pictures of wounds, swollen ankles, etc. An easy to use focusing adjustment and the freeze-frame video mode made it possible to transmit good quality images for evaluation. Participants in the monitoring group also received physiologic monitoring devices appropriate for their underlying health condition. CHF participants received pulse oximeters for measuring oxygen saturation (Onyx, Nonin Medical Inc, Minneapolis, MN) and automatic blood pressure cuffs; they used their own scale for monitoring weight. COPD participants received pulse oximeters, electronic spirometers (including handheld computers) for pulmonary function measurements (SpiroCard, QRS Diagnostic LLC, Minneapolis, MN) and automatic blood pressure cuffs. A set-top box with built in camera (ViaTV VC105, 8x8 Inc.) was used at each HHC agency.

**Did the patient receive education about their condition?** Not reported.

**Frequency of patient data transfer (monitoring studies only):** unclear, an electronic diary was used to report monitored measurements and symptom information; unclear if the healthcare professional accessed this data only during the video-conferences or daily.

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** virtual visits twice weekly

**Finkelstein 2006** (Continued)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: N/A
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** HHC nurses

**Duration of intervention:** not reported.

**Comparison intervention:** control group participants received standard HHC as determined by their underlying condition

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Mortality</li><li>• Morbidity (assessed by the Omaha Assessment Tool)</li><li>• Transfer to a higher level of care</li><li>• Costs</li></ul> <b>Follow-up time:</b> up to 6 months after discharge from HHC	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> informed consent was obtained; Ethic's approval not reported.  <b>Sources of funding:</b> the TeleHomeCare program was supported in part by grant #27-60-98031 from the Technology Opportunities Program, U.S. Department of Commerce, and matching funds from program clinical and industry partners.  <b>Conflict of interest:</b> not reported.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Unclear risk	No baseline outcome measures reported..
Were baseline characteristics similar?	Unclear risk	It was stated that age did not differ between groups, not other information provided.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the group assignment, and neither could the patient. However, the outcomes mortality, transfer to a higher level of care, and costs were objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professional delivering the intervention could not be blinded to the group assignment, neither could the patients. This may have affected the outcome of morbidity, assessed with the Omaha Assessment tool. No information of how the outcomes were assessed or by whom.

**Finkelstein 2006** (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Fifteen patients dropped out (22%), but unclear from which group.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Giordano 2009**

Methods	<p><b>Study design:</b> multicentre RCT</p> <p><b>Inclusion criteria:</b> patients hospitalised with confirmed diagnosis of heart failure (HF), LVEF &lt; 40% and at least one hospitalisation for acute HF in the previous year. Further, patients had to be clinically stable with optimised oral therapy including maximally tolerated doses of both an angiotensin-renin inhibitor and beta-blocker. The stability criteria required that patients were symptomatically improved, without intravenous therapy for at least 7 days, had stable oral therapy with no dose changes for 5 days and had stable weight (no change <math>\geq 1</math> kg) for 5 days.</p> <p><b>Exclusion criteria:</b> non-cardiac debilitating illness such as active malignancy, severe renal insufficiency (creatinine <math>\geq 3</math> mg/dL), cognitive impairment clinically evident, myocardial infarction or revascularization procedure within the preceding 30 days, planned coronary revascularisation or valvular surgery or heart transplantation.</p> <p><b>Method of patient recruitment:</b> patients were asked to participate 48 hours before hospital discharge.</p> <p><b>Study sample calculation:</b> based on results from a previous study, the authors assumed a one-year hospital re-admission rate of 24% in the HBT group and 36% in the usual care group. Based on 0.8 power to detect a significant difference (<math>p=0.05</math>, two-sided) 230 patients were required for each study group.</p> <p><b>Data collection:</b> the data and the cause of re-admission were obtained from the GP and confirmed by hospital records. Episodes of clinical instability were confirmed by the GP. Cardiovascular deaths were ascertained through the GP or hospital records.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> N = 508 patients were eligible, of which n = 48 refused to participate.</p> <p><b>No of patients randomised to groups:</b> n = 460; intervention: n = 230; control: n = 230.</p> <p><b>No of patients lost to follow-up:</b> n = 4 in the intervention group and n = 1 in the control group were lost to follow-up.</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: heart failure (HF)</p> <p>b) Age: intervention: <math>58 \pm 10</math> years; control: <math>56 \pm 10</math> years &gt; 60 years: intervention: 169 (73%); control: 189 (82%)</p> <p>c) Gender, female sex (%): intervention: 16; control: 14</p> <p>d) Ethnicity: not reported.</p> <p>e) Severity of condition:</p> <p>Patients with &gt; 2 hospitalisations for HF in the previous year: intervention: 110 (48%); control: 119 (52%)</p>

**Giordano 2009** (Continued)

NYHA functional class, number (%)

II: intervention: 124 (54%); control:150 (65%)

III-IV: Intervention:106 (46%); Control:80 (35%)

Mean LV ejection fraction (%): intervention:28 ± 7; control:26 ± 8

LVEF < 25%: intervention:97 (42%); control:121 (52%)

f) Major co-morbidities:

Common co-morbidities were previous myocardial infarction, chronic lung disease and diabetes.

g) Discharge medications: fewer patients on digitalis medication in the HBT (34%) group as compared with the usual care group (50%), and more beta-blockers in the HBT group (85%) as compared with in the usual care group (60%).

**Setting** (primary care/secondary care/patient's home): cardiovascular rehabilitation departments of "Salvatore Maugeri" Foundation and five departments in Lombardy (two), Piedmont, Campania and Apulia.

**Location** (rural/urban etc.): Lombardy, Piedmont, Campania and Apulia.

**Country:** Italy

**Interventions**

**Study objective:** to determine whether a home-based tele-management (HBT) programme in patients with HF decreased hospital re-admissions and hospital costs in comparison with the usual care follow-up programme over a one-year period.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** the system information flow was the following: a phone call arrived from the patient, automatically identified through the stored telephone number. Then the phone call was addressed to a free operator who recalls the patient's data and activated the "new call procedure", inserting new data. At this point the ECG trace could be received and the user was put in contact with the cardiologist or the nurse on duty (a three actor's call took place) who was connected to the central database through the Internet. The specialist or the nurse examined the stored informatic clinical report providing consultation or nursing triage. At the end the reported ECG trace and all patient's data were transferred to the web-server and were available "on the net" in the informatic clinical report, in an anonymous way and in cryptography for password owners only.

Tele-management included two different procedures:

**Scheduled appointments (tele-monitoring)** were done every week or every 15 days for patients with severe (III-IV New York Heart Association (NYHA)) or moderate HF (II NYHA). During these appointments the trained hospital nurse carried out a standardised interview on general clinical condition of the patients and dietary treatment (daily intake of fluids, patient's knowledge of fluid restriction, weight surveillance, salt and alcohol intake, intake of analgesics and smoking habits). The nurse asked about the self-measurement of weight and blood pressure, registered the episodes of hypotension (dizziness with a systolic blood pressure < 90 mmHg). The patients were asked the names and the doses of their prescribed drugs and whether they took them regularly. If necessary, the patients sent the ECG trace by telephone. The sent trace was compared with the basal one, to show or to exclude the presence of arrhythmias as important information for the patients' follow-up; the ECG trace also permitted to check the heart rate before to increase or to reduce the beta-blocking dosage as pre-planned by the physician. During the subsequent tele-monitoring phase, the nurse reinforced the initial educational intervention and offered strategies to improve patient's compliance.

**Occasional appointments (tele-assistance)** were done when the patient, in the presence of symptoms or signs of possible decompensation (as systolic blood pressure > 90 mmHg, increase in weight > 2 kg etc.) or with any doubt about therapy, called the nurse. The operative flow-chart is the same for tele-monitoring with particular attention to the symptoms and signs referred by the patients.

**Giordano 2009** (Continued)

**Type of technology and its application:**

Home-based tele-management is a multidisciplinary care approach referring to medical/nursing interventions made over the telephone, with the possibility to transmit an ECG trace to a workstation at each investigator site through a single Call Center. Patients assigned to the HBT strategy, received before hospital discharge a portable device (Card-Guard 2206) transferring by a fixed or mobile telephone, a one-lead trace to a receiving station, where a nurse or doctor were available 24 hours, 7 days/week.

**Did the patient receive education about their condition?** Before discharge, all patients across all centres were educated about HF, including advice on daily weights, daily self-measurement of blood pressure, rate of carrying out blood examinations, dietary restrictions, including sodium and fluid, and signs and symptoms of a HF decompensation.

**Frequency of patient data transfer (monitoring studies only):** every week, or every 15 days, for patients with severe (III-V NYHA) or moderate (II NYHA).

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** every week (severe condition) or every 15 days (moderately severe condition).

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse (the patient sometimes contacted the nurse- non-scheduled appointments).
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone.
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): in both tele-monitoring and tele-assistance at the end of the call phone the nurse took one of these actions: a) in presence of stable conditions, fixed a new scheduled appointment, determine drug modification pre-planned with the cardiologist or with general practitioner – asked for further investigations or scheduled cardiologist consultation, b) in presence of ECG trace modifications or of signs or symptoms of hemodynamic instability contacted the GP and or the cardiologist of the patients.

The cardiologist supervised implementation of therapy proposed by nurse and delegated the right to adjust treatment with specific drugs, as diuretics, ACE inhibitors and beta-blockers. Only the cardiologist and/or the patient's GP could decide to send the patients to the emergency or to a cardiology department. Once a week the cardiologist and the nurse met together to sum up a clinical course of the enrolled patients. In that occasion the cardiologist supervised all the calls received in the previous week.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** trained hospital nurses (who had underwent tailored education and training on HF); cardiologists, and GPs.

**Duration of intervention:** 12 months.

**Comparison intervention:** patients assigned to usual care were referred to their primary care physician. A structured follow-up with the cardiologist at 12 months in the hospital outpatient department and the appointment with the primary care physician within 2 weeks from the discharge were planned.

**Outcomes**
**Primary outcome:**

- Hospital re-admissions for cardiovascular reasons

**Secondary outcomes:**

- Hospitalisation for HF
- Episodes of haemodynamic instability
- Cardiovascular mortality
- Hospital costs

**Giordano 2009** (Continued)

**Follow-up time:** 12 months from randomisation

Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** a grant of the National Ministry of Health (Contract ICS 030.8/RF00.91).

**Conflict of interest:** not reported.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	See p.193. Col.2, Para 4  QUOTE:  "Patients were then assigned randomly to receive home-based telemanagement (HBT) or UC (UC) programme. Random permuted blocks for each center were used to allocate patients to treatment groups."
Allocation concealment (selection bias)	Unclear risk	Not described, only details are that a nurse randomised after collection of baseline data for cardiovascular event
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Unclear risk	The randomisation groups differed significantly only with regard to use of digitalis and beta-blockers, which was respectively higher and lower in the usual care group.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the group assignment, and neither could the patient. However, data on mortality and cause of re-admission were obtained from the GP and confirmed by hospital records. Episodes of clinical instability were confirmed by the GP. .
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few patients were lost to follow-up: N = 3/230 in the intervention group and n = 1/230 in the control group.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias

**Goldberg 2003**

Methods

**Study design:** RCT

**Inclusion criteria:** patients hospitalised with New York Heart Association (NYHA) class III or IV heart failure (HF), with a left ventricular ejection fraction (LVEF), measured within 6 months of enrolment, 35% were eligible for enrolment. These patients had to weigh less than 400 pounds (scale limit), have the ability to stand for at least 20 seconds without holding the wall, and speak either English or Spanish.

Treatment with a diuretic and vasodilator was required. Digoxin and  $\beta$ -blocker use were allowed

**Exclusion criteria:** patients were excluded if they had unstable coronary syndromes (unstable angina, angina-limited exercise, or myocardial infarction within the 8 weeks before enrolment), primary valv-



**Goldberg 2003** (Continued)

lar heart disease (primary stenotic valvular heart disease, a malfunctioning prosthetic heart valve), primary myocardial disease (obstructive cardiomyopathy, amyloidosis, or active myocarditis), pericardial disease, uncorrected thyroid disease, advanced renal disease (dialysis or creatinine 4.0 mg/dL), or requirement for chronic inotropic therapy. Patients with a heart transplant, an anticipated survival 6 months, or no phone line in their home were also excluded.

**Method of patient recruitment:** not reported.

**Study sample calculation:** not reported.

**Data collection:** clinical data for the trial were collected via in-person assessments by trained clinicians at discharge from the baseline hospitalisation, and at 2 weeks, 3 months and 6 months. Laboratory tests, including electrolytes and renal function, medications, and physical exams were obtained at each of these visits. To insure that all hospitalisations, emergency room visits, and deaths were identified, all patients were contacted by telephone on a monthly basis by a non-medical surveyor (blinded to patient treatment group randomisation), located outside of the enrolment sites and Alere monitoring centre. Records were obtained for each of these events, including those occurring outside of the participating health systems.

**Unit of analysis issues:** no

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Participants

**Total no of eligible patients:** not reported.

**No of patients randomised to groups:** n = 280; intervention: n = 138; control: n = 142.

**No of patients lost to follow-up:** n = 32, equally distributed between groups.

**Patient baseline characteristics:**

a) Clinical condition: heart failure (HF)

b) Age, mean years: intervention: 57.9 (15.7); control: 60.2 (14.9)

c) Gender, female sex: intervention: 42 (30.4); control: 49 (34.5)

d) Ethnicity; white: intervention 92 (66.7); control: 87 (61.3); African-American: intervention: 40 (29.0); control: 46 (32.4)

e) Severity of condition:

Duration of CHF (months): intervention: 42.3 (48.0); control: 45.4 (59.7)

NYHA class

III: intervention: 100 (75.8); control: 106 (75.2)

IV: Intervention: intervention: 32 (24.2); control: 35 (24.8)

LVEF%: intervention: 21.6 (6.8); control: 21.8 (6.8)

f) Major co-morbidities:

Hypertension: intervention: 84 (60.9); control: 93 (65.5)

Myocardial infarction: intervention: 53 (38.4); control: 56 (39.4)

g) Medications

Diuretic: intervention: 134 (97.1); control: 135 (95.1)

ACE Inhibitor: intervention: 102 (73.9); control: 104 (73.2)

Digoxin: intervention: 123 (89.1); control: 112 (78.9)

Beta-Blocker: intervention: 53 (38.4); control: 52 (36.6)

**Setting** (hospital/community/residential care): 8 cardiac transplant centres and 8 community-based cardiology practices

**Goldberg 2003** (Continued)

**Location** (rural/urban etc.): not reported.

**Country:** USA

Interventions

**Study objective:** to determine whether daily reporting of weight and symptoms in patients with advanced HF would reduce rehospitalisation and mortality rates despite aggressive guideline-driven HF care.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (in addition to usual care)

**Delivery of the intervention:** patients were instructed to weigh themselves and respond to questions about HF-related symptoms twice daily. The attending physician individualised the symptom questions and weight goals for each patient at the time of enrolment. The AlereNet nurses reviewed the patient's weights and responses on a daily basis (7 days/week, 365 days/year) and contacted the patient as necessary to verify any changes observed in symptoms or weight, per an individualised intervention protocol. Increases in weight beyond a prespecified amount and/or changes in the patient's symptoms were promptly reported to the physician by these nurses. These reports were made by a summary fax and direct verbal contact of the changes in symptoms and weights.

**Type of technology and its application:** patients randomised to the intervention received the AlereNet monitoring system using the DayLink monitor. The system includes an electronic scale placed in patients' homes and an individualised symptom response system (DayLink monitor) linked via a standard phone line using a toll-free telephone number to a computerised database monitored by trained cardiac nurses.

**Did the patient receive education about their condition?** Before discharge, all patients were educated about HF, including advice on daily weights, dietary restrictions including sodium and fluid, and signs and symptoms of a HF decompensation.

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned /scheduled no of TM contacts between patient and healthcare professional:** not reported.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: A trained cardiac nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): contacted the patient if necessary
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to verify any changes observed in symptoms or weight, per an individualised intervention protocol. Increases in weight beyond a prespecified amount and/or changes in the patient's symptoms were promptly reported to the physician by these nurses. These reports were made by a summary fax and direct verbal contact of the changes in symptoms and weights.

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** trained cardiac nurses (employed by Alere, Incorporated)

**Comparison intervention:** patients randomised to the standard care control group were instructed to contact their physician for weight increases of more than a prespecified amount or if their symptoms of heart failure worsened. These patients were asked to bring a copy of their home weight log to study visits. Follow-up visits, other than study visits, were at the discretion of the treating physician. Telephone contacts were permitted at the discretion of the treating physician or nurse.

Outcomes

**Primary outcome:**

- 180-day hospital re-admission rate

**Secondary outcomes**

## Goldberg 2003 (Continued)

- Mortality rate
- Heart failure hospitalisations
- ED visits
- QoL (assessed with the Medical Outcome Study 12 Item Short Form (SF-12), Medical Outcomes Study Health Distress Scale, Minnesota Living with Heart Failure Questionnaire)
- Patient Satisfaction (single item; used to assess satisfaction with HF care)

**Follow-up time:** 6 months after randomisation

**Notes**

**Ethic's committee approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Supported by grants from Alere Medical, Incorporated.

**Conflict of interest:** Not reported.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcome, except for quality of life, which was similar in both groups.
Were baseline characteristics similar?	Low risk	The 2 groups had comparable characteristics at baseline, including medications, 6-minute walk distance, ejection fraction, serum creatinine, sodium and norepinephrine levels (consistent with NYHA class III/IV symptoms). No difference in the baseline Minnesota Living with Heart Failure Questionnaire, SF-12 and Health Stress questionnaires was observed between the groups
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective outcomes of mortality and hospitalisation and therefore low risk of bias.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Quality of life assessed with more than one validated tool; unclear if the outcome assessor was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	During the study, 32 patients (11.4%) either refused follow-up data collection or were lost to follow-up. Seven patients received cardiac transplantation and were censored on the day of transplant. Excluding deaths, there was no difference between groups in the percentage of patients who failed to complete 6 months of follow-up.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Gray 2000

**Methods**

**Study design:** RCT

## Gray 2000 (Continued)

**Inclusion criteria:** all families of very low birth weight infants (LBWI) (less than 1500 g at birth) and admitted to the neonatal intensive care unit (NICU) were eligible. Eligibility requirements included survival for longer than 72 hours, integrated services digital network (ISDN) eligibility, attending physician approval and at least one English-speaking family member.

**Exclusion criteria:** if ISDN access was not available at their family's primary residence or if the infants expected length of stay in the study NICU was expected to be <14 days (e.g., because of need for transfer for surgical care at the nearby Children's Hospital, or because of planned transfer back to a referring community hospital for infants born weighing > 1250 g). In addition, infants were excluded if their family lacked a permanent residence, did not speak English, or if discharge to other than the biological family was expected. Lack of basic telephone service in the family residence was not used as an exclusion criterion. For such families, basic telephone service was arranged for the duration of the study period. Attending physicians could exclude a family from the study if they felt enrolling the family in a study would be clinically inappropriate. The families of eligible study infants were approached for consent to participate between the infant's third and tenth hospital day.

**Method of patient recruitment:** project participants were selected from very low birth weight (VLBW) infants born at Beth Israel Deaconess Medical Center, Boston Massachusetts, between November 1, 1997, and March 30, 1999 and cared for in its NICU. Families of eligible study infants were approached between infant's third and tenth hospital day.

**Study sample calculation:** not reported.

**Data collection:** post discharge surveys were administered to 51/75 families (68%) at between 1 and 4 months post discharge.

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** n = 88 infants were eligible for randomisation. The families of n = 9 infants declined to participate and n = 4 were unavailable to provide consent during the enrolment period.

**No of patients randomised to groups:** n = 56 ; intervention: n = 26; control: n = 30. Note: the study also included 19 siblings who were not randomised.

**No of patients lost to follow-up :** n = 5 families were not investigated because of n = 1 NICU death and n = 4 transferred to other facilities.

#### Patient baseline characteristics:

a) Clinical condition: low birth weight infants

b) Gestational age (weeks  $\pm$  SD): intervention: 27.8  $\pm$  2.4; control: 27.5  $\pm$  2.3

Birth weight (mean  $\pm$  SD): intervention: 960  $\pm$  278; control: 1026  $\pm$  302

< 750 g (n): intervention: 8; control: 8

750–999 g: intervention: 8; control: 7

1000– 1500 g: intervention: 10; control: 15

c) Gender, female (%): intervention: 35%; control: 30%

d) Ethnicity, maternal race (% African-Americans): intervention: 19%; control: 23%

e) Severity of condition: C-section, n (%): intervention: 2 (8%); control: 11 (37%)

f) Major co-morbidities: none stated

g) Other: more low-birth infants born to a single mother in the TM group as compared to the control group: 38.5% vs. 13.3%

**Setting** (hospital/community/residential care): one Medical Centre

**Location** (rural/urban etc.): urban (Boston)

## Gray 2000 (Continued)

Country: USA

## Interventions

**Study objective:** to evaluate an Internet-based TM program designed to reduce the costs of care, to provide enhanced medical, informational, and emotional support to families of VLBW infants during and after their NICU stay.

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conference, remote monitoring and World Wide Web technologies (Internet-based)

**Delivery of intervention:** Baby CareLink is a multifaceted TM program that incorporates video-conference and World Wide Web technologies to enhance interactions between families, staff, and community providers. The video-conference module allows virtual visits and distance learning from a family's home during an infants hospitalisation as well as virtual house calls and remote monitoring after discharge. Baby CareLinks web site contains information on issues that confront these families.

**Type of technology and its application:** Baby CareLink provides information to families using both a specially designed WWW-based system and a video conference system from the NICU. The CareLink system is programmed using Microsoft BackOffice (Microsoft Corporation, Redmond, WA) components including Internet Information Server 4.0, Active Server Pages and SQL Server 6.5. Security Services were provided using ACE Server (RSA Security Incorporated, Bedford, MA). Baby CareLink dynamically generates WWW pages that can be accessed from a standard web browser. Educational content is enhanced with video, audio, and ShockWave applets (Macromedia Company, San Francisco, CA). Six major areas of clinical content and resources are present within Baby CareLink Web including a daily clinical report, a message centre, a see your infant section, a family room, a clinical information section, and a section focused on preparation for discharge to home. Families enrolled in the intervention group had a standard 200 MHz Pentium Pro processor computer installed in their home 2 weeks after enrolment. Telemedicine personnel provide user training to families and ongoing support either in person or via telephone. The computer provides access to the Baby Care link system, which supplies educational information, infant specific information and photos. Families may access this system from any computer equipped with a standard web browser which allows families the capability of accessing information about their infant anywhere from. BabyCare Link has a security system of hardware tokens for user authentication and a sockets layer for data encryption, which maintains confidentiality. Each family in the Baby CareLink group was given a single training session that focused on the hardware and software to be used in their home. These sessions lasted between 45 and 120 minutes with most lasting <75 minutes. The local phone company installed ISDN lines in the family residence and computer hardware was placed and tested by a local hardware service provider. Hardware and ISDN lines were placed in most homes within 12 days of randomisation. In only 1 case, installation required more than 3 weeks. A project co-ordinator and research nurse co-ordinator provided in-service training to all clinical staff. The in services consisted of didactic presentations, hands on video-conference from one department to another, and review of staff resource book. A member of the training group was on-call as a resource for staff 24 hours a day.

**Did the patients receive education about their condition?** The carers of the low-birth infants received education through a web-page.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned contacts

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** NICU staff

**Gray 2000** (Continued)

**Duration of intervention:** 4 to 6 months after discharge

**Comparison intervention:** families of low birth weight infants in the control group received information and support as usually provided in the NICU.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Carer satisfaction with NICU care (assessed with unknown scale)</li><li>• Hospital days stayed</li><li>• Family visitation, and interaction with family and staff (no data provided)</li></ul> <b>Follow-up time: between</b> 1 and 4 months after discharge from the NICU	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes  <b>Sources of funding:</b> National Library of Medicine’s Telemedicine Initiative (NQI-LM-6-3535).  <b>Conflict of interest:</b> Dr Safran is CEO of Clinician Support Technology (CST). Ms Pompilio- Weitzner is currently clinical content specialist to CST. Dr Gray holds equity in and serves as a consultant to CST. CST is a developer and distributor of CareLink applications.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.1320, Col.1, Para.3  QUOTE  “infants were randomized to the intervention or control group using a birth weight-stratified permuted block design.”
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Low risk	N/A
Were baseline characteristics similar?	Unclear risk	The groups were similar in patient and family characteristics as well as rates of inpatient morbidity. However, significantly more infants in the Baby CareLink group were delivered by C-section (92.3% and 63.3%).
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the group assignment, and neither could the patient. Objective outcome of hospital length of stay at low risk of bias.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Non-objective self-reported outcomes (carer satisfaction) at unclear risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Post discharge surveys were administered to 51 /75 families (68%), the response rate on the satisfaction questionnaire was 61%.i.e., 31/75 enrolled families.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other source of bias identified.



## Halimi 2008

Methods	<p><b>Study design:</b> multicentre RCT</p> <p><b>Inclusion criteria:</b> (i) age .18 years;(ii) indication for first implant or replacement of a dual-chamber pulse generator; (iii) patient ability to comply with the study protocol and signature of an informed consent; (iv) stable medical and residential status; (v) ability to discharge the patient from the hospital 1 day after first device implant, or on the day of pulse generator replacement; (vi) absence of exclusion criterion</p> <p><b>Exclusion criteria:</b> patients were excluded if they (i) had a spontaneous ventricular rate, 30 beats per minute; (ii) were in overt heart failure (HF); (iii) had a history of cardiac surgery or myocardial infarction within 1 month; (iv) were systemically anticoagulated; (v) were unable to understand tele cardiology; (vi) lived in an area with insufficient GSM (global system for mobile communications) coverage</p> <p><b>Method of patient recruitment:</b> Patients in hospital for insertion of a pacemaker were recruited between April 2005 and December 2006..</p> <p><b>Study sample calculation:</b>used a non-inferiority hypothesis; alpha 0.05 and 80% power a sample size of 400 was calculated.</p> <p><b>Data collection:</b> 30 days after inclusion of the patient, or at the time of an additional follow-up visit, the investigator interrogated the pacing system and recorded the possible occurrence of an adverse event (AE). Quality of life was assessed at the end of the study and cost of care was calculated by review of the billing documents for private medical institutions and by compilation of customary reimbursement costs for the public medical centres.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> not reported.</p> <p><b>No of patients randomised to groups:</b> n = 379; Intervention: n = 184; Control: n = 195</p> <p><b>No of patients lost to follow-up:</b>(i) two enrolling centres were excluded because of randomisation and protocol violations, and ii) n = 7 patients because of exclusion criteria; n = 12 patients did not succeed to transmit data.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: patients after implantation or replacement of a dual chamber pacemaker</li> <li>b) Age, mean (SD): 75 (9.8) years</li> <li>c) Gender, 61% male</li> <li>d) Ethnicity: not reported</li> <li>e) Severity of condition: not reported</li> <li>f) Major co-morbidities: not reported</li> </ul> <p><b>Setting</b> (hospital/community/residential care): 38 French and 1 Belgian medical centres participated, including 22 public and 17 private institutions</p> <p><b>Location</b> (rural/urban etc.): not reported</p> <p><b>Country:</b> France and Belgium</p>
Interventions	<p><b>Study objective:</b> to determine if continuous monitoring of device function after implantation or replacement of dual-chamber pacemakers, using a tele-cardiology-based ambulatory surveillance programme, enables significant reduction of post-operative hospitalisation with preserved safety.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> remote monitoring (PM surveillance)</p>

## Halimi 2008 (Continued)

**Delivery of intervention:** patients were monitored daily by tele-cardiology, and the data transmitted analysed daily, with option of one or more visits by a home nurse.

**Type of technology and its application:** a Philos II DR-T PM (Biotronik), equipped with tele-cardiology, a system capable of automatically transmitting the data stored in implantable devices.

**Did the patient receive education about their condition?** not reported

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none planned or scheduled. Out of 12 warning messages 2 resulted in telephone communication and all resulted in a patient visit.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): in a couple of days (major adverse events) up to more than a week (non-major adverse events)
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): In the event of a device dysfunction (technical issue) or clinical event (medical issue), the cardiologist investigator was notified by e-mail, facsimile, or text message, allowing the rescheduling of the next follow-up visit, if necessary. However, the intervention was not a substitute for emergency medical service.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** cardiologist, home nurse

**Duration of intervention:** 24 days (SD 9.3)

**Comparison intervention:** control patients were managed according to the usual practice of each participating medical centre and discharged on the basis of their medical status and institutional guidelines. Although transmitted daily, these tele-cardiology data were not made available to the investigators and were analysed retrospectively. The option of one or more visits by a home nurse was also available.

Outcomes	<b>Primary outcome:</b> <ul style="list-style-type: none"><li>• Major adverse events</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>• Hospital length of stay</li><li>• Putative cost savings</li><li>• QOL (assessed with the SF36)</li></ul> <b>Follow-up time:</b> one month from randomisation	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes  <b>Sources of funding:</b> funding by Biotronik Inc. Funding to pay the Open Access publication charges for this article was provided by Biotronik Inc.  <b>Conflict of interest:</b> not reported.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	See p.1393, Col.2, Para 2

## Halimi 2008 (Continued)

### QUOTE:

“Patients who fulfilled the inclusion criteria and indications for permanent pacing described in the guidelines issued by professional societies were randomly assigned to an active vs. a control group by means of sealed envelopes.”

Allocation concealment (selection bias)	Unclear risk	Sealed envelopes were used, but unclear if these were opaque, numbered and shuffled.
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcome.
Were baseline characteristics similar?	Low risk	p.1395, Col.1, Para 1  QUOTE:  “The baseline clinical characteristics were similar in both study groups,”
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the group assignment, and neither could the patient. are objective. The main outcome (adverse events) was objective and assessed by the investigator who interrogated the pacing system and recorded the possible occurrence of an AE. Hospital length of stay and costs also objective measures.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Self-reported outcome (quality of life) is susceptible to bias if the participant is not blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	After randomisation 2 enrolling centres were excluded due to randomisation and protocol violations. 406 patients were initially randomised and 379 were retained.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Unclear risk	p.1397, Col.1, Para.2  QUOTE:  "In the overall population of 346 patients with operational HM systems, 139 (40.2%) transmitted no warning message. Among these 139 patients, 6 experienced an MAE and 1 experienced an NMAE."

## Harrison 1999

### Methods

**Study design:** cluster-RCT

**Inclusion criteria:** all patients referred from general practitioners (GPs) to six different specialities

**Exclusion criteria:** emergency referrals were excluded, and referrals to other specialities than those selected

**Method of patient recruitment:** For the duration of the study all the referral letters from the GP to the outpatient department at the Royal Free Hospital were re-directed initially to the study office. Eligible referrals were screened to ensure eligibility (that they fell into one of three categories: i) a routine referral, primarily for diagnosis; ii) a referral primarily for advice about management (where the decisions could be made on the basis of history and tests) and iii) a referral for tests to which the GP did not have direct access (e.g. magnetic resonance or endoscopic examination).

**Harrison 1999** (Continued)

**Study sample calculation:** not reported.

**Data collection:** on joining the trial, patients were sent the first questionnaire (covering demographic and personal details, and SF12). Immediately after the consultation a second questionnaire was sent (containing SVQ, STAI and a cost questionnaire), and three months after the appointment/tele consultation, a third questionnaire was sent to re administer the SF 12.

**Unit of analysis issues:** (yes/no): unclear: GPs unit of allocation and patients the unit of analysis

**Participants**

**Total no of eligible patients:** n = 142

**No of patients randomised in groups:** n = 132; Intervention: n = 62; Control: n = 70

**No of patients lost to follow-up:** n = 31 participants (22.3%) were lost to follow-up

**Patient baseline characteristics:**

a) Clinical condition: patients referred by GPs for outpatient consultation.

b) Age: not reported

c) Gender, female sex no (%): not reported

d) Ethnicity: not reported

e) Severity of condition: not reported

f) Major co-morbidities: not reported

**Setting** (hospital/community/residential care): four inner-city practices with registered populations ranging from 7800 to 10,300

**Location** (rural/urban etc.): urban

**Country:** UK

**Interventions**

**Study objective:** to determine the feasibility to use TM techniques to provide specialist consultations for patients from different specialities (orthopaedics, urology, gastroenterology, and otolaryngology).

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing

**Delivery of the intervention:** patient and GP jointly consulting hospital consultant via a video link from the GP surgery routine hospital outpatient appointments. Carers and relatives may also have been present in addition to the GP during the course of tele-consultation at the GP's surgery.

**Type of technology and its application:** The specialist and the GPs used a standard commercial PC-based video-conferencing equipment (VC8000, British telecom) connected by IDSN at 128 kbit/s. A mobile unit was developed for the consultants. This included a special camera-screen interface to enable better eye-to-eye contact with the patient.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Harrison 1999** (Continued)

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nine GPs ( 5.5 whole time equivalents) from four practices and six hospital consultants.-one from orthopaedics; otolaryngology; gastroenterology; urology; paediatrics and endocrinology respectively

**Duration of intervention:** the duration of one video-consultation

**Comparison intervention:** Routine outpatient consultations. All control groups patients attended the Royal Free Hospital, and saw the specialist alone unless accompanied by a carer or a relative.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Patient satisfaction (assessed with the Ware Specific Visit Questionnaire)</li><li>• State and trait anxiety (assessed with the Speilberger State-Trait Anxiety Inventory (STAI))</li><li>• Patient time taken for the visit</li><li>• Health status (assessed with the SF-12 instrument)</li></ul> <b>Folllow-up time:</b> 3 month after randomisation	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> consent to participate in the experimen- tal part of the arm was obtained for all but 13 participants.  <b>Sources of funding:</b> the study was funded by BT Laboratories and NHS R&D Programme.  <b>Conflict of interest:</b> not reported	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence genera- tion (selection bias)	Low risk	p.127, Col.1, Para3  QUOTE:  "Each GP was assigned by means of a random number table to one line in the matrix. Thus the GP used TM in half of the trial specialities, and in the other half the patients were seen in conventional outpatient clinics. Eligible patients were then assigned to the control or intervention group according to the allo- cation given to the referring GP in the balanced randomisation process"
Allocation concealment (selection bias)	Low risk	" For the duration of the study all referral letters from the GPs to the outpa- tients department at the Royal free Hospital were re-directed initially to the study office. This design obviated any temptation for GPs to allocate (or with- hold) patients selectively from the experimental service, leaving the choice to the patients themselves"
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes reported.
Were baseline characteris- tics similar?	Unclear risk	No information on age, gender, ethnicity etc.  "There was a balanced case-mix, with mean scores on the DUSOI of 51.3 (n=47) for the control group and 49.9 (n=43) for the intervention group."
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group: patient satisfaction, anxiety, health status, time taken for visit</b>  The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. Unclear if the out- come assessor was blinded. All outcomes are non-objective (but assessed with validated tools) and therefore the risk of bias unclear.

**Harrison 1999** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 132 patients entering the trial 13/62 (21%) randomised to the intervention group and 18/70 (26%) to the control group either refused consent to participate in the experimental arm of the trial or were lost to the trial owing to incorrect addresses or referral letters. Response rates for the various questionnaires ranged from 100% to 75%.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Hermens 2007**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> age &gt; 18 years; established diagnosis of the specific pathological condition Multiple Sclerosis (MS), stroke or Traumatic Brain Injury (TBI); nine hole peg test (NHPG) performed in more than 25 seconds; ability to move at least one peg in 180 seconds during the NHPG; sufficient autonomous functioning; Internet connection or telephone line and reachable Internet provider; stable clinical status; discharged from hospital or rehabilitation setting to his/her home</p> <p><b>Exclusion criteria:</b> disturbed upper limb function not related to MS, TBI or stroke; serious cognitive and/or behavioural problems; serious emotional problems; major visual problems; communication problems; medical complications; other problems possibly contra-indicating autonomous exercise at home.</p> <p><b>Method of patient recruitment:</b> Patients recruited by physicians at the three rehabilitation centres.</p> <p><b>Study sample calculation:</b> "... a total of 90 patients were necessary for the total trial, 60 patients in the intervention group and 30 patients in the control group".</p> <p><b>Data collection:</b> For the primary outcome: The H-CAD parameters received from H-CAD system during the month of intervention were analysed to detect a possible improvement in the time of executing the exercises (the averaged time for the first three days using the system was compared with the averaged time for the three last days using the system).</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n=112</p> <p><b>No of patients randomised to groups:</b> n = 81; Intervention: n = 55; Control: n = 26</p> <p><b>No of patients lost to follow-up:</b></p> <p>Intervention: n = 5; Control: n = 4 patients dropped out after randomisation</p> <p>Intervention: n = 4; Control: n = 2 patients dropped out after start of intervention</p> <p>Intervention: n = 7; Control: n = 4 patients had missing data on all tests</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: Multiple Sclerosis (MS), Traumatic Brain Injury (TBI) or stroke</p> <p>b) Age: intervention: 46.5 ± 17.7 years; usual care: 50.1 ± 18.2 years</p> <p>c) Gender, male/female: 47/34</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition:</p>



**Hermens 2007** (Continued)

Stroke: Intervention: n = 11; usual care: n = 5

TBI: Intervention: n = 20; usual care: n = 10

MS: Intervention: n = 24 ; usual care: n = 11

f) Major co-morbidities: not reported.

**Setting** (hospital/community/residential care): Unità Organica di Riabilitazione Intensiva Neuromotoria (UORIN, Italy), Foundation Institute Guttman (FPING, Spain) and from National Multiple Sclerosis Centre (NMSC, Belgium). UORIN included stroke patients, FPING TBI patients and NMSC MS patients.

**Location** (rural/urban etc.): unclear

**Country:** Italy, Spain and Belgium

**Interventions**

**Study objective:** to test the hypothesis that the H-CAD system is at least as effective as usual care for arm/hand function, measured with outcome measures for arm/hand function given to stroke, TBI and MS patients when patients are living at home.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (in addition to the H-CAD system)

**Delivery of intervention:** The actual intervention with the H-CAD system at home consisted of one month, whereby the patients had an average of one training session a day lasting 30 minutes for at least 5 days a week. The following exercises are part of the H-CAD system: key, light bulb, book, jar, writing, checkers and keyboard tasks. This set of exercises summarises the movements for a correct functional activity of the upper limb of the patient for reaching, grasping, lateral pinch, pinch grip, holding, manipulation and finger dexterity. The patient and the therapist had a weekly scheduled video-conference.

**Type of technology and its application:** The H-CAD system allows the execution of a configurable set of exercises at home. The rehabilitation treatment designed specifically for the patients' needs can be updated directly from the hospital environment. A link through Internet allows therapists and doctors to have an in-depth insight in the recovery of the patient since a recording of each exercise section is stored and transmitted to the hospital. The physical configuration of the portable unit can be suited to patients' needs and patients' posture. The patient can also contact the hospital at any time by activating the video-conference tool.

**Did the patients receive education about their condition?:** Not reported.

**Frequency of patient data transfer (monitoring studies only):** unclear if the exercise data was transferred daily or stored and sent at the end of the study; unclear also if the training program was adapted to this information if it was sent daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 30 minutes for at least 5 days a week during one month (20 sessions of 30 min each)

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a therapist

**Duration of intervention:** one month

**Hermens 2007** (Continued)

**Comparison intervention:** participants in the control group received usual care and generic exercises prescribed by their physicians. The therapists completed a diary which contained the exercises performed by the patients and the received treatment.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Arm/hand function (assessed with the Action Research Arm Test (ARA)test)</li><li>• Arm/hand disability (assessed with the Nine Hole Peg Test (NHPT) test)</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>• Functional ability (time to perform task assessed with the WMFT which is a lab-based test)</li><li>• Average exercise time per day</li><li>• Health outcome (the MOS 36-item short-form health survey (SF-36), Note: intervention group only)</li></ul> <b>Follow-up time:</b> one month from randomisation	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> EU study co-financed by the European Community Programme eTEN <b>Conflict of interest:</b> not reported.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	p.155, Col.1, Para.1  "A randomization scheme of 2:1 (two intervention group subjects for every one control group subject) was used"
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	p.158, Col.2, Para 3  No differences reported.
Were baseline characteristics similar?	Low risk	p.158, Col.2, Para 3  No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the intervention, and neither could the patient. However, outcomes of arm-hand function and arm-hand disability measured using validated tests.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	46/55 intervention participants (84%) and 20/26 control participants (77%) remained in the study i.e. different losses to follow-up between groups.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

## Hopp 2006

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> receiving home care services at the Richard L. Roudebush VAMC in Indianapolis, Indiana, one or more hospitalisations, two or more ED visits, or 10 or more outpatient visits in the prior 12 months, a care plan specifying two or more home care visits per month and an expected need of future visits for at least 1 month, as determined by a review of the care plan and the patient's condition by the home care treatment team.</p> <p><b>Exclusion criteria:</b> not having a telephone, being judged incapable of operating the TM system if sufficient caregiver support was lacking, or having a survival expectation of less than 6 months.</p> <p><b>Method of patient recruitment:</b> a research assistant (RA) contacted eligible patients by telephone to explain the study and arrange a meeting. At this meeting, the RA provided additional information about the study and obtained informed consent.</p> <p><b>Study sample calculation:</b> not reported.</p> <p><b>Data collection:</b> data were obtained from two major sources: a questionnaire at baseline and 6 months after baseline to obtain information on health-related quality of life (HRQOL) and patient satisfaction with home care services and national VA databases, to obtain data on number and duration of inpatient days, nursing home admissions and days, outpatient visits, ED visits, and in-person home care visits by a registered nurse during the 6-month study period.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 118, of which 81 (68.6%) declined to participate in the trial, and 37 (31.4%) were enrolled</p> <p><b>No of patients randomised to groups:</b> n = 37; Intervention: n = 18; Control: n = 19</p> <p><b>No of patients lost to follow-up:</b> n = 2 patients from each group (n = 4 total) died during the 6-month follow-up period.</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: home care patients at high risk of hospital resource utilisation</p> <p>b) Age : Intervention: 69.8 (11.6); Control: 69.5 (12.7)</p> <p>c) Gender: 100% male</p> <p>d) Ethnicity:</p> <p>African-American: Intervention: 33% (6); Control: 37% (7)</p> <p>Caucasian: intervention: 56% (10); Control: 47% (9)</p> <p>e) Severity of condition:</p> <p>Baseline measures of HRQOL, including both the PCS (mean 24.83; SD 7.47) and MCS (mean 40.52; SD 11.98), were below norms established for a general population.</p> <p>f) Major co-morbidities:</p> <p>Hypertension Intervention: 78% (14); Control: 84% (16)</p> <p>Diabetes Intervention: 50% (9); Control: 58% (11)</p> <p><b>Setting</b> (hospital/community/residential care): one VAMC inclusion in the home tele-health research study</p> <p><b>Location</b> (rural/urban etc.): Indianapolis, Indiana</p> <p><b>Country:</b> USA</p>

**Hopp 2006** (Continued)

## Interventions

**Study objective:** to determine whether adding tele-health technology to traditional homecare services increases HRQOL and homecare satisfaction, and decreases resource utilisation among homecare patients.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing and real-time monitoring

**Delivery of intervention:** intervention group patients, in addition to receiving traditional homecare services, had contact with the homecare staff using tele-health units. The focus of the tele-health visits was on providing nursing contacts beyond those available under traditional home care, to increase contact between patients and homecare staff members, facilitate more frequent monitoring of patient conditions, and provide greater encouragement for self-care practices. The frequency of video encounters was determined by the homecare nurse, in consultation with the patient's primary care provider and a review of the patient's medical record. Video-sessions included the following components: discussion of the patients overall health status; review of medications in terms of type and dosage; discussions of any health concerns by the patient; and nurse reminders concerning appropriate self-care behaviours, including diet, exercise, and monitoring of symptoms such as blood pressure and weight.

**Type of technology and its application:**

The TM equipment was an Aviva 1010 video monitor manufactured by American TeleCare, Inc. Each unit was 16 inches wide, 13 inches deep, and 10 inches tall. The system required a 110-V electrical connection and a regular analogue telephone line. Each TM unit consisted of several components: a home unit with interactive voice and video-technology, and a video-camera allowing the patients to be seen by the nurses in the homecare program. Some patients were also given units with peripheral attachments, such as blood pressure monitors, stethoscopes, and glucose monitors. A central unit (base station) was available to clinical providers. Patients were able to see the clinical staff members on the video-monitor, and clinical staff members were able to see the patient at home. When the unit was turned off, there was no ability for clinical staff and patients to communicate.

**Did the patient receive education about their condition?** Education was delivered as part of the intervention.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** The frequency of video encounters was determined by the homecare nurse, in consultation with the patient's primary care provider and a review of the patient's medical record.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: N/A
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** home healthcare nurses

**Duration of intervention:** 6 months

**Comparison intervention:** traditional home care patients received nursing services at home and periodic telephone contact with the clinical staff concerning their homecare services.

## Outcomes

**Primary outcomes:**

- Healthcare resource utilisation (number and duration of inpatient days, nursing home admissions and days, outpatient visits, ED visits, and in-person home care visits by a registered nurse)
- HRQOL (assessed with the SF-36V)

**Hopp 2006** (Continued)

- Patient satisfaction (assessed by a previously validated version of an instrument designed to assess satisfaction with outpatient clinical care, and adapted so that patients were specifically asked about their perceptions of homecare services)

**Follow-up time:** 6 months after randomisation

Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> VA Health Services Research and Development grant, “An Evaluation of Home-Based Telemedicine Services” (Grant No: VA HSRD–Tel: 20015-1).</p> <p><b>Conflict of interest:</b> not reported.</p>
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	See p.300, Col.1, Para 4  QUOTE:  “After completion of a baseline survey, the RA unsealed an envelope containing the randomized group assignment.”
Allocation concealment (selection bias)	Unclear risk	See quote above
Were baseline outcome measurements similar?	Low risk	There were no differences between groups for health related quality of life (HRQOL) or patient satisfaction measures.
Were baseline characteristics similar?	Low risk	p.303. Table 1  No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Resource use data retrieved from VA databases.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants and personnel could not be blinded to the intervention. Outcomes based on patients self-report are susceptible to bias due to non-blinding of patients.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A similar number of patients were lost to follow-up: two patients from each group (4 total) died during the 6-month follow-up period.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol are reported in the paper.
Other bias	Low risk	No evidence of other risk of bias

**Hui 2006**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> women aged 60 or over, with symptoms of urge or stress incontinence.</p>
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**Hui 2006** (Continued)

**Exclusion criteria:** Active urinary tract infection, a post-void residual volume by bladder ultrasound of more than 150 mL third degree uterine prolapse, and those already receiving treatment for their urinary symptoms.

**Method of patient recruitment:** Patients were recruited by referral from health professionals working in geriatric services and by advertisement at a community centre for seniors. Initial screening for urine incontinence was performed by research assistants. Suitable candidates were referred to a nurse specialist for a full assessment to confirm urge or stress incontinence

**Study sample calculation:** not reported.

**Data collection:** not reported.

**Unit of analysis issues:** (yes/no): no

**Participants**

**Total no of eligible patients:** n = 68, of which n = 4 refused to participate

**No of patients randomised to groups:** n = 64; Intervention: n = 32; Control: n = 32

**No of patients lost to follow-up:** n = 5 participants in the intervention group and n = 1 in the control group were lost to follow-up.

**Patient baseline characteristics:**

a) Clinical condition: urinary incontinence

b) Age (SD): Intervention: 73.6 (5.5); Control: 73.5(3.8)

c) Gender, female sex 100%

d) Ethnicity: no information

e) Severity of incontinence symptoms:

Severe: Intervention: 8 (30%) ; Control: 5 (17%)

Moderate Intervention: 14(52%) ; Control:15(52%)

Mild Intervention:5(19%) ; Control:8(28%)

None Intervention:0 ; Control:1(3%)

Missing Intervention:0 ; Control: 2

**Setting** (hospital/community/residential care): a hospital outpatient clinic, a community centre

**Location** (rural/urban etc.): urban

**Country:** Hongong, China

**Interventions**

**Study objective:** to compare TM with a conventional outpatient continence service (CS) in community-dwelling older women with urge or stress incontinence

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (behavioural therapy)

**Delivery of intervention:** The TM equipment was set up at the hospital outpatient clinic and at a community centre for seniors (not in the patient's home)

**Type of technology and its application:** Dual video output allowed the participants to see the nurse specialist and PowerPoint slides on two separate 86 cm TV screens. A 10 Mbit/s IP connection was used for data transmission.

**Did the patient receive education about their condition?** A nurse specialist provided behavioural training and provided overview of anatomy, pelvic floor exercises, fluid management, dietary factors. Participants were provided with a booklet on incontinence.

**Hui 2006** (Continued)

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** once a week for 8 weeks (8 times)

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse specialist

**Duration of intervention:** 8 weeks

**Comparison intervention:** face-to-face behavioural training and education

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>No of incontinence episodes</li> <li>Patient's perception of severity of symptoms</li> </ul> <p><b>Follow-up time:</b> 8 weeks after randomisation</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> informed consent was obtained but it was unclear if the ethic's committee had approved the study</p> <p><b>Sources of funding:</b> TM equipment supplied by SK Yee Medical Foundation.</p> <p><b>Conflict of interest:</b> not reported.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	See p.344, Col.2, Para 2  QUOTE:  "Randomisation was performed for 64 subjects using a table of random numbers."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	Mean number of incontinence episodes and mean voiding frequency were similar in the two groups.
Were baseline characteristics similar?	Low risk	p.345, Col.2, Para 1  No difference reported for socio-demographic characteristics at baseline.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	Participating patients and personnel could not be blinded to the group assignment. All outcomes, were based on patient self-report. No information on how the outcomes based on patients' self-report were assessed.
Incomplete outcome data (attrition bias)	Unclear risk	More patients dropped out from the intervention group (5 patients, 15%) than in the control group (one patient, 3%).



**Hui 2006** (Continued)

## All outcomes

Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Izquierdo 2003**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> adult patients with diabetes, 18-75 years old, participants must not have received diabetes education for at least 1 year and be able to read, understand, and sign the consent document.</p> <p><b>Exclusion criteria:</b> a history of not keeping doctor's appointments, profound visual or hearing impairment, psychiatric illness not controlled with medications, a history of illicit drug use or heavy alcohol consumption (more than four alcoholic drinks per day), and were not willing to travel to Syracuse if randomised to receive diabetes education in person.</p> <p><b>Method of patient recruitment:</b> Patients with diabetes, who presented to the Joslin Diabetes Center at SUNY Upstate Medical University in Syracuse, New York, and to satellite offices in Oswego, New York, and Oneida, New York, were asked to participate in this study.</p> <p><b>Study sample calculation:</b> Yes, but the calculation was not described in the paper. The authors however state that "we were not powered to detect small differences".</p> <p><b>Data collection:</b> At baseline, immediately after the third educational visit (visit 3), and 3 months after the third educational visit, each participant was asked to complete the Problem Areas in Diabetes (PAID) scale, the Diabetes Quality of Life (DQOL) scale, and one measure of cognitive appraisal, the Appraisal of Diabetes Scale (ADS). Participants also completed the Diabetes Treatment Satisfaction Questionnaire (DTSQ), which has been specifically designed to measure satisfaction with diabetes treatment regimens in people with diabetes.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients in groups:</b> n = 46; Intervention: n = 24; Control: n = 22</p> <p><b>No of patients lost to follow-up:</b> n = 5 patients were lost to follow-up</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: diabetes (Type I and II)</p> <p>b) Age (years): Intervention: 53.95 ± 10.08 (36.3–70.0); Control: 61.37 ± 8.95 (44.8–80.2)</p> <p>c) Gender, (M/F): Intervention: 8/16; Control: 13/9</p> <p>d) Ethnicity: most of the participants were Caucasian (95%)</p> <p>e) Severity of condition:</p> <p>Diabetes type: (Type 1/Type 2) Intervention:3/21; Control:2/20</p> <p>BMI, kg/m<sup>2</sup> ± SD (range): Intervention:35.95 ± 9.22 (22.41 to 56.80); Control: 31.34 ± 6.20 (20.57 to 44.15)</p> <p>Duration of diabetes (years): Intervention: 15.78 ±11.54 (1.75 to 49.03); Control: 11.72 ± 8.2 (1.42 to 35.02)</p> <p>f) Major co-morbidities: no information</p>

**Izquierdo 2003** (Continued)

**Setting** (hospital/community/residential care): out-patient settings (Joslin Diabetes Center at SUNY Upstate Medical University in Syracuse, New York, and to satellite offices in Oswego, New York, and Oneida, New York)

**Location** (rural/urban etc.): urban

**Country:** USA

Interventions

**Study objective:** To determine whether diabetes education can be provided as effectively through TM technology as through in-person encounters with diabetes nurse and nutrition educators.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing/education

**Delivery of the intervention:** the TM group had the information presented one-to-one via teleconferencing. During the TM session, the patients and educators were able to see and hear one another in real-time using tele-conferencing hardware and software over a private ISDN (integrated services digital network) line. The ISDN line provided about 128 kilobits of data to flow between sites with improved real-time voice, video, and graphic transmission. There was a slight delay in sound, which was well accepted. A document camera was provided for the educators to enlarge brochures and text, and food models were used to demonstrate portion sizes.

**Type of technology and its application:** Real-time teleconferencing session with a document camera to enlarge brochures and text.

**Did the patient receive education about their condition?** Dietician and nurse educators delivered a programme recognised by the American Diabetes Association. Sessions were interactive.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 3 educational sessions: the 1st included a 1 hour consultation with the diabetes nurse educator and dietician, followed up by two 30 minute appointments at 4 to 6 weeks and 8 to 12 weeks.

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** two nurse educators and one dietitian educator (all certified diabetes educators who had extensive experience in providing diabetes education)

**Duration of intervention:** 12 weeks (3 education sessions: the first included a 1 hour consultation with the diabetes nurse educator and dietician, followed up by two 30-minute appointments at 4 to 6 weeks, and 8 to 12 weeks.)

**Comparison intervention:** The in-person group had the information presented one-on-one in person on-site (3 sessions).

Outcomes

**Primary outcome:**

- HbA1C

**Secondary outcomes:**

- Psychosocial functioning (assessed by PAID scale and ADS scale)
- DQOL (assessed with the Diabetes Quality of Life questionnaire)

**Izquierdo 2003** (Continued)

**Follow-up time:** 3 months after the intervention

**Notes**
**Ethics approval and written informed consent obtained:** yes

**Sources of funding:** part funded by the Bayer Institute for Health Care Communication, Bell Atlantic, the New York State Department of Health, and the SUNY Upstate Medical University.

**Conflict of interest:** not reported.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.1004, Col.1, Para.2  QUOTE:  "Eligible patients were randomized into the two treatment arms using a stratified randomization procedure for random permuted blocks, as described by Pocock (18). Stratification was by type of diabetes (type 1/type 2), yielding two total strata. A block size of four was used. This process ensured an equal number of patients in the two groups and equal distribution of patients by diabetes type."
Allocation concealment (selection bias)	Low risk	See above
Were baseline outcome measurements similar?	Unclear risk	No information in text or tables.
Were baseline characteristics similar?	Unclear risk	p.1004, Col.3, Para.1  QUOTE:  "The in-person group was significantly older than the TM group, with mean (SD) ages of 61.37 (9.85) years and 53.96 (10.08) years, respectively."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention was blinded to the intervention, but not the patient. However, there were objective outcomes  p.1003, Col.2, Para1  QUOTE:  "Subjects in each group were managed in the same manner, and the treating physician was unaware to which group the subjects were randomized", The primary outcome HbA1c was objective."
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Participating patients and personnel could not be blinded to the group assignment. Psychosocial functioning and quality of life were based on patient self-report. No information on how the outcomes were assessed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	TM 19/24 (80%) provided data for primary outcome; control 18/22 (82%) provided data for primary outcome.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Izquierdo 2009

Methods	<p><b>Study design:</b> cluster-RCT</p> <p><b>Inclusion criteria:</b> school children with diabetes, age 5 to 14 years</p> <p><b>Exclusion criteria:</b> not reported.</p> <p><b>Method of patient recruitment:</b> not reported.</p> <p><b>Study sample calculation:</b> not reported.</p> <p><b>Data collection:</b> All outcomes were measured at the beginning of study (baseline) and longitudinally at 3-month intervals for 1 year. Initial (baseline) values were collected just before the beginning of the second semester, the 6-month data were collected at the end of the school year, and the 9-month data were collected just before beginning the new school year after a 2.5-month summer vacation. Satisfaction surveys were administered at the end of the study.</p> <p><b>Unit of analysis issues:</b> (yes/no): schools randomised and participants assessed</p>
Participants	<p><b>Total number of patients:</b> unclear no of children who had diabetes for a mean of 5 years and who took 4 injections of insulin per day, or using an insulin pump</p> <p><b>Number of patients randomised in groups:</b> n = 41; Intervention: n = 23 (12 schools); Control: n = 18 (13 schools)</p> <p><b>No of patients lost to follow-up:</b> no information</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: diabetes .</li> <li>b) Age: Intervention: <math>9.74 \pm 2.18</math> years; Control: <math>10.56 \pm 2.50</math> years, (P = 0.27)</li> <li>c) Gender, female sex no (%): no information</li> <li>d) Ethnicity: most participants were white, Intervention: one Afro-American; Control: three Afro-Americans (P = 0.30)</li> <li>e) Condition specific characteristics:</li> </ul> <p>The mean duration of diabetes: Control: 4.7 (3.4) years; Intervention: 5.1 (3.3) years (P = 0.67)</p> <p>Baseline A1c levels % (SD): Intervention: 8.53 (1.86); Control: 8.67 (1.05) (P = 0.79)</p> <p>Mean BMI: Intervention: 18.2 kg/m<sup>2</sup>; Control: 20.3 kg/m<sup>2</sup>, (P = 0.02).</p> <p><b>Setting</b> (hospital/community/residential care): Joslyn Diabetes Center at SUNY Upstate Medical University, 12 control schools and 13 intervention schools (school nurse's office)</p> <p><b>Location</b> (rural/urban etc.): urban, Syracuse, New York</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b> To test the feasibility and effectiveness of the use of TM to improve care for children with Type I diabetes in school .</p> <p><b>Type of TM/ mode of delivery (e.g. remote monitoring, video-conference etc.):</b> video-conferencing (consultation /treatment/ education; additional to UC)</p> <p><b>Delivery of the intervention:</b> The intervention group, once a month, used a school TM system to facilitate communication between the school and diabetes centre. The application portal allowed school nurses to use either a single mouse click or finger touch to a labelled "button" on the monitor screen to launch a collaborative synchronous consultation where they could hear, see and exchange graphical and tabular blood glucose measurement information with the diabetes centre nurse practitioner.</p>

**Izquierdo 2009** (Continued)

The launch of a prescheduled regular monthly meeting (10 to 20 minutes) between the school nurse, student with or without a parent, and diabetes nurse practitioner was usually accomplished without prompting, by both parties launching the V-Connect application. Failing that, either the diabetes centre nurse practitioner would call the school nurse to prompt the connection, or the school nurse would use a beeper to alert the nurse practitioner they were ready to conference. Treatment orders were written at the conclusion of tele-visits. The application portal also made available an educational curriculum that reviewed blood glucose self-monitoring, diabetes overview, exercise, hyperglycaemia, hypoglycaemia, insulin therapy, medical accommodations in schools, medical alert tools, nutrition, and sick day management. These topics were arranged into 18 short modules designed to give greater specificity and personalisation of the content for the school nurse and personnel in other school roles, such as school administrators, teachers, physical education teachers, sports coaches, bus drivers, and other school staff. An initial one-on-one, in-person tutoring session by the project IT co-ordinator was used to train the school nurse or diabetes centre nurse practitioner. This session was completed in 1.5 hours. Subsequent remedial operations help was initiated as needed by a call to the project toll-free help desk number. The frequency of use of this toll-free line was minimal and limited to a small proportion of school nurses.

**Type of technology and its application:** A TM system with a centrally-managed Internet-based portal (Progressive Expert Consulting, Inc., Syracuse, New York) connecting the school and diabetes centre. This portal supported a teleconferencing collaboration software application (V-Connect, McLean, VA) and content to address generally accepted requirements for clinical data exchange and school-based care diabetes-related education, 3-5 together with commercially available blood glucose data interpretation and collaboration software for the LifeScan One-Touch Ultra 2 home glucose monitoring device (LifeScan). Off-the-shelf hardware components (personal computer with min 512 MB internal RAM; touch screen 17-inch monitor, and peripheral components consisting of a web-cam; document camera, 400 by 500 USB Tablet, compact colour printer, all-in-one speaker and microphone, and dedicated cable to download the glucose monitoring device), were integrated into a custom-designed cabinet to give the unit password and physical lock security. An operations manual was provided..

**Did the patient receive education about their condition?** All participants had received standard diabetes self-management education and training with diabetes nurse and dietitian educators.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** monthly video conferences (12 during the study period) and clinic visits every third month

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a 'diabetes team' and a school nurse

**Duration of intervention:** 12 months

**Comparison intervention:** UC- medical visits every 3 months, and communication between school nurse and diabetes team as needed by phone.

**Outcomes**
**Primary outcome:**

- HbA1C (e-mailed author for raw-data 26/02/13)

**Secondary outcomes:**

- Paediatric QOL (e-mailed author for raw-data 26/02/13)
- Urgent encounters

**Izquierdo 2009** (Continued)

- Urgent calls
- Treatments needed

**Follow-up time:** 12 months after randomisation

## Notes

**Ethics committee approval and informed consent obtained:** yes

**Sources of funding:** Department of Health and Human Services (equipment), New York State Department of Health; and the Children's Miracle Network. LifeScan Inc., donated home glucose monitoring devices and test strips for this project.

**Conflict of interest:** The authors declared no conflict of interest.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	see p.378, Col 1, Para 2  QUOTE:  "Baseline HbA1c levels were similar in the intervention (n = 23) and UC (n = 18) groups (8.53% 1.86 and 8.67% 1.05%; P = .79),"
Were baseline characteristics similar?	Unclear risk	see p.378, Col 1, Para 2  Baseline age was similar in both groups (9.74 2.18 and 10.56 2.50 years; mean body mass index was lower in the intervention group compared with the control group (18.2 kg/m <sup>2</sup> and 20.3 kg/m <sup>2</sup> ).
Blinding (performance bias and detection bias) Objective outcomes	Low risk	HbA1c, and healthcare use are objective measures of outcome.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants and the personnel could not be blinded to the group allocation. Outcomes based on patients self-report of quality of life (QOL) may be at risk of bias (no numerical QoL data provided)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol were reported in the full text paper.
Other bias	Low risk	No other risk of bias identified.

**Jan 2007**

## Methods

**Study design:** RCT

Jan 2007 (Continued)

**Inclusion criteria:** ages between 6 and 12 years, access to the Internet by their caregivers, and diagnosed as having persistent asthma following the GINA clinical practice guidelines.

**Exclusion criteria:** broncho-pulmonary dysplasia, or other chronic co-morbid condition that could affect the quality of life were excluded.

**Method of patient recruitment:** All eligible patients and their caregivers were informed about the study and given the opportunity to participate in the study.

**Study sample calculation:** A sample size calculation determined that 100 children in each of the two groups would have a power of 94% for detecting an effect size of 0.5 (the difference in the group means divided by the common standard deviation (SD) for any of the variables studied. This study was under-powered.

**Data collection:** Treatment adherence was assessed by examining selected aspects of therapeutic and diagnostic monitoring. We defined therapeutic monitoring as outcomes that directly reflect adherence to therapeutic regimens, including controller medication use and test score for dry powder inhaler (DPI) or metered dose inhaler (MDI) with the spacer technique. Diagnostic monitoring included reviewing the asthma symptom diary and records of electronic peak flow meter use. Adherence to the web-based asthma diaries or traditional diary records was also measured. A survey on satisfaction with the Internet-based interactive and tele-monitoring system (i.e., Blue Angel for Asthma Kids) was completed at the end of the study.

**Grading of symptom scores:** The scoring method of asthma symptom is divided as daytime symptom (0: no asthma symptoms; 1: symptoms occur several times, but do not interfere with daily activities; 2: symptoms interfere with daily activities; 3: symptoms stop all activity) and night-time symptoms (0: no asthma symptoms; 1: wake up once because of asthma symptoms, 2: wake up several times due to asthma symptoms; 3: symptoms stop sleeping and cause the patient to stay awake during the night).

**Unit of analysis issues:** (yes/no):no

## Participants

**Total no of eligible patients:** not stated, n = 5 families declined to participate;

**No of patients randomised to groups:** n = 196; Intervention: n = 97; Control: n = 99

**No of patients lost to follow-up:** n = 15 participants (n = 6 from control and n = 9 from intervention group) were excluded (on their own request or for lack of data due to Internet failure); n = 7 families dropped out (were unavailable at 12-week follow-up; n = 6 patients in the intervention group and n = 5 in the control group)

**Patient baseline characteristics:** for Intervention: n = 88; Control: n = 76 (83 % of patients randomised)

a) Clinical condition: asthma

b) Age, years (SD): Intervention: 10.9 (2.5); Control: 9.9 (3.2)

c) Gender, male sex no (%): Intervention: 35 (39.7); Control: 28 (36.8)

d) Ethnicity: no intervention

e) Severity of condition:

Asthma severity (persistent)

Mild: Intervention: 33 (37.5); Control: 33 (43.4)

Moderate: Intervention: 43 (48.9); Control: 35 (46.1)

Severe: Intervention: 12 (13.6); Control: 8 (10.5)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one paediatric allergy and asthma clinic at National Kung University Medical Center)

**Location** (rural/urban etc.): urban (Tainan)

**Country:** Taiwan



Jan 2007 (Continued)

## Interventions

**Study objective:** to assess the effectiveness of Blue Angel for Asthma Kids, an Internet-based interactive asthma educational and monitoring program, used in the management of asthmatic children.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring and education

**Delivery of intervention:** Patients were encouraged to fill out the electronic diary daily and follow the instructions given by the computer and the physician; thereafter the decision-support system was used to check whether asthma had been brought under control. Physicians then instructed patients by e-mail or telephone to increase, decrease, or continue the usual treatment. Families were given a demonstration on how to log on to the Internet website and complete the daily inquiry about asthma symptoms and medications and upload the information to the central server at the data information centre of National Cheng Kung University. They also received training on how to use the peak flow meter. The nurse then conducted a standardised 10-minute education session using a video and a booklet in which each participating child, who was given an electronic peak flow measuring device, was instructed on proper techniques, and how to establish his or her personal best.

**Type of technology and its application:** Blue Angel for asthma kids comprised i) basic information regarding the care of the asthmatic child, ii) an electronic diary, iii) an action plan for the patients and iv) a retrieval analysis system to review the accumulated data on symptoms score and PEF variability. In addition to this, the patients were given an electronic peak flow meter (Microlife PF 100 Electronic Asthma Monitor, Microlife Ltd., Taipei, Taiwan) which measures daily PEF and forced expiratory volume in one second (FEV1) and stores the date and time of performance in memory. The monitor can be connected via a USB with the computer, and all memory data can be analysed by Microlife Asthma Monitor software program. In this setting, patients were able to complete the electronic asthma diary, and record symptoms, need for rescue medication and PEF values. The Internet tool's action plan comprised a three colour warning system accompanied by a written treatment plan.

**Did the patient receive education about their condition?:** Yes, and all control group participants received asthma education as part of usual care, including verbal and printed information on the disease and concepts related to its control.

**Frequency of patient data transfer (monitoring studies only):** daily (PEF-values and symptom scores)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** daily (either through e-mail or over the telephone)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail or telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear, but probably daily, since the healthcare professional contacted the patient daily
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the physician advises the patient to increase, decrease or continue medication all depending on the data received.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians

**Duration of intervention:** 12 weeks

**Comparison intervention:** The control group received a traditional asthma care plan consisting of a written asthma diary supplemented with instructions for self-management patients, they were treated according to their current severity level, and they were taught how to adjust their medication.

## Outcomes

**Primary outcomes:**

Jan 2007 (Continued)

- Disease control (PEF values, symptom scores and asthma test scores- assessed with the Childhood Asthma Control Test)
- Adherence (assessed by therapeutic and diagnostic monitoring)
- Quality of life (QOL) (assessed with the Pediatric Asthma Quality of Life)
- Asthma knowledge

**Follow-up time:** 12 weeks from randomisation

Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** a grant from the National Science Council (NSC 94-2815-C-426-005-E) and a grant from Bureau of Health Promotion, Department of Health (DOH 93-HP-1124), Taiwan, R.O.C.

**Conflict of interest:** no information

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	See p.259, Col.1, Para 2  QUOTE:  "Following the session, the nurse opened a sealed envelope containing the treatment assignment, and the children were randomised to either traditional asthma education and treatment (control group) or interactive Web-based education and asthma monitoring (intervention group)."
Allocation concealment (selection bias)	Unclear risk	See quote above
Were baseline outcome measurements similar?	Unclear risk	No differences reported.
Were baseline characteristics similar?	Low risk	p.260, Col.2, Para 2  QUOTE:  "The intervention and the control group had similar demographic characteristics, illness history, home environment and use of health services at baseline."
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professionals delivering the intervention could not be blinded to the patient allocation, and neither could the patient. Disease control and adherence outcomes were based on patients self-report and diary entries. Quality of life was assessed with a standardised tool, and therefore at unclear risk.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intervention:82/97; Control: 71/99 (78 % of patients randomised remained in the study at 12 weeks follow-up). Baseline characteristics of children who did not complete the trial did not differ from those who did.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Jansa 2006

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> patients 18 to 50 years of age, with type I diabetes for at least 2 years treated with at least 3 doses of insulin/day and a HbA1c &gt; 8%.</p> <p><b>Exclusion criteria:</b> patients beginning continuous subcutaneous insulin infusion. Plans to become pregnant, psychiatric disorders and lack of appointment compliance (50%).</p> <p><b>Method of patient recruitment:</b> from 2001 to 2003 patients were invited to participate on attending routine clinical out-patients appointments. Eligible patients were evaluated by a diabetes nurse with medical consultation, if necessary, before randomisation to determine: insulin schedule, self-management, body mass index (BMI), metabolic control, meal planning and quality of life. An agreement was made between the patient and the diabetes team to adapt the insulin therapy programme and set the goals to be achieved. On detection of a poor diabetes knowledge score with the DKQ2 test the patient followed an interactive structured group (6 hours).</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> At the beginning, at 6 months (end of study) and at 12 months, metabolic control (the primary end point), self-management and quality of life were evaluated. The patient and family costs as well as health provider costs related to appointments (secondary end point) were evaluated at the end of the study. Hypoglycaemic episodes were estimated from logbooks and memory of glucometers. Self-management was evaluated by blood glucose testing frequency and insulin modification determined from logbooks and the meter downloads for each patient, and the diabetes knowledge questionnaire 2 (DKQ2)</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 50 patients of whom 40 (80%) accepted to participate</p> <p><b>No of patients randomised to groups:</b> n = 40; Intervention: n = 20; Control: n = 20</p> <p><b>No of patients lost to follow-up:</b> n = 4 patients in the TM group (one lost to follow-up) and n = 6 in the control group (two lost to follow-up) were excluded due to early lack of protocol compliance.</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: Type I diabetes with poor metabolic control</p> <p>b) Age, years (SD): Intervention: 27(11); Control: 23(5)</p> <p>Weight: Intervention: 68.4 10.5; Control: 69.3 9.6</p> <p>BMI (kg/m<sup>2</sup>): Intervention: 23.3 ± 2.6; Control: 23.5 ± 2.5</p> <p>c) Gender, Sex, male/female: Intervention: 10/9; Control: 11/5</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition:</p> <p>Insulin (IU/kg/day): Intervention: 0.8 ± 0.2; Control: 0.8 ± 0.2</p> <p>DM evolution (years): Intervention: 12 6; Control: 10 6</p> <p>f) Major co-morbidities: no information</p> <p><b>Setting</b> (hospital/community/residential care): one Diabetes Unit of the Hospital Clinic of Barcelona</p> <p><b>Location</b> (rural/urban etc.): urban (Barcelona)</p> <p><b>Country:</b> Spain</p>
Interventions	<p><b>Study objective:</b> To test if TM appointments integrated in a structured Therapeutic Education programme are effective and cost-effective.</p>

Jansa 2006 (Continued)

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (+ education)

**Delivery of intervention:** Those allocated in the intervention were trained in the management of the GlucoBeep system. The patient was instructed as how to send data via fax, e-mail or telephone in the case of problems with the telematic system. GlucoBeep is a system of tele-support in diabetes which allows the transmission of blood glucose values data from the self-monitoring instruments to a dedicated server by means of a fixed or a mobile telephone. The physician recalls his patients data from the server through an Internet connection, in order to visualise it in the EuroTouch software and carry out therapeutic adjustments, whenever necessary. The patient connects the GlucoBeep device (size similar to glucometer) to the glucometer and places its loudspeaker on the telephone microphone. After having sent all the glycaemia values electronically, the server invites the patient to leave a 1-min vocal message concerning insulin doses and events. All these data are encoded and stored in the server to be unloaded by the diabetes team, which thereafter provides the appropriate counselling.

**Type of technology and its application:** Glukobeeep system (Medimatica s.r.l. Italy. <http://www.glukobeeep.com>) Structure: a) Glukobeeep patient device, b) Glukobeeep patient software, c) Glukobeeep server package central unit which operates as an information concentrator and distributor and d) Glukobeeep professional software. The patients connect the GlucoBeep device (size similar to a glucometer) to the glucometer and place its loudspeaker on the telephone microphone. After having sent all the glycaemia values electronically, the server invites the patient to leave a 1 minute vocal message concerning insulin doses and events. All these data are encoded and stored in the server to be uploaded by the diabetes team, which thereafter provide the appropriate counselling. The GlukoBeep per telephone was used. All the patients used the same meter (Esprit, Beyer Diagnostics Europe, Dublin, Ireland).

**Did the patient receive education about their condition?** Both groups were helped in decision-making concerning insulin dose adapted to self-monitoring of blood-glucose, carbohydrate intake, physical activity plan and other possible events related to metabolic control, reinforced with the usual topics on diabetes self-management for Type I diabetes.

**Frequency of patient data transfer (monitoring studies only):** unclear if daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 12 clinical appointments (the intervention group made 9 telematic appointments with the GlucoBeep system and 3 outpatients face to face appointments (0, 3 and 6 months)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): unclear
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): appropriate counselling and therapeutic adjustments

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** diabetes nurses/diabetes team

**Duration of intervention:** 6 months

**Comparison intervention:** Conventional intensive follow-up; 12 outpatient appointments.

## Outcomes

### Primary outcome:

- HbA1c

### Secondary outcomes:

- Hypoglycaemic events
- Self-management (insulin doses)
- QOL (assessed with the Spanish Diabetes Quality of Life Test (DQOL) and the SF-12 Health Survey)

## Jansa 2006 (Continued)

- Costs

**Follow-up time:** 6 months after the end of intervention

### Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** This research was supported by grants from :Agencia d'Avluacio de Tecnologia Medica (ATTM), Barcelona, Spain.S.A Croniweb provided the GlucoBeep telematic devices

**Conflict of interest:** no information

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.27, Col 1, last para, and Col 2, first para  QUOTE:  "The patients were randomised to one of two study groups (TG) or (CG) with a random variable generator."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	p.29, table 2  No difference in baseline HbA1c values between groups (primary outcomes).
Were baseline characteristics similar?	Low risk	p.28, Col.2, Para.5  QUOTE:  "The baseline characteristics were comparable in the two experimental groups (Table 1)."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the patient allocation, and neither could the patient. However, primary outcome of HbA1c is objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants and the personnel could not be blinded to the group allocation. Non-objective self-reported outcomes of quality of life (QoL) and hypoglycaemic events may have been affected by non-blinding. QoL assessed with validated tool at unclear risk, and self reported hypoglycaemic events at high risk.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Thirty patients (75%) completed the study (16 TG, 14 CG). Intention to treat analysis.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found
Other bias	Low risk	No evidence of other risk of bias.

## Jerant 2001

### Methods

**Study design:** 3-armed RCT

**Jerant 2001** (Continued)

**Inclusion criteria:** aged 40 and older, had an active telephone line in their home, were English-speaking, and had a family physician or general internist primary care provider (PCP) in the UCD Health System. In addition, potential participants (or a designated caretaker) needed to have vision and hearing adequate to utilise a telephone or telecare equipment.

**Exclusion criteria:** a Charlson comorbidity score (Charlson, Pompei, Ales, & MacKenzie, 1987) of six or greater (equivalent to metastatic cancer, full-blown acquired immunodeficiency syndrome, or several chronic diseases with end-organ manifestations); a 15-item Geriatric Depression Scale score (Sheikh & Yesavage, 1986) of seven or greater; a Mini-Mental State Exam score (Folstein, Folstein, & McHugh, 1975) of 20 or lower; or a Symbol Digits Modalities Test (Smith, 1973) score of greater than or equal to two standard deviations (SD) below age- and education-adjusted mean scores.

**Method of patient recruitment:** Between July 1, 1999 and June 30, 2000, all patients admitted to the University of California Davis (UCD) Medical Center Hospital with a primary admission diagnosis of CHF were screened for eligibility to participate in the trial.

**Study sample calculation:** Calculations based on 1998 to 1999 UCD Hospital CHF admission rates and charges indicated that a sample size of 69 (23 patients per group) would provide 80% power at a confidence level of 95% to detect a 45% difference in mean CHF-related re-admission charges between groups.

**Data collection:** Healthcare utilisation and charges were tracked for 180 days from the date of the first home nurse visit, as previously described (Jerant, Azari, & Nesbitt, 2001). Patients in all groups received an in-person home nurse visit shortly after discharge and a second in-person home nurse visit approximately 60 days later. During both visits, participants completed the Medical Outcomes Study SF-36 generic health status questionnaire as well as the Minnesota Living with Heart Failure Questionnaire. Patient satisfaction with care was assessed at both in-person visits using the eight-item Client Satisfaction Questionnaire.

**Unit of analysis issues:** (yes/no):no

**Participants**

**Total no of eligible patients:** n = 339 patients were admitted with a verified primary diagnosis of congestive heart failure (CHF), and 236 had at least one exclusion criteria. An additional 66 participants who may have been eligible did not undergo detailed evaluation: 19 declined evaluation and 47 were discharged before the RA could evaluate them.

**No of patients randomised in groups:** n = 25; Telecare: n = 13; UC: n = 12. Note: a third intervention group (telephone, n=12) was not included in this review

**No of patients lost to follow-up:** no information

**Patient baseline characteristics::**

a) Clinical condition: Congestive heart failure (CHF)

b) Age, years (%): Telecare: 66.6 (10.9); Usual care: 72.7 (11.4)

Weight, kg, mean (SD): Telecare: 88.2 (23.6); UC: 84.0 (39.2)

c) Gender: no male/female, (%): Telecare: 6/7 (46/54); UC: 6/6 (50/50)

d) Ethnicity: Race, no (%):

Telecare: 8 (62) African-Americans, 4(31) Caucasians

UC: 4 (33) African-Americans; 7(58) Caucasians

e) Severity of condition:

NYHA class

II: Telecare: 9 (69%); UC: 7 (58%)

III: Telecare: 3 (23%); UC: 5 (42%)

IV: Telecare: 1 (8%); UC: 0 (0)

**Jerant 2001** (Continued)

CHF duration, months, mean (SD);Telecare: 11.0 (16.5); UC: 30.4 (30.0)

Functional impairment, no (%)

Intermediate: Telecare:3 (23); UC: 5 (42)

High: Telecare:10 (77); UC: 7 (58)

f) Major co morbidities:

Charlson comorbidity score, mean (SD):Telecare:1.8 (1.2); UC:1.8 (0.9)

**Setting** (hospital/community/residential care): one University Medical Center Hospital

**Location** (rural/urban etc.): urban

**Country:** USA

**Interventions**

**Study objective:** to compare three post-hospitalisation nursing care models ((a) video-based home telecare; (b) telephone calls; and (c) UC.) for reducing CHF re-admission charges during 180-days of follow-up.

**Type of TM/ mode of delivery (e.g. remote monitoring, video-conferencing etc.):** video-conferencing (real-time assessment of vital signs and education)

**Delivery of the intervention:** Patients assigned to telephone care received scheduled phone calls from the study nurse in the intervening period. Those assigned to the video-based telecare group received scheduled home telecare visits using the equipment described above. For urgent questions or problems occurring between 8 AM and 5 PM, Monday through Friday, patients in the telephone and telecare groups had access, via the medium appropriate to their group assignment, to the study nurse. They were given emergency contact numbers for usual methods of care during all other hours. Patients randomised to the telecare group had an Aviva SL1010 Personal Telecare unit (American TeleCare, Eden Prairie, MN) installed in their home at the initial in-person visit. The patient and, when applicable, lay caregivers were instructed in its use. During all types of nursing encounters, the Visiting Nurse Association (VNA) CHF Care Steps protocol was used to guide patient assessment (Strategic HealthCare Programs, 1997). This protocol includes assessment of items such as vital signs, activities of daily living, coping skills, medication use, dietary factors, and degree of signs and symptoms such as dyspnoea and weight gain. Patients are educated regarding each item, and patient-centred goals for the frequency and content of follow-up visits are developed. To help determine the adequacy of CHF medication regimens, the investigators developed a second set of algorithms based on national consensus recommendations (Advisory Council to Improve Outcomes Nationwide in Heart Failure, 1999) updated to include the appropriate use of potassium-sparing diuretics (Bertram et al., 1999). Following each encounter, the nurse reviewed her assessment with the principal investigator and, if appropriate, then sent a letter containing non-urgent recommendations for improving CHF care to the PCP. Urgent recommendations were also conveyed immediately by telephone.

**Type of technology and its application: Telecare group:** The units operated over standard analogue telephone lines and allowed real-time videoconferencing with the study nurse at a central monitoring computer at the medical centre. A small camera on an extension cable allowed observation of facial expressions, respiratory effort, lower extremity edema, and objects such as digital scale displays. A voice signal was transmitted simultaneously via a microphone. An integrated electronic stethoscope was utilised by having the patient or caregiver apply the device to standard heart and lung auscultation points. Posterior lung auscultation was omitted in patients without an assisting caregiver.

**Did the patient receive education about their condition?** Patients were educated regarding each item in the nursing protocol, and patient-centred goals for the frequency and content of follow-up visits were developed.

**Frequency of patient data transfer (monitoring studies only):** Telecare: data transferred during 9 scheduled telecare sessions

**Planned/scheduled no of TM contacts between patient and healthcare professional:** at least 9:

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A



**Jerant 2001** (Continued)

- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 6 months

**Comparison intervention:** Patients randomised to UC received only the care directed by their PCP in the period between in-person visits. Patients in the UC group did not have access to the study nurse beyond the initial and terminal in-person visits but were also provided with usual emergency contact numbers. All participants received in person visits at baseline and at 60 days.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>CHF-related hospital re-admission charges</li></ul> <p><b>Secondary outcomes</b></p> <ul style="list-style-type: none"><li>CHF-related hospital admissions</li><li>Mean length of stay</li><li>All-cause re-admissions</li><li>All-cause length of stay and associated charges</li><li>Quality of Life (QoL) and health status outcomes assessed by the SF-36 and MLHFQ reported in Jerant 2003.</li><li>Patient self-care adherence (reported in Jerant 2003)</li><li>Medications (reported in Jerant 2003)</li><li>Satisfaction with care (assessed with the Client Satisfaction Questionnaire and reported in Jerant 2003)</li></ul> <p><b>Follow-up time:</b> 6 months after first visit</p>	
Notes	<p><b>Ethic's committee approval and informed consent obtained:</b> yes</p> <p><b>Sources of funding:</b> UCD School of Medicine Hibbard E. Williams research grant.</p> <p><b>Conflict of interest:</b> no information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	see p.5, Para 2  QUOTE:  "For patients who agreed to participate, informed consent was obtained and random assignment to one of the three care models was achieved prior to hospital discharge using sealed envelopes containing randomly generated numbers."
Allocation concealment (selection bias)	Low risk	see p.5, Para 2  QUOTE:  "...random assignment to one of the three care models was achieved prior to hospital discharge using sealed envelopes containing randomly generated numbers."

**Jerant 2001** (Continued)

Were baseline outcome measurements similar?	Low risk	see p.9, Table 2  QUOTE:  No differences reported.
Were baseline characteristics similar?	Low risk	see p.9, Table 2  Baseline characteristics were similar in the three groups.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The health professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, all primary outcomes objective and tracked through hospital records.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The participants and the personnel could not be blinded to the group allocation. Non-objective self-reported outcomes, which may have been affected by non-blinding. Questionnaire outcomes of QoL, health status, self-care adherence and medication use were assessed during home nurse visits.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two participants were lost to follow-up in the telephone group (which was not included in the analysis)
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Kashem 2008**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> New York Heart Association (NYHA) class 2, 3 or 4 heart failure (HF), at least one HF re-admission within the past 6 months, telephone and Internet access, be able to read and write, and know basic skills of computer use and Internet navigation.</p> <p><b>Exclusion criteria:</b> unstable angina, significant cognitive deficits from stroke or dementia, dialysis or end-stage renal disease, planned discharge to nursing home, boarding on care facility, anticipated survival of less than 6 months, and unable to use scale, pedometer, and digital sphygmomanometer.</p> <p><b>Method of patient recruitment:</b> patients with HF attending the HF practice at Temple University Medical Center were invited to participate.</p> <p><b>Study sample calculation:</b> population size was calculated based on an expected reduction in total hospital days of 50% in the TM group compared with controls.</p> <p><b>Data collection:</b> outpatient charts were reviewed for all study patients and note was made of hospital admissions, emergency department visits, scheduled and unscheduled office visits, and telephone encounters.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 75</p> <p><b>No of patients randomised to groups:</b> n = 48 Intervention: n = 24; Control: n = 24</p> <p><b>No of patients lost to follow-up:</b> no information</p> <p><b>Patient baseline characteristics:</b></p>

**Kashem 2008** (Continued)

- a) Clinical condition: advanced HF
- b) Age, mean (SD): Intervention:54 (10); Control: 53 (11)
- Weight (lb): Intervention: 202 ± 48; Control:206 ± 67
- BMI (kg/m<sup>2</sup>): Intervention:30 ± 7 ; Control:32 ± 13
- c) Gender: Female (%): Intervention: 27%; Control: 23%
- d) Ethnicity: Caucasians (%): Intervention: 61%; Control: 71%
- e) Severity of condition:
- NYHA class
- Class II: Intervention:42%; Control:43%
- Class III: Intervention:58%; Control:52%
- Class IV: Intervention:0%; Control:5%
- Ejection fraction (%): Intervention:25 ± 3; Control:26 ± 3
- f) Major co-morbidities:no information

**Setting** (hospital/community/residential care): one HF practice at Temple University Medical Center

**Location** (rural/urban etc.): urban

**Country:** USA

**Interventions**

**Study objective:** to test an Internet-based store-and-retrieval TM system to communicate between patients and their healthcare provider which provides frequent surveillance of the health status of the patient with HF

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (Internet-based with automatic replies or when needed tailored messages)

**Delivery of intervention:** all patients were given a sphygmomanometer and a pedometer, and were instructed on their use. The patients recorded their blood pressure, body weight, and total number of steps/day in a logbook. Each patient was instructed in how to use the TM system. The system presents to the patient several web screens (messages, input information, medications, laboratory values, and education).The input web screens prompt data entries of weight obtained with a scale, steps per day with a pedometer, blood pressure and heart rate obtained with a personal sphygmomanometer, a short questionnaire regarding any changes in current symptoms, and a text entry box used for unstructured comments.The patient can review their data by trend charts and numerical tables displayed on the computer screen. Because the TM system was constructed for maintenance care and not for emergency care, patients were instructed to either call the practice-on-call number or report to the nearest hospital of they needed urgent or emergency care. The patient made a first time data entry with coaching by the study nurse. A second data transmission without coaching followed shortly, but with observation by the study nurse. The patient was then instructed to send a dataset from home within two days. Blood pressure, pulse, steps per day, and weight together with symptoms were entered. The most recent laboratory data was entered by the practice, and the patient was instructed to review the laboratory values and transmit any questions to the practice.

The provider (physician or nurse) logs in with a user ID and password. The provider domain presents a different screen set (patient review, message log, medications, laboratory data). To facilitate rapid patient status review data for 10-15 patients are presented simultaneously on the screen. The patient data are colour coded red if values are outside of pre-set values for that patient. For example, if the patient's blood pressure is above guidelines, This value is in red and a flag symbol appears with the patient menu. Two response buttons are on the provider screen, 'ok' and 'send message'. The 'ok' button sends a short message to the patient stating that his/her measures are acceptable. The send mes-

## Kashem 2008 (Continued)

sage button allows the healthcare provider to send a text message to the patients. The provider screen contains the links to trend graphs and laboratory data. These allows the provider to obtain a quick overview of the patient's general health status.

**Type of technology and its application:** The TM system (Insight Telehealth Systems (ITS) Valley Forge, PA) is a disease management interactive healthcare delivery system comprising a secure Internet server and a database with web-based access by patients and providers. This system provides Internet access to a Clinical Status database for multiple patients. The server contains the Clinical Status database linked to a browser interface.

This arrangement allows patients to send data directly to the database via the Internet, and to receive data for disease management from the database. The web-site is divided into patient and provider domains. Each in accessible only by secure log on. All information transfer us accomplished via a secure server using the Lasso (OmniPilot, Dania Beach, FL) Web data engine.

**Did the patient receive education about their condition?** All patients were recruited from our clinical HF centre, and had completed their initial encounter with a physician, education by the nursing team, initial clinical testing and therapy. Care strategy was discussed among the HF team, and the patient was educated on dietary and other aspects of HF. A therapeutic and diagnostic plan was also established and implemented.

**Frequency of patient data transfer (monitoring studies only):** 3 times per week

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned real-time contacts

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: An advanced HF nurse was dedicated to reviewing HF patient information and was responsible for communicating with the patients through the website.

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): HF nurse usually answered the HF patient messages using Internet- based text messaging. The study nurse talked to the patients in the Internet and UC groups by telephone when status was in doubt or when instructions were complicated enough that verification of understanding was needed.

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): usually within a day

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): The information sent to the patient was intended to adjust the patient's general health status to maintain a stable HF state. The healthcare provider transmits instructions to the patient that can include medication or dietary changes, or instructions to call or visit the office.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physician; nurses

**Duration of intervention:**12 months

**Comparison intervention:** All patients received the present standard care provided by our advanced HF and cardiomyopathy program, care was guideline based with tailored medication therapy based on the patient's clinical status, co-morbidities, drug tolerance, age and ethnic background. All patients were given a digital sphygmomanometer, a pedometer and a scale.

### Outcomes

#### Primary outcome:

- Total hospitalisations at 1 year

#### Secondary outcomes:

- Total clinic telephone calls
- Scheduled clinic visits
- Unscheduled clinic visits
- Emergency department visits

## Kashem 2008 (Continued)

- Hospital days stayed (for HF)
- Hospital days stayed (all causes)
- Mortality

**Follow-up time:** 12 months after randomisation

### Notes

**Ethical approval and informed consent obtained (yes/no):** unclear whether or not approval was obtained from the ethic's committee

**Sources of funding:** National Institutes of Health grant no.HL065073.

**Conflict of interest:** Alfred A Bove, M.D., PhD., is a consultant for InSight Telehealth, Inc. William P Santamore, PhD., owns stock in InSight TeleHealth, Inc.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	See p.123. Col.1, Para 1.  QUOTE:  "Our statistician created a blinded randomisation chart that was opened on the day of enrolment for every patient. Patients who consented to be in the study were assigned a randomisation number at the time of enrolment, and the number was matched to the randomisation table provided by our statistician to determine their group assignment."
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	In both groups, the average body mass index (BMI) was >30 and left ventricular ejection fraction was depressed. Systolic and diastolic blood pressures were not significantly different between the groups (Table 1).
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The health professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, outcomes of healthcare resource use, length of stay and mortality were objective. Outpatient charts were reviewed for all study patients and note was made of hospital admissions, emergency department visits, scheduled and unscheduled office visits, and telephone encounters.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information in text or tables.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias

## Kearney 2009

Methods	<p><b>Study design:</b> RCT (by 5 time points (baseline, pre-cycle 2, pre-cycle 3, pre-cycle 4 and pre-cycle 5)</p> <p><b>Inclusion criteria:</b> A diagnosis of breast, lung or colorectal cancer; commencing a 'new' course of chemotherapy treatment (defined as those patients commencing a new chemotherapy regimen irrespective of stage of disease or line of treatment); receiving out-patient chemotherapy; aged 18 years or over; written informed consent given; able to read and write English and deemed by members of the clinical team as being physically and psychologically fit to participate in the study.</p> <p><b>Exclusion criteria:</b> Patients who were unable to meet the inclusion criteria and who did not agree to give access to their case records.</p> <p><b>Method of patient recruitment:</b> Patients were recruited between March 2006 and September 2006 from 7 clinical out-patient clinics throughout the UK (6 Scotland/1 England).</p> <p><b>Study sample calculation:</b> The study aimed to randomise a total of 150 patients in equal proportion to the two randomised groups (75 in each group), giving approximately 85% power at a 5% level of significance to detect a difference in any of the six individual mean symptom scores between the mobile phone and the control groups of 0.5 standard deviations (SD) (an effect size of 0.50). For the binary outcomes of occurrence of the symptoms and taking the most variable case of an incidence of 50%, the study would have 85% power to detect a halving of this incidence to 25%.</p> <p><b>Data collection:</b> All patients were asked to complete a paper version of the electric symptom questionnaire at their pre-chemotherapy assessment (baseline) and before chemotherapy cycles 2,3,4, and 5. This was completed by both groups at their clinic visit prior to administration of chemotherapy.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> NA</p> <p><b>No of patients in groups:</b> n = 112; Intervention: n = 56; Control: n = 56</p> <p><b>No of patients lost to follow-up:</b> 1 withdrew prior to contributing data, 3 died prior to data collection, 2 withdrew because they did not like their mobile phone. Follow-up at end of 4th cycle n = 29/56 (52%) in the intervention group and n = 29/56 (52%) patients in the control group contributed data.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: Patients with breast, lung or colorectal cancer receiving outpatient chemotherapy,</li> <li>b) Age, mean (SD): Intervention:55.1 (10.6) years; Control: 56.9 (10.5) years</li> <li>c) Gender, n(%): Intervention:Male:15 (26.8); Female: 41(76.3); Control: Male: 11 (19.6); Female:45 (80.4)</li> <li>d) Ethnicity: NA</li> <li>e) Severity of condition:</li> </ul> <p>Tumour type n (%):</p> <ul style="list-style-type: none"> <li>Breast: Intervention:34 (60.7) Control:36 (64.3)</li> <li>Lung: Intervention:13 (23.2); Control:13 (23.2)</li> <li>Colorectal: Intervention:9 (16.1); Control:7 (12.5)</li> </ul> <ul style="list-style-type: none"> <li>f) Major co-morbidities:NA</li> </ul> <p><b>Setting</b> (hospital/community/residential care): five specialist cancer centres and two local district hospitals</p> <p><b>Location</b> (rural/urban etc.): unclear; 6 sites in Scotland and one in England</p> <p><b>Country:</b> Scotland and England</p>

## Kearney 2009 (Continued)

### Interventions

**Study objective:** To evaluate the impact of a mobile phone-based, remote monitoring, advanced symptom management system (ASyMS) on the incidence, severity and distress of six chemotherapy related symptoms (nausea, vomiting, fatigue, mucositis, hand foot syndrome, diarrhoea) in patients with lung, breast or colorectal cancer.

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of the intervention:** Patients transferred symptom scores twice daily to clinic via a mobile, phone based remote monitoring advanced symptom management system (ASyMS<sup>®</sup>) throughout 4 cycles of chemotherapy, and received appropriate automated feedback in addition to UC. The participants' clinicians, were alerted via a dedicated 24-hour pager system, of any incoming symptom reports that were considered to be clinically important, and were advised to contact patients within one hour of receipt of a red alert. In the event of either amber or a red alert, study clinicians could access secure web pages to view the patients' symptom reports to assist their clinical decision making. The nurses received training by the study team on how to use ASyMS system. Patients were trained on how to use the system by nurses working in their local area who had received training by the study team on how to use ASyMS system.

**Type of technology and its application:** Patients in the intervention group used a mobile phone-based remote monitoring advanced symptom management system (ASyMS<sup>®</sup>) throughout 4 cycles of chemotherapy. As ASyMS was developed to complement standard care, patients using the system were also advised to follow procedures and guidelines related to the monitoring and reporting of chemotherapy related toxicity in their local area. On days 1-14, in the morning, evening and at any time they felt unwell, patients randomised to the ASyMS mobile phone group were asked to complete a symptom questionnaire that integrated the Common Toxicity Criteria Adverse Events (CTCAE) grading system and the Chemotherapy Symptom Assessment Scale. The symptom information was immediately sent in 'real-time' via secure General Packet Radio Services (GPRS) connections to the study server. After completing the electronic symptom questionnaire, patients immediately received written feedback on the mobile phone interface, comprising of tailored self-care advice directly related to the severity of the symptoms they had just reported. This included simple instructions which patients could use to manage their symptoms including advice on pharmacological use, the use of distraction and relaxation techniques and dietary advice where appropriate. An evidence-based risk assessment tool was integrated into the ASyMS server software. This alerted participants' clinicians, via a dedicated 24 hour pager system, of any incoming symptom reports that were considered to be clinically important. An 'amber alert' was used to indicate to clinicians that a patient was experiencing toxicities at home that were not severe or life-threatening but in which early intervention might prevent further symptom progression. This included combinations of mild or moderate symptom reports which resulted in significant symptom burden or for symptoms which were moderate in severity but had persisted over a period of 48-72 hours. A 'red alert' was used to indicate to clinicians that a patient was pyrexial and/or experiencing severe toxicities at home (for example severe diarrhoea). Clinicians were advised to contact patients within one hour of receipt of a red alert. In the event of either amber or a red alert, study clinicians could access secure web pages to view the patients' symptom reports to assist their clinical decision making.

**Did the patient receive education about their condition?** They received written information as well as verbal information from the nurses administering chemotherapy.

**Frequency of patient data transfer (monitoring studies only):** 2 times/day or more if unwell (for the first 14 days)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned contacts

**Clinician response to receipt of data:**

a) Who contacts the patient?: The physician contacts the patient if the transferred data triggers a 'red alert'; unclear what happens in case of an 'amber alert'

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): NA



**Kearney 2009** (Continued)

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): at the latest one hour after a 'red alert' (unclear timing in case of an 'amber alert')

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): symptom management

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians

**Duration of intervention:** 12 to 16 weeks

**Comparison intervention:** Patients in the control group received standard care following guidelines and procedures related to the monitoring and reporting of chemotherapy related toxicity in their local area. This included written information as well as verbal information from the nurses administering chemotherapy.

Outcomes	<b>Primary outcome:</b> <ul style="list-style-type: none"><li>• Symptoms of chemotherapy related toxicity</li></ul> <b>Follow-up time:</b> after each of 5 pre-cycles of chemotherapy	
Notes	<b>Ethic's committee approval and informed consent obtained:</b> yes <b>Sources of funding:</b> Stirling University Research Enterprise <b>Conflict of interest:</b> NA	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	See. P.418, Col.2, Para 4  QUOTE:  "One hundred and twelve patients were randomised using an automated Interactive Voice Response system (IVR) telephone randomisation at the Centre for Healthcare Randomised Trials Health Services Research Unit, University of Aberdeen. The randomisation used a minimisation algorithm based on centre and tumour type."
Allocation concealment (selection bias)	Low risk	See. P.418, Col.2, Para 4  A centralised randomisation scheme was used (see quote above)
Were baseline outcome measurements similar?	Unclear risk	Baseline symptom data not reported.
Were baseline characteristics similar?	Low risk	see p.441, Col 1, para 1  QUOTE:  "At baseline both groups were similar (see Table 1) with more women than men recruited as breast cancer was the most common tumour type."
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professional delivering the intervention could not be blinded to the group assignment of patients, and neither could the patients. All outcomes were based on patients' self-report of toxicity, but these were automatically assessed through the system.
Incomplete outcome data (attrition bias)	High risk	see p.441, Fig.2

**Kearney 2009** (Continued)

## All outcomes

Only half of the patients remained in the study at the end of follow-up, but equally many were lost in both groups. Analysis was based on intention-to-treat.

Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.
Other bias	Low risk	No evidence of other risk of bias.

**Kim 2007**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> participants able to perform blood glucose self-testing and self-injection of medication, access websites and who have their own cellular phone</p> <p><b>Exclusion criteria:</b> a clinical history of severe illness, renal insufficiency with a creatinine level &gt; 0.08 mmol/L or had been using insulin pumps.</p> <p><b>Method of patient recruitment:</b> Patients were recruited from the endocrinology outpatient department of a tertiary care hospital located in an urban city of South Korea.</p> <p><b>Study sample calculation:</b> For repeated measures analysis of variance (for an effect size of 0.60, at a power of 0.80 and at an alpha level of 0.05), 25 participants in each group were required in order to ensure an adequate trial for 1% reduction of HbA1c levels at post-test compared with pre-test (Machin et al., 1997).</p> <p><b>Data collection:</b> HbA1c, FPG and 2HPMG levels were measured in a laboratory at the university-affiliated medical centre. HbA1c levels were determined using a high-performance liquid chromatography technique using Variant II (Bio-Rad, Montreal, Que., Canada). FPG and 2HPMG levels were analysed by the glucose oxidase method using a Hitachi 7600 (Hitachi, Hitachi, Japan)</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 60; Intervention: n = 30; Control: n = 30</p> <p><b>No of patients lost to follow-up:</b> n = 5 participants in the intervention group did not record their glucose levels for more than 4 weeks, and n = 4 participants were lost before completing the post-test in the control group: one moved to another city and three decided to opt out of the programme before completing the post-test.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: Type II diabetes</li> <li>b) Age, years, SD, IQR: Intervention: 46.8 ± 8.8 (43.2, 50.5); Control: 47.5 ± 9.1 (43.8, 51.2)</li> <li>c) Gender, male/female: Intervention: 11/14; Control: 11/15</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition: Diabetes duration, years: Intervention: 5.2 ± 5.9 (2.6, 7.8); Control: 8.0 ± 4.9 (5.9, 10.1)</li> <li>f) Major co-morbidities: patients were excluded if they had other severe illnesses)</li> </ul> <p><b>Setting</b> (hospital/community/residential care): one outpatient department</p> <p><b>Location</b> (rural/urban etc.): urban</p>

Kim 2007 (Continued)

Country: South Korea

## Interventions

**Study objective:** To investigate the effectiveness of an educational intervention that used both the cellular phone and the Internet to provide a short messaging service (SMS) relating to plasma glucose levels.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** Remote monitoring (+Education)

**Delivery of intervention:** Patients contacted a website and logged in whenever it was convenient for them. They then sent their self-monitored blood glucose levels and drug information, including the kinds and dosages of insulin and oral anti-diabetic medication that they used for diabetes control. This data were transported to an Internet server system, and automatically displayed on the individual electronic chart on a homepage. Patients were able to see the recommendations from their nurses and physicians, as well as the laboratory data. The researcher could view the information on each patient, including the blood glucose levels, medication and details on some events that were provided by the patient. In addition to this information, a nurse could also view basic personal history, including historical data, family history, smoking habits, BMI, BP and baseline laboratory data.

After the integration of this information the nurse sent optimal recommendations to each patient, weekly by an SMS, a cellular phone or wired Internet. The intervention thus consisted of continuous education and reinforcement of diet, exercise, medication adjustment, as well as frequent self-monitoring of glucose levels. The researcher (a professor at a nursing college) could adjust medications after reviewing the blood glucose log and discussing glucose values with the patients. All medication adjustments were communicated to the participant's diabetes doctors. Before the intervention, each patient was instructed, for 30 minutes by a researcher, about inputting data into the website.

**Type of technology and its application:** SMS, cellular phone or wired Internet.

**Did the patient receive education about their condition?** Yes, as part of the intervention

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** weekly feedback (no real-time contacts)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): by an SMS, a cellular phone or wired Internet
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): reviewed in a week
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): continuous education and reinforcement of diet, exercise, medication adjustment

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse, a researcher (professor at a nursing college)

**Duration of intervention:** 6 months

**Comparison intervention:** Participants in the control group met the endocrinologist specialist once or twice during the 12 weeks. The control patients were provided with recommendations about medication, medication dosage and lifestyle modification by the endocrinologist specialist when visiting the diabetes centre. When the doctor chose to consult with the patient to disclose particular information, or if the patient wished, the nurse or dietician came to aid with more individualised and detailed information relating to lifestyle modification,

## Outcomes

Primary outcomes:

Interactive telemedicine: effects on professional practice and health care outcomes (Review)

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## Kim 2007 (Continued)

- HbA1c
- FBG - fasting blood glucose
- 2HPMG- two hours post meal glucose

**Follow-up time:** 3 and 6 months from randomisation

Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> This work was supported by the Korea Research Grant funded by the Korean Government (MOEHRD) (KRF-2005-015-E00232).</p> <p><b>Conflict of interest:</b> No information.</p>
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## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>See p.688, Col.2, last paragraph</p> <p>QUOTE:</p> <p>"They were randomised by random, permuted block design using a random number table, and assigned to one of two groups.."</p>
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	No differences in baseline outcome measures between groups.
Were baseline characteristics similar?	Low risk	<p>See.p.689,Col2, last para, and p.690, Col.1, Para1</p> <p>QUOTE:</p> <p>"There was no significant difference in age, gender, BMI, duration of diabetes, treatment method or blood glucose levels between the two groups."</p>
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p><b>Outcome group:HbA1c, fasting blood glucose, two hours post meal glucose</b></p> <p>The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, all outcomes were objective and assessed at laboratory using reliable methods..</p>
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>A similar number of participants were lost from each group.</p> <p>See.p.689, Col.1, Para.1</p> <p>QUOTE:</p> <p>"Only 51 subjects completed the entire study: 25 intervention patients and 26 control patients. Five subjects did not record their glucose levels for more than 4 weeks on the website in the intervention group. In addition, four subjects were lost before completing the post-test in the control group: one moved to another city and three decided to opt out of the programme before completing the post test."</p>
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## King 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients being advanced to a more intensive treatment schedule because of a partial and poor response to lower steps of care, self-reported access to a computer with Internet connection, and agreeing to random assignment to one of the two service delivery options for the intensified services.</p> <p><b>Exclusion criteria:</b> no information</p> <p><b>Method of patient recruitment:</b> no information</p> <p><b>Study sample calculation:</b> no information</p> <p><b>Data collection:</b> Participants completed a Patient Satisfaction Survey at the end of the study, it is not clear if this was validated.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> A total of n = 50 outpatients in the Addiction Treatment Services (ATS) program in Baltimore, MD, were enrolled in the study: 37 were ultimately randomised to study conditions. Approximately 20 % of the patients approached for the study reported having access to a computer with Internet connection.</p> <p><b>No of patients randomised to groups:</b> n = 37; Intervention: n = 20; Control: n = 17</p> <p><b>No of patients lost to follow-up:</b> N = 13 (26%) were withdrawn from the study for the following reasons: failure to have a working computer in their home (n = 2); (b) recurrent problems establishing Internet connection with the e-Getgoing website (n = 2); (c) and non-adherence to the initial 'registration' process necessary to gain access to the Internet site, despite repeated opportunities (n = 9).</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: substance abuse</li> <li>b) Mean age (years): Intervention: 42.7; Control: 41.4</li> <li>c) Gender: Female sex (%): Intervention: 65%; Control: 47%</li> <li>d) Ethnicity: Minority (%): Intervention: 40%; Control: 41%</li> <li>e) Severity of condition: N/A</li> <li>f) Major co-morbidities: no information</li> </ul> <p><b>Setting</b> (hospital/community/residential care): outpatients in the Addiction Treatment Services (community care)</p> <p><b>Location</b> (rural/urban etc.): urban (Baltimore)</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b> to assess treatment satisfaction and response to Internet-based (CRC Health Group's e-Getgoing) group counselling for partial responders to methadone maintenance treatment</p> <p><b>Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> video-conference (treatment)</p> <p><b>Delivery of intervention:</b> The TM patients received 2 video-sessions per week for 6 weeks (12 in total).</p> <p><b>Type of technology and its application:</b> E-Getgoing is a Joint commission and Commission on Accreditation of Rehabilitation Facilities accredited, Internet-based video-conference platform that was specifically developed to deliver verbal-and visual-based therapy to people with substance abuse.</p>

King 2009 (Continued)

**Did the patient receive education about their condition?** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 12 treatment sessions

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** unknown number of psychotherapists

**Duration of intervention:** 6 weeks

**Comparison intervention:** Participants received daily methadone and were required to attend weekly individual counselling with their primary counsellor. Participants were also required to submit one observed urine sample per week on a random schedule: urine samples were tested for opioids, cocaine, benzodiazepines, amphetamine, and cannabis.

Outcomes	Primary outcomes: <ul style="list-style-type: none"><li>• Counseling adherence</li><li>• Response to treatment (drug use assessed by urine samples)</li><li>• Step completion</li><li>• Treatment satisfaction (assessed with a non-validated questionnaire)</li></ul> <b>Follow-up time:</b> 6 weeks from recruitment	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes  <b>Sources of funding:</b> partially supported by a contract between CRC-Health Group and Institutes for Behavior Resources, Inc.  <b>Conflict of interest:</b> No information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.332, Col.2, Para 2 No differences reported.

## King 2009 (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blind- ed to the group allocation, and neither could the patients. However, all main outcomes (response to treatment, adherence and completion of programme) were objective.
Incomplete outcome data (attrition bias) All outcomes	High risk	N = 13 out of 20 intervention patients (65%) were withdrawn from the study for the following reasons: failure to have a working computer in their home (n = 2); (b) recurrent problems establishing Internet connection with the e-Getgoing website (n = 2); (c) and non-adherence to the initial 'registration' process nec- essary to gain access to the Internet site, despite repeated opportunities (n = 9). All control participants remained in the study at follow-up .
Selective reporting (re- porting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Koehler 2011

Methods	<b>Study design:</b> RCT  <b>Inclusion criteria:</b> 1. Ambulatory congestive heart failure (CHF) NYHA II or III; 2. Left ventricular ejec- tion fraction (LVEF) $\leq 35\%$ and cardiac decompensation with hospitalisation for heart failure (HF) or therapy with intravenous diuretics ( $> 40$ mg furosemide/day) within 24 months prior to enrolment or LVEF $\leq 25\%$ , measured twice within past 6 months; 3. Optimal medical treatment for CHF (b-blocker, ACE-inhibitor/ ARB, diuretics) including implantable cardioverter defibrillator/cardiac resynchronisa- tion therapy (ICD/CRT), if indicated;  4. Age $\geq 18$ years; 5. Informed consent  <b>Exclusion criteria:</b> 1.Existence of any disease (HF excluded) reducing life expectancy to less than 1 year; 2. Insufficient compliance to tele-monitoring or study visits; 3. Impairment to use the tele-mon- itoring equipment or appear to study visits (e.g. dementia, impaired self-determination, lacking abil- ity to communicate); 4. Pregnancy; 5. Concurrent participation in other therapy trials; 6. Hospitalisa- tion for cardiac decompensation within 7 days before inclusion in trial; 7. Implanted cardiac assist sys- tem; 8. Unstable angina pectoris; 9. Congenital heart defect; 10. Primary heart valve disease; 11. Hyper- trophic or restrictive cardiomyopathy; 12. Arrhythmogenic right ventricular cardiomyopathy; 13. Acute myocarditis diagnosis ,1 year; 14. Actively listed for heart transplantation; 15. Planned revascularisa- tion or CRT implantation; 16. Chronic renal insufficiency with creatinine $>2.5$ mg/dl; 17. Liver cirrhosis; 18. Known alcohol or drug abuse  <b>Method of patient recruitment:</b> between January 10, 2008, and June 22, 2009, 710 eligible patients with chronic HF were enrolled from 165 cardiology, internal medicine, or general medicine practices  <b>Study sample calculation:</b> The initial sample size of 600 patients (300 patients per study group) had a 90% power to detect a hazard ratio of 0.59 at a 2-sided type I error level of 0.05.5 Following a recom- mendation by the Data Safety Monitoring Board at the end of 2008, the sample size was increased to 710 patients (355 patients per study group), and the follow-up was extended by 12 months because, at that time, there was a lower than anticipated event rate after 1 year of follow-up.  <b>Data collection:</b> a quality control system to ensure the accurate and complete reporting of hospitalisa- tions.was used.  <b>Unit of analysis issues:</b> (yes/no):no	
Participants	<b>Total no of eligible patients:</b> no information  <b>No of patients randomised to groups:</b> n = 710; Intervention: n = 354; Control: n = 356	



**Koehler 2011** (Continued)

**No of patients lost to follow-up:** Four participants from each group were lost to follow-up.

**Patient baseline characteristics:**

- a) Clinical condition: heart failure
- b) Age (years), mean, (SD): TM: 66.9 (10.8); UC: 66.9 (10.5)
- c) Gender, male sex, no. (%) : TM:285 (80.5); UC: 292 (82.0);
- d) Ethnicity: no information
- e) Severity of condition:  
NYHA class, no. (%)  
II: TM: 176 (49.7); UC: 180 (50.6)  
III : TM:178 (50.3); UC: 176 (49.4)  
LVEF, %: TM:26.9(5.7); UC: 27.0 (5.9)  
Duration of HF, years: TM:6.7(6.6); UC: 6.8 (6.4)  
Ischaemic cause of HF, No. (%): TM:202 (57.1; UC:) 194 (54.5)
- f) Other characteristics  
Living alone, no. (%): TM: 75 (21.2); UC: 77 (21.6)  
Body weight, kg: TM: 84.7(18.9); UC: 84.7 (18.3)  
Body mass index, kg/m<sup>2</sup>\*: TM: 28.4 (5.4); UC: 28.2 (5.3)  
Blood pressure, mm Hg  
Systolic: TM: 121 (16 ); UC:122 (17)  
Diastolic: TM: 74 (10); UC: 74 (10)
- f) Major co-morbidities:  
Hypertension: TM: 241 (68.1); UC: 235 (66.0)  
Hyperlipidemia : TM:262 (74.0); UC: 266 (74.7)  
Diabetes mellitus:TM: 141 (39.8); UC: 140 (39.3)

**Setting** (hospital/community/residential care):165 cardiology, internal medicine, or general medicine practices

**Location** (rural/urban etc.): no information

**Country:** Germany

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Interventions

**Study objective:**to determine whether physician-led remote telemedical management (RTM) compared with UC would result in reduced mortality in ambulatory patients with CHF.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (as an alternative to UC)

**Delivery of intervention:** the patient performed a daily self-assessment with these devices, and the data were transferred to the responsible telemedical centre. Data privacy was ensured with dynamic encryption.The RTM equipment was installed, and training was given to patients within a maximum of 5 working days after randomisation.The 2 telemedical centres provided physician-led medical support 24 hours per day, 7 days per week for the entire study period with the use of standard operating procedures. The patient was contacted by the telemedical centre physician in accordance with the standard

## Koehler 2011 (Continued)

operating procedures in place or when requested by the patient to verify measurements, to give consultation, or to institute treatment. The telemedical centre contacted the patient's local physician at least every 3 months. The general responsibility for the patient's care remained with the local physician

**Type of technology and its application:** the TM system is based on a wireless Bluetooth device, together with a personal digital assistant, as the central structural element (Figure 2). Data transfer was performed with the use of cell phone technologies. The following devices were part of the integrated sensor network: a 3-lead ECG, a blood pressure device, and a weighing scale with 50-g precision.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The telemedical centre physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): no information
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): in accordance with the standard operating procedures in place or when requested by the patient
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to verify measurements, to give consultation, or to institute treatment

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians

**Duration of intervention:** 12 months

**Comparison intervention** (e.g. face-to-face, telephone, none): Patients assigned to the UC group were followed and treated in the same manner as patients assigned to RTM. At the study start, all investigators were instructed to treat patients in accordance with the current guidelines for the management of HF, irrespective of group assignment.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Death from any cause</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Composite of cardiovascular death and hospitalisation for HF</li> <li>• Days lost because of death or Clinical End Point Committee–adjudicated HF hospitalisation,</li> <li>• Duration of hospitalisation for HF,</li> <li>• Rate of hospitalisation for a cardiovascular reason</li> <li>• Rate of hospitalisation for HF</li> <li>• NYHA functional classification (no numerical data provided by authors)</li> <li>• Physical functioning (assessed with SF-36 physical functioning score; no total scores reported)</li> <li>• Depression (assessed with PHQ-9 depression score) (no numerical data provided by authors)</li> </ul> <p><b>Follow-up time:</b> median 26 months follow-up (minimum 12 months)</p>
Notes	<p><b>Ethical approval and informed consent obtained(yes/no):</b> yes</p> <p><b>Sources of funding:</b> The technology development as well as the clinical trial was funded in a public–private partnership through a research grant of the German Federal Ministry of Economics and Technology (01MG531) and by the following companies: Robert Bosch Healthcare GmbH, Waiblingen, Germany; InterComponentWare AG, Walldorf, Germany; and Aipermon GmbH &amp; Co KG, Munich, Germany.</p>

## Koehler 2011 (Continued)

**Conflicts of interest:** Dr Anker is a consultant for Robert Bosch Healthcare GmbH, Thermo Fisher Scientific Germany, and St. Jude Medical GmbH, and received honoraria for speaking from Thermo Fisher Scientific Germany and St. Jude Medical GmbH. The other authors report no disclosures.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p. Col. Para.  QUOTE:  "Eligible patients were then randomly assigned in a 1:1 ratio to receive either RTM or UC. As described previously, Pocock's minimization algorithm, with 20% residual randomness, was used to ensure balance of important clinical characteristics."
Allocation concealment (selection bias)	Low risk	see above
Were baseline outcome measurements similar?	Unclear risk	No baseline measures of outcomes.
Were baseline characteristics similar?	Low risk	Baseline characteristics were similar between the RTM (n354) and control (n356) groups
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective outcomes mortality and resource use.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	New York Heart Association functional classification; physical functioning and depression (assessed with validated scales). Patient-reported and physician-assessed outcomes may be at risk of bias in unblinded trials.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Four participants from each group were lost to follow-up.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol were reported in the FT.
Other bias	Low risk	No other risk of bias identified.

## Koff 2009

### Methods

**Study design:** RCT

**Inclusion criteria:** GOLD stage 3 or 4 COPD; and a telephone land line.

**Exclusion criteria:** active treatment for lung cancer; illiteracy; non-English speaking; and inability to complete a 6-minute walk distance (6MWD) test.

**Method of patient recruitment:** Patients were recruited from the chronic obstructive pulmonary disease (COPD) clinic and the general pulmonary clinic at the University of Colorado Hospital (Aurora, CO, USA) between November 2004 and June 2005. Method not further described.

**Koff 2009** (Continued)

**Study sample calculation:** The study sample size was estimated using data from BOURBEAU et al. [14]. The current authors estimated that 20 patients per group would be necessary to have a 90% chance of seeing a 2.0 unit improvement in the St George's Respiratory Questionnaire (SGRQ) with an SD of 1.9 and an  $\alpha$  of 0.05.

**Data collection:** The SGRQ was administered to both groups at baseline and after 3 months. The healthcare resource use was based on patients self-report (but checked against hospital records).

**Unit of analysis issues:** (yes/no): no

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**Participants**

**Total no of eligible patients:** NA

**No of patients randomised to groups:** n = 40; Intervention: n = 20; Control: n = 20

**No of patients lost to follow-up:** two patients, one in each group, were lost to follow-up

**Patient baseline characteristics:**

a) Clinical condition: COPD

b) Age, mean  $\pm$  SD: Intervention: 66.6  $\pm$  9.1 years; Control: 65.0  $\pm$  8.2 years

c) Gender, female sex (%) ; Intervention: 55; Control: 50

d) Ethnicity, no whites: Intervention: n = 17 ; Control: n = 19

e) Severity of condition:

FEV1 % pred: Intervention: 33.6  $\pm$  9.1; Control: 31.1  $\pm$  10.2

Long-term oxygen therapy %: Intervention: 95; Control: 95

Resting oxygen saturation %: Intervention: 92.5  $\pm$  2.6; Control: 93.2  $\pm$  2.5

f) Major co-morbidities: NA

**Setting** (hospital/community/residential care): one pulmonary clinic at University hospital (acute setting)

**Location** (rural/urban etc.): Colorado

**Country:** USA

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**Interventions**

**Study objective:** To determine whether integration of self-management education with proactive remote disease monitoring would improve health-related outcomes in COPD patients.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (self-management education)

**Delivery of intervention:** Patients were remotely monitored Monday to Friday for changes in symptoms, oxygen saturation, forced expiratory volume in one second (FEV1), and steps in a 6MWD test. The system pulls the monitored parameters to the databank by the silent phone call each night. The study coordinator reviewed the results of these sessions the following morning. Health Buddy System algorithms segregated patients into three groups, based on their daily responses to symptom-based questions, medication compliance and monitored parameters. Each day the study co-ordinator viewed patient names that were colour-coded according to their risk, where green indicated stability, yellow indicated caution and red indicated a potential change in health status. The study co-ordinator then called all patients with red flags and used discretion for patients who had persistent red flags or yellow flags.

**Type of technology and its application:** A small telecommunication device (Health Buddy System), that connects directly to a home telephone, with an interactive dialogue reinforcing disease-specific education (and monitoring) on a daily basis.

**Did the patients receive education about their condition?** Yes, as part of the intervention.

**Koff 2009** (Continued)

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** only one planned

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The healthcare provider
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week):next morning, during the work week
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):to facilitate the resolution of a clinical problem by calling the patients' primary care physician, or In the event of an important non-clinical problem,to help the patient make the appropriate contacts

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a registered respiratory therapist

**Duration of intervention:**3 months

**Comparison intervention:** Patients in the UC group received none of these interventions and continued on the treatment regimen prescribed by their healthcare provider. Specifically, the coordinator made no effort to change any aspect of the patient's treatment regimen at enrolment.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• Quality of Life (assessed by the St George's Respiratory Questionnaire (SGRQ))</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Healthcare costs (included visits to clinics and the emergency room, hospitalisations, radiology services and other diagnostic tests, and blood tests)</li><li>• Identification of unreported exacerbations</li></ul> <p><b>Follow-up time:</b> 3 months</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> informed consent was obtained from patients, unclear if ethical approval was sought</p> <p><b>Sources of funding:</b>The University of Colorado Hospital supported the study financially and supported the salary of a member of staff for N.F. Voelkel. R.W. Vandivier has received funds for research, salary support and funds for a staff member from the University of Colorado Hospital.</p> <p><b>Conflict of interest:</b>A statement of interest for this study can be found at <a href="http://www.erj.ersjournal-s.com/misc/statements.dtl">www.erj.ersjournal-s.com/misc/statements.dtl</a>. Could not access the disclosure.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Low risk	p.1032, Col.2, Para. 2  QUOTE:  "Following informed consent, patients randomly selected their group assignment by choosing a blinded envelope that contained a group indicator."

**Koff 2009** (Continued)

Were baseline outcome measurements similar?	Low risk	See quote below
Were baseline characteristics similar?	Low risk	p.1034, Col.1, Para.4  QUOTE:  "Baseline characteristics of the groups were similar (table 2), including SGRQ (quality of life) and healthcare costs for the 12 weeks prior to initiation of the study (table 3)."
Blinding (performance bias and detection bias) - Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the intervention, and neither could the patients. However, objective outcomes of resource use and cost.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants and the personnel could not be blinded to the intervention, which may have affected the patient-reported outcome quality of life.
Incomplete outcome data (attrition bias) All outcomes	Low risk	One participant from each group was lost to follow-up.
Selective reporting (reporting bias)	High risk	Results for many outcomes listed in the trial protocol were not reported in the paper (i.e. guideline-based medical care, oxygen utilisation and pre/post exercise oxygen saturations, smoking status, exercise status measured by the 6 minute walk test, symptoms including cough, sputum production and dyspnoea, body mass index, obstruction, dyspnoea, exercise capacity (BODE) index and healthcare utilisation).
Other bias	Low risk	No evidence of other risk of bias.

**Kwon 2003**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> men and women diagnosed with type 2 diabetes for 1 year and &gt;30 years of age, with Internet access in their homes for this specialised web-based diabetes management system</p> <p><b>Exclusion criteria:</b> patients were excluded if they had any significant diseases that were likely to affect the outcome and compliance of this study. Such diseases or conditions included heart failure, hepatic dysfunction, renal insufficiency with a creatinine level 1.5 mg/dL, and use of insulin pumps. Patients who had any history of participating in other programs that provided any information or education for diabetes management from specific websites other than ours were also excluded.</p> <p><b>Method of patient recruitment:</b> through a bulletin board at the hospital.</p> <p><b>Study sample calculation:</b> the sample size was sufficient to provide a power of 80% to detect a 10% (absolute value 0.75%, estimated SD 1.0) change in HbA1c at the 5% level of significance, based on our previously unpublished data.</p> <p><b>Data collection:</b> HbA1c and other laboratory tests were performed twice, once at the beginning of the study and again at the end of the study.</p> <p><b>Unit of analysis issues:</b> no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 180, of which 70 were excluded of different reasons</p> <p><b>No of patients randomised to groups:</b> n = 110; Intervention: n = 55; Control: n = 55</p>

**Kwon 2003** (Continued)

**No of patients lost to follow-up:** Of 110 patients who participated in this study, 101 (91.8%) completed the final clinical examination. Four of the patients in the intervention group were lost to follow-up, two patients were withdrawn for not following the study protocol, and two more because they did not revisit the diabetes centre after 12 weeks. Five patients in the control group were excluded for not revisiting the diabetes centre.

**Patient baseline characteristics:**

a) Clinical condition: Type 2 diabetes

b) Age, mean years: Intervention: 53.5 (8.8); Control: 54.7 (9.4)

c) Gender, male/female sex: Intervention: 35/16; Control: 32/18

d) Ethnicity: no information

e) Severity of condition:

Diabetes duration (years): Intervention: 7.0 (6.3); Control: 6.6 (5.7)

BMI (kg/m<sup>2</sup>): Intervention: 24.4 (3.4); Control: 23.9 (3.1)

Systolic blood pressure (mmHg): Intervention: 124.7 (15.8); Control: 128.5 (17.0)

Diastolic blood pressure (mmHg): Intervention: 77.5 (8.7); Control: 77.0 (9.7)

HbA1c (%): Intervention: 7.59 (1.43); Control: 7.19 (1.17)

Fasting plasma glucose (mg/dl): Intervention: 136.0 (35.0); Control: 136.4 (32.3)

Total cholesterol (mg/dl): Intervention: 188.8 (30.10); Control: 180.9 (28.9)

Triglyceride (mg/dl): Intervention: 154.7 (98.1); Control: 136.8 (94.0)

HDL (mg/dl): Intervention: 47.7 (11.0); Control: 47.9 (13.2)

Blood urea nitrogen (mg/dL): Intervention: 15.2 (3.8); Control: 16.2 (5.2)

Creatinine (mg/dL): Intervention: 0.9 (0.2); Control: 0.9 (0.3)

f) Major co-morbidities:

Diagnosis of hypertension (n): Intervention: 17; Control: 13

**Setting** (hospital/community/residential care): one outpatient clinic of Kangnam St. Mary's Hospital Diabetes Center

**Location** (rural/urban etc.): no information

**Country:** South Korea

**Interventions**

**Study objective:** To investigate the effectiveness of an Internet-based blood glucose monitoring system (IBGMS) on controlling the changes in HbA1c levels.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (web-based, substituting for UC)

**Delivery of the intervention:** The patients sent information about their self-monitored blood glucose levels before and after eating (fasting and postprandial) and drug information including the types and dosages of insulin and oral antidiabetic medication used for diabetes control. In addition, when necessary, changes in their blood pressure or weight and any questions or detailed information the patient may have (for example, diet, exercise, hypoglycaemic event, or other factors that can cause changes in the glucose level) were also recorded.

For the TM group, two endocrinology fellows checked in with the system daily. They analysed all uploaded blood glucose data or questions regarding medication and hypoglycaemic episodes and sent recommendations to the patients in the intervention group according to the diabetes management guidelines based on "Korean Staged Diabetes Management Guidelines." But, we did not adopt any automated algorithm in this whole process of our study. If there was any need to change the patient's medication or dosage, the two endocrinology fellows referred the case to the professor. Three nurses mainly commented upon lifestyle modification, including exercise, and the two dietitians supplied indi-



**Kwon 2003** (Continued)

vidually modified medical nutrition therapy. All of the responses from the nurses and dietitians were also monitored by medical staff. The medical staff (two fellows and one professor) had meetings regularly to develop the appropriate individual recommendations.

**Type of technology and its application:** website (www.biodang.com)

**Did the patient receive education about their condition?:** Yes, as part of the intervention

**Frequency of patient data transfer (monitoring studies only):** at least once a week

**Planned /scheduled no of TM contacts between patient and healthcare professional:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: Both endocrinology fellow and nurses
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): Internet (through the patient's own individual chart system)
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): daily (no automated algorithm; no alerts); 2 endocrinology fellows checked in with the system daily.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to give optimal recommendations according to guidelines; If there was any need to change the patient's medication or dosage the fellows referred the case to the professor. Three nurses mainly commented upon lifestyle modification, including exercise, and the two dietitians supplied individually-modified medical nutrition therapy. All of the responses from the nurses and dietitians were also monitored by the medical staff.

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** two endocrinology fellows; three nurses

**Duration of the intervention:** 12 weeks

**Comparison intervention:** Participants in the control group met the professor two or three times during the 12 weeks. They were provided recommendations about medication, medication dosage, lifestyle modification, and so on from the endocrinology specialist (professor, not fellows). When the doctor chose to consult for special education or if the patient wished, the dietitian or nurse came to aid with a more individualised and detailed information for lifestyle modification.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>HbA1c</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Fasting blood glucose</li> <li>Triglycerides</li> <li>Total cholesterol</li> <li>LDL</li> <li>HDL cholesterol</li> </ul> <p><b>Follow-up time:</b> 12 weeks from randomisation</p>
Notes	<p><b>Ethic's committee approval and informed consent obtained:</b> yes</p> <p><b>Sources of funding:</b> 2001 Korea Health Promotion Research Program and the Korea Health 21 R&amp;D Project, Ministry of Health and Welfare of Republic of Korea Grant 02-PJ1-PG3- 21906-0004.</p> <p><b>Conflict of interest:</b> no information</p>
<b>Risk of bias</b>	

**Kwon 2003** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Adaptive randomisation.
Allocation concealment (selection bias)	Unclear risk	Not reported
Were baseline outcome measurements similar?	Low risk	There were no differences between the two groups with respect to laboratory data, including baseline HbA1c, fasting plasma glucose, total cholesterol, triglyceride, HDL, blood urea nitrogen, and creatinine.
Were baseline characteristics similar?	Low risk	There were no differences between the two groups with respect to age, BMI, diabetes duration, and glucose control methods or in terms of laboratory data, including baseline HbA1c, fasting plasma glucose, total cholesterol, triglyceride, and HDL.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	All outcomes are objective, and at low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 110 patients who participated in this study, 101 (91.8%) completed the final clinical examination. The drop-out rates were similar between the intervention and control group.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Lewis 2010**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> A primary diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD), according to a standard definition and prescribed optimal medication, and who had completed at least 12 of 18 sessions of our PR program. To help ensure standardisation, all patients also had to be known to our community-based Chronic Disease Management Team .</p> <p><b>Exclusion criteria:</b> chronic asthma and ILD, no longer living at home, and attended less than 12 PR sessions.</p> <p><b>Method of patient recruitment:</b> The patients were contacted in chronological order (since completing PR) by telephone or face-to-face to ask if interested in participation. Posted/given patient information sheet and contacted again after 7 days.</p> <p><b>Study sample calculation:</b>not stated</p> <p><b>Data collection:</b> Hospital, chronic disease management team and primary care contacts were collected from medical records and hospital computers and primary care data were collected from their computerised databases corroborated by a researcher (blinded to group allocation) phoning each primary care practice monthly during the monitoring periods.A senior respiratory clinician (separate from the research team) independently reviewed the medical records of any deaths or withdrawals to determine if telemonitoring contributed towards adverse consequences e.g., unusual delays in treatment.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 77 eligible patients were approached until 40 patients were obtained .</p>

**Lewis 2010** (Continued)

**No of patients randomised to groups:** n = 40 Intervention: n = 20; Control: n = 20

**No of patients lost to follow-up:** Intervention: n = 3 (2 patients died, and 1 withdrew); Control: 0 patients

**Patient baseline characteristics:**

- a) Clinical condition: a primary diagnosis of moderate or severe COPD
- b) Age, mean (SD): Intervention: 67 (9); Control: 70 (10)
- c) Gender, Male, %: Intervention: 50%; Control: 50%
- d) Ethnicity: NA
- e) Severity of condition: MRC dyspnoea score: Intervention: 4.0(0.7); 3.4 (0.8)
- f) Major co-morbidities: Known co-morbidity: Intervention: 92%; Control: 88%

**Setting** (hospital/community/residential care): outpatient care

**Location** (rural/urban etc.): NA

**Country:** Wales/UK

Interventions

**Study objective:** To see if home telemonitoring could reduce healthcare use in those with optimised COPD.

**Type of TM /mode of delivery** (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.): remote monitoring

**Delivery of intervention:** The participants in the TM group received standard care plus a handheld monitor for 26 weeks and completed symptoms and physical observations (they recorded their oral temperatures, using a manual thermometer and typed the result into the HUB, They placed their index finger into a pulse oximeter probe twice daily, data were stored and then uploaded at 2 a.m. through a Freephone land line transferred to the central server. Health professionals (primarily the chronic disease management team, but also a respiratory consultant and a specialist hospital nurse), could access the server via a secure Internet connection at any time, or if the patient phoned with worsening condition. In addition of regular reviews of results (daily, Monday to Friday) on the doc home web page, an alerting e-mail was sent to the chronic disease management team and hospital respiratory nurses with a combination of two or more of recordings indicating a worsening condition (four questions) on a single session upload.

**Type of technology and its application:** A handheld monitor- the Docobo Health HUB (Docobo, Bookham, UK). No Internet connections is needed as the HUB integrates through a Freephone land line with the DocHOMEcare management system, a generic web-based tele monitoring system that can be pre-configured to specific needs. A pulse oximeter probe (part. No.3832-001, Nonin Inc, Minnesota, USA) connected to the HUB.

**Did the patient receive education about their condition?** NA

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** NA

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The chronic disease management team
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): on receipt of the alerting e-mail (during working hours)

**Lewis 2010** (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):  
NA

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a chronic disease management team, a respiratory consultant and a specialist hospital nurse

**Duration of intervention:** 26 weeks (6 months)

**Comparison intervention:** All patients were treated according to the clinical discretion of their primary care doctors, specialist nurses and hospital specialists.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Hospital admissions</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Emergency Department attendances for COPD</li> <li>Hospital days stayed</li> <li>Primary care contacts (chest and non-chest)</li> <li>Phone calls to the chronic disease management team</li> <li>Home visits by the chronic disease management team</li> </ul> <p><b>Follow-up time:</b> 6 months from start of intervention and 6 months after the end of intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> The medical Electronics Department, Prince Philip Hospital and Docobo Ltd, UK. Grant number C046225, from the European eTen initiative for better breathing, supported this work.</p> <p><b>Conflict of interest:</b> The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	See p.45, Col.2, Para 1  QUOTE:  "Subjects were randomised using the Statistical Package for the Social Sciences (SPSS, Chicago, Illinois), version 12.0, random number generator, into 2 groups.."
Allocation concealment (selection bias)	Unclear risk	See p.45, Col.2, Para 1  QUOTE:  ".. and allocated using sealed envelopes."
Were baseline outcome measurements similar?	Low risk	No difference in COPD hospital admissions at baseline.
Were baseline characteristics similar?	Unclear risk	See p.47, Table 1  Dyspnoea score higher in the intervention group, other characteristics were similar in both groups.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group assignment of patients, and neither could the patients. However,

## Lewis 2010 (Continued)

		outcomes of admissions, clinic visits and length of stay were objective and retrieved from hospital records.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few patients were lost to follow-up (n = 3 in the intervention group and none in the control group).
Selective reporting (reporting bias)	High risk	Results for two outcomes listed in the trial protocol were not reported in the full text paper (quality of life and cognitive ability)
Other bias	Low risk	No evidence of other risk of bias.

## Madigan 2013

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Heart failure (HF) diagnosis (primary or secondary), NYHA class II-IV.</p> <p><b>Exclusion criteria:</b> inability to stand on a scale, weight over 500 pounds, unable to hear and/or see, no working phone line, unstable angina, myocardial infarction (MI) and/or coronary artery bypass graft (CABG) in the previous 6 weeks, severe uncorrected valvular disease, home inotropes, oxygen dependent lung disease, active cancer, uncorrected thyroid disease, AIDS, or end-stage renal disease on dialysis.</p> <p><b>Method of patient recruitment:</b> Patients referred to a participating Home Health Care agency by their discharging hospital were offered participation</p> <p><b>Study sample calculation:</b> not stated although authors says the study was underpowered.</p> <p><b>Data collection:</b> Data on patient demographics, HHC visits, and all-cause re-hospitalisations were collected using the HHC chart and the Outcome and Assessment Information Set (OASIS) data set. Re-hospitalisations were collected and reported at 30 days. The KCCQ was administered at baseline and at HHC discharge. Telephone follow-up was performed at 90 and 180 days post-HHC discharge to document re-hospitalisations during the post-intervention period.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 514 patients were screened, n = 415 were excluded: n = 299 did not meet the inclusion criteria; n = 110 declined to participate; and for n = 6 patients the MD requested patient to be telemonitored.</p> <p><b>No of patients randomised to groups:</b> n = 99; Intervention: n = 55; Control: n = 44</p> <p><b>No of patients lost to follow-up:</b> Intervention group: n = 4: 1 moved; 1 insurance changed and changed from homecare agency; 1 LCT, I refused HC visits; Control group: n = 5:1 insurance change and changed homecare agency; 4 LCT, hospice</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: heart failure</p> <p>b) Age (years), mean ± SD : Intervention: 75.2 ± 12.0; Control: 74.4 ± 11.3</p> <p>c) Female, n (%): Intervention: 40(72.7); Control: 27(61.4)</p> <p>d) Ethnicity: African-American Race, n (%): Intervention: 9(16.4); Control: 15(34.1)</p> <p>e) Severity of condition:</p> <p>NYHA Class, n (%)</p> <p>NYHA 2: Intervention: 23 (42.6); Control: 18 (42.9)</p>

**Madigan 2013** (Continued)

NYHA 3: Intervention: 28 (51.9); Control: 20 (47.6)

NYHA 4: Intervention: 3 (5.6); Control: 4 (9.5)

Preserved systolic function: 60.3%

f) Major co-morbidities (excluded?): approximately 25% of the patients had diabetes

**Setting** (hospital/community/residential care): Six Ohio-based HHC agencies

**Location** (rural/urban etc.): 44 counties in Ohio

**Country:** USA

## Interventions

**Study objective:** to compare follow-up of HF patients with UC plus telemonitoring with UC alone.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of the intervention:** The TM was installed in the patient's home and prompted the patient to measure blood pressure, pulse, oxygen saturation and weight daily at a pre-specified time. Data were transmitted through the patient's telephone line to a central monitoring station at the HHC agency. A trained nurse reviewed the data within a few hours. The study protocol did not provide instructions on when a physician should be contacted or how to respond to abnormal data. This was performed according to the HHC agency's protocol. Nurses did not have the authority to change medications without a physician's order. HHC staff were given an intensive 8 hour course adapted from the National Heart Failure Training Program (NHeFT). The educational program assured that all the nurses were equally knowledgeable about HF management and supported standardised patient education on HF self-management.

**Type of technology and its application:** no information

**Did the patient receive education about their condition?** Standardised patient education on HF self-management.

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no information

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The nurses contacted the patient in the case the values deviated from normal, to suggest repeat measurement
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): data were reviewed within a couple of hours, unclear timing of the response
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the nurse contacted the physician, actions not further described

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** HHA nurses (working together with a physician)

**Duration of intervention:** 30 days (or until discharge from HHA)

**Comparison intervention:** Patients in UC received the same HF education from their HHC nurse as the TM group. Patients were taught to follow their own weights and symptoms. Visits to the home were based on each individual agencies protocol and the needs of the patient.

## Outcomes

Primary outcomes:

- Re-hospitalisations, emergency department and urgent care visits

**Madigan 2013** (Continued)

Secondary outcomes:

- Health status (no data presented)

**Follow-up time:** 90 and 180 days post-HHC discharge

Notes	<p><b>Ethical approval and informed consent obtained:</b> yes</p> <p><b>Sources of funding:</b> this work are supported by the KL2RR024990 and made possible by the Case Western Reserve University/Cleveland</p> <p>Clinic CTSA Grant Number UL1 RR024989 from the National Center for Research Resources (NCRR), a component of the NIH and NIH roadmap for Medical Research</p> <p><b>Conflicts of interest:</b> no information</p>
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>p.60, Para.4</p> <p>QUOTE:</p> <p>"Patients were randomized within each HHC site to either UC or TM following an unconstrained randomization scheme with 50% chance of allocation to each arm."</p>
Allocation concealment (selection bias)	Low risk	<p>p.60, Para.4</p> <p>QUOTE:</p> <p>"The randomization sequence was held by an investigative team member who was responsible for following the randomization protocol at each HHC site and who was un-involved with the consenting process or the patient's care. All records were kept as confidential."</p>
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome (re-hospitalisations).
Were baseline characteristics similar?	Unclear risk	No information.
Blinding (performance bias and detection bias) Objective outcomes	Unclear risk	The health professional delivering the intervention could not be blinded to the group assignment. Data on re-hospitalisations during follow-up assessed through telephone interview. Unclear if outcome assessors were blinded.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants could not be blinded to the group assignment for assessment of health status.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information..
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.



## Madsen 2008

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Age 20-80 years, both men and women, elevated office BP (&gt; 150/95 mmHg or systolic BP &gt;150 mmHg and diastolic BP &lt; 90 mmHg) both treated and untreated hypertension.</p> <p><b>Exclusion criteria:</b> 24-hour ambulatory BP&lt;125/80, atrial fibrillation (AF)(ECG at randomisation) and lack of mental or physical capacity to perform HBPM.</p> <p><b>Method of patient recruitment:</b> Patients were recruited by their PCP.</p> <p><b>Study sample calculation:</b>Power calculations indicated that a sample of at least 200 patients was necessary to detect 5-point differences in SF-36 scores with a power of 80% at a significance level of 5%.</p> <p><b>Data collection:</b> no information</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b>n = 237,of which one declined participation</p> <p><b>No of patients randomised to groups:</b> n = 236 (13 lost to follow-up); Intervention: n = 113; Control: n = 123</p> <p><b>No of patients lost to follow-up:</b> n = 13 in total (5.5%): Intervention: n = 7; Control: n = 5</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: hypertension</p> <p>b) Age, years (SD): Intervention: 54.5 (11.5); Control: 56.7 (11.5)</p> <p>Body mass index (SD): Intervention: 28.0 (6.6); Control: 29.5 (12.5)</p> <p>c) Gender, female sex no, % (SD): Intervention: 54 (51.4); Control: 59 (50.0)</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition:</p> <p>Years since diagnosis of hypertension: Intervention: 3.1 (5.9); Control: 3.3 (5.9)</p> <p>Number of antihypertensive drugs: Intervention: 1.3 (0.9); Control: 1.5 (1.2)</p> <p>f) Major co-morbidities:</p> <p>Diabetics: Intervention: 8 (7.6); Control: 11 (9.3)</p> <p>History of coronary heart disease: Intervention: 4 (3.8); Control: 3 (2.6)</p> <p>History of stroke: Intervention: 5 (4.8); Control: 4 (3.4)</p> <p>History of peripheral vascular disease :Intervention: 4 (3.8); Control:4 (3.4)</p> <p>g) Current smokers: Intervention: 26 (24.8); Control: 37 (31.6)</p> <p><b>Setting</b> (hospital/community/residential care): GP clinics (primary care)</p> <p><b>Location</b> (rural/urban etc.): unclear</p> <p><b>Country:</b> Denmark</p>
Interventions	<p><b>Study objective:</b> To compare the effectiveness of antihypertensive treatment based on telemonitoring of home blood pressure and conventional monitoring of office BP, and to compare HRQOL using a generic scale (SF-36) for these patient groups.</p>

**Madsen 2008** (Continued)

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (for antihypertensive treatment)

**Delivery of intervention:** Patients measured their BP between 09.00 and 20.00 hours, three times weekly during the first 3 months and once weekly during the last 3 months. Each BP measurement consisted of three readings with 1-minute intervals. Doctors instructed their patients in correct BP measuring technique. Instruction of or changes in antihypertensive treatment were at the discretion of the patient's usual GP. The goal was to achieve target home BP for each patient.

**Type of technology and its application:** Patients in the intervention group were provided with equipment for HBPM. This equipment included a validated, semi-automatic oscillometry BP measuring device (Omron 705 IT, Omron Matsusaka Co., Ltd., Japan) connected to a personal digital assistant (Hewlett Packard iPAQ Pocket PC, Hewlett-Packard Company, Houston, TX, USA) with a software interface developed for BP measurement (Bang and Olufsen, Medicom, Struer, Denmark and CIM Electronics, Hasselager, Denmark). Home BP measurements were transferred to a central server by a PDA-embedded mobile phone unit. Doctors assessed their patient's BP measurements on a secure home page. Each patient could assess their own BP measurements on this web page, where they could also communicate with their doctor by e-mail. For patients with no Internet access, the PDA could record and send spoken messages to the general practitioner, who could respond by written messages to the PDA. GPs were instructed to give their patients instruction in correct BP measuring technique (2,20), to check the website on a weekly basis to monitor BP levels of their patients and contact patients if BP measurements were not performed, and to institute or change antihypertensive treatment at their own discretion with the goal to achieve target home BP for each patient.

**Did the patient receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** Three times per week for the first 3 months and once a week for the last 3 months of monitoring.

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no information

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician (s/he may contact the patient)
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail, or through the PDA
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): to check the website on a weekly basis to monitor BP levels of their patients and contact patients if BP measurements were not performed
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): contact patients if BP measurements were not performed, and to institute or change antihypertensive treatment at their own discretion with the goal to achieve target home BP for each patient, (and to instruct patients in correct technique to measure BP)

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** GPs

**Duration of intervention:** 6 months

**Comparison intervention:** The frequency of office visits was decided by the patient's GPs according to usual practice. Office BP was measured with the same type BP device as used in the intervention group. Institution of or changes in antihypertensive treatment were at the discretion of the patient's usual doctor.

**Outcomes**
**Primary outcome:**

- Systolic daytime ABPN (reported in Madsen 2008 a)

**Secondary outcomes:**

**Madsen 2008** (Continued)

- HRQOL (reported in another Madsen 2008 paper)
- Diastolic daytime ABPM
- Systolic and diastolic nighttime ABPM
- Number of patients who achieved normal daytime ABPM and target BP (home BP in the intervention group, office BP in the control group)

**Follow-up time:** 6 months from start of intervention

## Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Ringkjøbing County, the Danish Ministry of Science and the Danish Heart Foundation (07-4-B340-A1446-22372).

**Conflict of interest:** No information

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.228, Col.1, Para 5  QUOTE:  "A random number generator produced a random allocation sequence".
Allocation concealment (selection bias)	Low risk	p.228, Col.1, Para 5  QUOTE:  "Allocations were transferred to sealed, opaque envelopes and opened by the participant after enrolment at the Department of Medical Research".
Were baseline outcome measurements similar?	Low risk	p.81, Col.2, Para.2  QUOTE:  "At baseline, systolic daytime ABPM was similar in the two groups as shown in Table II."  p.82, Col.1, Para 2  "At baseline, diastolic daytime ABPM was also similar in the two groups as Table II shows"  No baseline HRQOL score measure.  "As the SF-36 questionnaire was only filled out at follow-up, it is not entirely possible to rule out that the observed difference between the intervention and control group was present at baseline"  Comment: main outcome similar at baseline in the two groups.
Were baseline characteristics similar?	Low risk	p.229, Col.1, Para 4  No differences in baseline characteristics between the groups."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, the outcome of blood pressure was objective.

**Madsen 2008** (Continued)

Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participants or outcome assessor could not be blinded to the group allocation. Non-objective outcomes based on patients self-report may be at risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	For the main (blood pressure) outcome, an intention to treat analysis was conducted.  As no baseline measure of HRQOL was obtained, the patients not attending follow-up were excluded from the analysis.  p.229, Col.1, Para.4  QUOTE:  “Of the randomised patients, 13 (8 patients form the intervention group and five form the control group) did not attend the follow-up visit and, as they did not take part in the SF-36 survey, they were excluded.”
Selective reporting (reporting bias)	Low risk	All outcomes listed in the trial protocol were covered in the results section of the paper, HRQOL was an additional outcome not listed in the trial protocol.
Other bias	Low risk	No other risk of bias identified.

**Marrero 1995**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> the patient had to be a current member of the paediatric diabetes clinic population at St James Whitcomb Riley Hospital for Children in Indianapolis, Indiana; at least 5 years of age; have had an insulin-dependent diabetes mellitus for more than 6 months; and have a telephone in their home; both the participant and the parent had to be capable of providing informed consent which included willingness to be randomised to either the experimental or control site.</p> <p><b>Exclusion criteria:</b> none stated</p> <p><b>Method of patient recruitment:</b> Recruitment was conducted during routine clinic visits.</p> <p><b>Study sample calculation:</b>no</p> <p><b>Data collection:</b> Metabolic control was measured by HbA1c at BL, 6 and 12 months, diabetes related hospitalisations/ED visits were documented by a chart audit at the conclusion of the study period, and the patients were interviewed to determine whether other hospitalisations or ED visits at other facilities had occurred during the study period. Psychological status was only assessed in the subgroup of patients who were aged 11 or over. Family dynamics, diabetes specific QOL and responsibility for diabetes care were all assessed by different questionnaires/instruments, while attitudes about the diabetes regimen was assessed through a structured interview, and nursing time on task by evaluating the number of telephone calls (and their duration) made by the nurse practitioner and/or the patients .</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 106 families with a diabetic child; <b>Intervention:</b> n = 52 <b>Control:</b> n = 54</p> <p><b>No of patients lost to follow-up:</b>no information</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: insulin dependent diabetes (Type I)</p>

**Marrero 1995** (Continued)

b) Age, mean (SD): Intervention: 13.3 (4.5); Control: 13.3 (4.9)

c) Gender, male (%): Intervention: 59.6%; Control: 59.2%

d) Ethnicity, white (%): Intervention: 98%; Control: 94%

e) Severity of condition:

HbA1c: Intervention: 9.4 (1.9); Control: 9.9 (1.6)

Duration of diabetes: Intervention: 4.3 (3.4); Control: 8.0 (4.7)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one paediatric outpatient clinic

**Location** (rural/urban etc.): Indianapolis, Indiana

**Country:** USA

Interventions

**Study objective:** To evaluate the efficacy of using a tele-communication system to assist in the outpatient management of paediatric patients with insulin-dependent diabetes.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** Care given to all patients by a multidisciplinary team. Telephone contact with the experimental group maintained by specialist nurse practitioner members of the team. Paediatric patients transferred self-monitored blood glucose results to clinic via telephone modem, every two weeks, and received appropriate telephone counselling, together with three-monthly routine clinic visits. The nurse practitioners only called the patient in case the values were out of range, otherwise they only sent a postcard saying how well the values were kept under control.

**Type of technology and its application:** Glucometer M and M+ glucose reflectance meters with a DataLink modem for transmission of the blood glucose data. Glucofacts Data Management System was used to analyse the received data.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** once every two weeks

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned/scheduled telephone contacts (only 3 routine clinic visits)

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The nurse

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): only in case the values are out of range, otherwise the nurse sends a postcard saying how well the blood glucose values are kept within range

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): to discuss possible regimen adjustments, the need for a clinic visit, or the initiation of referral to dietary services, social work or physical therapy

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse practitioners

**Duration of intervention:** 12 months

**Comparison intervention:** Control participants received standard care by a multidisciplinary diabetes team with regimen adjustments made by physicians. Routine clinics were scheduled approximately every three months. Their glucometer data was downloaded on a computer during their routine clinic

**Marrero 1995** (Continued)

ic visit and reviewed during the visit by an endocrinologist using the Glucofacts Data Management System printouts.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• HbA1c .</li><li>• Total no of hospital visits</li><li>• Total no of ED visits,</li><li>• Nursing time on task (number of telephone calls, and duration of calls)</li><li>• Psychological status (assessed with the OFFER Self-image questionnaire)</li><li>• Family dynamics (assessed with the Family Assessment Device (FAD))</li><li>• Diabetes-Specific Quality of Life (Diabetes Quality of Life for Youth (DQOLY) measure)</li><li>• Responsibility for diabetes care (assessed with the Parent-Child Responsibility(PCR) Scale)</li><li>• Attitudes about the diabetes regimen</li></ul> <b>Follow-up:</b> 12 months	
Notes	<b>Ethic's approval and written informed consent obtained:</b>  <b>Sources of funding:</b> NIH Grant No. PHS P60DK20542, and a grant from Miles Inc. Diagnostics Division, and the Regenstrief Institute for Health Care, Indiana University School of Medicine.  <b>Conflict of interest:</b> no information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence genera- tion (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	HbA1c levels were similar in the two groups. No baseline data was provided for the other outcome measures, but the authors state that there were no differ- ences between groups..
Were baseline characteris- tics similar?	Unclear risk	p.314, Col.1, Para.3  No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients, HbA1c and hospital and ED visits were objective outcomes, the latter assessed through chart re- view.Visits to other hospitals/clinics were assessed through patient interview.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The participating patients could not be blinded to the intervention, which may have affected self-reported outcomes. Outcomes assessed with validated tools at unclear risk and all others at high risk.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (re- porting bias)	Unclear risk	No trial protocol found.

**Marrero 1995** (Continued)

Other bias	Low risk	No evidence of other risk of bias.
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**McCarrier 2009**
**Methods**
**Study design:** RCT

**Inclusion criteria:** Patients between the ages of 21 and 49 years were eligible for inclusion in the study if they carried a diagnosis of Type 1 diabetes, had two or more clinical encounters at the DCC and at least one A1C test result in the previous 12 months, had a most recent A1C value >7%, and resided within King or Snohomish County.

**Exclusion criteria:** if they did not receive multiple daily injection therapy with insulin glargine, were currently receiving continuous subcutaneous insulin infusion (or were transitioning to pump therapy), were terminally ill, had documentation of significant mental illness or substance abuse in their charts, or did not speak and read English.

**Method of patient recruitment:** Potential study participants were identified in the clinic's electronic medical record (EMR). Patients meeting these eligibility criteria were recruited via letter and telephone. During the recruitment call, potentially eligible patients were further screened to ensure that they had a home computer with Internet access. Interested and eligible patients were then scheduled for an enrolment appointment at the clinic.

**Study sample calculation:** Given the enrolled sample size, the trial had sufficient statistical power (80%) to detect a difference in A1C change of 0.65% between study groups and 99% power to detect a treatment difference of 1.0%, similar to that seen in an earlier trial of the intervention in patients with Type 2 diabetes

**Data collection:**
**Unit of analysis issues:**
**Participants**

**Total no of eligible patients:** n = 130 (27 were contacted but refused to participate, and study staff was unable to contact another 25)

**No of patients randomised to groups:** n = 77, Intervention: n = 41; Control: n = 36

**No of patients lost to follow-up:** n = 13, 7 from the intervention group and 6 from the control group

**Patient baseline characteristics:**

a) Clinical condition: Type 1 diabetes

b) Age, mean years: Intervention: 36.8 (8.5); Control: 37.8 (7.67)

c) Gender, %female sex: Intervention: 36.60%; Control: 27.80%

d) Ethnicity, % Caucasian: Intervention: 95.10%; Control: 97.20%

e) Severity of condition:

Mean PHQ-9 severity score: Intervention: 4.85 (4.9); Control: 5.26 (5.3)

Mean (SD) baseline HbA1C: Intervention: 7.99 (1.05); Control: 8.05 (1.32)

Glycaemic control at baseline

A1C 7–8%: Intervention: 63.40%; Control: 66.70%

A1C >8% : Intervention: 36.60%; Control: 33.30%

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one Diabetes Care Center, a subspecialty clinic located 1 mile from the main University of Washington Medical Center



**McCarrier 2009** (Continued)

**Location** (rural/urban etc.): urban

**Country:** USA

## Interventions

**Study objective:** To determine whether a web-based diabetes case management program based in an electronic medical record can improve glycaemic control (primary outcome) and diabetes-specific self-efficacy (secondary outcome) in adults with Type 1 diabetes,

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (additional to UC)

**Delivery of the intervention:** Patients assigned to the intervention arm received an initial 1-hour consultation with the case manager and one-on-one instruction with the trial's web module from the study co-ordinator. During this initial orientation, the study co-ordinator provided patients with study reference materials and provided a brief hands-on introduction to the LWD Websites. During the consultation with the case manager, patients discussed areas of concern with their diabetes self-management, performed "live" data entry and upload to the LWD system, and worked with the case manager to develop an individualised action plan. Following the initial clinic visit, all remaining intervention activities took place remotely via e-mail and web resources. The case manager reviewed patient-uploaded data weekly and initiated weekly e-mail contact with patients during the first month, after which she initiated contact based on individual patient goals (with a minimum of once per month) but continued to review records weekly and provide feedback to patients uploading information or initiating e-mail contact.

**Type of technology and its application:** web-application consisting of 5 modules, a health record; an upload meter; a diabetes daily diary; an action planner and an educational module

**Did the patient receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** unclear (probably weekly as the nurse provides weekly feedback at least the first month)

**Planned /scheduled no of TM contacts between patient and healthcare professional:** weekly the first month and thereafter at least monthly

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient? the nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail or web-resources
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): weekly (the first month) and after this at least monthly
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): discussed patients' goal-based actions; provide feedback on uploaded data

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** an advanced registered nurse practitioner with 25 years of experience as a certified diabetes educator and 10 years of experience as a primary care practitioner in diabetes.

**Duration of intervention:** 12 months

**Comparison intervention:** UC

## Outcomes

**Primary outcome:**

- Change in HbA1C values

**Secondary outcome:**

- Change in self-efficacy (assessed with the Diabetes Empowerment Scale, DES)

## McCarrier 2009 (Continued)

**Follow-up time:** 12 months from randomisation

### Notes

**Ethic's committee approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Aventis Pharmaceuticals, Inc. through a research grant to H.I.G. and I.B.H. and through funds from grant T32 HS013853 from the Agency for Healthcare Research and Quality to K.P.M.

**Conflict of interest:** I.B.H. and J.D.R. have received research funding from Sanofi-Aventis. I.B.H. is also a consultant to Eli Lilly, Johnsons & Johnson, and Roche Pharmaceuticals. No competing financial interests exist for the remaining authors.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.212, Col.2, Para.1  QUOTE:  "Patients were randomly assigned to the two study arms based on an allocation sequence using a 1:1 ratio in blocks of 10."
Allocation concealment (selection bias)	Low risk	p.212, Col.2, Para.1  QUOTE:  "The allocation sequence was developed by the study statistician and programmed into an electronic database to conceal allocation from other study staff during recruitment efforts. Although the allocation assignment was known to the study coordinator during the enrolment visit, this assignment was not disclosed to participants until written informed consent had been given and all baseline data collection had been completed."
Were baseline characteristics similar?	Low risk	p.214, Col.2, Para.2  The two treatment groups were similar for almost all measured characteristics at baseline.
Blinding (performance bias and detection bias) - Objective outcomes	Low risk	<b>Outcome group: HbA1c</b> (objective outcomes). No blinding. However, this should have no effect on objective outcomes.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<b>Outcome group : self-efficacy</b> (non-objective outcomes). No blinding. Patient-reported outcomes may be at risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.214, Col.2, Para.1  QUOTE:  "Of patients randomized, 13 (17%) did not have an HbA1C value during the period 10–18 months after baseline and were considered lost to follow-up, and one individual was excluded because this individual's baseline A1C value was conducted on the high-performance liquid chromatography analyzer and thus was not comparable to the other participants. Analysis was based on intention to treat."
Selective reporting (reporting bias)	Unclear risk	No trial protocol found.
Other bias	Low risk	No other risk of bias identified.

## McCrossan 2012

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> complex congenital heart disease (CHD) or congestive heart failure (CHF), as well as infants with corrected CHD who had a difficult perioperative course. The essential inclusion criterion was if the attending paediatric cardiologist felt that the clinical condition of the patient would require significant support following discharge from hospital.</p> <p><b>Exclusion criteria:</b> The only exclusion criterion was if there was no fixed address at which to install the equipment.</p> <p><b>Method of patient recruitment:</b> All paediatric cardiology admissions between August 2005 and October 2008 were considered for inclusion in the study.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> Qualitative data was collected prospectively from families and clinicians by means of structured questionnaires, devised by the research team, involving a Likert scale. Healthcare resource usable data was acquired from the relevant hospital and primary care databases</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 85 patients and families were eligible for inclusion in the study. Two families refused consent leaving 83 patients and families recruited to the study.</p> <p><b>No of patients randomised to groups:</b> n = 59; Intervention (video conference): n = 35; Control: n = 24. Note: a third arm (telephone, n=24) was not included in this review.</p> <p><b>No of patients lost to follow-up:</b> none</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: congenital heart disease</li> <li>b) Age at time of first consultation (days): Video: 63 days; Control: 38.5 days</li> <li>c) Gender, % male: Video: 63; Control: 75</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition:</li> </ul> <p>Physiology, % :Univentricular: Video: 57; Control: 42</p> <p>Biventricular: Video: 43; Control: 58</p> <ul style="list-style-type: none"> <li>f) Surgical status, % :</li> </ul> <p>Preoperative: Video: 3; Control: 16</p> <p>Palliated: Video: 77; Control: 63</p> <p>Repaired: Video: 20; Control: 21</p> <p><b>Setting</b> (hospital/community/residential care): one department of paediatric cardiology, Royal Belfast Hospital for Sick Children</p> <p><b>Location</b> (rural/urban etc.): Belfast</p> <p><b>Country:</b> UK/ Ireland</p>
Interventions	<p><b>Study objective:</b> To assess the sustainability, clinical utility and acceptability to clinicians and parents of a tele-homecare programme for infants with major CHD, and to evaluate the impact on healthcare resource use.</p>

## McCrossan 2012 (Continued)

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** videoconferencing + UC, or telephone consultation + UC,

**Delivery of intervention:** Scheduled video consultations. The video consultation consisted of an initial enquiry if there were any ongoing concerns followed by systematic questioning relating to feeding, weight gain, respiratory status, general form and review of medications. The clinician then visually assessed the patient. Pulse oximetry was obtained from patients in whom variations in oxygen saturation were felt to indicate deviations in their cardiac status.

A summary of the clinical assessment was related to the parent along with the clinician's recommendations for management until the next assessment. Parents were encouraged to ask questions. Video consultations were arranged on a weekly or twice-weekly basis depending on the wishes of the parents or clinician. There was also the facility of 'urgent' consultations whereby parents could request a video consultation before the next one scheduled if they had any concern regarding the clinical condition of their baby. These were not 'emergency' consultations. The study protocol did not stipulate specific parameters (oxygen saturations/weight loss) to prompt urgent consultation as the cohort comprised a heterogeneous group of lesions.

**Type of technology and its application:** Commercially available tele-medicine equipment was utilised. A Tandberg 880TM codec (Lysaker, Norway) in the hospital and a Tandberg 1000TM 'Classic' (Lysaker, Norway) in their homes. The pulse oximeter distributed to selected patients was the Massimo SET (Neuchatel, Switzerland). VCs were performed across standard tele-medicine links. Initially, Integrated Systems Digital Network lines (ISDN 6,384 Kbps) were used as we had experience using this connection. During the last 12 months of the study following pilot testing, the tele-link was changed to an Asynchronous Digital Subscriber Loop (ADSL, 256 Kbps) which is a form of Internet connection.

**Did the patient receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 2-3 times weekly depending on the wishes of the parents and the provider

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** clinicians, probably heart specialists

**Duration of intervention:** planned 10 weeks

**Comparison intervention:** Parents in this group were informed that they had been randomised to the control group and would still receive the same level of care from the paediatric cardiology team as if they were not involved in the study.

## Outcomes

### Primary outcomes:

- Healthcare resource use/total no of NHS episodes
- Admissions to hospital
- Total healthcare costs (per patient)
- Satisfaction with care/provider satisfaction (comparison only between video and telephone interventions, but not with control)
- Clinicians' and parents' opinions on quality of intervention (comparison only between video and telephone interventions, but not with control)

## McCrossan 2012 (Continued)

**Follow-up time:** 10 weeks (an average 12.1 weeks video and 11.3 weeks in telephone group)

### Notes

**Ethical approval and informed consent obtained (yes/no):** This study was conducted with the approval of the research ethics committee of Queen's University, Belfast.

**Sources of funding:** This work was supported by: (1) The Paediatric Cardiology Charitable Funds of the Royal Belfast Hospital for Sick Children; was paid the research salary. (2) Questmark Limited video-conferencing company. This took the form of not charging for the use of the video-conferencing equipment and technical support. It also included paying the cost of phone line rental.

**Conflict of interest:** This study was partially funded by a video-conferencing company Questmark limited. None of the researchers have received any payments from this company.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p. 1523, Col.1, last para  QUOTE:  "Participants were randomly allocated (computer generated random numbers) to one of the three study groups depending on the availability of VC equipment. If VC equipment was available, a 2:1:1 randomisation weighted towards the VC group was employed. If no codec was available, then participants were randomised on a 1:1 basis between the telephone and control groups. On nine occasions, VC equipment was not available."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Low risk	No differences between groups.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Neither healthcare professionals nor patients were blinded to the group allocation.  Healthcare resource data were collected from the relevant hospital and primary care databases.
Incomplete outcome data (attrition bias) All outcomes	Low risk	p.1526, Col.2, Para.2  QUOTE" ..98% (83/85) of individuals agreed to participate, and no one dropped out."
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## McMahon 2005

### Methods

**Study design:** RCT

## McMahon 2005 (Continued)

**Inclusion criteria:** HbA1c  $\geq 9.0\%$ , age  $> 18$  years, ability to understand written and spoken English, and willingness to use a notebook computer, glucose and blood pressure monitoring devices; a VA-based primary care provider at one of 4 hospital-based clinics or 10 community-based outpatient clinics, and access to a telephone.

**Exclusion criteria:** none stated

**Method of patient recruitment:** Hospital laboratory data were screened monthly for individuals with an HbA1c  $\geq 8.8\%$ . Potential participants were sent a letter and/or brochure describing the study and a follow-up telephone call was attempted at least 2 weeks later to solicit participation. In-person screening was provided to interested and potentially eligible participants between October 2001 and April 2003.

**Study sample calculation:** A sample size of 50 participants in each group was determined to have 80% power ( $\alpha = 0.05$ ) to detect a between group difference of 0.8% for HbA1c, 6 mm Hg for systolic blood pressure and 5 mm Hg for diastolic blood pressure.

**Data collection:** Research staff recording outcome measures were not masked to study group assignment.

**Unit of analysis issues:** no

### Participants

**Total no of eligible patients:** no information

**No of patients randomised to groups:** n = 104; Intervention: n = 52; Control: n = 52

**No of patients lost to follow-up:** Intervention: n = 7 lost to follow-up and n = 1 discontinued; Control: n = 11 lost to follow-up, and n = 1 withdrew

**Patient baseline characteristics:**

a) Clinical condition: poorly controlled diabetes mellitus

b) Age, mean years: Intervention:  $64 \pm 7$ ; Control:  $63 \pm 7$

c) Gender, % male: Intervention: 99%; Control: 100%

d) Ethnicity: no information

e) Severity of condition:

Diabetes Medication (n, %)

Oral medication only: Intervention: 27 (52%); Control: 26 (50%)

Insulin: Intervention: 25 (48%); Control: 26 (50%)

HbA1c (mean %): Intervention:  $10.0 \pm 0.8$ ; Control:  $9.9 \pm 0.8$

Blood Pressure (mm Hg)

Systolic: Intervention:  $141 \pm 21$ ; Control:  $139 \pm 20$

Diastolic: Intervention:  $81 \pm 7$ ; Control:  $80 \pm 7$

Lipids (mg/dl)

LDL cholesterol: Intervention:  $100 \pm 35$ ; Control:  $97 \pm 21$

HDL cholesterol: Intervention:  $43 \pm 14$ ; Control:  $40 \pm 8$

Triglycerides: Intervention:  $178 \pm 112$ ; Control:  $204 \pm 140$

BMI (kg/m<sup>2</sup>): Intervention:  $32.3 \pm 5.6$ ; Control:  $34.1 \pm 7.0$

f) Major co-morbidities:

no information

**Setting** (hospital/community/residential care): one Veteran's Affairs (VA) Boston Healthcare System.

**Location** (rural/urban etc.): no information

**Country:** USA

## McMahon 2005 (Continued)

### Interventions

**Study objective:** To assess the effects of web-based care management on glucose and blood pressure control over 12 months in patients with poorly controlled diabetes mellitus.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (web-based care management + education + UC)

**Delivery of the intervention:** Home blood pressure monitoring was encouraged at least 3 times weekly; recommendations for home glucose testing were individualised for each patient. The MyCareTeam™ website (<https://mycareteam.georgetown.edu/vaboston>) was designed and hosted at the Imaging Science and Information Systems Center at Georgetown University. Participants used coded identifiers when interacting with the website, which was accessed using secure socket layer encryption via secure http (i.e. https) to ensure the confidentiality of data transfer. The website accepted uploads from blood pressure and glucose monitoring devices and displayed these data in graphic and tabular form for the participant and care manager to review. An internal messaging system allowed participants to send and receive secure messages to and from the care manager via the website. The care manager responded to queries within one working day during office hours. The website contained web-enabled diabetes educational modules and had links to other web-based diabetes resources. Participants that did not login to the website during a 2 week period were contacted by a study co-ordinator by telephone to encourage website usage. An advanced practice nurse and certified diabetes educator (H.E.G.) reviewed participant data from the website and, using treatment algorithms for glucose and hypertension management, provided recommendations to the primary care provider and participants. The care manager and primary care providers communicated predominantly via the hospital e-mail system; the physician entered medication changes suggested by the care manager directly into the pharmacy's electronic ordering system. The care manager and participants had contact through the website's internal messaging system and occasionally through telephone contact.

**Type of technology and its application:** a notebook computer, a glucometer and a blood pressure monitor. The notebook computer was programmed to connect to a diabetes education and management website (see below) using complimentary toll-free dial-up Internet access. Computer training and support was provided by one of the study staff for a mean total of 2.3 hours [range 1.0–6.6 hours] per participant.

**Did the patient receive education about their condition?** Eligible participants attended a half-day self-management education session for instruction in diabetes core-content areas as recommended by the American Diabetes Association. They met with a nurse, nutritionist and pharmacist, all of whom were certified diabetes educators.

**Frequency of patient data transfer (monitoring studies only):** unclear (patients were encouraged to measure BP three times per week, B-glucose measurements frequency were individualised)

**Planned /scheduled no of TM contacts between patient and healthcare professional:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The care manager/ the advanced practice nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): messaging system, and occasionally telephone contact
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): provide recommendations to the primary care provider and participants

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** advanced practice nurse, and care manager

**Duration of intervention:** 12 months



## McMahon 2005 (Continued)

**Comparison intervention:** Those randomised to UC continued with ongoing care by their primary care provider as needed. Study staff had contact with these participants only to arrange follow-up visits for outcome measures.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• HbA1c</li><li>• Systolic and diastolic blood pressure (only a subgroup of patients)</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Fasting triglycerides</li><li>• LDL cholesterol</li><li>• HDL cholesterol</li></ul> <p><b>Follow-up time:</b> 12 months after randomisation</p>	
Notes	<p><b>Ethic's committee approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> the Department of the Army Cooperative Agreement # DAMD 17-98-2-8017, Department of Veterans Affairs- Health Services Research and Development Program (TEL-02-100) and NIH K24-DK06321.</p> <p><b>Conflict of interest:</b> no information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.2 , Para.4  QUOTE:  "Participants were then randomized to one of two study groups through use of a random variables generator and a series of sealed envelopes."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	Similar at baseline.
Were baseline characteristics similar?	Low risk	Similar at baseline.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	All outcomes were objective.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A similar number of participants were lost to follow-up or withdrew in both groups. Analysis based on intention-to-treat.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Meyer 2008

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> at least 18 years, were able to sign consent (or have surrogate), and had symptoms of acute stroke</p> <p><b>Exclusion criteria:</b> none specified.</p> <p><b>Method of patient recruitment:</b> When a patient arrived at a participating spoke ED with acute stroke symptoms, the hub stroke team was contacted by pager system. If eligible consent was obtained at the spoke and faxed to the hub consultant, using an Internet fax technique, prior to randomisation.</p> <p><b>Study sample calculation:</b> To estimate power, we used a Chi-square test (2 sided alpha = 0.05) and assumed 80% correct decision rate with telephone, a 10% TM effect size, and sample size of 400; power was 80%.</p> <p><b>Data collection:</b> no information</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 223</p> <p><b>No of patients randomised to groups:</b> n = 222; Intervention: n = 111; Control: n = 111</p> <p><b>No of patients lost to follow-up:</b> Intervention: n = 7 (one consultation aborted due to technical problems and six patients lost to follow-up); Control: n = 8 (one withdrew consent, six patients lost to follow-up)</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: stroke</p> <p>b) Age: Intervention: 70.4 ± 14.5 years; Control: 69.0 ± 14.9 years</p> <p>c) Gender, female sex no (%); Intervention: 57 (51); Control: 57 (51)</p> <p>d) Ethnicity, white no (%): Intervention: 106 (96); Control: 105 (95)</p> <p>e) Severity of condition:</p> <p>Baseline mRS (Complete Scale) n (%), dichotomised (0-1): Intervention: 78 (72); Control: 86 (78)</p> <p>Baseline NIHSS (National Institute of Health Stroke Score), mean (SD) Intervention: 11.4 (8.7); Control: 7.7 (7.0) (S)</p> <p>NIHSS Mean ± SD (Median): Intervention: 8.8 ± 7.4 (8); Control: 5.9 ± 5.9 (4)</p> <p>CT scan normal, no (%): Intervention: 29(26); Control: 49 (45)</p> <p>f) Major co-morbidities:</p> <p>Coronary disease, n (%): Intervention: 37 (33) (3% unknown); Control: 24 (22) (10% unknown)</p> <p>MI, n (%): Intervention: 12 (11) (12% unknown); Control: 5 (5) (15% unknown)</p> <p>Prior CVA, no (%): Intervention: 40 (36) (5% unknown); Control: 41 (37) (5% unknown)</p> <p>Hypertension, no (%): Intervention: 83 (75) (5% unknown); Control: 81 (73) (2% unknown)</p> <p><b>Setting</b> (hospital/community/residential care): emergency departments (acute care)</p> <p><b>Location</b> (rural/urban etc.): 4 remote sites (spokes) located 30 to 350 miles from an academic hub.</p> <p><b>Country:</b> USA</p>

**Meyer 2008** (Continued)

## Interventions

**Study objective:** To assess whether TM (real-time, 2 way audio/video and DICOM interpretation) or telephone was superior for decision-making in acute TM consultations.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing and DICOM viewer (used to assess CT images)

**Delivery of intervention:** If the patient was randomised to TM, the consultation commenced using site-independent access to the TM system. The hub consultant turned on the camera and immediately performed a history and NIHSS examination. Other examination elements were performed by or reported to the consultant as able. Head CT images were viewed using a DICOM viewer.

**Type of technology and its application:** Equipment included Internet enabled laptops (used by a pool of 3 fellowship trained vascular neurologists) and the TM systems at remote Emergency Department (ED) facilities. Software enabled site-independent access to 2-way audio/high resolution video, over standard Internet (BF Technologies, Inc, San Diego, CA).

**Did the patients receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** only one index consultation

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** hub consultant and spoke practitioner

**Duration of intervention:** the duration of one index consultation

**Comparison intervention:** Telephone. If the patient was randomised to telephone, the hub consultant queried the spoke practitioner about history, physical, laboratory, and local radiologist's report of the CT, and directed the local practitioner in performing NIHSS elements. Neither the video nor the head CT images were viewed by the consultant.

## Outcomes

**Primary outcomes:**

- Correct decision to treat with thrombolytics

**Secondary outcomes:**

- Rate of Intravenous thrombolytic use
- 90-day functional outcomes
- Intracerebral haemorrhage
- Data completeness
- Technical observations

**Follow-up time:** 90 days after index consultation

## Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** the National Institute of Neurological Disorders and Stroke (NINDS) (P50NS044148), the California Institute of Telecommunications Technology (Cal IT2), and the Department of

**Meyer 2008** (Continued)

ment of Veterans' Affairs, Research Division. The TM application (AccessVideo™) was provided by BF Technologies, Inc.

**Conflict of interest:** There are no conflicts of interest to disclose. Neither the NINDS, Cal (IT)2, nor the Department of Veterans' Affairs had a role in study design; in collection, analysis, or interpretation of data; in writing of the report; or in decision to submit the paper for publication.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	QUOTE:  "Patients were randomized using permuted blocks, stratified by study site to prevent group imbalances. Randomization to 'TM' or 'telephone- only' consultation was done in real-time using a web-based randomization system, thus eliminating practitioner preference bias."
Allocation concealment (selection bias)	Low risk	See quote above.
Were baseline outcome measurements similar?	Low risk	No baseline outcome measurement.
Were baseline characteristics similar?	Low risk	A few difference reported, analyses were adjusted for baseline differences.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the intervention, and neither could the patients. However, objective outcomes of treatment decision was assessed by a blinded outcome assessor.  QUOTE:  "The Stroke DOC Adjudicating Committee (SDAC) was composed of specialist physicians with training in acute stroke, and excluded practitioners from the remote spoke facilities. Level 1 adjudication included the hub consultant's review of the case, with the SDAC blinded as to consultation technique. For Level 2a adjudication, an independent monitor reviewed the spoke's ED/admission record, and adjudicated the correctness of the rt-PA decision based solely on the NINDS rt-PA inclusion/exclusion. <sup>3,4</sup> Based on detailed discussions, still blinded to the group assignment, the SDAC rendered a separate Level 2b determination as to whether the decision was appropriate based on all information that would have been available at the ED bedside."  The secondary outcomes were objective.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Ninety-day outcomes were available for 92.9%. In intervention group 104/111 participants completed the study and in the control group 103/111 participants.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol were reported in the paper.
Other bias	Low risk	No evidence of other risk of bias.

**Mitchell 2008**

Methods

**Study design:** RCT

## Mitchell 2008 (Continued)

**Inclusion criteria:** at least 18 years of age, met DSM-IV criteria for BN (purging or non-purging subtype) or eating disorder-not otherwise specified (EDNOS) with one of the following: (1) DSM-IV criteria for BN except binge eating/purging at a minimum frequency of once per week; (2) DSM-IV criteria for BN with only subjective binge-eating episodes.

**Exclusion criteria:** body weight less than 85% of ideal weight (Metropolitan Life Insurance Table, 1983), had received a change in prescribed psychotropic medication in the previous 6 weeks, had ever received eight or more sessions of cognitive behavioural therapy (CBT), abused alcohol or drugs as defined by DSM-IV in the previous 6 months or were dependent in the previous 1 month, pregnancy, significant active medical illness that would jeopardise safe study participation (e.g., type I diabetes mellitus), significant risk of suicide as determined by a trained assessor, were actively psychotic, or had a current or past DSM-IV diagnosis of schizophrenia or bipolar disorder.

**Method of patient recruitment:** Participants were recruited in waves through mailings to local physicians and psychologists and through advertisements in the media. Recruitment took place between October 1999 and September 2003.

**Study sample calculation:** Based upon a two-tailed  $\alpha$  of .05 and an attrition rate of 15% during therapy and 10% at follow-up, a randomised sample size of 65 per group (130 total) would provide a power of .80 to detect a difference of .50 standard deviations between intervention and control in binge eating and purging frequencies.

**Data collection:** A self-assessment battery was administered at baseline, end-of-treatment, and 3- and 12-month follow-ups. Data were obtained on other psychiatric treatments received at the 3- and 12-month follow-up assessments.

**Unit of analysis issues:** (yes/no):no

### Participants

**Total no of patients:** n = 142 patients assessed for eligibility, n = 14 excluded of different reasons

**No of patients randomised to groups:** n = 128; Intervention: n = 62 Control: n = 66

**No of patients lost to follow-up:** Intervention: n = 27 (43.5%); Control: n = 25 (37.9%)

#### Patient baseline characteristics:

a) Clinical condition: bulimia nervosa (or other binge eating disorder)

Current diagnosis: Bulimia nervosa, no (%): Intervention: 33 (53.2); Control: 38 (57.6);  
Eating disorder not otherwise specified, no (%): Intervention: 29 (46.8); Control: 28 (42.4)

b) Age, mean (SD): Intervention: 28.4 (10.4); Control: 29.6 (10.9)

c) Gender, female sex no (%): Intervention: 62 (100); Control: 64 (97.0)

d) Ethnicity, Caucasian no (%): Intervention: n = 61 (98.4) ;Control: n = 62 (93.9)

e) Condition specific characteristics:

Body mass index (kg/m<sup>2</sup>), mean (SD): Intervention: 23.5 (5.4); Control: 23.3 (5.0)

Objective binge episodes previous 28 days b, men (SD) Intervention: 19.1 (24.7); Control: 21.9 (27.3)

Vomiting episodes previous 28 days, mean (SD) Intervention: 28.5 (28.3); Control: 31.3 (34.3)

f) Major co-morbidities: lifetime mood disorder, lifetime anxiety disorder

**Setting** (hospital/community/residential care): one regional healthcare system facility

**Location** (rural/urban etc.): small urban and rural locations (nine regions in eastern North Dakota and northwestern Minnesota)

**Country:** USA

### Interventions

**Aim of intervention:** to compare the efficacy of CBT for bulimia nervosa delivered via TM versus face-to-face

**Mitchell 2008** (Continued)

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conference

**Delivery of the intervention:** The therapy consisted of 20 sessions delivered over a 16-week period. TV-CBT was delivered using a TM system linking a regional healthcare system facility using T1 lines. Participants interacted with the therapist only through TM. Units were placed so as to mimic the interpersonal distance and height equality used in face-to-face therapy. Rooms at distal sites were chosen for their privacy and lack of excessive noise.

**Type of technology and its application:** video-conference technology which is not further described

**Did the patient receive education about their condition?** Psychoeducation was delivered.

**Frequency of patient data transfer:** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 20 sessions over a 16 weeks period

**Clinician response to receipt of data:** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** six doctoral-level psychologists

**Duration of intervention:** 16 weeks

**Comparison intervention:** 20 face-to-face CBT sessions for bulimia nervosa.

**Outcomes**
**Primary outcomes:**

- Abstinence rates for objective binge eating, purging (vomiting, laxative abuse and diuretic abuse)
- Combined objective binge eating and purging

**Secondary outcomes:**

- EDE (restraint, eating concerns, shape concerns, weight concerns)
- Depression (assessed with the Hamilton depression scale)
- Self-esteem (assessed with the Rosenberg self-esteem scale)
- Quality of Life (assessed with the SF-36)
- Costs (reported in Crow 2009)

**Follow-up time:** 12 months

**Notes**

**Ethical approval and written informed consent obtained (yes/no):** yes

**Sources of funding:** the National Institute of Mental Health and the National Institute of Diabetes and Digestive and Kidney Diseases (R01-MHDK-58820), the National Institute of Mental Health (KO2 MH65919) and the Neuropsychiatric Research Institute.

**Conflicts of interest:** NA

**Risk of bias**
**Bias**
**Authors' judgement**
**Support for judgement**

## Mitchell 2008 (Continued)

Random sequence generation (selection bias)	Low risk	see p.584, last paragraph  QUOTE:  "The randomization sequence was generated by an independent statistician. Randomization was stratified by eating disorder diagnosis (BN vs. eating disorder-not otherwise specified) and antidepressant medication history (never/previous vs. current) to achieve balance on these variables, resulting in four allocation strata. Within each stratum, randomisation was performed in blocks of four to control for potential changes in participant characteristics or study conduct (e.g., personnel changes) over time."
Allocation concealment (selection bias)	Low risk	see p.584, end of last paragraph  QUOTE:  "Treatment assignment codes were concealed from study personnel until time of randomization..."
Were baseline outcome measurements similar?	Low risk	No statistically significant differences in baseline outcome measures (objective episodes and vomiting frequency).
Were baseline characteristics similar?	Unclear risk	see p.585, end of page  QUOTE:  Participants in the treatment groups were similar in baseline socio-demographic and clinical characteristics (Table 1); differences reported for current mood disorder, where 36% of TV-CBT participants met criteria compared with only 20% of face-to-face CBT participants.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The health professionals delivering the intervention could not be blinded to the group assignments, and neither could the patients. However, objective outcomes of abstinence (verified by urine test) and cost.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Self-reported outcomes. Assessors were blinded to therapy administration technique throughout, although this was at times difficult to achieve because of statements made about this therapy when being assessed.
Incomplete outcome data (attrition bias) All outcomes	High risk	Out of n = 66 patients randomised to intervention and n = 62 to control 39/41 (59%/66%) remained at end of treatment assessment 35/37 (53%/59.7%) remained at 3 month follow-up 25/27 (37.9%/43.5%) remained at 12-month follow-up.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias

## Morland 2010

### Methods

### Study design: RCT

**Inclusion criteria:** post traumatic stress disorder (PTSD) (current or lifetime) as determined by the clinician administered PTSD scale; score of 20 or higher on the 10-item trait anger sub-scale on the Stit-Trit Anger Expression Inventory indicating moderate to severe anger problems; stable medication regimen for a minimum of 2 months prior to study entry.



**Morland 2010** (Continued)

**Exclusion criteria:** female veterans; active psychotic symptoms/disorder; active homicidal or suicidal ideation; significant cognitive impairment or history of organic mental disorder and current substance dependence or unwillingness to refrain from substance abuse during treatment.

**Method of patient recruitment:** Patients were recruited at 3 VA clinical sites and 3 Vet centres across the Hawaiian islands of Hawaii, Maui, and Oahu.

**Study sample calculation:**

**Data collection:** Based on anticipated effect sizes and out preset margins for non-inferiority, we estimated that a total sample size of 180 participants would give us a 86% to 97% power to detect the non-inferiority of video-conference versus in person on primary outcomes.

**Unit of analysis issues:** (yes/no):no

Participants

**Total no of eligible patients:** n = 134 met the inclusion criteria, of which n = 9 declined participation and n = 9 had a scheduling conflict.

**No of patients randomised to groups:** n = 125; Intervention: n = 61; Control: n = 64

**No of patients lost to follow-up:** n = 6 patients in the control group and n = 5 patients in the intervention group did not complete the intervention; loss to follow-up after 3 months: Intervention: n = 6; Control: n = 1, at 6 months: Intervention: n = 8; Control: n = 5

**Patient baseline characteristics:**

a) Clinical condition: PTSD

b) Age: Intervention: 54.8 ± 9.3 years; Control: 54.7 ± 9.7 years

c) Gender: 100% male

d) Ethnicity. no (%):

Asian: Intervention: 13 (21.3); Control: 21 (32.8)

White: Intervention: 21 (34.4); Control: 22 (34.8)

Pacific Islander: Intervention: 22 (36.1); Control: 19 (29.7)

e) Severity of condition:

PTSD severity (CAPS total score): Intervention: 80.2 (17.1); Control: 77.8 (15.4)

f) Combat exposure: Intervention: 55 (90.2); Control: 60 (93.8)

**Setting** (hospital/community/residential care): 3 VA clinics; 3 VA centres

**Location** (rural/urban etc.): the Hawaiian islands of Hawaii, Maui, and Oahu

**Country:** USA (Hawaii islands)

Interventions

**Study objective:** to demonstrate the non-inferiority of a TM modality, video-conference, compared to traditional in-person service delivery of a group psychotherapy intervention for rural combat veterans with PTSD

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conference (therapy/treatment)

**Delivery of intervention:** Both intervention and control group received their treatment at the clinic. The therapist travelled to the clinic for the face-to-face sessions, but remained at the Honolulu VA for the video-conference sessions. Both treatment groups received the same manual based 12 sessions AMT protocol, with 2 sessions per week over a 6-week period.

**Type of technology and its application:** not described (video-conference equipment)

## Morland 2010 (Continued)

**Did the patient receive education about their condition?:** NA

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 12 sessions

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** 5 doctoral-level therapists

**Duration of intervention:** 6 weeks

**Comparison intervention:** Face-to-face delivered manual-based 12 sessions AMT protocol, with 2 sessions per week over a 6 week period.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>Anger severity (anger expression, trait anger, anger disposition as measured by the State-Trait-anger expression inventory 2 scale (STAXI-2) and the Novaco Anger Scale Total score ( NAS-T)</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>PTSD symptom reduction (assessed with the PCL-M)</li></ul> <p><b>Process outcomes:</b></p> <ul style="list-style-type: none"><li>Attrition</li><li>Treatment adherence</li><li>Patient satisfaction (assessed with the Charleston Psychiatric Outpatient satisfaction scale-VA)</li></ul> <p><b>Follow-up time:</b> 6 months post-treatment</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> partially funded by grant TEL03-080-3 from the Veteran’s Affairs Health Services Research and Development. This work was also supported by the Office of Research and Development, Medical Research Service, Department of Veterans affairs.</p> <p><b>Conflict of interest:</b>The authors have no affiliations with or financial involvement with any organisation or entry with a financial interest in or financial conflict with the subject matter or materials discussed in this article.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.856,Col.2, Para.3</p> <p>QUOTE:</p> <p>“..participants in each clinic were stratified by war era (Vietnam, Desert storm or other) and randomly assigned by an off-site statistician to one of two treatment conditions at their local VA site.”</p>

## Morland 2010 (Continued)

Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Low risk	p.859, Col.2, Para.3 Baseline scores did not differ.
Were baseline characteristics similar?	Low risk	p.856, Col.2, Para.4 QUOTE: “..participants in the two conditions did not differ by demographic variables, psychiatric co-morbidity, severity of PTSD.”
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professionals delivering the intervention could not be blinded to the group assignment of patients, and treated patients in both groups. Non-objective outcome of anger severity.
Incomplete outcome data (attrition bias) All outcomes	High risk	High loss to follow-up after 6 months (20/64 (31.3%) in intervention group and 11/61(18.0%) in control group )
Selective reporting (reporting bias)	Unclear risk	According to the protocol, the authors planned to use the Assault Behavior Scale (ABS) to assess anger, but results for this outcome were not reported on in the paper.
Other bias	Low risk	No evidence of other risk of bias

## Mortara 2009

Methods	<p><b>Study design:</b> RCT (multi-centre)</p> <p><b>Inclusion criteria:</b> age &gt; 18 and &lt; 85 years; NYHA class II to IV; aetiology Ischaemic, idiopathic, hypertensive or valvular; left ventricular ejection fraction (LVEF) &lt; 40 %; abnormal diastolic echocardiographic pattern (from E/A &lt;1 to a more severe pattern); hospital admission for heart failure (HF) or de-compensation in the previous 12 months and optimised medical therapy.</p> <p><b>Exclusion criteria:</b> Myocardial infarction, revascularisation or implantable cardioverter defibrillator (ICD) implantation in the previous 6 months, angina or objective myocardial ischaemia requiring future revascularization, implanted ventricular or atrial pacemaker (except DDD pacemakers with good sinus activity, insulin dependent diabetes or severe disease-limiting survival, poor compliance with HT systems or inclusion in another trial.</p> <p><b>Method of patient recruitment:</b> no information</p> <p><b>Study sample calculation:</b> assumed that patients in the control arm would show a median bed-days occupancy of 20 bed-days/year (95% confidence interval:11–73 bed-days/year) based on two admissions of 10 days each and that this would be reduced by 25% by HT. To detect this change with a two-sided type I error of 0.05 and a power of 85%, a sample size of at least 450 participants, with participants allocated in a ratio of 1:2 between usual clinical care and HT, respectively, was necessary.</p> <p><b>Data collection:</b> no information (but probably register data rather patient self-report)</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 617 eligible patients were identified; of these, 103 declined to participate and 50 were excluded for logistical reasons. Therefore, the final enrolment included 464 patients, of which three could not participate due to technical problems with activating the tele-monitoring device at home, leaving a final sample of 461 participants.</p>

**Mortara 2009** (Continued)

**No of patients randomised to groups:** n = 461 (n = 215 from Italy, n = 187 from Poland, and n = 59 from the UK)

**Intervention:** n = 301

Italy, n = 143; UK, n = 38 (fewer participants due to problems with recruitment); Poland, n = 120

**Control:** n = 160; Italy, n = 72; UK, n = 21; Poland, n = 67

**No of patients lost to follow-up:** n = 18 patients dropped out, and n = 33 patients died (30 from cardiac causes); unclear how the deaths were divided between groups

**Patient baseline characteristics:**

a) Clinical condition: heart failure

b) Age: Italy: Intervention: 57(11) years; Control: 59 (12) years; UK: Intervention:71(9) ;Control:68 (11); Poland: Intervention: 59(10); Control: 59 (10)

c) Gender, female (%) ; Italy: Intervention:11; Control:17; UK: Intervention:13 Control:33; Poland: Intervention:17 Control:12

d) Ethnicity: no information

e) Severity of condition:

NYHA class, mean (SD): Italy: Intervention:2.4 (0.6); Control:2.4 (0.6); UK: Intervention:2.3 (0.4) Control:2.2 (0.7); Poland: Intervention:2.5 (0.5) Control:2.3 (0.5)

NYHA>3 (%):Italy: Intervention:41; Control:39; UK: Intervention:26 Control:25; Poland: Intervention:51 Control:32

LVEF %:Italy: Intervention:29(7); Control:28 (6); UK: Intervention:26(6) Control:26 (6); Poland: Intervention:29 (7) Control:32(7)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): HF centres in 3 countries, co-ordinating centre in Italy

**Location** (rural/urban etc.): no information

**Country:** Italy, Poland and UK

Interventions

**Study objective:** to assess the feasibility of a new system of home tele-monitoring on clinical outcomes in heart failure.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** patients allocated to HT were then further randomised into following three groups of increasing complexity (Figure 1). The first group (strategy 1) received monthly supportive telephone contacts from a study nurse to check on their clinical status. The second group (strategy 2) received the same telephone support, but also transmitted their vital signs and other data (discussed subsequently), including details of changes in weight, blood pressure, and symptoms, weekly by telephone. Patients assigned to strategy 2 also performed monthly cardiorespiratory recordings; however, these data were transmitted for research purposes only and were not made available to the clinical team. The third group (strategy 3) carried out the same measurements as patients in strategy 2, but the monthly 24-hour cardiorespiratory recordings were made available for clinical management (if required). The patients enrolled in HT strategies 2 and 3 transmitted weekly records of the following data to the coordinating centre via an automated interactive voice response (IVR) system: (i) weight; (ii) heart rate; (iii) systolic arterial pressure; (iv) dyspnoea score (1–10); (v) asthenia score (1–10); (vi) oedema score (1, feet swell in the morning; 2, in the evening; 3, always swollen); (vii) changes in therapy; and (viii) blood results.

**Mortara 2009** (Continued)

Patients in HT strategies 2 and 3 were also given a portable device (a solid-state lightweight Holter-style recorder with built-in signal pre-processing, FM, Monza, Italy), which continuously recorded ECG, respiration, and physical activity over 24 hours at home. The recorders (managed by the patients) automatically transmitted data by a telephone, through a dedicated modem (Appel Electronica srl, Torino, Italy), for analysis by the coordinating centre.

A 24-hour answering machine allowed each patient to contact his/her reference hospital at any time and leave a message requesting help or advice (all HT groups). As tested in a previous pilot study, each transmitted vital sign parameter was subjected to an automatic range check and to a stability check, based on the rate of change of each parameter over time. Any suspect data elicited a request for checking by the monitoring nurse or attending physician. No specific rules were given in the protocol for medical interventions when one of the specific parameters exceeded the pre-specified personalised normal range and the range of variation. Investigators (nurses or physicians) could choose the best action to re-establish the haemodynamic balance following modern guidelines.

**Type of technology and its application:** care and practice sessions were devoted to educating the patients in the use of the HT devices: the cardiorespiratory recorder and the modem, the digital blood pressure monitor (UA-767, A&D Company), and the electronic weighing scale. A detailed user manual, a diary, and study forms for measuring and transmitting vital signs were given to the patients. Technical support for the enrolling centres and the national co-ordinating centres was provided by the co-ordinating centre (Montescano, Italy), using remote assistance with occasional onsite support. In Poland and the UK, first-level technical support was provided by the central signal analyst. Support for the IVR system was provided by the manufacturer (Appel Elettronica).

Monitoring cardiorespiratory signals and physical activity at home. Recording and transmission of collected data to the analysis centre (the co-ordinating centre of each country) was done by the patient. A specific device was designed for the project (FM, Monza MI); it is a solid-state light-weight Holter-style recorder with built-in signal pre-processing. Within the device, two sensors monitor continuously body position (supine vs standing) and acceleration. The Holter will be self-positioned by the patients and the data after 24-hour recording easily transmitted through a dedicated modem to the co-ordinating centre for analysis. The processor within this special dedicated modem (Appel Electronica srl, Torino) is able to dial the reference centre, set-up a standard modem connection, communicate with the recorder processor, start the transfer of data from the recorder to the transmission box and from the latter to the reference centre, check the correctness of the transmission and start again all the operations in case of failure of data transfer. At the reference centre no human intervention is needed to handle the transmission of the data. Transmission management and data storage is automatically performed

by a specialised module integrated within the IVR system.

**Did the patient receive education about their condition?:** no information

**Frequency of patient data transfer (monitoring studies only):** weekly

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data (monitoring studies only):** data that elicited a request for checking by the monitoring nurse or attending physician. No specific rules were given in the protocol for medical interventions when one of the specific parameters exceeded the pre-specified personalised normal range and the range of variation. Investigators (nurses or physicians) could choose the best action to re-establish the haemodynamic balance following modern guidelines (no information on when, or how, the healthcare professional responded and with what actions)

a) Who contacts the patient?: Nurse or physician

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): unclear

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): according to modern guidelines

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses and physicians

**Mortara 2009** (Continued)

**Duration of intervention:** 12-month observation period after the enrolment period

**Comparison intervention:** follow-up according to usual clinical practice plus pre-discharge NICRAM (blind)

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• Bed-days occupancy for HF in acute medical/surgical beds and</li><li>• Composite endpoint of cardiac death and hospitalisation due to HF.</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Bed-days occupancy for all cardiovascular reasons;</li><li>• All-cause bed-days occupancy for HF in acute medical/surgical beds,</li><li>• All cause mortality;</li><li>• All-cause hospitalisations.</li></ul> <p><b>Follow-up time:</b>12 months after enrolment</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> no information</p> <p><b>Sources of funding:</b>HHH was supported by E.C. grant (Action line 10.1 ‘Public Health,contract no. QL-GA-CT-2001-02424).</p> <p><b>Conflict of interest:</b>no information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.313, Col.2, Para 4</p> <p>QUOTE:</p> <p>“The randomisation list was generated by the coordinating centre in Montecano, Italy, with separate blocks held in each country. The individual patient allocation was to be revealed only after the patient identifiers (name, surname and the date of birth) had been received at each national randomisation centre.”</p>
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Unclear risk	<p>p.315, Col.1, Para.2</p> <p>The baseline characteristics (Table 2) of the treatment groups were well balanced in both Italy and the UK. However, some differences between groups in participants recruited in Poland.</p>
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p>The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients.However, all outcomes were objective and the outcome assessor was blinded.</p> <p>p.314, Col.1, Para.1</p> <p>QUOTE:</p>

**Mortara 2009** (Continued)

“All endpoints were adjudicated by an independent, blinded, Endpoint Committee.” Plus objective outcomes.		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	18 patients dropped out of the study and 33 died (30 from cardiac causes). It was unclear how the losses to follow-up were distributed between groups.
Selective reporting (reporting bias)	Unclear risk	Trial protocol no found
Other bias	Low risk	No evidence of other risk of bias.

**Nguyen 2008**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> a diagnosis of chronic obstructive pulmonary disease (COPD) and being clinically stable for at least 1 month; spirometry results showing at least mild obstructive disease defined as post-bronchodilator forced expiratory volume in 1 s (FEV1) to forced vital capacity (FVC) ratio &lt; 0.70 with FEV1 &lt; 80% predicted, or FEV1/FVC &lt; 0.60 with FEV1 &gt; 80% predicted; ADL limited by dyspnoea; use of the Internet and/or checking e-mail at least once per week with a Windows operating system; oxygen saturation &gt; 85% on room air or ≤ 6 L/min of nasal oxygen at the end of a 6-minute walk distance (6-MWD).</p> <p><b>Exclusion criteria:</b> active symptomatic illness (i.e., cancer, heart failure, Ischaemic heart disease with known coronary artery or valvular heart disease, psychiatric illness, or neuromuscular disease); participation in a pulmonary rehabilitation program in the last 12 months; or currently participating in &gt; 2 days of supervised maintenance exercise.</p> <p><b>Method of patient recruitment:</b> Participants were recruited from a combination of web-based and non-web-based sources. Recruitment announcements were sent to various e-mail distribution lists and online support groups for patients with COPD and older adults. E-mail postings were sent via a web-vendor intermediary who produced decision-support content for patients with COPD. Other recruitment activities included chest clinic referrals, letter mailings to university clinic patients with a COPD-related diagnosis, announcements at Better Breathers support groups and pulmonary rehabilitation programs, and newspaper advertisements.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> Baseline assessments included spirometry, completion of web questionnaires, and 6-MWD tests. All participants returned to the clinic within one week for an initial face-to-face dyspnoea and exercise consultation with the study nurse coach and continued to participate in their respective intervention programs for the next 6 months. They returned to the medical centre at 3 and 6 months for testing by study staff who were not involved in the intervention. Individual semi-structured interviews were conducted either in person or via telephone at the final visit by the evaluation staff or investigators who were not directly involved in the intervention.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>	
Participants	<p><b>Total no of eligible patients:</b> n = 90</p> <p><b>No of patients randomised to groups:</b> n = 50; Intervention: n = 26; Control: n = 24</p> <p><b>No of patients lost to follow-up:</b> n = 11 (42%) patients dropped out from the intervention group due to technical difficulties</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: patients with moderate to severe COPD</p> <p>b) Age, mean (SD) years: Intervention: 68.0 (8.3); Control: 70.9 (8.6)</p>	



## Nguyen 2008 (Continued)

- c) Gender, female no (%): Intervention: 8(39); Control: 9(45)
- d) Ethnicity, Caucasian no (%): Intervention: 18(95); Control:20(100)
- e) Severity of condition: FEV1/FVC, mean(SD): Intervention: 0.49 (0.14); Control:0.46 (0.11)
- f) Major co-morbidities: Cardiovascular (HTN and CAD), no (%):Intervention: 9(50%); Control: 10(50%)

**Setting** (hospital/community/residential care): 2 academic medical centres, University of California San Francisco, and University of Washington, Seattle

**Location** (rural/urban etc.): urban

**Country:** USA

### Interventions

**Study objective:**to test the efficacy of two 6-month dyspnoea self-management programs, Internet-based (eDSMP) and face-to-face (fDSMP), on dyspnoea with ADL in people living with COPD.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** web-based tool (for dyspnoea self-management)

**Delivery of intervention:** The eDSMP participants submitted real-time information about their symptoms (dyspnoea, sputum, sputum purulence, symptoms of a cold, wheezing, and cough) and exercise (mode, duration, and worst dyspnoea) via the PDA or website. Participants in the eDSMP group were encouraged to communicate their exercise goals and progress to the nurse by using a web-based goal-setting tool. The nurses reviewed this information to provide individualised feedback and reinforcement to participants regarding their use of dyspnoea management strategies and exercise progress via e-mail (eDSMP), weekly for the first month and then biweekly for the next 5 months. These contacts were designed to be as similar as possible for the two groups. One difference was that automated e-mail alerts were sent to the study nurses based on real-time symptom (worsening of symptoms from usual) and exercise (reports of not performing exercise for at least 3 consecutive days) data that the eDSMP participants submitted.

**Type of technology and its application:** At the end of the baseline visit, the study nurse introduced the personal digital assistant (PDA), a Blackberry 680, to the eDSMP participants; they were encouraged to play an electronic game on the PDA to increase their comfort with the device since it would be used to record their real-time symptom and exercise data. The eDSMP incorporated technological enhancements to support earlier recognition of worsening symptoms through real-time monitoring, more prompt feedback, and convenient access to information and support, which were hypothesised to attenuate the possible disadvantages of decreased face-to-face contact. We used a vendor-supported, web-based application that was configured to our study specifications for the eDSMP. The eDSMP participants were provided with a detailed paper help manual on how to navigate and use the website tools and their PDA. They received training on how to use the website to access the education modules, self-monitoring tools, and communication tools using the clinic computer. The patients also received training on how to record their daily exercise and symptoms using the PDA.

**Did the patient receive education about their condition?** All participants received education on shortness of breath (SOB), breathing strategies to reduce SOB, exercise and SOB, modifying activities to reduce SOB, coping with SOB and stress, and medications to manage SOB and COPD flare-ups. The eDSMP group accessed web-based education modules. The content from these modules was reinforced by study nurses during six-weekly live chat sessions with participants from both clinical sites (eDSMP). These education sessions were designed to encourage peer interactions and mutual support.

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** weekly for the first month and then bi-weekly for the next 5 months

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail

Nguyen 2008 (Continued)

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): real-time data transfer, but unclear when the nurses responded to the receipt of data (alerts)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): individualised feedback and reinforcement to participants regarding their use of dyspnoea management strategies and exercise progress

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 6 months

**Comparison intervention:** The fDSMP (= control) participants completed paper diaries and mailed them back weekly to the study office. the fDSMP group set exercise goals during the telephone calls. The nurses reviewed this information to provide individualised feedback and reinforcement to participants regarding their use of dyspnoea management strategies and exercise progress via telephone (fDSMP), weekly for the first month and then biweekly for the next 5 months. These contacts were designed to be as similar as possible for the two groups. There were no alerts for the fDSMP participants.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>Dyspnoea with ADL</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>Exercise behaviour</li><li>Exercise performance</li><li>Self-efficacy for managing dyspnoea</li><li>HRQOL (assessed with the The CRQ and Medical Outcomes Study Short-Form 36 (SF-36)</li><li>Acute COPD exacerbations</li><li>Perception of support (assessed with the information and emotional sub scale of the Medical Outcomes Study Social Support Scale)</li></ul> <p><b>Follow-up time:</b> 6 months after randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Robert Wood Johnson Health e-Technologies Initiative grant RWJ49153 to Dr. Carrieri-Kohlman, General Clinical Research Centers at the University of Washington (MO1-RR-000037) and UC San Francisco (MO1-RR-00079) and Grant Number 1KL2RR025015-01 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH) and NIH Roadmap for Medical Research.</p> <p><b>Conflict of interest:</b> None stated.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.4, Para.3</p> <p>QUOTE:</p> <p>“An investigator who was not involved in the day-to-day study operations generated the randomization sequence using the SPSS version 14.0 (SPSS Inc, Chicago, IL, USA) random sequence generator feature and placed the randomization in separate sealed opaque envelopes. The randomization scheme was stratified by the two clinical sites in blocks of six to ensure balanced allocation to the two treatment groups.”</p>
Allocation concealment (selection bias)	Low risk	p.4, Para.3 and quote above

## Nguyen 2008 (Continued)

"Since registration and access to the Web questionnaires on the vendor-supported website required designation of a treatment group early in the baseline visit, the study nurse opened the randomization envelope during the first half of the visit. While the study nurse was privy to the treatment assignment, participants were not informed of their assignment until the visit was complete."		
Were baseline outcome measurements similar?	Low risk	Baseline outcome measures similar.
Were baseline characteristics similar?	Low risk	Participants in both treatment groups were similar on all baseline characteristics, suggesting that randomisation was successful (Table 2).
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	<p><b>Outcome group: dyspnoea with ADL, exercise behaviour and performance, HRQOL, acute exacerbations, perceived support</b></p> <p>The healthcare professional delivering the intervention could not be blinded to the group allocation of patients, and neither could the patients. Outcomes were based on patient self-report.</p> <p>p.4</p> <p>QUOTE:</p> <p>"..testing by study staff not involved in the intervention" "Individual sem-structured interviews were conducted either in person or via telephone at the final visit by the evaluation staff or investigators (HQN and VCK) who were not directly involved in the intervention."</p>
Incomplete outcome data (attrition bias) All outcomes	High risk	The study was stopped early and only 39 of 50 participants (78%) completed the study. Eleven patients (42%) dropped out from the TM group due to technical difficulties. No losses to follow-up in the control group. Analysis based on Intention- to-treat.
Selective reporting (reporting bias)	Unclear risk	Results for most of the outcomes listed in the trial protocol were reported in the paper, with the exception of health resource use.
Other bias	Low risk	No evidence of other risk of bias.

## Noel 2004

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Documented high use of healthcare resources and barriers to accessing healthcare services due to geographic, economic, physical, linguistic, technologic, and/or cultural factors. Candidates who qualified for participation had been actively receiving nurse case management for at least 6 months preceding the study and throughout study participation.</p> <p><b>Exclusion criteria:</b> no information</p> <p><b>Method of patient recruitment:</b> Study patients were identified through the medical centre's database.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> Subjective and objective quality-of-life measures were taken at baseline and quarterly by a research nurse. Cost data were collected for 6 months preceding study entry and 6 months during participation in the study. The VACT electronic database was used to collect healthcare use for BDOC, total visits, urgent visits (unscheduled clinic and emergency room), A1C levels for the diabetic sample,</p>
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**Noel 2004** (Continued)

and coumadin visits for the anticoagulated sample. Number of nurse home visits was collected from community agencies and VACT's home-based program.

**Unit of analysis issues:** (yes/no): no

Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients randomised to groups:</b> n = 104 Intervention: n = 47; Control: n = 57</p> <p><b>No of patients lost to follow-up:</b> no information</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: patients with complex heart failure (HF), chronic lung disease, and/or diabetes mellitus</p> <p>b) Age, years: Intervention: 72 years; Control: 70 years</p> <p>c) Gender, male no (%): Intervention: 44(42%); Control: 57 (55%)</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition: no information</p> <p>f) Major co-morbidities: CHF (n = 59), COPD (n = 35), DM (n = 58)</p> <p><b>Setting</b> (hospital/community/residential care): one Veteran's Affairs Healthcare System</p> <p><b>Location</b> (rural/urban etc.): Connecticut</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b> To determine whether home tele health, when integrated with the health facility's electronic medical record system, reduces healthcare costs and improves quality-of-life outcomes relative to usual home healthcare services for elderly high-resource users with complex co-morbidities.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> monitoring(home telehealth plus nurse case management)</p> <p><b>Delivery of intervention:</b> Vital sign data and answers to quizzes related to disease-specific education modules were acquired via home-based telehealth units, which used standard phone lines to communicate with the hospital. FDA-approved peripheral devices monitored vital signs and valid questionnaires were used to evaluate quality-of-life outcomes. Out-of-range data triggered electronic alerts to nurse case managers.</p> <p><b>Type of technology and its application:</b> A device with a touch screen interface with 16-bit colour, and step-by-step instructions using graphics, large text, and audio. Peripheral devices plug into the telehealth unit and collect data for temperature, blood pressure, pulse, blood glucose, 3-lead electrocardiogram, stethoscope for heart and lung sounds, pulse oximetry, and weight. Pain level (0–9) is self-reported using a simple questionnaire. Data are transmitted over POTS (plain old telephone system) lines to VACT's web-based Intranet system and directly into the facility's electronic database (VISTA). Out-of-range patient data trigger VA alerts via the web to nurse case managers. The device supports on-screen hospital-to-home messaging, scheduling, and advice from providers to patients. Incoming data were automatically written into the VA's electronic patient record to progress notes or the vital sign record. A digital camera (Nikon Coolpix 880) was used to monitor wound care with images transmitted to the web server. Disease-specific patient education modules included pass/fail tests to demonstrate learning achieved. Patients completed on-screen assessment surveys for pain, well-being, and patient satisfaction.</p> <p><b>Did the patient receive education about their condition?</b> Patients received education through a disease specific patient education module.</p> <p><b>Frequency of patient data transfer (monitoring studies only):</b> no information</p>

Noel 2004 (Continued)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no information

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: Nurse case managers and/or providers
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): on screen hospital to home messaging
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): All vital sign data collected in the home are written to VISTA and available for clinicians within 10 minutes of being received.
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): scheduling or advice to patients

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse case managers, healthcare providers

**Duration of intervention:** 6 to 12 months

**Comparison intervention:** usual home healthcare services plus nurse case management.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Subjective and objective QOL measures</li> <li>• Health resource use</li> <li>• Costs</li> </ul> <p><b>Follow-up time:</b> 12 months</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> This research was funded by VA Health Services Research and Development (HSR&amp;D).</p> <p><b>Conflict of interest:</b> No information.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	Quality of life functional measures were higher in the control group. Some of the measures of health resource use showed a tendency to be different between groups.
Were baseline characteristics similar?	Unclear risk	The patients' mean age was similar in the two groups, but 23 % of patients in the intervention group had a carer, compared to 0% in the control group.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, measures of resource use are objective and collected from registers. Also, the outcome assessors were blinded to the patients' allocation

## Noel 2004 (Continued)

Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Participants could not be blinded to the group allocation. Self-reported outcomes quality of life may have been affected by non-blinding. However, the outcome assessors were blinded to the patients' allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Oakley 2000

Methods	<p><b>Study design:</b> RCT (multicentre)</p> <p><b>Inclusion criteria:</b> patients with a dermatological conditions requiring a specialist referral</p> <p><b>Exclusion criteria:</b> none stated</p> <p><b>Method of patient recruitment:</b> Patients were invited to participate in the trial by their GP</p> <p><b>Study sample calculation:</b> no information</p> <p><b>Data collection:</b> All data based on patients self-report and assessed by questionnaire. Follow-up information was collected until the end of the study (December 1998), that is for 1 to 12 months.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 203; Intervention: n = 109; Control: n = 94</p> <p><b>No of patients lost to follow-up:</b> one patient lost to follow-up.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: dermatologic conditions</li> <li>b) Age, mean yrs: 41 years</li> <li>c) Gender, male/female sex (%) ; 48/42%</li> <li>d) Ethnicity: no info</li> <li>e) Severity of condition: no information</li> <li>f) Major co-morbidities: no information</li> </ul> <p><b>Setting</b> (hospital/community/residential care): one local health centre (in Roturoa or Taupo); the Waikato Hospital in Hamilton</p> <p><b>Location</b> (rural/urban etc.): Hamilton</p> <p><b>Country:</b> New Zealand</p>
Interventions	<p><b>Study objective:</b> To evaluate patient cost-benefits of real-time tele-dermatology and compare data with from northern Ireland.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> video-conferencing</p>

## Oakley 2000 (Continued)

**Delivery of intervention:** Patients attended a tele-dermatology consultation at their local health centre.

**Type of technology and its application:** Low cost PCs (DEC Pentium 166) with video-conferencing capability (SmartSytation 128, V-tel) were installed at the health centres. At Waikato Hospital, the department of dermatology's video-conferencing system (S-Max, V-Tel) was up-graded with similar PC hardware and SmartStation software. Transmission was via basic-rate ISDN lines at 128 kbit/s. Additional handheld cameras (Sony Camcorder) were used to transmit close-up images of the patient.

**Did the patients receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** one consultation

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** primary care physicians; dermatology specialists

**Duration of intervention:** the duration of one consultation

**Comparison intervention:** One face to face out-patient consultation.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Total time involved in attending appointment, including waiting, consultation and travel time</li><li>• Proportion of follow-up appointments</li></ul> <b>Follow-up time:</b> one to 12 months	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes  <b>Sources of funding:</b> New Zealand Ministry of Health, New Zealand Health Informatics Foundation, V-Tel (Australia), B&H (NZ) Ltd, Digital Equipment Corporation, Leo Pharmaceuticals Ltd, CSL (NZ) Ltd.  <b>Conflict of interest:</b> no information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	N/A



## Oakley 2000 (Continued)

Were baseline characteristics similar?	Unclear risk	No information.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional could not be blinded to the intervention, and neither could the patients. However, primary outcome of number of follow-up appointments was objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professional could not be blinded to the intervention, and neither could the patients. Time for appointment based on self-report.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only data for one patient missing at follow-up.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Parati 2009

### Methods

**Study design:** multicentre RCT

**Inclusion criteria:** age between 18 and 75 years, a diagnosis of uncontrolled essential hypertension, as defined by the occurrence of an office SBP of at least 140 mmHg or DBP of at least 90 mmHg and by an ambulatory mean daytime SBP of at least 130 mmHg or DBP of at least 80 mmHg (regardless of whether patients were or were not treated).

**Exclusion criteria:** a diagnosis of secondary hypertension; major systemic diseases; atrial fibrillation or frequent cardiac arrhythmias or severe atrio-ventricular block, that is, conditions that could make HBPM and ABP measurements unreliable; obesity (BMI > 30 kg/m<sup>2</sup>) or an arm circumference of more than 32 cm or both, to avoid inaccuracies in automated BP readings due to arm-cuff mismatch; and any condition that might prevent patients' participation in the study, for example, technical problems due to incompatible phone lines at home.

**Method of patient recruitment:** Three hundred and ninety-one hypertensive patients, consecutively seen in the GPs' offices, were screened for inclusion in the study.

**Study sample calculation:** On the basis of the expectation of a 15% difference in the number of patients reaching average daytime ABP normalisation in favour of the group randomised to HBPM and tele-monitoring as compared with the control group, a minimum number of 288 patients were required to guarantee a power of 80% and a minimum level of significance of 0.05.

**Data collection:** All patients were subjected to at least five office visits: at screening (visit one), at randomisation (visit two, after 1 week), and during follow-up (visits three to five, after 4, 12, and 24 weeks, respectively). At each visit, BP was measured according to the same procedure, and information was obtained on adverse events and the occurrence of changes in the treatment regimen made by the patient. In patients randomised to TeleBPCare, information was also obtained on the patients' compliance with HBPM using the data available at the call centre. In each patient, additional measurements included haematology and chemistry values; an ECG; two 24-hour ABP monitoring (randomisation and study end) by means of a validated oscillometry device (Tensioday, Tensiomed) using the same hardware components and software as the Tensiophone device used for home and office BP measurements; and a quality of life score, assessed by the administration of a modified short form-12 questionnaire at randomisation and at the end of follow-up. Information on additional doctors' visits as well as on treatment changes between visits was also obtained from the electronic clinical chart.

**Parati 2009** (Continued)

**Unit of analysis issues:** (yes/no):no

Participants	<p><b>Total no of eligible patients:</b> n= 329</p> <p><b>No of patients randomised to groups:</b> n = 329; Intervention: n = 216; Control: n = 113</p> <p><b>No of patients lost to follow-up:</b> n = 41 (12.5%) patients did not have a complete data set: n = 29 patients from the TeleBPCare group and n = 1 patient from the control group- unclear how the remaining patients lost to follow-up were divided between groups. Out of the 329 patients, 288 (87.5%) patients, for whom all data were available at the end of the study, were included in the intention-to-treat analysis</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: hypertension</li> <li>b) Age, mean (SD) years: Intervention: 57.2(10.7); Control: 58.1(10.8)</li> <li>c) Gender, male sex, n (%): Intervention: 102 (54.5); Control: 60 (54.1)</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition: no information</li> <li>f) Major co-morbidities: no information</li> </ul> <p><b>Setting</b> (hospital/community/residential care): unclear number primary care practices (12 PC physicians)</p> <p><b>Location</b> (rural/urban etc.): Urban (Milan area)</p> <p><b>Country:</b> Italy</p>
Interventions	<p><b>Study objective:</b> To demonstrate the ability of HBPM data tele transmission as compared with UC based on office BP measurements only, to obtain a higher rate of ABP normalisation.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> remote monitoring</p> <p><b>Delivery of intervention:</b> Self-monitored BP values were regularly transmitted to a referral centre where data were checked and stored in a digital database. Values exceeding upper and lower predefined arbitrary safety thresholds (180/110 and 100/60 mmHg, respectively) triggered an alarm, on the basis of which a dedicated trained nurse called the patient at home to check his/her clinical status and the possibility of artefactual measurements. Whenever needed, the physician in charge was immediately alerted, and an additional office visit was scheduled. At each of the subsequent visits, BP was measured according to the same procedure, and information was obtained on adverse events and the occurrence of changes in the treatment regimen made by the patient. In patients randomised to TeleBPCare, information was also obtained on the patients' compliance with HBPM using the data available at the call centre. This information was sent to the GPs together with the processed HBPM data by regular mail, fax, or e-mail immediately before any scheduled office visit</p> <p><b>Type of technology and its application:</b> A validated oscillometry device was used for HBPM (Tensio-phone device; Tensiomed, Budapest, Hungary). The device is equipped with a built-in modem permanently plugged to the house phone line and subjected to remote programming of the frequency of measurements as well as of the time of a tele reminding beep, which can be sent to the patient to stimulate adherence to measurement schedule whenever appropriate.</p> <p><b>Did the patient receive education about their condition?</b> no information</p> <p><b>Frequency of patient data transfer (monitoring studies only):</b> no information other than that data was regularly transmitted</p> <p><b>Planned/scheduled number of TM contacts between patient and healthcare personnel:</b> none, but five in office visits</p>

**Parati 2009** (Continued)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): no information
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): checked and stored at the referral centre
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): Whenever needed, the physician in charge was immediately alerted, and an additional office visit was scheduled.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physician/nurses/referral centre personnel

**Duration of intervention:** 6 months

**Comparison intervention:** Office-based BP management, treatment being aimed at reducing office BP to less than 140/90mmHg.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Percentage of patients who reached normalisation of daytime ambulatory SBP and DBP (i.e. &lt;130/80 mmHg) at the end of the follow-up period</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Rate of normalisation of office SBP/DBP</li> <li>Frequency of treatment changes originated either by the physician or by the patient</li> <li>QOL (assessed with the SF-12)</li> <li>Costs.</li> </ul> <p><b>Follow-up time:</b> 24 weeks after the start of intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Research funds were obtained from our Institution along with an unrestricted re-search grant from Boehringer Ingelheim, Italy.</p> <p><b>Conflict of interest:</b> Dr Miklos Illyes is a scientific consultant for Tensiomed Ltd. There are no conflicts of interest.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	Similar baseline outcome measures (BP and QoL).
Were baseline characteristics similar?	Low risk	p.200, Col.1, Para.2 QUOTE:

## Parati 2009 (Continued)

“Table 1 shows that the baseline demographic and clinical characteristics of the 288 patients of the intention-to-treat population were similar in the two groups.”		
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional could not be blinded to the intervention. However, the primary outcome was objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professional could not be blinded to the intervention, and neither could the patients. Non-objective outcome of quality of life may have been affected by non-blinding..
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	41 patients did not have a complete data set: n= 29 patients from the TeleBP-care group and n= 1 patient from the control group- only the patients with complete data sets were included in the intention to treat analysis. It is unclear if the patients who were not included were significantly different from those who remained in the study.
Selective reporting (reporting bias)	Unclear risk	No trial protocol found.
Other bias	Low risk	No evidence of other risk of bias.

## Piron 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Upper limb paresis after stroke</p> <p><b>Exclusion criteria:</b> clinical evidence of cognitive impairment, such as apraxia (score lower than 62 points at De Renzi test), neglect and language disturbances interfering with verbal comprehension (more than 40 errors in the Token test)</p> <p><b>Method of patient recruitment:</b> The patients were recruited 7-32 months after the ischaemic event (mean 13.3 (SD5.5) months) from among outpatients of the ART Education and Rehabilitation Centre, Genoa.</p> <p><b>Study sample calculation:</b> no information</p> <p><b>Data collection:</b> The motor deficit and the functional activities of the upper extremity were assessed with the Fugl-Meyer scale for the upper extremity (Fugl-Meyer UE) and the ABILHAND scale. In addition, spasticity of the arm was determined with the Ashworth scale. The timing of assessments was: one month prior to starting therapy (T0), at the commencement of (T30) and at the termination of the therapies (T60) and, finally, one month after termination (T90). The examining neurologist was blind to the treatments administered to the patients.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients randomised to groups:</b> n = 36; Intervention: n = 18; Control: n = 18</p> <p><b>No of patients lost to follow-up:</b> All patients completed the training and did not experience any problems handling the VRRRS.net system</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: paretic upper limb after stroke</p> <p>b) Age, year, mean (SD): Intervention: 66.0(7.9); Control: 64.4 (7.9)</p>

**Piron 2009** (Continued)

c) Gender, men/women: Intervention: 11/7; Control: 10/8

d) Ethnicity: no information

e) Severity of condition: no information

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one stroke clinic

**Location** (rural/urban etc.): no information

**Country:** Italy

**Interventions**

**Study objective:** To evaluate the effectiveness of a remotely controlled programme to treat motor-deficits in post stroke patients and compare it with traditional motor rehabilitation methods.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing

**Delivery of intervention:** Five virtual tasks, comprising simple arm movements, were devised for training the patient's left or right arm deficits. During the rehabilitation session, the patient moved the real object following the trajectory of the corresponding virtual object displayed on the computer screen in accordance with the requested virtual task. The participant could see not only his or her movement, but also the correct trajectory pre-recorded in the virtual scene (virtual teacher). In addition, the therapist provided the patient with information about the tasks' exactness through the videoconferencing system. Prior to entering the study, the patients were trained to utilise the computerised rehabilitation system, to locate the magnetic receiver correctly, and to execute the requested motor task adequately.

**Type of technology and its application:** The tele rehabilitation system (VRRRS.net) was developed at the Massachusetts Institute of Technology (Cambridge, Ma, USA) and consisted of two dedicated personal computers (PC)-based workstations, one located at the patient's home and the second in the rehabilitation hospital. The VRRRS.net was equipped with 3D motion tracking system (Polhemus, 3SpaceFasttrac, Vermont, USA) to record arm movements via a magnetic receiver attached to a real object. The system transformed the receiver into a virtual image (virtual object), which changed position on the screen according to the motion of the receiver.

**Did the patient receive education about their condition?** no information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** 1 hour a day, 5 days per week for one month

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** Physiotherapists

**Duration of intervention:** 4 weeks

**Comparison intervention:** Ordinary physiotherapy treatment face-to-face 1 hour a day, 5 days a week for one month. Control group participants, treated with conventional physical therapy, were asked to perform specific exercises for the upper limb with a strategy of progressive complexity. First they were requested to control isolated motions without postural control, then postural control was included and, finally, complex motion with postural control was practiced. For example, patients were asked to

**Piron 2009** (Continued)

touch different targets arranged in a horizontal plane in front of them, to manipulate different objects, to follow trajectories displayed on a plane, and to recognise different arm positions.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Functional (motor) performance</li> </ul> <p><b>Follow-up time:</b> 30 days after the end of the intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> No information.</p> <p><b>Conflict of interest:</b> No information.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>p.1017, Col.1, Para.2</p> <p>QUOTE:</p> <p>“..patients were assigned to 2 groups according to a simple randomisation technique using sequentially numbered, opaque sealed envelopes: one group was treated at home with the Telerehabilitation system (18 participants, Telerehab group), the other group was treated with conventional physiotherapy in the local health district (18 participants control group). The envelopes containing the paper sheet with the type of treatment and a sheet of carbon paper were obscured with aluminium foil, shuffled, then numbered sequentially, and placed in a plastic container, in numerical order, ready to use for the allocation.”</p>
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	High risk	<p>P 1018, Table 1 and 2</p> <p>Unclear time from lesion to enrolment between groups, Ashworth score (spasticity) was higher in the tele-rehab group and ABILHAND score (functional status) was lower in the tele-rehab group.</p>
Were baseline characteristics similar?	Low risk	<p>p.1018, Col.1, Para.1</p> <p>No difference reported.</p>
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	<p><b>Outcome group: functional motor performance</b></p> <p>p.1017, Col.1, Para.2</p> <p>QUOTE:</p> <p>“The examining neurologist was blind to the treatments administered to the patients.”</p> <p>Comment: However, blinding was incomplete: It cannot be ruled out that several patients could have informed the neurologist about their intervention group, deliberately or not. The ABILHAND scale is more subjective than the two other outcomes, since it is based on patients' answers. It is therefore the more likely to be biased.</p>

**Piron 2009** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	p.1018, Col.1, Para.1  QUOTE:  “All patients completed the training and did not experience any problems handling the VRRRS.net system”
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

**Poon 2005**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Mild cognitive impairment as assessed by the Cantonese version of the mini-mental state examination (C-MMSE score 14-22), and confirmed by geriatrician.</p> <p><b>Exclusion criteria:</b> no information</p> <p><b>Method of patient recruitment:</b> Participants were recruited from a neighbourhood social centre for seniors. Potential candidates were first screened by the Cantonese version of mini-mental state examination (C-MMSE). Those who scored below the cut-off points (taking into account their educational level) for cognitive impairment were referred to a geriatrician for confirmation of diagnosis.</p> <p><b>Study sample calculation:</b> not stated</p> <p><b>Data collection:</b> Cognitive assessments used at baseline and after completion of the program included: Cantonese version of Mini-Mental State Examination (C-MMSE) (Chui et al., 1994), Cantonese version of Rivermead Behavioural Memory test (C-RBMT) (Wilson et al., 1985; Ng et al., 1996) and Hierarchic Dementia Scale (HDS) (Cole and Dastoor, 1983). A user satisfaction questionnaire towards VC was distributed to participants and staff at the social center after the program.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n= 22 Intervention: n =11; Control: n =11</p> <p><b>No of patients lost to follow-up:</b> no information</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: cognitive impairment or dementia</li> <li>b) Age: Intervention: no information</li> <li>c) Gender; no information</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition: mild cognitive impairment/dementia</li> <li>f) Major co-morbidities: no information</li> </ul> <p><b>Setting</b> (hospital/community/residential care): social centre for the elderly (ELSK Lek Yuen Multiservice Elderly Centre, Shatin) and outpatient hospital clinic (at Shatin hospital)</p> <p><b>Location</b> (rural/urban etc.): urban (Hongkong)</p> <p><b>Country:</b> China</p>



**Poon 2005** (Continued)

## Interventions

**Study objective:** to examine and compare the feasibility, acceptability, and clinical outcome of a cognitive intervention program for older patients with mild cognitive impairment and mild dementia using TM versus a conventional face-to-face method.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing

**Delivery of intervention:**no information, other than that a social worker at the centre co-ordinated the intervention

**Type of technology and its application:** The VC system was linked via broadband (1.5 Megabytes per second bandwidth). A high-resolution document camera was used to project images during assessment and intervention.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:**12 video-conferencing sessions

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** Not stated directly, hospital staff implied. Social worker at the centre co-ordinated the project.

**Duration of intervention:**6 weeks

**Comparison intervention:** A total of 12 CI sessions were conducted over 6 weeks through face-to-face method.

## Outcomes

**Primary outcomes:**

- Cognitive improvement (cognitive status; behavioural memory; dementia grade)
- Acceptability and adherence (fidelity with TM) with intervention

**Follow-up time:** 6 weeks from start of intervention

## Notes

**Ethical approval and informed consent obtained (yes/no):** unclear

**Sources of funding:** SK Yee Medical Foundation contract/grant number 202214

**Conflict of interest:** no information

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.

**Poon 2005** (Continued)

Were baseline outcome measurements similar?	Low risk	p.286, Col.1, Para 2  QUOTE:  "At baseline, no significant difference was found between the two intervention groups in their clinical and demographic characteristics as well as the scores of neuropsychological tests. Table 1."
Were baseline characteristics similar?	Unclear risk	No data on baseline characteristics reported, just that there were no differences between groups.see quote above.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. Non-objective outcomes of cognitive status; no information on blinding of outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Unclear risk	Difficult to judge possible other risk of bias due to the scarce information provided in this short report.

**Ralston 2009**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> patients 18 to 75 years old with type 2 diabetes, whose most recent glycated haemoglobin (GHb) in the prior 12 months was 7%, and who had made at least two visits to GIMC during the prior year.</p> <p><b>Exclusion criteria:</b> participation in the pilot study of the intervention, major psychological illness, non-English speaking, had a resident as a primary physician, or were followed primarily in a specialty clinic.</p> <p><b>Method of patient recruitment:</b> Electronic medical record data were used to identify potential participants complying with the inclusion criteria. Following an invitation letter, the study co-ordinator contacted potential participants by phone to assess study eligibility. At the end of the recruitment phone call, the study co-ordinator invited eligible participants to participate.</p> <p><b>Study sample calculation:</b> The trial was designed to have 80% power to detect a difference of 0.5% in GHb concentration (two-sided significance level of <math>P &lt; 0.05</math>; SD of mean GHb 1.26; mean change in Z score SD in GHb levels 0.87).</p> <p><b>Data collection:</b> Baseline data for all participants were from automated data in the electronic medical record. Participants were called 12 months after randomisation for a GHb test if one had not been obtained between 9 and 12 months post-randomisation. We used the GHb measure closest to 12 months after randomisation and no earlier than 9 months or later than 15 months after randomisation.</p> <p><b>Unit of analysis issues:</b> no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 102 (n = 19 refused to participate)</p> <p><b>No of patients randomised to groups:</b> n = 83; Intervention: n = 42 ; Control: n = 41</p>

**Ralston 2009** (Continued)

**No of patients lost to follow-up:** n = 9 patients dropped out, three from the web-based care group and six from the control group.

**Patient baseline characteristics:**

- a) Clinical condition: Type 2 diabetes
- b) Age, mean years: Intervention: 57.0; Control: 57.6
- c) Gender, % female sex: Intervention: 47.6 : Control: 51.2
- d) Ethnicity, Non-Hispanic white (%): Intervention: 89.7; Control: 73.0
- e) Severity of condition:

Insulin use (%): Intervention: 38.1; Control: 39.0

Baseline values of outcomes

GHb (%): Intervention: 8.2; Control: 7.9

Systolic blood pressure (mmHg): Intervention: 133.3; Control: 133.0

Diastolic blood pressure (mmHg): Intervention: 76.3; Control: 76.0

Total cholesterol (mg/dl): Intervention: 188.8; Control: 192.7

Outpatient visits (n): Intervention: 9.6; Control: 10.3

Primary care, annual (n): Intervention: 4.3; Control: 3.3

Specialty care, annual (n): Intervention: 5.3; Control: 7.0

Inpatient days (n): Intervention: 0.3; Control: 0.7

**Setting** (hospital/community/residential care): one UW General Internal Medicine Clinic (GIMC), a teaching clinic that provides care to 7,707 patients. The clinic is staffed by 25 faculty and 48 resident providers and employs a nurse practitioner to provide case management services to chronic-disease patients.

**Location** (rural/urban etc.): no information

**Country:** USA

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Interventions

**Study objective:** To test web-based care management of glycemic control using a shared electronic medical record with patients who have Type 2 diabetes.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (additional to UC)

**Delivery of the intervention:** Participants in the care management intervention initially met with the care provider during a 1-hour visit. The care manager introduced the participants to the web-based programme and encouraged them to review on-line medical records, send blood glucose readings weekly and send secure e-mails as needed. She responded to patients' messages Monday through Friday, reviewed blood glucose levels at least once a week, adjusted hypoglycaemic medications and conferred with the primary care physician as needed.

**Type of technology and its application:** The web-based program included patient access to electronic medical records, secure e-mail with providers, feedback on blood glucose readings, an educational web site, and an interactive online diary for entering information about exercise, diet, and medication.

**Did the patient receive education about their condition?** Only through the educational web site

**Frequency of patient data transfer (monitoring studies only):** once a week

**Planned /scheduled no of TM contacts between patient and healthcare professional:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The care manager
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): unclear (or e-mail?)

**Ralston 2009** (Continued)

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): once a week

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): adjusted hypoglycaemic medications and conferred with the primary care physician as needed.

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** one case manager

**Duration of intervention:** 12 months

**Comparison intervention:** All participants received care from a physician that was board certified in internal medicine at the UW GIMC. All providers used the same electronic medical record, which included patient specific reminders for measurements of HbA1c < 7%.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• HbA1c</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• HbA1c &lt; 7%</li><li>• Serum glucose (unclear if fasting values)</li><li>• Total cholesterol (no raw-data provided)</li><li>• Blood pressure (no raw-data provided)</li><li>• Outpatients visits</li><li>• Inpatients days</li></ul> <p><b>Follow-up time:</b> 12 months after randomisation (data were collected at between 9 and 15 months follow-up)</p>	
Notes	<p><b>Ethic's committee approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> a grant from the Center for Health Management Research.</p> <p><b>Conflict of interest:</b> J.D.R. received grant funding from Sanofi-Aventis between 1 July 2004 and 30 June 2006. I.B.H. has been a consultant for Eli Lilly, Novo Nordisk, Abbott Diabetes Care, and Roche and has received grant support from Sanofi-Aventis. No other potential conflicts of interest relevant to this article were reported.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.,234 Col.3, Para.5</p> <p>QUOTE:</p> <p>“The study’s statistician used a computer random number generator to create a random number table in a non blocked sequence.”</p>
Allocation concealment (selection bias)	Low risk	<p>p.,234 Col.3, Para.5</p> <p>QUOTE:</p> <p>"Allocation to the study group was concealed from the study coordinator and the participant until after the recruitment phone call."</p>
Were baseline outcome measurements similar?	Low risk	No differences between groups.

## Ralston 2009 (Continued)

Were baseline characteristics similar?	Low risk	Baseline characteristics were similar in both groups, apart from a larger percentage of Caucasians in the intervention group (89.7%) as compared to control (73%).
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Blinding was not possible. However, all outcomes were objective and therefore the risk of bias low.
Incomplete outcome data (attrition bias) All outcomes	Low risk	N = 9 patients dropped out, 3 of 42 patients (7.1%) from the web-based care group and 6 of 41 (14.6%) from the control group. For missing data baseline data was carried forward.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol are reported in the paper.
Other bias	Low risk	No other risk of bias identified.

## Rasmussen 2005

Methods	<p><b>Study design:</b> RCT (3-armed)</p> <p><b>Inclusion criteria:</b> age 18-45 years, Asthma diagnosed on the basis of a combination of respiratory symptoms and at least one objective measurement of asthma (i.e., airway hyper-responsiveness to inhaled methacholine of 4 mmol, peak expiratory flow (PEF) variability of 20%, and/or a minimum of 15% (300 mL) increase in FEV<sub>1</sub> after bronchodilation).</p> <p><b>Exclusion criteria:</b> no information</p> <p><b>Method of patient recruitment:</b> In 2001, a random sample of participants with diabetes living in the catchment area of H:S Bispebjerg University Hospital of Copenhagen, Denmark, was sent the American College of Allergy, Asthma, and Immunology asthma questionnaire with the purpose of including 300 patients with definite asthma. Letters were posted until 300 asthmatic participants had been enrolled.</p> <p><b>Study sample calculation:</b> On a 95% power to detect a significant difference in AQLQ, 80 patients were required in each group. An estimated loss of 20% in each group at follow-up was expected, resulting in enrolment of 300 asthmatic participants, 100 in each group.</p> <p><b>Data collection:</b> At 2 scheduled visits 6 months apart the questionnaires were filled in, spirometry was performed, measurement of airway responsiveness with methacholine was conducted by trained laboratory assistants, and each patient was interviewed by the physician.</p> <p><b>Grading of symptoms:</b> The severity of symptom was graded as follows: very mild, respiratory symptoms less than once a week and nocturnal symptoms not more than twice a month; mild, respiratory symptoms 2 to 6 times a week and nocturnal symptoms more than twice a month but not weekly; moderate, respiratory symptoms daily and nocturnal symptoms more than once a week; and severe, respiratory symptoms constantly and nocturnal symptoms more than 4 times a week</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 200; Internet-based monitoring: n = 100; GP care (Control): n = 100. Note: a third group (specialist care, n=100) was not included in this review.</p> <p><b>No of patients lost to follow-up:</b> No significant difference was found in the dropout rate of the 3 groups (15, 12, and 20 participants, in the Internet-based group, the specialist care group and the GP group respectively)</p> <p><b>Patient baseline characteristics:</b></p>

## Rasmussen 2005 (Continued)

Internet group: n = 85; Specialist group: n = 88; GP group: n = 80

a) Clinical condition: Asthma

b) Age, year: Internet-based monitoring: 28 (18-44); GP care: 30 (20-45)

c) Gender/Sex (F/M): Internet-based monitoring: 58/27; GP care: 58/30

d) Ethnicity: no information

e) Severity of condition:

FEV1, % predicted: Internet group: 91 (14); GP group: 92 (12)

AHR logDRS: Internet group: 1.03 (0.5); GP group: 1.02 (0.5)

Symptoms grading:

Very mild (%): Internet-based monitoring: 1; GP care: 1

Mild (%): Internet-based monitoring: 49; GP care: 50

Moderate (%): Internet-based monitoring: 25; GP care: 24

Severe (%): Internet-based monitoring: 25; GP care: 25

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): primary care (GP clinics) and an outpatient clinic

**Location** (rural/urban etc.): urban (Copenhagen)

**Country:** Denmark

## Interventions

**Study objective:** To investigate the outcome of monitoring and treatment using a physician-managed online interactive asthma monitoring tool and to assess whether the outcomes differ from that of monitoring and treatment in an outpatient respiratory clinic or in primary care.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** internet-based monitoring

**Delivery of intervention:**

**Internet-based monitoring :**

*The first internet consultation:* Patients with persistent asthma received one month of treatment with a high dose of inhaled corticosteroids, and thereafter the decision support system was used to check whether the asthma had been brought under control; the physician then instructed the patient by e-mail or telephone to increase, decrease, or continue the usual treatment. *The second Internet consultation:* Patients treated with a moderate dose of inhaled corticosteroid were reduced to a low dose of inhaled corticosteroid if the decision support system recommended it. However, if the patients' symptoms were not controlled, they either had to step up or continue on the moderate dose, depending on the instructions given by the decision support system. If patients had been treated for two months with a high dose of inhaled corticosteroid, the decision support system was used to see whether they could be reduced to a moderate dose of inhaled corticosteroid or had to continue another month on the high dose together with addition of a long-acting  $\beta_2$ -agonist. *The third Internet consultation:* Patients with well-controlled symptoms taking a low dose of inhaled corticosteroid continued on this dose for another month. Patients treated with a moderate or high dose of inhaled corticosteroid with or without a long-acting  $\beta_2$ -agonist were checked by the decision support system to see whether a reduction was possible; if not, they continued to take the same dose for yet another month. *The fourth Internet consultation:* If symptoms of patients treated with a low dose of inhaled corticosteroid were well controlled, they continued on this dose until the scheduled 6-month visit at the clinic. If they were treated with a moderate dose of inhaled corticosteroid with or without a long-acting  $\beta_2$ -agonist, they continued receiving this dose until the 6-month visit. If they still were treated with a high dose of inhaled corticosteroid,

## Rasmussen 2005 (Continued)

teroid with or without a long-acting  $\beta_2$ -agonist, they continued on the same dose the next month. *An extra Internet consultation:* The patients receiving a high dose of inhaled corticosteroid or patients experiencing an exacerbation were checked with the decision support system one more time before the 6-month visit to the clinic.

### Specialist group:

Patients were treated according to their current severity level, and they were taught how to adjust their medication. A peak flowmeter and a written action plan were given to the patients, and they were asked to use them regularly, preferably daily. The action plan comprised a 3-colour warning system based on the symptom score and PEF values.

**Type of technology and its application:** The Internet-based asthma management tool comprised of (1) an electronic diary, (2) an action plan for the patients, and (3) a decision support system for the physician. Patients were given a peak flowmeter (Vitalograph, Ltd, Maid Moriton, Buckingham, United Kingdom) and instructed in the use of the Internet diary. If the patient did not have access to a computer, a push-button telephone was used. Using either option, patients were able to complete the electronic asthma diary and record symptoms, need for rescue medication, and PEF values. The Internet tool's action plan comprised a 3-colour warning system accompanied by a written treatment plan. Patients were encouraged to fill in the electronic diary daily and to follow the instructions given by the computer and the physician.

**Did the patient receive education about their condition?** No information

**Frequency of patient data transfer (monitoring studies only):** daily

**Frequency/number of TM contacts between patient and healthcare personnel**

**a) Planned/scheduled number of contacts:** 2 scheduled visits 6 months apart

**b) Actual number of contacts:** unclear

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The physician

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): e-mail or telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week):no information

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): changing medication treatment (increase, decrease or continue the current treatment)

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** asthma specialist physician, GPs

**Duration of intervention:** 6 months

**Comparison intervention:**The patients were asked to contact their GP immediately after enrolment and pass on a letter describing the study and giving the test results. The letter did not contain particulars about the recommended therapy, but in 2001, all the GPs in the Copenhagen area had been sent a circular about asthma and GINA guidelines by the local authority. The GP was to assess the patient's asthma symptoms and the test results and from this decide the patient's need for pharmaceutical treatment. The patients in the GP group did not receive any treatment or information about asthma from the study physician.

## Outcomes

### Primary outcomes:

- Asthma symptoms (assessed through interview)
- AQOL (assessed with the Asthma Quality of Life Questionnaire)
- Lung function
- Airway responsiveness



**Rasmussen 2005** (Continued)

- Hospitalisations (assessed through interview)
- Adverse reactions (assessed through interview)

**Follow-up time:** 6 months from randomisation

Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** grants from H:S Corporation of University Hospital of Copenhagen, AstraZeneca, and private funds, none of whom had any role in writing the protocol; collecting, analysing, or interpreting the data; or writing of the article.

**Conflict of interest:** A grant, managed by V. Backer, was given by AstraZeneca. K. Phanareth was employed as a consultant on an hourly basis by AstraZeneca DK during the first 2 years of the project, No other conflicts of interest are disclosed

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.1138, Col.1, Para.1  QUOTE:  "The patients were randomized consecutively by using the sealed envelope technique, irrespective of computer experience and smoking status,"
Allocation concealment (selection bias)	Unclear risk	see quote above
Were baseline outcome measurements similar?	Low risk	p.1139, Col.1, Para 1  No differences between groups.
Were baseline characteristics similar?	Low risk	p.1139, Col.1, Para 1  No differences between groups.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, the outcomes were objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participating patients could not be blinded to the intervention allocation. Outcomes were based on patients self-report; no information on blinding of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.1139, Col.1, Para 1  QUOTE:  "Two hundred fifty-three subjects completed both the screening and follow-up visits. The dropout rate of the 3 groups was 15, 12, and 20 subjects. Comment: no information if the characteristics of patients who dropped out differed significantly from those who remained in the study.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Rodriguez-Idigoras 2009

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients &gt; 30 years of age diagnosed with Type 2 diabetes and on self-monitoring for at least 6 months before the beginning of the study.</p> <p><b>Exclusion criteria:</b> Patients with difficulties in using the system because of the number and severity of their complications and co-morbidities of diabetes, as well as those who required a caregiver.</p> <p><b>Method of patient recruitment:</b> A total of 35 family physicians and 24 nurses from the province of Malaga voluntarily participated in the study. Study participants were selected from their patients. Eight to 10 participants were selected from each physician's patients. An updated list including each physician's Type 2 diabetes patients was obtained, and subsequently participants were selected through a systematic sampling design with a random start. Patients remained in the same order in which they had been selected.</p> <p><b>Study sample calculation:</b> The trial has an 80% statistical power to detect differences of 10% between both groups in the decrease of patients with HbA1c &gt; 8% over the course of the study.</p> <p><b>Data collection:</b> Collection of data was performed at 3 and 6 months and by the end of the trial. During the study follow-up period, we collected data on metabolic parameters (HbA1c) and blood glucose values. We also recorded the frequency and results of blood glucose readings for each patient. Patients in the control group recorded them on their patient chart, and results from the tele assistance group were recorded on the call centre application.</p> <p><b>Unit of analysis issues:</b> (yes/no):</p>
Participants	<p><b>Total no of eligible patients:</b> n = 2184 fulfilled the study inclusion criteria, of whom 717 were randomly selected for participation. However, in 389 cases there was some reason for exclusion (low cultural level, complications and/or co-morbidities, and patients who needed a caregiver); another 143 refused to participate.</p> <p><b>No of patients randomised to groups:</b> n = 328: Intervention: n = 161; Control: n = 167</p> <p><b>No of patients lost to follow-up:</b> Intervention: n = 15; Control: n = 16</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition: Type 2 diabetes</li> <li>b) Age, median (range): Intervention: 63.32 (61.60, 65.04); Control: 64.52 (62.96, 66.09)</li> <li>c) Sex (male/female) (% male): Intervention: 87/74 (54.0); Control: 82/85 (49.1)</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition: <ul style="list-style-type: none"> <li>Duration of disease (years): Intervention: 11.32 (10.16, 12.50); Control: 10.18 (9.11, 11.25)</li> </ul> </li> <li>f) Major co-morbidities: excluded</li> </ul> <p><b>Setting</b> (hospital/community/residential care): community health centres</p> <p><b>Location</b> (rural/urban etc.): province of Malaga, Andalucia</p> <p><b>Country:</b> Spain</p>
Interventions	<p><b>Study objective:</b> to evaluate the impact of a tele assistance system on the metabolic control of Type 2 diabetes patients.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> tele assistance and telephone to assist self-monitoring</p>

**Rodriguez-Idigoras 2009** (Continued)

**Delivery of intervention:** Patients in the intervention group sent, in real-time and via their mobile phone, their blood glucose measurements to the call centre. When blood glucose levels were not within normal range, the system sent an alarm to the call centre, and previously established protocol interventions were implemented. Patients could also telephone their physician or the call centre professional staff (a physician and a nurse specializing in diabetes and diabetes education), if they were not connected to the system. Physicians could contact their patients via mobile phone and have access to any information patients sent through the web page. Each call or alarm was answered using standard protocols, and all interventions were recorded.

Training activities were carried out for healthcare professionals to become familiar with the telemetric system to be used. Patients were instructed in the use of the glucometer and the mobile phone.

**Type of technology and its application:** An ACCU-Chek Compact glucometer (Roche Diagnostics, Mannheim, Germany), for determination of glucose in fresh capillary blood by reflectance photometry, was provided to all patients at the beginning of the study. In addition, patients assigned to the intervention group and their family physicians were given a mobile phone. Patients and physicians' mobile phones, together with the call centre, made up the tele assistance system, DIABECOM, from Roche Diagnostics.

**Did the patient receive education about their condition?** No information

**Frequency of patient data transfer (monitoring studies only):** no information, only that it was real-time data transfers

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone):mobile phone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week):answered using a standard protocol, with immediate response when necessary
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):Standard protocol used to decide on interventions

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** a specialist physician and a nurse specialising in diabetes and diabetes education; a family physician

**Duration of intervention:**12 months

**Comparison intervention:** Control patients were being regularly followed up at their healthcare centre.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Systolic and diastolic blood pressure,</li> <li>• Total cholesterol,</li> <li>• Low-density lipoprotein (LDL) cholesterol,</li> <li>• Body mass index (BMI)</li> </ul> <p><b>Follow-up time:</b> 12 months from start of intervention</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Emminens, the company that finances the research on which this article is based. Roche Diagnostics Spain (Diabetes Care) provided glycometers and mobile phones..</p>

**Rodriguez-Idigoras 2009** (Continued)

**Conflict of interest:** The authors declare that Emminens, does not use the work system described in the mentioned article, and therefore there is no duality of interest. All authors declare no competing financial interests

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.432, Col.2, Para.2  QUOTE:  "In order to ensure that each physician's patients were randomly allocated in a balanced way, block randomization was used, with an allocation sequence being generated by means of a table of random numbers."
Allocation concealment (selection bias)	Low risk	p.432, Col.2, Para.2  QUOTE:  "Allocation was concealed,"
Were baseline outcome measurements similar?	Low risk	p.435, Table 1  Baseline outcome measures of the individuals from both groups were similar (Table 1).
Were baseline characteristics similar?	Low risk	p. 433, first paragraph under 'Results'  QUOTE:  "Baseline characteristics of the individuals from both groups were similar (Table 1)."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, all outcomes were objective (BP, BMI, metabolic).
Incomplete outcome data (attrition bias) All outcomes	Low risk	A similar number of patients were lost from each group.  p.433, first paragraph under 'Results'  QUOTE:  "During the trial seven patients died, and another 24 were lost to follow-up; therefore, in 1 year we followed 146 patients (91%) from the intervention group and 151 (90%) from the control group."
Selective reporting (reporting bias)	Low risk	No evidence of selective outcome reporting.
Other bias	Low risk	No evidence of other risk of bias.

**Rogers 2001**

Methods

**Study design:** RCT

**Rogers 2001** (Continued)

**Inclusion criteria:** adults with a previous diagnosis of essential hypertension who were under evaluation for a change in antihypertensive therapy because of 1) elevated blood pressure (systolic blood pressure >140 or diastolic pressure >90 mm Hg) despite current antihypertensive therapy, 2) undesirable side effects of current antihypertensive medication, or 3) office systolic pressure of at least 180 mm Hg or diastolic pressure of at least 110 mm Hg with no current use of antihypertensive medication.

**Exclusion criteria:** younger than 18 years; pregnancy, secondary hypertension, or did not have the capacity to monitor blood pressure at home.

**Method of patient recruitment:** From May 1999 to April 2000 five internists from the Department of medicine at the State university of New York Upstate Medical University in Syracuse recruited patients from internal medicine outpatient practices affiliated with the general medicine division.

**Study sample calculation:** A priori sample size was calculated to detect a mean ( $\pm$  SD) difference in blood pressure of  $3 \pm 5$  mm Hg between the two study groups. this yielded 60 patients per group with 90 % power.

**Data collection:** A clinical research nurse (the case manager) fitted the participants with a 24-hour ABPM device at baseline and at exit. The nurse gave the patients detailed instructions for using the device. The device automatically recorded blood pressure values every 30 min between certain hours.

**Unit of analysis issues:** (yes/no):no

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Participants

**Total no of eligible patients:** n = 167

**No of patients randomised to groups:** n = 121; **Intervention:** n = 60; **Control:** n = 61

**No of patients lost to follow-up:** 7% of patients in the intervention group and 10% of patients in the control group were lost to follow-up.

**Patient baseline characteristics:**

- a) Clinical condition: essential hypertension
- b) Age, mean (SD): Intervention: 62.6 (10.0) years; Control: 60.3 (11.9) years
- c) Gender, female sex no (%) ; Intervention: 34 (56.7); Control: 27 (44.3)
- d) Ethnicity, white no (%): Intervention:46 (80.7) ; Control: 52 (91.2)
- e) Severity of condition: BMI, mean (SD), kg/m<sup>2</sup>: Intervention: 31.5 (7.6); Control: 28.9 (5.2)
- f) Major co-morbidities:
  - Diabetes, no (%): Intervention:13 (22.8); Control: 15 (26.3)
  - Cardiovascular disease, no (%): Intervention:7 (13.0) ; Control:11 (20.0)

**Setting** (hospital/community/residential care): university affiliated primary care outpatient clinics

**Location** (rural/urban etc.): urban (New York)

**Country:** USA

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Interventions

**Study objective:** To determine the efficacy of a telecommunication service in reducing blood pressure.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** Patients were instructed to take their blood pressure three times in the morning before eating or drinking and three times in the evening before going to bed. After each reading, the device automatically dialled the Service and Support Center at Welsh Allyn, and transmitted the data. Patients were asked to conduct this routine at least 3 days each week for a minimum of 8 weeks, and could take additional readings if they desired. A computer program displayed the results in a report form, which was then faxed to each patient's physician. Both physicians and patients received a report form each week, as well as a summary report at the end of the trial. When physicians received

**Rogers 2001** (Continued)

report forms that indicated elevated pressure, they adjusted antihypertensive medications through a telephone call, an office visit or both

**Type of technology and its application:** A blood pressure monitoring device that transmitted data over analogue telephone lines (Model 52500, Welsh Allyn, Inc. Skaneateles Falls, New York). The oscillometry device (16.26 cmX10.92 cmX6.6 cm) had a digital display for blood pressure and pulse and used automatic pressurization and exhaust for cuff inflation and deflation.

**Did the patients receive education about their condition?** The patients received printed educational material on non-pharmacological approaches to blood pressure control from the national Heart, Lung and Blood Institute.

**Frequency of patient data transfer (monitoring studies only):** at least 3 times per week

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The physician
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone, office visit or both
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): the report was faxed to the physician one a week (unclear when), after s/he could take actions in case of elevated pressure
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): adjustment of antihypertensive medication

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians (internists)

**Duration of intervention:** at least 8 weeks (the median time from baseline to exit was 11 weeks)

**Comparison intervention:** Patients assigned to UC were treated for hypertension according to the guidelines of the Joint national Committee on Prevention, Detection, and Treatment of High Blood Pressure.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• Change in mean arterial pressure (measured as diastolic pressure 1 1/3 [systolic pressure - diastolic pressure]).</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Changes in systolic pressure, diastolic pressure, and heart rate (by using 24-hour ABPM).</li><li>• Percentage of readings above target levels</li></ul> <p><b>Follow-up time:</b> at least 8 weeks from randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Welsh Allyn, Inc.(the same company that provided the equipment for the study)</p> <p><b>Conflict of interest:</b> The funding source did not participate in the study design, implementation, or data analysis and had no role in the decision to publish the results.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.1025, Col.2, Para.2  QUOTE:

**Rogers 2001** (Continued)

		“..we used a blocking procedure with random permuted blocks of varying size to reduce predictability. Randomisation was stratified by the number of pre-prescription medications patients were taking. Sequentially numbered, sealed opaque envelopes were used for assignments ”
Allocation concealment (selection bias)	Low risk	p.1025, Col.2, Para.2  QUOTE:  “Sequentially numbered, sealed opaque envelopes were used for assignments ”
Were baseline outcome measurements similar?	Unclear risk	No information.
Were baseline characteristics similar?	Unclear risk	Higher BMI in the intervention group as compared to the controls.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients; objective outcome of BP.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only four patients in the intervention group and six patients in the control group were lost to follow-up (93% vs. 90 % of patients remained in the study at follow-up).
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Ruskin 2004**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> score 16 or higher on the Hamilton depression scale and meeting the DSM-IV (SCID) criteria for one of the following five diagnoses: major depressive disorder, dysthymic disorder, adjustment disorder with depressed mood, mood disorder due to a general medical condition, or depressive disorder not otherwise specified.</p> <p><b>Exclusion criteria:</b> if meeting the criteria for bipolar disorder or schizophrenia at any point in their lifetime or met the criteria for substance abuse or dependence within the past year; if they required hospitalisation or if they had been receiving pharmacological treatment for depression for more than a month immediately before the initial visit.</p> <p><b>Method of patient recruitment:</b> Veterans who were referred to any of three mental health clinics within the Department of Veterans Affairs (VA) Maryland Health Care System were evaluated for participation</p> <p><b>Study sample calculation:</b> The size of the study group was originally chosen to detect small to moderate effect sizes. With the group sizes of 60 that were obtained, there was 80% power for the detection of a standardised difference of 0.5 standard deviation (a moderate effect size) at any given follow-up time point and of an average difference of 0.28 standard deviation (a rather small effect size) over three follow-up time points.</p> <p><b>Data collection:</b> the raters were not blind to treatment condition, their ratings might have been biased in favour of or against telepsychiatric treatment.</p>
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**Ruskin 2004** (Continued)

**Unit of analysis issues:** (yes/no):no

**Participants**

**Total no of eligible patients:** unclear, 561 patients were contacted for possible participation in the study and of these 436 were interested in the study and were screened for eligibility- 131 were found eligible

**No of patients randomised to groups:** n = 119; Intervention:59 ; Control: 60

Twelve of the 131 eligible patients (eight in the remote treatment condition and four in the in-person treatment condition) were withdrawn at the start of the study of different reasons (active substance abuse). Sixteen participants (27%) in the remote group and 18 (30%) in the in-person group dropped out of the study. Patients lost to follow-up were retained in the analysis by using their last observable score for all the remaining time points. Withdrawal after randomisation: TM:8; UC:4

**No of patients lost to follow-up:** TM: n = 16 (27%); UC:18 (30%) dropped out of the study

**Patient baseline characteristics:**

- a) Clinical condition: depression
- b) Age, mean  $\pm$ SD: 49.7 years (12.8)
- c) Gender, male/female: 105/14
- d) Ethnicity, white %: 61%
- e) Severity of condition: NA
- f) Major co-morbidities: NA

**Setting** (hospital/community/residential care): three mental health clinics within the Department of Veterans Affairs (VA) Maryland Health Care System

**Location** (rural/urban etc.): unclear

**Country:** USA

**Interventions**

**Study objective:** To compare treatment outcomes of patients with depressive disorders treated remotely by means of telepsychiatry to outcomes of depressed patients treated in person

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conference (consultation/psychotherapy treatment/education)

**Delivery of intervention:** Remote treatment occurred in one of the following two arrangements: 1) psychiatrists located at Baltimore saw patients located at Perry Point or Cambridge or 2) psychiatrists located at Perry Point or Cambridge saw patients located at Baltimore. Psychiatric treatment lasted 6 months and consisted of psychotropic medication, psycho-education, and brief supportive counseling.

**Type of technology and its application:** VTEL software (VTEL Corp., Austin, Tex.) and cameras mounted on the monitors. The equipment was connected to integrated services digital network lines, and transmission usually occurred at a rate of 384 kbit/second.

**Did the patients receive education about their condition?** NA

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** eight sessions

**Clinician response to receipt of data (monitoring studies only):** N/A

- a) Who contacts the patient?: N/A

## Ruskin 2004 (Continued)

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone):N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week):N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** Eight board-certified or board-eligible psychiatrists provided treatment throughout the study. Each psychiatrist saw patients in both treatment conditions.

**Duration of intervention:** 6 months

**Comparison intervention:** Face-to-face treatment sessions -eight sessions with a psychiatrist over a 6-month period.

Outcomes	<p>Primary outcomes:</p> <ul style="list-style-type: none"><li>• Treatment response (measured with the 24-item Hamilton depression scale (weeks 0, 7, 15, and 26), Beck Depression Inventory (weeks 0, 1, 3, 7, 11, 15, 19, and 26) (18), Spielberger Trait AnxietyInventory Scale (weeks 0 and 26) (19), the Spielberger State AnxietyScale (19) (weeks 0, 1, 3, 7, 11, 15, 19, and 26), Global Assessmentof Functioning Scale (GAF) (weeks 0 and 26), Clinical GlobalImpression (CGI) (20) (weeks 0 and 26), and Medical OutcomesStudy 12-Item Short-Form Health Survey (21) (weeks 0 and 26).)</li><li>• Adherence (assessed in terms of dropout rates, time course of dropouts, number of session appointments kept, and pill counts)</li><li>• Resource consumption (all medical events, including the psychiatry visits in the study, were tracked through the electronic medical records system)</li><li>• Costs (was measured in two ways: 1) by estimating the marginal costs of operating the tele-psychiatry session compared to the in-person session (intervention cost) and 2) by examining whether the telepsychiatry intervention increased or decreased total Veterans Health Administration healthcare resource consumption for these patients during the 6-month study period (intervention’s cost consequences).</li><li>• Satisfaction (assessed with non-validated scale that was developed for this study, results not included in the review)</li></ul> <p><b>Follow-up time:</b> 6 months after randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding</b> the VA Office of Research and Development Health Services Research and Development Service, the VA Maryland Health Care System, and the VISN 5 Mental Illness Research, Education and Clinical Center</p> <p><b>Conflict of interest:</b> None stated.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.1472, Col.1, Para.2</p> <p>QUOTE:</p> <p>“A stratified, variable block randomization procedure was used to make treatment assignments on the basis of age (young: &lt;50 years, old: ≥50 years) and depression severity (mild: Hamilton depression scale score &lt;24, severe: Hamilton depression scale score ≥24).”</p>
Allocation concealment (selection bias)	Low risk	See quote above.

**Ruskin 2004** (Continued)

Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.1474, Col.1, Para.1 No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Neither patients nor healthcare professionals could be blinded to the intervention. Psychiatrist saw patients in both treatment conditions. However, the objective outcome data on treatment adherence, resource use and cost were retrieved from registers.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Neither patients nor healthcare professionals could be blinded to the intervention. Psychiatrist saw patients in both treatment conditions.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.1474, Col.1, Para.5 QUOTE: "Sixteen participants (27%) in the remote group and 18 (30%) in the in-person group dropped out of the study" Patients lost to follow-up were retained in the analysis by using their last observable score for all the remaining time points. Withdrawal after randomisation:TM:8; UC:4
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol reported in the paper.
Other bias	Low risk	No evidence of other risk of bias.

**Scherr 2009**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients were eligible for the study if they met all of the following inclusion criteria: acute worsening of heart failure (HF) (acute cardiac decompensation) with hospital admission lasting &gt; 24 hours within the last 4 weeks, treatment according to the guidelines of the European Society of Cardiology (ESC) with an angiotensin converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), diuretic, and beta-blocker (except in cases with documented intolerance to beta-blockers). Initially, patients older than 18 years and younger than 75 years were eligible; the latter was amended to 80 years after 4 months of recruitment.</p> <p><b>Exclusion criteria:</b> Patients with one of the following conditions were not eligible for MOBTEL: unstable coronary artery disease (CAD) with revascularisation within the last 6 months, planned revascularisation (percutaneous or surgical) for CAD, planned heart valve surgery, planned or completed heart transplantation, uncontrolled arterial hypertension, acute myocarditis, inability to read the display of a handheld phone, or malignancy.</p> <p><b>Method of patient recruitment:</b> no information</p> <p><b>Study sample calculation:</b> To show a statistically significant difference at an error of .05 with a power of 80%, a sample size of 240 participants was calculated.</p> <p><b>Data collection:</b> Baseline demographics and medication were recorded for all patients, and an appointment for the 6-month follow-up was made. No further information on how the different outcomes were collected.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
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**Scherr 2009** (Continued)

Participants

**Total no of eligible patients:** no information

**No of patients randomised to groups:** n = 120: Intervention: n = 66; Control: n = 54

**No of patients lost to follow-up:** 12 patients (20%) in TM group emerged unable to begin transmission of data and were lost to follow-up. Furthermore, there were four patients (6.7%) in the TM group who requested early termination of the study.

**Patient baseline characteristics:**

a) Clinical condition: HF

b) Median age, years (IQR): Intervention: 65 (62-72); Control: 67 (61-72)

c) Gender, male, no. (%); Intervention: 40 (74); Control: 39 (72)

d) Ethnicity: no information

e) Severity of condition:

Median LV ejection fraction (IQR): Intervention: 25 (20-38); Control: 29 (21-36)

NYHA class II, no. (%): Intervention: 7 (13); Control: 7 (13)

NYHA class III, no. (%): Intervention: 33 (61); Control: 37 (68.5)

NYHA class IV, no. (%): Intervention: 14 (26); Control: 10 (18.5)

Median number of HF hospitalisations in past 12 months, no. (IQR): Intervention: 1 (1-2); Control: 1 (1-2)

Median length of stay for HF hospitalisations, days (IQR): Intervention: 12 (9-15); Control: 11 (7-17)

f) Major co-morbidities:

Ischaemic heart disease, no. (%): Intervention: 20 (37); Control: 23 (43)

Hypertension, no. (%): Intervention: 29 (54); Control: 24 (44)

Valvular disease, no. (%): Intervention: 1 (2); Control: 1 (2)

Diabetes mellitus, no. (%): Intervention: 12 (22); Control: 16 (30)

g) Medications at BL:

ACE inhibitor, no. (%): Intervention: 45 (83); Control: 41 (76)

ARB, no. (%): Intervention: 9 (17); Control: 13 (24)

Diuretic, no. (%): Intervention: 49 (91); Control: 44 (81)

Beta-blocker, no. (%): Intervention: 47 (87); Control: 42 (78)

Spirolactone, no. (%): Intervention: 21 (39); Control: 23 (43)

**Setting** (hospital/community/residential care): no information

**Location** (rural/urban etc.): no information

**Country:** Austria

Interventions

**Study objective:** To evaluate the impact of home base tele-monitoring using Internet and mobile phone technology on the outcome of heart failure patients after acute decompensation.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

## Scherr 2009 (Continued)

**Delivery of intervention:** Patients randomised into the tele-group were equipped with mobile phone-based patient terminals for data acquisition and data transmission to the monitoring centre. They were asked to measure vital parameters (blood pressure, heart rate, body weight) on a daily basis at the same time, preferably in the morning after emptying the bladder and before dressing and taking medication. Thereafter, patients were advised to enter these values as well as their dosage of heart failure medication into the mobile phone's Internet browser and send them to the monitoring centre provided by the Austrian Institute of Technology (AIT) – Information Management & eHealth, Graz. Study physicians had access to a secure web site providing both numerical and graphical depiction of data for each patient. Whenever necessary, study physicians could contact patients using the mobile phone. At the monitoring centre, data were depicted both numerically and graphically in an electronic case record form. Study physicians had continuous access to the case reports forms (CRFs) of their patients via a secure web site. Physicians were advised to use the automated warning system for the monitoring of vital parameters of their patients. If transmitted values went outside individually adjustable borders, study physicians were sent an e-mail alert. Additionally, an e-mail alert was generated if a patient's body weight increased or decreased more than 2 kg in 2 days. After receiving an alert, study physicians could contact the patient directly via the mobile phone to confirm the parameters and, if appropriate, could ask the patient to adjust his or her medication. For technical questions, patients had access to a 24-hour hotline at the service centre.

**Type of technology and its application:** The tele-monitoring equipment consisted of three commercially available components: (1) a mobile phone (Nokia 3510, Finland), (2) a weight scale with 0.1 kg accuracy and electronic display (Soehnle creta, Germany), and (3) a sphygmomanometer for fully automated measurement of blood pressure and heart rate (BosoMedicus, Bosch&Sohn, Germany). Tele-group patients were trained in measurement of blood pressure and weight using the equipment prior to discharge home. Furthermore, tele-group patients were instructed by a study technician in the use of the mobile phone.

The MOBITEL telemedicine platform was developed as a three-tier, client-server architecture (data, logic, and representation layers) using state-of-the-art Internet technology. The Zope Web/application server (Zope 2.6.1, Zope Corporation, Fredericksburg, VA, USA) and the relational database system (Interbase 6.0, Borland Software Corporation, Cupertino, CA, USA) were chosen for the basic system.

While the application server provided core logic, particular services were developed as independent modules in the sense of service-oriented architecture (SOA). Particular functions were clustered into services that were able to communicate and share data with each other.

- data processing and graphic service: For sophisticated data processing and visualisation of time-series data (e.g. blood pressure measurements), the MatLab 6.5 environment (The MathWorks, Natick, MA) was used.
- notification service: The database was checked at regular intervals for arrival of new alerts, notifications, or reminders generated by the data processing service. Subsequently, a personalised message was composed and sent to the responsible physician by text messaging, e-mail, or both.

The components of the MOBITEL telemedicine platform were designed with respect to a high level of security and confidentiality to comply with regulatory requirements. Data transfer was encrypted, and access to the data was restricted to authorised users.

**Did the patients receive education about their condition?:** Yes

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none planned

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The physician

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): mobile phone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): directly (unclear if this was only done during office hours)

## Scherr 2009 (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): medication adjustment

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** physicians

**Duration of intervention:** 6 months

**Comparison intervention:** Care as usual.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Hospitalisation for worsening CHF</li> <li>• Cardiovascular mortality</li> </ul> <p><b>Secondary outcomes/process outcomes:</b></p> <ul style="list-style-type: none"> <li>• System availability</li> <li>• Cumulative transmissions</li> <li>• Transmissions per patient.</li> </ul> <p><b>Follow-up time:</b> 6 months after randomisation</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> This study was partly funded by restricted research grants from Novartis Pharma Austria, Roche Pharma Austria, and Mobilcom Australia.</p> <p><b>Conflict of interest:</b> None declared.</p> <p><b>Note:</b> Randomisation was stopped after 120 patients due to an increasing number of never beginners who were unable to operate the mobile phone, indicating the urgent need for a new technology. However, as we tried to avoid a mix of technologies within one study, we decided to stop randomisation in coordination with the ethics committee of the Medical University Graz. Therefore, the results must be interpreted cautiously.</p>

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	QUOTE: "The adaptive randomization procedure was stratified by patient age, New York Heart Association (NYHA) class, gender, and study center."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	No differences reported.
Were baseline characteristics similar?	Low risk	No differences reported.
Blinding (performance bias and detection bias) - Objective outcomes	Low risk	Neither the healthcare professional nor the participating patients could be blinded to the intervention. However, the outcome of mortality is objective.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Unclear how the hospitalisations were assessed if it was through patient interview or through registers.

## Scherr 2009 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	QUOTE:  "In the tele group, 12 patients (20%) emerged unable to begin transmission of data and were classified as never beginners. Never beginners were included in the intention-to-treat analysis but not the per-protocol analysis. Furthermore, there were four patients (6.7%) who requested early termination of the study and were included in both the intention-to-treat analysis and the per-protocol analysis."
Selective reporting (reporting bias)	Unclear risk	This study has no trial protocol.
Other bias	Low risk	No evidence of other risk of bias.

## Schwarz 2008

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> patients who routinely used the hospital, were aged 65 or older, had a diagnosis of NYHA class II, III or IV and were functionally impaired in at least one activity of daily living (ADL), or one instrumental activity of daily living (IADL), necessitating assistance of a family caregiver. They received home care from the participating home care agency if it was ordered by their physician, had Medicare eligibility and an operating telephone line, and were able to speak English. Inclusion criteria for caregivers: being cognitively intact, having a familial relationship to the patient and providing assistance with at least 1 ADL or 1 IADL.</p> <p><b>Exclusion criteria:</b> Planned discharge to a nursing home, inability to be interviewed because of physical illness, current use of tele-monitoring scale, inability to be contacted post-discharge, receiving regular infusions or dialysis, NYHA class I, independence in performing ADL, no caregiver, use of hospice care, client of non-participating home healthcare agency, participation in another study, dementia, planned surgery, inability to speak English, planned hospitalisation, and inability to stand on a scale.</p> <p><b>Method of patient recruitment:</b> Potential participants were identified by the heart failure (HF) care manager with the assistance of care managers from 4 hospital units. (While making daily rounds, the HF care manager informed potential participants about the study and gained oral permission from the PI to contact them before hospital discharge. Prior to discharge, the PI briefly explained the study to the patient, and/or caregiver, provided a letter of explanation, and received oral consent for a chart review to verify whether they met study criteria.)</p> <p><b>Study sample calculation:</b> yes</p> <p><b>Data collection:</b> Hospital re-admissions for HF symptoms, ED visits for HF, days to re-admission were collected by medical record review 90 days post-discharge. Physiologic health indicators were assessed at baseline (BL) and at 3 months later. Functional status, depressive symptomatology and QOL were assessed at BL and 90 days postdischarge.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 152 eligible older adults with heart failure, of which n = 50 refused participation and n = 102 (67%) agreed to participate</p> <p><b>No of patients randomised to groups:</b> n = 102; Intervention: n = 51; Control: n = 51</p> <p><b>No of patients lost to follow-up:</b> n = 18 patients were lost to follow-up, n = 40 vs n = 44 patients completed the study in the UC group and the intervention group respectively</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: patients with HF failure and their caregivers</p> <p>b) Age: Intervention: 77.1 ± 7.3 years; Control: 79.1 ± 6.9 years</p>



**Schwarz 2008** (Continued)

c) Gender, female sex no (%) ; Intervention: 22 (43); Control: 31 (61)

d) Ethnicity, white, no (%): Intervention:41 (80); Control: 42(82)

e) Severity of condition:

NYHA class II, no (%): Intervention: 12 (24); Control: 9 (18)

NYHA class III, no (%): Intervention: 23 (45); Control: 26 (51)

NYHA class IV, no (%): Intervention:16 (31); Control: 16 (31)

f) Major co-morbidities: Intervention: 4.2;±2.4; Control:4.9±2.1

**Setting** (hospital/community/residential care): one tertiary teaching hospital in Northeastern Ontario

**Location** (rural/urban etc.): no information

**Country:** USA

Interventions

**Study objective:** to examine whether tele-monitoring by an advanced practice nurse may reduce subsequent hospital re-admissions, emergency department visits, and days to re-admission due to HF

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring + UC

**Delivery of intervention:** participants in the intervention group received the Cardiocom EHM system (Cardiocom, LLC, Chanhassen, MN) at the first interview, and the nurse removed the equipment 90 days later, at the second interview. The HF care manager trained the PI about the use of the EHM system, and ensured its availability. The RN data collector was further trained by the PI about the equipment and taught the patient/caregiver dyad how to use the system. The PI met with the HF care manager weekly to discuss technical issues with the equipment. The RN data collector placed a weight scale in the participants' homes and connected via the telephone line to a computer system in the collaborating hospital. The data receiving computer was positioned in an office on the telemetry unit of the study hospital. The EHM system was programmed to measure weight on a daily basis. The display on the device asked the participants to answer 'yes' or 'no' to questions of shortness of breath, cough, fatigue, swelling, chest discomfort, urination, exercise, dizziness, medication use or sodium intake. The computer stored each patient's electronic health file and **automatically displayed clinical variances when prescribed parameters exceeded predetermined ranges**. Variances included failure to call daily, changes in symptoms, and weight outside prescribed parameters. The HF care manager was responsible for daily monitoring of parameters received electronically. When participants had values outside of prescribed parameters, the monitoring nurse called the caregiver of the dyad to further assess the situation, and update the medication regimen. In addition, the APN notified the primary physician or cardiologist about the patient's status as needed.

**Type of technology and its application:** the Cardiocom EHM system (Cardiocom, LLC, Chanhassen, MN) and an electronic scale

**Did the patient receive education about their condition?:** no information, the caregivers received education and support

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient? The monitoring nurse

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): when the measurements were outside prescribed parameters

## Schwarz 2008 (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital); up-date of medication regimen, and if necessary contact the primary physician or cardiologist

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 3 months

**Comparison intervention:** usual post-hospital discharge care.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• Hospital re-admissions for HF</li><li>• ED visits for HF</li><li>• Time to re-admission</li><li>• Costs</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Depressive symptomatology</li><li>• QOL</li><li>• Caregiver mastery</li><li>• Social support</li></ul> <p><b>Follow-up time:</b> 3 months after the start of the intervention</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Grant Number 1 R15 R008698-01 from the National Institute of Nursing Research, national Institute of Health (NIH), and the Ohio Board of Regents</p> <p><b>Conflict of interest:</b> No information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	<p>p.20, Col3, Para 1</p> <p>QUOTE:</p> <p>“ participants were randomised to usual post-hospital discharge care or to UC with a tele-monitoring scale by drawing from a pre prepared sealed envelope”</p>
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Unclear risk	<p>p.22, Table 1</p> <p>A larger number of patients in the intervention group received more education.</p>
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professional delivering the intervention could not be blinded to the group allocation, and neither could the patients.However, objective outcomes of re-admission, ED visits and costs were assessed through records review.

## Schwarz 2008 (Continued)

Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professional delivering the intervention could not be blinded to the group allocation, and neither could the patients. Non-objective patient-reported outcomes. No information on whether the outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	p.20, Col.2, Para.1  QUOTE:  "Attrition was equivalent between groups."
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found..
Other bias	Low risk	No evidence of other risk of bias.

## Seto 2012

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> eligible participants were ambulatory patients diagnosed with heart failure (HF), 18 years of age or older, ability to speak and read in English, not on the heart transplantation list, an expected survival of greater than one year, and a left ventricular ejection fraction (LVEF) less than 40%.</p> <p><b>Exclusion criteria:</b> none stated</p> <p><b>Method of patient recruitment:</b> during their Heart Function Clinic visit, patients who met the inclusion criteria (as deemed by their cardiologist), were invited to speak to the study co-ordinator (ES) regarding participation in the study, between mid-September 2009 and February 2010.</p> <p><b>Study sample calculation:</b> A sample size calculation was based on the Self-Care of Heart Failure Index (SCHFI), using a population standard deviation (SD) of 20 and an effect size of 10 (effect size represents a clinically significant change of more than half a standard deviation) as determined in previous studies (alpha = 0.05, power = 0.8). We calculated the required sample size per group to be 34, and recruited 50 participants for the intervention group and 50 for the control group to compensate for the patients estimated as lost to follow-up, including due to mortality, over the 6-month trial.</p> <p><b>Data collection:</b> The health outcome data were obtained through patient charts, the hospital's electronic health records, and pre- and post-trial patient questionnaires. The process outcome data (e.g., number of alerts sent and number of clinical interventions) were obtained through manual tracking of clinical actions during the trial and retrieving information from the data servers.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 300 patients were screened for eligibility, of which 163 did not meet the inclusion criteria, 12 patients declined participation and 25 were not asked to see the study co-ordinator</p> <p><b>No of patients randomised to groups:</b> n = 100; Intervention: n = 50; Control: n = 50</p> <p><b>No of patients lost to follow-up:</b> n = 3 participants from the intervention group discontinued, and no patients were lost to follow-up in the control group</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: HF</p> <p>b) Age (years), mean, (SD): TM:55.1 (13.7); UC: 52.3 (13.7)</p> <p>c) Gender, male npo (%): TM:41 (82%); UC: 38 (76%)</p>

**Seto 2012** (Continued)

d) Ethnicity:white Caucasian no (%):TM:39 (78%); UC: 33 (66%)

e) Severity of condition:

NYHA class II : TM: 21 (42%); UC: 22 (44%); II/III: TM: 6 (12%); UC: 5 (10%); III: TM: 21 (42%); UC: 21 (42%); IV: TM: 2 (4%); UC: 2 (4%)

LVEF, % (SD): TM: 27.1 (7.8);UC: 27.0 (9.9)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one UHN Heart Function Clinic

**Location** (rural/urban etc.): no information

**Country:** Canada

**Interventions**

**Study objective:** to develop a rule-based expert system for a HF mobile phone-based tele-monitoring system, to evaluate the expert system, and to generalise the lessons learned from the development process for use in other healthcare applications.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote (mobile phone-based) monitoring with alerts (in addition to UC)

**Delivery of intervention:** the participants in the tele-monitoring group received the tele-monitoring system in addition to standard care. They were asked to use the tele-monitoring system for 6 months to take daily morning weight and blood pressure readings as well as weekly single-lead electrocardiograms (ECGs), if provided with an ECG recorder. They were also asked to answer daily morning symptom questions on a mobile phone. Only the 17 patients who did not have an implantable cardioverter defibrillator (ICD) were provided with an ECG recorder because the recorder was not certified for use with ICDs. Patients were also told to report their symptoms through the mobile phone if they did not feel well during the day. The patients in the tele-monitoring group were given an individual training session on how to use the system during the recruitment session, and were provided with technical support by telephone throughout the study. The daily measurements took about 5 minutes each morning.

**Type of technology and its application:**The developed tele-monitoring system enabled patients to take their weight, blood pressure, heart rate, and single-lead electrocardiogram (ECG) with wireless medical devices. Patients were provided with instructions on the mobile phone screen regarding which parameter to take next. The devices sent the data automatically through Bluetooth to the mobile phone. The patient was also prompted to answer a few yes/no questions on the mobile phone regarding symptoms. The values were then sent automatically from the mobile phone to the hospital data servers for analysis. Depending on the readings, an alert might be generated and sent to the patient's mobile phone. When an alert was generated, an e-mail alert was sent to the mobile phone of the on-call clinician along with all relevant patient information. The patients were instructed to take all the readings each morning once they woke up, and to use the tele-monitoring system during the day if they felt a change in their symptoms.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer:** daily, and more if it felt needed

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data:**

a) Who contacts the patient?: The clinician

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): within a few minutes of an alert

**Seto 2012** (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): e.g. calling the patient, modification of medications, etc.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** five clinicians (three cardiologists and two nurse practitioners) from the Heart Function Clinic. For the trial, the on-call clinician was the clinical champion of the project. She was the main cardiologist for the large majority of the patient participants, and therefore was familiar with the medical history and personalities of the participants.

**Duration of intervention:** 6 months

**Comparison intervention** (e.g. face-to-face, telephone, none): The standard care group received standard care at the UHN Heart Function Clinic, which includes visiting the clinic between once every 2 weeks to once every 3 to 6 months, depending on the severity of the patient's heart failure condition and the need for optimising their medication. Standard care also includes HF education during preliminary visits at the Heart Function Clinic and the ability to telephone the clinic as necessary. Participants in the standard care group were not contacted again regarding the study until the end of the trial.

**Outcomes**

**Primary outcomes:**

- Quality of life (assessed with the MLWHF questionnaire),
- Brain Natriuretic Peptide (BNP) values (surrogate for HF prognosis)
- Self-care (as measured with the Self-Care of Heart Failure Index ).

**Secondary outcomes:**

- Hospitalisation rate
- Number of nights in hospital
- Number of emergency department visits
- Number of Heart Function Clinic visits.
- Mortality
- In addition, LVEF, NYHA class, medication prescriptions, and blood test results (specifically creatinine, sodium, potassium, haemoglobin, and urate values) were also subsequently analysed.

**Follow-up time:** 6 months from randomisation

**Notes**

**Ethical approval and informed consent obtained (yes/no):** yes:

**Sources of funding:** the Toronto General Hospital Foundation and a Natural Sciences and Engineering Research Council of Canada Strategic Research Network Grant (Healthcare Support through Information Technology Enhancements – hSITE).

The study sponsors had no involvement in the study and the production of this manuscript.

**Conflicts of interest:** The researcher who developed the expert system also was the study coordinator for the randomised controlled trial.

**Reimbursements:** Each participant received Can \$24 as reimbursement for travel and parking expenses.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>QUOTE:</p> <p>"The 100 participants were randomized into the telemonitoring (TM) group and standard care (SC) group using stratified four-block randomization. Stratification was based on NYHA classification (NYHA class II-III and NYHA class IV). There were no participants in NYHA class I. An online computer-generated randomization tool, Research Randomizer, was used to determine the order of participants in the TM and SC groups."</p>

## Seto 2012 (Continued)

Allocation concealment (selection bias)	Low risk	QUOTE:  "The study coordinator was blinded to which group the patient would be assigned until each patient consented to participate in the trial."
Were baseline outcome measurements similar?	Low risk	No differences reported.
Were baseline characteristics similar?	Low risk	The profiles of the tele-monitoring and standard care groups were similar and representative of the patient population attending the UHN Heart Function Clinic.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The health outcome data and data on hospitalisations were obtained through patient charts, and the hospital's electronic health records. Objective outcomes.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Quality of life data and self-care data were obtained through pre- and post-trial patient questionnaires. As the participants were not blinded to the intervention, these outcomes may have been at risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Three participants from the intervention group (6%) discontinued the study, no participants from the standard care group (0%) dropped out.
Selective reporting (reporting bias)	Low risk	Results for all outcomes listed in the trial protocol are reported in the paper.
Other bias	Low risk	No other risk of bias identified.

## Shea 2006

### Methods

### Study design: RCT

**Inclusion criteria:** age 55 years or older; being a current Medicare beneficiary; having diabetes mellitus defined by a physician's diagnosis and being on treatment with diet, an oral hypoglycaemic agent, or insulin; residence in a federally-designated medically underserved area (either of two federal designations, medically underserved area [MUA] or health professional shortage area [HPSA]) in New York State; and oral fluency in either English or Spanish. No specific threshold level of HbA1c was required.

**Exclusion criteria:** moderate or severe cognitive, visual, or physical impairment or the presence of severe co-morbid disease. It is important to note that neither literacy nor any prior computer experience was required of participants.

**Method of patient recruitment:** Participants were enrolled through primary care practices in New York City. Systematic review of patient panels was conducted at participating practices in order to identify potentially eligible patients. Eligibility was screened by telephone prior to the baseline examination and again at the baseline examination. Potentially eligible participants were contacted by mail and telephone and invited to attend the baseline examination, where consent was obtained.

### Study sample calculation: yes

**Data collection:** Participants were instructed to come to the baseline and follow-up examinations fasting and having held their glycaemic control medications. For New York City participants, all examination data were collected at Columbia University Medical Center. For Upstate participants who could conveniently travel to Syracuse, these data were collected at the SUNY Upstate Medical University, while for those living too distant, examinations were performed in regional medical centres and medical offices. For participants unable to travel, home visits were made by trained nurses who carried with them phlebotomy equipment, a cooler for transport of blood and urine specimens, a blood pressure

**Shea 2006** (Continued)

device with various-size cuffs, and a scale, a stadiometer, and a measuring tape. Demographic and other questionnaire data were collected by interviewers at the baseline examination

**Unit of analysis issues:** (yes/no):no

**Participants**

**Total no of eligible patients:** n = 9597 eligible participants

**No of patients randomised to groups:** n = 1665 **Intervention:** n = 844; **Control:** n = 821

**No of patients lost to follow-up:** n = 306 patients (18.3%): Intervention: n = 201; Control: n = 105

**Patient baseline characteristics:**

a) Clinical condition: diabetes mellitus

b) Age:55–64 years: Intervention: 12.1; Control: 11.9

65–69 yr: Intervention: 33.2; Control: 34.0

70–74 years: intervention: 26.9; Control: 25.1

75–79 years: Intervention: 17.7; Control: 18.0

>80 years: intervention: 10.2; Control: 11.0

c) Gender,

Male: Intervention: 36.5; Control: 37.9

Female: Intervention: 63.5; Control: 62.1

d) Ethnicity:

African-American (non-Hispanic)

Intervention: 15.3; Control: 14.5

Hispanic: Intervention: 35.8; Control: 34.6

White (non-Hispanic): Intervention: 48.2; Control: 50.6

Other: Intervention: 0.7; Control: 0.2

e) Severity of condition:

Duration of diabetes (yr)

< 5: Intervention: 30.8; Control: 29.7

5–9; Intervention: 19.0; Control: 21.3

10–14: Intervention: 18.1; Control: 15.8

> 15: Intervention: 30.8; Control: 32.2

Data missing Intervention: 1.3; Control: 1.0

f) Major co-morbidities:

g) Other treatments received:

Diabetes treatment

Pills alone: Intervention: 65.3; Control: 65.4

Insulin alone: Intervention: 14.5; Control: 14.4

Insulin and pills : Intervention:14.8 ; Control: 15.3



## Shea 2006 (Continued)

Diet alone : Intervention:5.1; Control: 4.9

Data missing: Intervention: 0.4; Control: 0.0

**Setting** (hospital/community/residential care): primary care practices

**Location** (rural/urban etc.): urban (New York City)

**Country:** USA

## Interventions

**Study objective:** to compare TM case management to UC for older medically underserved diabetic patients

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing, remote monitoring and education through web page

**Delivery of intervention:**
*(i) Video-conferencing (over plain old telephone service)* allowing patients to interact with nurse case managers

*(ii) Remote monitoring of glucose and blood pressure* with electronic upload and integration with the Columbia EMR57;

*(iii) Dial-up Internet service provider access to a web portal providing access to patients' own clinical data and secure Web-based messaging with nurse case managers;* and

*(iv) Access to an educational website* created for the project by the American Diabetes Association in English and Spanish and in regular and low-literacy versions in each language.

Some participants also received glucose test strips for the specific glucose monitor provided by the study. Participants were trained in the use of the HTU at the time of installation and were selectively re-trained during the study based on the assessment of the nurse case manager. Intervention participants were assigned to a project case manager under supervision of diabetologist at the Joslin or Berrie Diabetes Centers (upstate and New York City participants, respectively).

**Type of technology and its application:** a home TM unit consisting of a web-enabled computer with modem connection to an existing telephone line. The HTU provided four major functions (described above). Case managers interacted with patients using the HTU and case management software. We used Version 2.2b (updated May 2000) of the Veterans Health Administration Clinical Practice Guidelines for the Management of Diabetes Mellitus in the Primary Care Setting. These guidelines are flexible, annotated, evidence-based, and algorithmic in format. The primary care physicians of intervention patients retained full responsibility and control over their patients' care. The case managers' notes were reviewed by the supervising diabetologist, and when a change in management was suggested, the primary care physician was contacted by e-mail, fax, letter, or phone.

**Did the patient receive education about their condition?** Yes, through a web page.

**Frequency of patient data transfer (monitoring studies only):** no information

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no information

**Clinician response to receipt of data (monitoring studies only):** no information

a) Who contacts the patient?: The project case manager

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no): through the home TM unit and case management software that incorporated the Veterans Health Administration Clinical Practice Guidelines for the management of diabetes mellitus in the Primary Care Setting

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): unclear

## Shea 2006 (Continued)

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the case managers notes were reviewed by the supervising diabetologist, and when a change in management was suggested, the primary care physician (who retained full responsibility and control for their patient's care) was contacted by e-mail, fax, letter or phone

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse case managers, physicians

**Duration of intervention:** 12 months

**Comparison intervention:** Patients in the UC group remained under the care of their primary care providers. These primary care providers cared for patients in both the intervention and UC groups, following the design whereby randomisation was clustered within clinical practice. The primary care providers received a mailing with current guidelines for the care of patients with diabetes. The clinical care that patients in the UC group received was delivered by their primary care providers, without other guidance or direction from study personnel.

Outcomes	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"><li>• HbA1c</li><li>• Blood pressure</li><li>• LDL cholesterol levels</li></ul> <p><b>Other outcomes:</b></p> <ul style="list-style-type: none"><li>• Depression, diabetes distress, self-efficacy (reported in Trief 2007)</li><li>• Costs (reported in Moreno 2009)</li></ul> <p><b>Follow-up time:</b> 12 months from randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Cooperative Agreement 95-C-90998 from the Centers for Medicare and Medicaid Services.</p> <p><b>Conflict of interest:</b> No information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.42, Col.1, end of para.2, and Col.2, Para 1</p> <p>QUOTE:</p> <p>"Randomization to telemedicine case management or to UC was assigned in a 1:1 ratio by the study coordinating center (Research Division of the Hebrew Home for the Aged at Riverdale) immediately upon completion of the baseline examination."</p>
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Low risk	<p>p.46, Col.2, Para.1</p> <p>QUOTE:</p> <p>"The intervention and UC groups did not differ with respect to ...and clinical characteristics (Table 1)."</p>
Were baseline characteristics similar?	Low risk	<p>p.46, Col.2, Para.1</p> <p>QUOTE:</p>

## Shea 2006 (Continued)

		"The intervention and UC groups did not differ with respect to baseline demographic ... (Table 1)."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	<p>The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. All primary outcomes were objective and outcome assessor was blinded.</p> <p>p.42. Col.2, Para.1</p> <p>QUOTE:</p> <p>"Personnel conducting these examinations were blinded to intervention status and were not involved in supporting the technical aspects of the intervention or in delivering diabetes case management services."</p>
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professionals delivering the intervention could not be blinded to the allocation of patients. The participating patients and personnel could not be blinded to the group allocation. Non-objective self-reported outcomes of depression and self-efficacy.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>p.47, col.2, Para.1</p> <p>QUOTE:</p> <p>"The one-year follow-up examination was not completed by 248 of the 1,665 randomized subjects (14.9%), of whom 144 were assigned to intervention and 104 to UC."</p>
Selective reporting (reporting bias)	Low risk	Results for all primary outcomes listed in the trial protocol reported in the paper, and a couple of additional secondary outcomes.
Other bias	Low risk	No evidence of other risk of bias.

## Soran 2008

### Methods

### Study design: multicentre RCT

**Inclusion criteria:** medicare beneficiary; > 65 years of age; discharged from hospital with a primary (diagnosis-related group 127) or secondary diagnosis of heart failure (HF) in the 6 months prior to recruitment; evidence of systolic dysfunction via a left ventricular ejection fraction (LVEF) of < 40% documented by echocardiography, radionuclide ventriculography, or a contrast ventricular angiogram; current symptoms of HF including dyspnoea on exertion, orthopnoea, paroxysmal nocturnal dyspnoea, fatigue, abdominal or lower extremity oedema or swelling; and receiving optimal medical care consistent with recent guidelines published by the Heart Failure Society of America and by the American College of Cardiology/American Heart Association Task Force. Intolerance of standard medications was documented among patients not receiving optimal medical therapy. Additionally, study participants also had to be able to stand for 20 seconds without holding the wall, weigh < 400 pounds, and speak either English or Spanish (requirements for use of the HFMS)..

**Exclusion criteria:** participation in another HF study; prior experience with HFMS for the inability to activate the system; significant symptomatic Ischaemic heart disease; renal failure requiring dialysis or a serum creatinine  $\geq 2.5$ ; chronic or intermittent inotropic therapy; uncorrected primary stenotic valvular disease, pericardial disease, amyloidosis, active myocarditis, or malfunctioning prosthetic heart valve; uncorrected thyroid disease; chronic obstructive pulmonary disease (COPD) with a  $Fev1 < 50\%$ ; a life expectancy less than 6 months; or Medicare Choice subscribers; or white non-Hispanic men.

**Method of patient recruitment:** patients were recruited between April 2002 and September 2005 through the development of co-operative networks that had been established with primary care groups in each of these cities.

## Soran 2008 (Continued)

**Study sample calculation:** with a power of 80% and a 2-sided alpha level of 0.05, 315 patients were required.

**Data collection:** the trial used an independent adjudication event committee to classify deaths, hospitalisations, and adverse events and was monitored by an independent data safety monitoring board. All patients were seen in clinic or in their primary care physician's office by the study nurse co-ordinator during their baseline and 6-month end-of-study visits. Patients were also contacted by telephone 30 days and 3 months after randomisation by non-medical personnel masked to treatment assignment to collect clinical data, including vital status, the type and date of cardiovascular-related hospital visits, and the administration of 2 quality of life instruments, the Medical Outcome Study 12 Item Short Form (SF-12),<sup>14</sup> and the Kansas City QOL Questionnaire (KCCQ).

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** no information

**No of patients randomised to groups:** n = 315; Intervention: n = 160; Control: n = 155

**No of patients lost to follow-up:** n = 8 patients refused to be contacted after randomisation and were considered lost to follow-up.

#### Patient baseline characteristics:

a) Clinical condition: HF

b) Mean age (years): Intervention: 76.9 ± 7.1; Control: 76.0 ± 6.8

Weight, mean kg: Intervention: 72.5 ± 18.8 ; Control: 72.8 ± 17.7

c) Gender, Female (%): Intervention: 68.7; Control: 60.6

d) Ethnicity: White/Black (%): Intervention: 57.5/41.9; Control: 47.7/52.3

e) Severity of condition:

NYHA classification (%)

II : Intervention: 57.5; Control: 59.3

III: Intervention: 42.5; Control: 40.7

LVEF %, mean: Intervention: 24.3 ± 8.8 ; Control: 23.8 ± 8.7

Mean duration, years: Intervention: 2.9 (3.6); Control: 3.4 (3.7)

f) Major co-morbidities:

Documented myocardial infarction (MI) TM: 82.4; UC: 74.7, P = .21

**Setting** (hospital/community/residential care): primary care overseen by 3 academic sites with affiliations to a major academic medical centre: Pittsburgh, PA (University of Pittsburgh), Cleveland, OH (Case Western Reserve University), and Miami Beach, FL (Mount Sinai Medical Center).

**Location** (rural/urban etc.): urban

**Country:** USA

### Interventions

**Study objective:** to compare a computer-based telephonic HF monitoring system in Medicare-eligible patients with a control group receiving standard HF care only

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring + standard care

**Delivery of intervention:** patients were instructed to weigh themselves and respond to HF symptom questions daily. Each patient's primary care physician was responsible for selecting the monitoring parameters according to their patients' disease status. The HFMS nurses reviewed the transmitted data.

## Soran 2008 (Continued)

ta daily (7 days/week, 365 days/year) and contacted the patient to verify any changes observed in HF symptoms or weight. Changes in weight beyond a prespecified amount or changes in symptoms were reported to the attending primary care physician. There was a standardised alert in which physicians individually chose the parameters for their patients. If, on review by the HFMS nurse, benchmarks were met for weight alerts or symptom alerts, the HFMS nurse immediately contacted the patient to ensure that the alerts had been met. After nurse-patient interactions, the primary physician was immediately notified of the change in either weight or symptoms by a fax report. Comments by an HFMS nurse were added when data were sent; however, medical recommendations were not made to the physicians. This report also graphically demonstrated trends in both weight and symptoms. A follow-up call was made to the physician's office to ensure that the information was received. During periods of clinical stability, reports were faxed to the physician's office at predetermined points as requested by the physician. Physicians were then able to adjust medications, schedule an office visit, or initiate other therapeutic changes with the goal being to prevent further deterioration and to stave off the need for a hospitalisation.

**Type of technology and its application:** The computer-based telephonic HF monitoring system (HFMS: Alere Day Link Heart Failure Monitoring System, Alere Medical, Reno, NV) includes an electronic scale and an individualised symptom response system (DayLink monitor) linked via a standard phone line to a computerised database staffed by trained nurses.

**Did the patient receive education about their condition?** All participants were provided with educational materials and information as to when they should seek medical attention related to the worsening of their heart failure. The study nurse co-ordinator conducted a 1-to-1 educational session with the patient, which included the "Living with Heart Failure Booklet".

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned /scheduled number of TM contacts between patient and healthcare personnel:** no information

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The TM nurses
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): immediately in case of an alert
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the nurse confirmed with patient notified the physician about worsening symptoms; the physician could adjust medications, schedule an office visit, or initiate other therapeutic changes with the goal being to prevent further deterioration and to stave off the need for a hospitalisation.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** registered nurses, primary care physicians, and "clinics"

**Duration of intervention:** 6 months

**Comparison intervention:** patients randomised to SC were provided a digital home scale and instructed to weigh themselves daily and record HF symptoms. All participants were provided with educational materials and information as to when they should seek medical attention related to the worsening of their HF. Standard heart failure care included patient 1-on-1 education, availability of education to clinicians, an effort to use evidenced-based optimal medical treatment, and a commercially available digital home scale with management by primary physician.

### Outcomes

#### Primary outcomes:

- Treatment failure = a composite of cardiovascular death or re-hospitalisation for HF within 6 months of enrolment
- Length of hospital stay (among patients re-hospitalised for HF)

#### Secondary outcomes:

## Soran 2008 (Continued)

- All cause re-hospitalisations
- HF related re-hospitalisations
- QOL (will be reported separately in another publication)
- Costs (will be reported separately in another publication)

**Follow-up time:** 6 months from randomisation (but mean follow-up period actually  $171 \pm 30$  days, range 4-184 days, as patients died)

### Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Centers for Medicare & Medicaid Services Baltimore, Maryland.

**Conflict of interest:** None stated.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Low risk	p.713, Col.2, Para.5  QUOTE:  "As shown in Table 1 and 2, baseline characteristics including age, race/ethnicity, sex, and laboratory evaluations were equivalent in both treatment groups. The proportion of patients taking selected cardiac medications at baseline was also similar. Mean values for quality of life, as measured by the KCCQ and the SF-12, were also similar by treatment arm (Table 3)."
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the allocation into groups, and neither could the patients. However, outcomes were objective and independently assessed.  p.712, Col.1, Para.3  QUOTE:  "The HFHC Trial was a multicenter, randomized controlled clinical trial with blinded end point evaluation"  Also, the trial used an independent adjudication event committee to classify deaths, hospitalizations and adverse effects."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only n = 8 patients, who refused to be re-contacted after randomisation were lost to follow-up .
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Spaeder 2006

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> male or female patients who understood spoken English, were at least 21 years of age with NYHA class II or III HF and an ejection fraction of &lt; 40%, and who were clinically euvolemic and receiving appropriate afterload reducing agents (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers or hydralazine/nitrates) of at least intermediate dose (equivalent to a dose of enalapril of at least 5 mg bid).</p> <p><b>Exclusion criteria:</b> treatment with any h-blocking agent within the 6 months before enrolment, unstable angina or myocardial infarction within 6 weeks, contraindications to h-blocker therapy, a pulse &lt; 60 beat/min, and a systolic blood pressure (SBP) &gt; 90 mm Hg, pregnancy, active substance abuse, uncontrolled psychiatric illness, a life expectancy of &lt; 12 months</p> <p><b>Method of patient recruitment:</b> Potential study participants were identified from the inpatient medicine services at Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center, who were admitted with the diagnosis of decompensated heart failure (HF) as well as patients referred to the outpatient HF clinics of these 2 institutions</p> <p><b>Study sample calculation:</b> To show a 50% reduction in the titration time compared with the CO group, a Wilcoxon rank sum test was used for sample size calculations, which projected that 42 patients (21 in each group) would provide an 80% power at the <math>\alpha = .05</math> level of significance. To account for drop out, target enrolment was 50 patients (25 in each group).</p> <p><b>Data collection:</b> On days when patients were eligible for carvedilol titration, clinical information was obtained from either the clinic visit or the TeleWatch (TW) system by the study nurse who summarised and presented data concerning heart rate and blood pressure as well as any symptoms related to carvedilol side effects in a standard format to one of the investigators without revealing the patient's name or group assignment.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 49 ; Intervention: n = 25; Control: n = 24</p> <p><b>No of patients lost to follow-up:</b> Two patients withdrew from the study, one each from the CO and TW groups, and 1 patient from the TW group was withdrawn by investigators because of a violation of eligibility criteria. Of the n = 46 patients who underwent carvedilol titration, n = 2 patients (4.3%), one from each group, were unable to tolerate the lowest dose of carvedilol. Fourteen patients (30.4%) were unable to achieve the dose of carvedilol 25 mg bid, n = 6 in the CO group, and n = 8 in the TW group ( P = 0.54).</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: CHF due to impaired left ventricular systolic function</p> <p>b) Age, mean: Intervention: 56.4 (14.4); Control: 52.7 (17.2)</p> <p>c) Gender, male sex, no (%): Intervention: 18 (72%); Control: 15 (63%)</p> <p>d) Ethnicity: white, no (%): Intervention: 19 (76%); Control: 13 (54%)</p> <p>e) Severity of condition:</p> <p>NYHA class</p> <p>II: Intervention: 11 (44%); Control: 14 (58%)</p> <p>III: Intervention: 14 (56%); Control: 10 (42%)</p> <p>LVEF%, mean (SD)</p> <p>Intervention: 22.1 (7.9)</p>



**Spaeder 2006** (Continued)

Control:22.3 (6.0)

Years diagnosed with HF: TM:1 (0-3); UC: 2 (0.5-4, P = 0.16

f) Major co-morbidities:

Hypertension: Intervention: 9 (36%); Control: 14 (58%).

COPD: Intervention: 6 (24%);Control:5 (21%)

g) Other information:

Hospitalised within 1 month: Intervention: 10 (40%); Control:8 (33%)

Months since last hospitalisation Intervention: 2 (1-15); Control: 4 (1-38)

**Setting** (hospital/community/residential care): two out-patients clinics

**Location** (rural/urban etc.): urban

**Country:** USA

**Interventions**

**Study objective:** to investigate if an automated TM system named TeleWatch could facilitate carvedilol titration in outpatients with left ventricular systolic dysfunction

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring with alerts, in combination with clinic visits

**Delivery of intervention:** Patients self-collected appropriate physiologic data (weight, pulse, blood pressure) using digital scales and Omron HEM 601 automated wrist sphygmomanometers (Bannockburn, IL). Patients then accessed the TM System by calling a telephone number which connected the patient with the computer application. Once the patient's identity was verified with a unique user ID and pass code, TW sequentially played 12 to 15 prerecorded questions which had numeric, yes/no, or multiple-choice answers to which the patient responded using the telephone keypad. These questions related to 4 main topics: physiologic parameters (weight, pulse, blood pressure); evidence of CHF exacerbation (dyspnoea, lower extremity oedema, paroxysmal nocturnal dyspnoea); medication adherence; and medication side effects. The system analysed the responses using a data validation algorithm to insure proper data entry, and abnormal data prompted the system to ask additional prerecorded questions in a rule-based fashion (e.g., evidence of increasing fluid accumulation prompted questions about dietary intake, adherence with fluid restriction, and medication adherence). **The system generated alerts to the study nurse when prespecified symptoms or physiologic changes were detected.** Patients in the TW group were requested to call the system on a daily basis; however, patients in both groups were able to directly contact the study nurse. Study participants from both groups were seen in the study clinic every 2 weeks during carvedilol titration (titration phase) and then monthly thereafter (follow-up phase). During the titration phase, the CO patients were eligible for carvedilol titration only during the bi-weekly clinic visits, and the TW patients were eligible for carvedilol titration on a weekly basis (during biweekly clinic visits and once a week on a specific day during the intervening week). On days when patients were eligible for carvedilol titration, clinical information was obtained from either the clinic visit or the TW system by the study nurse who summarised and presented data concerning heart rate and blood pressure as well as any symptoms related to carvedilol side effects in a standard format to one of the investigators without revealing the patient's name or group assignment. Using a predefined titration algorithm and while blinded to the patient's group assignment, the investigator used these data to make a titration decision which the study nurse then implemented.

**Type of technology and its application:** The TW System is a telephone-based, automated, voice-interactive, 2-way store and forward telemedicine system (TeleWatch version 1.0), which was written in Microsoft Visual Basic 6.0 (Redmond, Wash) with data stored in a Microsoft Access 2000 database. The software application resided on a Dell Optiplex GX 110 Mini-Tower PC (Round Rock, TX) which operated at 733 MHz and was accessed by patients through analogue telephone lines connected to an Intel/Dialogic D/4PCI 4-line telephone interface board (Santa Clara, CA) (Figure 1). The database was accessible through a locally secured intranet with pre configured client-server connectivity.

**Spaeder 2006** (Continued)

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** no planned TM contacts (only in case of an alert), but bi-weekly clinic visits

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The nurse

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): the data were reviewed daily and the patient immediately contacted in the case of an alert

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): the investigator used data to make a titration decision which the study nurse then implemented.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses, physicians

**Duration of intervention:** 3 months

**Comparison intervention:** bi-weekly face-to-face clinic every 2 weeks during carvedilol titration (titration phase) and then monthly thereafter (follow-up phase)

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Time to reach final carvedilol dose (the time from initiation of carvedilol to achieving the final dose of carvedilol)</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Adverse events</li> <li>Mean carvedilol dose</li> </ul> <p><b>Follow-up time:</b> 3 months from recruitment</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> No information.</p> <p><b>Conflict of interest:</b> Footnotes state that Johns Hopkins has applied for a patent for the TeleWatch system described and that some of the authors have been named as co-inventors, and therefore are entitled to a share of income received by the University related to products described in this article. The terms of this arrangement are being managed by the Johns Hopkins University in accordance with its conflict of interest policies.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.844, e4

**Spaeder 2006** (Continued)

**QUOTE:**

"The groups were equivalent with respect to all enrolment variables."

Blinding (performance bias and detection bias) Objective outcomes	Low risk	The treating physician were blinded to the group allocation. Objective outcomes of adverse events and time to reach final medication dose.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.844, Col.2, Para.2  <b>QUOTE:</b>  "Two patients withdrew from the study, one each from the CO and TW groups, and 1 patient from the TW group was withdrawn by investigators because of a violation of eligibility criteria. Of the 46 patients who underwent carvedilol titration, 2 patients (4.3%), 1 from each group, were unable to tolerate the lowest dose of carvedilol. Fourteen patients (30.4%) were unable to achieve the dose of carvedilol 25 mg bid, 6 in the CO group, and 8 in the TW group ( P = .54)."
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Stone 2010**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Veterans who had at least one outpatient visit in a primary care clinic between 1 June 2004 and 31 December 2005, were aged &lt; 80 years, received pharmacological treatment for diabetes for &gt; 12 months, had no referrals to the VAPHS Diabetes Clinic in the preceding 18 months, and had a most recent HbA1c &gt; 8.0%.</p> <p><b>Exclusion criteria:</b> Veterans were excluded if they had a life expectancy of &lt; 6 months, were participating in another study, resided in an institutional setting, or did not have a land-based, analogue home telephone line as required for the home tele-monitoring device used.</p> <p><b>Method of patient recruitment:</b> Under a separate VAPHS-approved protocol, a sampling frame of potentially eligible veterans was developed from VAPHS electronic medical and pharmacy records using the inclusion criteria above. Approximately 20% of veterans with diabetes in our sampling frame met that HbA1c criterion. Eligibility was further verified by a point-of-care capillary HbA1c 7.5% at enrolment.</p> <p><b>Study sample calculation:</b> This study was designed to detect a 1% difference in HbA1c with 80% power using a 0.05-level two-sided test.</p> <p><b>Data collection:</b> At baseline, 3 months, and 6 months, participants presented to VAPHS for measurement of HbA1c, blood pressure, and weight and a fasting lipid panel. Baseline medication regimen (dose) and changes in the regimen (dose and date) for oral hypoglycaemic agents, insulin, antihypertensive medications, and lipid-lowering medications were abstracted from the electronic pharmacy records and verified by participant interview.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> 1055 veterans were deemed eligible; 658 (62.4%) responded to letters of invitation to participate; 381 (57%) agreed to be contacted; 211 presented to VAPHS for signed informed consent, additional screening, and baseline measurements. The 150 consenting veterans who had a capillary HbA1c &gt; 7.5% were randomised.</p>

**Stone 2010** (Continued)

**No of patients randomised to groups:** n = 150; Intervention: n = 73 Control: n = 77

**No of patients lost to follow-up:** n = 2 control participants withdrew before the initial education session and n = 6 intervention participants withdrew afterward.

**Patient baseline characteristics:**

a) Clinical condition: diabetes

b) Age, mean yrs (%): <45 years : Intervention (ACM + HT): 3 (4.7); Control (CC): 4 (5.5);

45-65 years: Intervention: 38 (59.4); Control (CC): 43 (58.9);

>= 65 years: Intervention: 23 (35.9); Control (CC): 26 (35.6);

c) Gender, male sex no (%) ; Intervention: 64(100); Control (CC): 71 (97.3)

d) Ethnicity: white race no (%): Intervention:46 (71.9) ; Control (CC): 59 (80.8)

e) Severity of condition: NA

f) Major co-morbidities, coronary artery disease: Intervention (ACM + HT):25 (39.1) ; Control (CC): 24 (32.9)

**Setting** (hospital/community/residential care): one VA Pittsburgh Healthcare System (VAPHS) at one of the three main Pittsburgh campuses or five outlying community-based clinics

**Location** (rural/urban etc.): the Pittsburgh area, urban

**Country:** USA

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Interventions

**Study objective:** To compare the short-term efficacy of home tele-monitoring coupled with active medication management by a nurse practitioner with a monthly care coordination telephone call on glycaemic control in veterans with Type 2 diabetes and entry HbA1c 7.5%.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** On office days, the nurse practitioner reviewed SMBG, blood pressure, weight, and risk stratification reports generated by the Viterion and contacted participants as necessary. The nurse practitioner provided timely telephone follow-up, including further self-management education for participants who generated "high-risk" reports based on unacceptably high or low SMBG or blood pressure readings. Medications for glycaemic, blood pressure, and lipid control were adjusted by the nurse practitioner supervised by the study endocrinologist without prior approval of the PCP who was informed retrospectively of all changes. The nurse practitioner maintained records of all medication changes made in the ACMHT group. The nurse practitioner also called ACMHT participants monthly to provide individualised self-management counselling tailored to specific issues, based on the status of glucose and blood pressure control from the transmitted data

**Type of technology and its application:**

Participants randomly assigned to the ACMHT group received a 6-month diabetes management support intervention using a (the Viterion 100 Monitor) home tele monitoring device. The device permits continuous home messaging with reminders and education; ongoing monitoring of SMBG, blood pressure, and weight; and daily transmission of these data to study providers via a secure network. Participants were instructed to transmit uploaded measurements from Viterion-compatible peripheral devices to the study nurse practitioner daily.

**Did the patient receive education about their condition?:** Participants in both groups attended an initial 2-hour educational session for diabetes self-management and nutrition.

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** monthly counselling sessions

**Stone 2010** (Continued)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The nurse practitioner
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): reviewed immediately (unclear if only during office hours)
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): Medications for glycaemic, blood pressure, and lipid control were adjusted by the nurse practitioner supervised by the study endocrinologist without prior approval of the PCP who was informed retrospectively of all changes.

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurse practitioners, endocrinologists

**Duration of intervention:** 6 months

**Comparison intervention:** monthly telephone calls from the study diabetes nurse educator regarding general health conditions, status of glycaemic control, blood pressure, and weight from daily logs maintained by the participants and compliance with the prescribed diabetic regimen. Issues requiring active intervention were referred to their PCP. Participants also could initiate contact with the study diabetes nurse educator to discuss concerns related to diabetes management..

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• HbA1c</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Blood pressure</li><li>• Lipids</li><li>• Weight</li></ul> <p><b>Follow-up time:</b> 3 and 6 months after randomisation</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b>This work was supported by award W81XWH-04-2-0030 from the U.S. Air Force, administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, Maryland, and by resources and the use of facilities</p> <p><b>Conflict of interest:</b> No potential conflicts of interest relevant to this article were reported.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>p.479, Col.1, Para 5</p> <p>QUOTE:</p> <p>“Participants were randomly assigned to the ACMHT or CC group. Randomization was stratified by quartile of capillary A1C within each site and blocked on time. The project statistician generated the random sequences, the study nurses enrolled the participants, and the study coordinator informed the nurses of the intervention assignment after each participant was enrolled. After an initial education session, participants were informed of their intervention assignments.”</p>

**Stone 2010** (Continued)

Allocation concealment (selection bias)	Low risk	See quote above.
Were baseline outcome measurements similar?	Low risk	No differences reported.
Were baseline characteristics similar?	Low risk	p.480, Col.1, Para.4 No differences reported. Table A1.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The study nurses delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, all outcomes (HbA1c, weight, blood pressure) were objective and outcome assessors blinded.  p.479, Col.2, Para 1  QUOTE:  "neither participants nor study nurses could be blinded. However, primary outcomes were ascertained by personnel unconnected to this study who were unaware of intervention assignments."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	A similar number of patients were lost to follow-up in each group, 2 control participants withdrew before the initial education session and 6 intervention participants withdrew afterwards.
Selective reporting (reporting bias)	High risk	Resource use and patients satisfaction were not reported as outlined in the protocol.
Other bias	Low risk	No evidence of other risk of bias.

**Taylor 2006**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients diagnosed with Obstructive sleep apnoea syndrome (OSAS) who were prescribed continuous positive airway pressure (CPAP) as therapy were considered for enrolment in the study. OSAS was defined as a respiratory disturbance index (RDI) greater than 4 accompanied by symptoms of excessive daytime sleepiness.</p> <p><b>Exclusion criteria:</b> Patients currently or previously treated with nasal CPAP or other therapies such as an oral appliance or surgery for OSAS were excluded from the study.</p> <p><b>Method of patient recruitment:</b> Participants were prospectively enrolled in this study at the Sleep Disorders Center at Walter Reed Army Medical Center (WRAMC) in Washington, DC.</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> Time of CPAP use was documented by downloading the automated data recorder in the CPAP device at the 30-day follow-up visit. Nasal CPAP use was presented as duration (average hours of CPAP use) and frequency (the proportion of CPAP use of at least 4 hours on all of the days monitored) over 30 days of observation.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 160</p> <p><b>No of patients randomised to groups:</b> n = 160: <b>Intervention:</b> n = 62; <b>Control:</b> n = 59 (according to table 1)</p>

**Taylor 2006** (Continued)

**No of patients lost to follow-up:** n = 27 patients were identified as screening failures (10 were excluded due to their unwillingness to initiate CPAP therapy. Three participants were intolerant of the CPAP titration study and were ambivalent about obtaining a repeat sleep study. Seven participants were removed from the analysis since they did not meet the criteria for the diagnosis of OSAS. Six participants had sleep studies that were found to be incomplete. One participant died during the screening phase); n = 17 patients were lost to follow-up: n = 8 patients in the control group and n = 9 patients in the intervention group were withdrawn after randomisation. One hundred and fourteen participants (58 in the traditional care group and 56 in the TM care group) completed the study.

**Patient baseline characteristics:**

a) Clinical condition: obstructive sleep apnoea syndrome (OSAS)

b) Mean age (years±SD): Intervention: 45.8 ± 10; Control: 44.6 ± 8.5

c) Gender, male (n, %): Intervention: 39 (66); Control: 44 (71)

d) Ethnicity:

African-Americans (n, %): Intervention: 25 (42); Control: 25 (40)

Caucasians (n, %): Intervention: 29 (49); Control: 37 (60)

e) Severity of condition:

OSAS severity (n, %)

Mild: Intervention: 17 (31); Control: 15 (25)

Moderate: Intervention: 19 (35); Control: 16 (27)

Severe: Intervention: 19 (34); Control: 28 (48)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one university-affiliated sleep disorders centre

**Location** (rural/urban etc.): urban, Washington DC

**Country:** USA

**Interventions**

**Study objective:** to compare continuous positive airway pressure (CPAP) use, functional status, and client satisfaction in obstructive sleep apnoea syndrome (OSAS) patients randomised to either TM support or traditional care.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring of patient status

**Delivery of intervention:** Each day, the patient was greeted with three questions regarding reported hours of nasal CPAP use, reported hours of sleep including naps, and quality of sleep including naps. The patient was expected to enter data into the Health Buddy computer as a self-reported response. According to the patient's response to the question, the patient received three or four "branching" questions specifically related to the four general aspects of OSAS care. A fourth question was asked daily regarding the most troublesome problem the patient experienced during the night, followed with a choice of responses. Only those patients who completed all four questions daily over the 30-day observation period were included in the analysis. The patient's responses to these questions were monitored daily by the sleep medicine practitioner. Each possible response was stratified into a high-, medium-, or low-risk category. Patients were categorised as high risk if they reported less than 4 hours of CPAP use during sleep, medium risk if they reported at least 4 hours of sleep with CPAP but rated their quality of sleep as poor, and low risk if they used CPAP for more than 4 hours of sleep and reported good quality of sleep on CPAP. The stratified responses were colour coded on the ICare Desktop for ease of interpretation. A set of guidelines indicated the appropriate course of action for each of the three response categories. Patients with responses that resulted in a high-risk (red) category for more than 3 days were contacted by telephone by the sleep medicine practitioner within 24 hours. Patients with responses



**Taylor 2006** (Continued)

that resulted in a medium-risk (yellow) and low-risk (green) responses were monitored daily, but no telephone contact was initiated.

**Type of technology and its application:**

The intervention group received a prescheduled number of questions that were provided via a home computer called the "Health Buddy." The Health Buddy OSAS Library was customised with information and suggested interventions. The library comprised pre-programmed questions and answers in a patient-provider dialogue covering four general aspects of OSAS care: symptom management, health behaviour, knowledge, and general questions. The patient-provider dialogues were designed to provide education in the pathophysiology of OSAS, reinforce knowledge regarding nasal CPAP use, encourage skills mastery techniques and self-management behaviours, and interpret nasal CPAP symptoms and common side effects.

**Did the patient receive education about their condition?: Yes.** Patients in both groups were outfitted for masks and instructed on initial CPAP use in the same manner. This included general patient education on OSAS, a film on OSAS and CPAP therapy, as well as fitting of the CPAP mask.

**Frequency of patient data transfer (monitoring studies only):** daily (answers to Health Buddy questions only)

**Frequency/number of TM contacts between patient and healthcare personnel**

**a) Planned/scheduled number of contacts:** no planned contacts

**b) Actual number of contacts:** Both groups had a similar number of patient-initiated complaints either through telephone or e-mail, eight in the TM group (six calls and two e-mails), and seven in the traditional care group. However, the traditional care group had more walk-in visits, three per week compared to one per week in the TM group. For this study, the number of practitioner-triggered calls to the patient was not monitored.

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: The sleep medicine practitioner

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): within 24 hours if answers to Health Buddy question for 3 days in a row indicates a worsening condition

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): actions according to a set of guidelines; Consultation on improving CPAP use, or provision of different mask

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** sleep practitioner

**Duration of intervention:** 30 days

**Comparison intervention:** UC included a scheduled clinic visit 1 month after initiating nasal CPAP and any subsequent clinic visits felt

necessary by the care provider to manage OSAS. Participants in the control group were also able to access the sleep medicine practitioner through the use of telephone consultation and walk-in visits in addition to the scheduled clinic visits.

**Outcomes**
**Primary outcomes:**

- CPAP use (outcome included in this review)
- Functional status (assessed using a non-validated Modified Functional Outcomes of Sleep Questionnaire)
- Client satisfaction (assessed using a non-validated questionnaire)

**Follow-up time:** 30 days after randomisation

## Taylor 2006 (Continued)

### Notes

**Ethical approval and informed consent obtained (yes/no):** Ethic's committee approval was obtained. No information on whether informed consent was obtained or not.

**Sources of funding:** Supported by the Telemedicine Directorate, Walter Reed Army Medical Center, Washington, DC.

**Conflict of interest:** No information.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.133, Col.1, Para.3  QUOTE:  "Randomization to one of the two study groups (telemedicine or traditional) was conducted after subjects were stratified according to age, gender, and OSAS disease severity (mild, moderate, or severe). Randomization to either the telemedicine or traditional group was balanced within each stratum through the use of a software-generated blocked randomization schedule. Twelve stratified groups numbered from 1 to 12 were generated to determine which of the 12 randomized blocked schedules would be used. The blocked randomization schedule for each stratum was then used to assign the patient to either the telemedicine or traditional group."
Allocation concealment (selection bias)	Low risk	See comment above
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome reported in the text or tables.
Were baseline characteristics similar?	Low risk	p.135, Col.2, Para 2  No differences between groups, apart from marital status.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The health professional delivering the intervention could not be blinded to the group allocation, and neither could the patients. Objective data on CPAP use was downloaded from the automated data recorder in the CPAP device
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	n = 27 patients were identified as screening failures; n = 8 patients in the control group and n = 9 patients in the intervention group were lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Thompson 2009

### Methods

**Study design:** RCT

**Inclusion criteria:** participants had to live within an approximate 200-mile radius, as transplant recipients living farther than 200 miles from the transplant clinic usually have a different pattern of follow-up care. Participants also needed to be assigned to a nurse practitioner (NP) for the majority of their follow-up care, be at least 18 years of age, have a functioning transplanted organ, possess a working knowledge of the English language, and be willing and able to complete all surveys. Participants

**Thompson 2009** (Continued)

randomised to the telehealth (TH) group must also be willing to travel to one of the three distant TH sites used for the study.

**Exclusion criteria:** none stated

**Method of patient recruitment:** Participants were recruited from the existing patient population of the transplant centre. All transplant recipients were eligible to participate, but because of provider hesitancy to use TH, the prospective participant had to be cleared by the provider prior to being approached by the study recruiter. As a result, newly transplanted recipients (less than 6 months) were routinely not cleared for approach. [NB Participants in Leimg 2008 (companion paper) were enrolled between August 2005 to October 2006.]

**Study sample calculation:** not stated

**Data collection:** Depressive symptoms were measured by the Center for Epidemiologic Studies–Depression (CES-D™) survey at study entry and at 6 and 12 months post consent into the study. For both SC and TH groups, the TH co-ordinator did a visual calculation of the CES-D immediately to ascertain the depressive symptoms. If the score was found to be 16 or greater, the NP was notified. In addition, patients in both groups were given as much time as needed to complete the survey. Verbal assistance was offered to patients who exhibited visual impairment and/or requested assistance. For participants whose data collection points came between clinic appointments, the participant was contacted by phone and either completed questionnaires over the phone with the TH co-ordinator or received the questionnaire packet in the mail with an enclosed self-addressed stamped envelope for survey return. Transplant outcomes were collected from participants' medical records at study entry and at 6 and 12 months after entry.

**Unit of analysis issues:** (yes/no): no

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**Participants**

**Total no of eligible patients:** n = 3 000 (no information on no of participants who declined participation)

**No of patients randomised to groups:** n = 138 participants; Intervention: n = 70; Control: n = 68 [NB Leimg 2008 reports 6 month follow-up N=121].

**No of patients lost to follow-up:** N=15 (reported in Leimg 2008).

**Patient baseline characteristics:**

a) Clinical condition: solid organ transplant recipients

b) Age: no information

c) Gender, male, no (%): Intervention: 39 (55.7); Control: 38 (55.9)

d) Ethnicity:

White: Intervention; 35 (50.0); Control: 31 (45.6)

Black: Intervention: 33 (47.1); Control: 37 (54.4)

e) Severity of condition:

Transplant type: Kidney, no (%): Intervention: 58 (82.9); Control: 52 (76.5)

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): one main transplant clinic and three remote locations (19, 90 and 120 miles from the standard care clinic)

**Location** (rural/urban etc.): remote locations

**Country:** USA

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**Interventions**

**Study objective:** To investigate the effectiveness of screening for depression of 138 transplant recipients receiving follow-up care via telehealth (TH) and standard care (SC); and compare infection, rejection

**Thompson 2009** (Continued)

tion, and hospitalisation events in participants randomised to telehealth or to standard posttransplant care.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing (assessment/screening)

**Delivery of intervention:** For the TH group, the procedure mimicked the SC visit closely. To keep the visits as similar as possible, the connection between sites was generally established approximately 15 minutes prior to each appointment to allow time for the resolution of any technical difficulties. At that time, the analogue stethoscope connection would also be made between sites. The tasks of each visit were kept in the same order as if the participant were being seen face-to-face. The TH co-ordinator collected the chart and billing documents while the distant site nurse reviewed medications, assessed vital signs, and documented any complaints or concerns. The NP was informed of the established connection. Medical notes were faxed to the distant site. During the NP visit, the participant was placed in the centre of the screen and the TH co-ordinator used the hand-held remote to zoom-in or out as needed. If additional close-ups were needed, the hand-held digital camera could be used for additional magnification. At the completion of the NP medication/lab review and physical assessment any prescriptions, lab orders, and clinic appointment cards were faxed to the distant and a follow-up visit was scheduled. The telehealth nurse at the remote site would also review discharge instructions with the patient. In the event the patient had signs or symptoms that required urgent measures, arrangement for overnight hospitalisation or same day testing could be made. If deemed necessary by the nurse practitioner, patients with non-urgent problems could be scheduled to be seen in the standard care clinic.

**Type of technology and its application:** The TH receiving room consisted of an examination room within the SC transplant clinic. The room was equipped with a PolyCom VSX 7000 camera system (PolyCom, Pleasanton, CA), a 32-inch video monitor, a telephone line and headset for the AMD-3450R analogue stethoscope (AMD, Boston, MA), and a separate phone line for a receiving phone/fax machine. The PolyCom camera system and monitor were controlled by a handheld remote control that was manipulated by the TH Co-ordinator during the patient visits. Each of the three distant TH sites was also equipped with Polycom VSX 7000 camera systems and 19-inch dual-screen video monitors. In addition, distant sites were equipped with AMD-2015 ENT digital otoscopes, Sony DCR-TRV840 hand-held digital cameras (Sony, Tokyo, Japan) for close examination of skin conditions, and AMD- 3450S analogue stethoscopes systems for the distant-site nurses to use during patient examinations.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** The study protocol did not dictate the number of visits, or when a visit occurred.

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: N/A
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** TH co-ordinator, distant nurse, nurse practitioner,

**Duration of intervention:**12 months after randomisation

**Comparison intervention:** Patients in the control group were seen through the usual procedures in the transplant clinic. Laboratory results, review of medication, and physical assessment were performed by the nurse practitioner according to current transplant clinic policies.

**Outcomes**
**Primary outcome:**

**Interactive telemedicine: effects on professional practice and health care outcomes (Review)**

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**Thompson 2009** (Continued)

- Depression assessed with the CES-D instrument

**Follow-up time:** 12 months from randomisation

## Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** Part of a larger National Institute of Nursing Research-funded randomised clinical trial.

**Conflict of interest:** No competing financial interests exist.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.702, Col.1, Para.1  QUOTE:  "Prior to study initiation, a table of random numbers was generated to assign individuals to groups."
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Low risk	No differences between groups. Table 3.
Were baseline characteristics similar?	Low risk	p.203, Col.1, Para.4  No differences reported (Table 1)."
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. The same TH co-ordinator assessed both groups using a validated tool. For both SC and TH groups, the TH coordinator did a visual calculation of the CES-D immediately to ascertain the depressive symptoms.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Van der Meer 2010**

## Methods

**Study design:** RCT

**Inclusion criteria:** physician-diagnosed asthma coded according to the International Classification of Primary Care in the electronic medical record (12), age 18 to 50 years, prescription of inhaled corticosteroids for at least 3 months in the previous year, no serious co-morbid conditions that interfered with asthma treatment, access to the Internet at home, and mastery of the Dutch language.

## Van der Meer 2010 (Continued)

**Exclusion criteria:** asthma patients who were receiving maintenance oral glucocorticosteroid treatment.

**Method of patient recruitment:** On the basis of diagnosis, age, prescribed asthma medication, and co-morbid conditions, we sent eligible patients an invitation letter followed by 1 reminder letter after 2 to 4 weeks if they did not respond to the first. We continued this process until a total of 200 patients had entered the study (September 2006).

**Study sample calculation:** With a total of 100 patients per group, an SD of 0.75 (17), and a correlation coefficient of 0.5, our repeated-measures analysis had a statistical power of 80% (at the 2-tailed 5% significance level) to detect a 0.26-point difference in Asthma Quality of Life Questionnaire score.

**Data collection:** We extracted the frequency of Internet-based monitoring from website log files and included optional daily lung function and symptom monitoring and weekly Asthma Control Questionnaire monitoring. Medication use was reported at baseline, 3 months, and 12 months. For each patient, we measured the number of medication changes (or steps) by comparing treatment step at 3 months with treatment step at baseline (number of medication changes in first 3 months) and treatment step at 12 months with treatment step at 3 months (number of medication changes in the next 9 months). We totaled the numbers of medication changes in the first 3 months and next 9 months and reported averages per patient. We assessed all outcomes except for exacerbations over 2 weeks, at 3 months, after the baseline period, and again at 12 months. During these assessments, all patients kept Internet-based daily diaries as they had during the baseline period.

**Unit of analysis issues:** no

### Participants

**Total no of eligible patients:** n = 930 patients who met the selection criteria were invited to participate in the study. Patients who consented to participate (n = 200 [21.5%]) did not differ from non participants in age (mean age, 36.6 years vs. 35.8 years; P = 0.27) or socioeconomic status (living in an underprivileged area, 5.0% vs. 7.1%; P = 0.29), but they did differ in sex ratio (women, 69.5% vs. 59.7%; P = 0.012).

**No of patients randomised to groups:** n = 200; Intervention: n = 101; Control: n = 99

**No of patients lost to follow-up:** none

#### Patient baseline characteristics:

a) Clinical condition: asthma

b) Age, mean years (range): Intervention: 36 (19–50); Control: 37 (18–50)

c) Gender, % male sex: Intervention: 32; Control: 29

d) Ethnicity: no information

e) Severity of condition:

Mean asthma duration (range), years : Intervention: 15 (1–47); Control: 18 (0–47)

Mean FEV1 (pre-bronchodilator) (range): Intervention: 3.08 (1.14–5.19); Control: 3.13 (1.56–5.23)

Mean predicted FEV1 (pre-bronchodilator) (range), % Intervention: 88 (34–133); Control: 90 (53–118)

f) Medication:

Mean daily inhaled corticosteroid dose (range), g Intervention: 497 (0–1000); Control: 517 (0–2000)

Inhaled long-acting 2-agonist use, % Intervention: 59; Control: 60

Leukotriene modifier use, % Intervention: 3; Control: 2

f) Major co-morbidities: no information

g) Baseline measures of outcome:

Mean educational outcomes (range):

Asthma knowledge: Intervention: 8.74 (2–12); Control: 8.32 (3–12)

**Van der Meer 2010** (Continued)

Inhaler technique: Intervention:4.34 (3–5); Control:4.11 (1–5)

Self-reported medication adherence: Intervention:6.46 (0–7); Control:6.19 (0–7)

Clinical outcomes:

Mean Asthma Quality of Life Questionnaire score (range) Intervention: 5.73 (3.66–6.94); Control: 5.79 (3.03–7.00)

Mean Asthma Control Questionnaire score (range): Intervention: 1.12 (0.07–3.22); Control:1.11 (0–3.86)

Symptom-free days (range), % Intervention:44.9 (0–100); Control:44.5 (0–100)

**Setting** (hospital/community/residential care): 37 general practices (69 general practitioners) and one Outpatient Clinic of the Department of Pulmonology at Leiden Medical Center

**Location** (rural/urban etc.): urban(the Leiden and The Hague area)

**Country:** Germany

**Interventions**

**Study objective:** to assess the long-term clinical effectiveness of Internet-based self-management education compared with usual physician-provided care alone.

**Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring (automatic algorithm-based responses) but mostly education (in addition to UC)

**Delivery of the intervention:** Patients monitored their asthma weekly by completing an electronic version of the Asthma Control Questionnaire on the website and instantly received feedback on the current state of their asthma control along with advice on how to adjust their treatment according to a predefined algorithm and treatment plan. Depending on the scores submitted, patients received 4 types of self-treatment advice. When 4 consecutive Asthma Control Questionnaire scores were 0.5 or less, patients were advised to decrease treatment according to treatment plan. When 2 consecutive scores were greater than 0.5 but less than 1.0, patients were advised to increase treatment. When 1 score was 1.0 or more but less than 1.5, patients were advised to immediately increase treatment. Finally, when 1 score was 1.5 or more, patients were advised to immediately increase treatment and contact the asthma nurse.

**Type of technology and its application:** The Internet-based self-management program consisted of the 4 principal components of asthma self-management and was accessed through the specially designed website, which allowed monitoring through the website (or text message on a mobile telephone), use of an Internet-based treatment plan, online education, and web communications with a specialised asthma nurse.

**Did the patient receive education about their condition?** Self-management education consisted of both web-based and face-to-face, group-based education. Web-based education included asthma information, news, frequently asked questions, and interactive communication with a respiratory nurse specialist. We scheduled 2 group-based education sessions, which lasted 45 to 60 minutes, for patients in the Internet-based self-management group within 6 weeks after entering the trial. Both sessions included exploration of a patient's interests and previous knowledge (negotiating an agenda and patient-centred education), personalised feedback, and empowerment of self-management (self-efficacy and implementing a plan for change). The first educational session also included pathophysiology of asthma, information on the web-based action plan, and information and review of inhalation technique. The second educational session gave information about the mechanisms and side effects of medication and explained trigger avoidance.

**Frequency of patient data transfer (monitoring studies only):** weekly

**Planned /scheduled no of TM contacts between patient and healthcare professional:** two educational sessions

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A



## Van der Meer 2010 (Continued)

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): immediate

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): medication adjustment if needed

**Providers (e.g., no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 12 months

**Comparison intervention:** Patients in the UC group received asthma care according to the Dutch general practice guidelines on asthma management in adults, which recommend a medical review and treatment adjustment every 2 to 4 weeks in unstable asthma and medical review once or twice yearly for patients whose asthma is under control.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• Astma QoL (assessed with the Asthma Quality of Life Questionnaire)</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Asthma control (self-reported)</li><li>• Symptom-free days (a night and day without asthma symptoms or being awakened by asthma symptoms, as measured by the TRUST (The Regular Use of Salbutamol Trial) diary card)</li><li>• Lung function (pre-bronchodilator FEV1)</li><li>• Daily inhaled corticosteroid dose (calculated daily as fluticasone equivalents)</li><li>• Exacerbations (defined as deterioration in asthma that required emergency treatment or hospitalisation)</li><li>• Process outcomes (= educational outcomes, as per below);</li></ul> <p>- asthma knowledge (assessed with the 12-item Consumer Asthma Knowledge Questionnaire)</p> <p>- inhaler technique (assessed with the standardised checklist of the Dutch Asthma Foundation)</p> <p>- self-reported medication adherence</p> <p>- healthcare provider contacts for asthma</p> <p>- use of the Internet-based monitoring tool</p> <p>- medication changes</p> <p><b>Follow-up time:</b> 12 months after randomisation</p>	
Notes	<p><b>Ethic's committee approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> By the Netherlands Organization for Health Research and Development (ZonMw grants 945-04-061 and 920-03-354) and Netherlands Asthma Foundation (grant 3.4.03.45).</p> <p><b>Conflict of interest:</b> The Netherlands Organization for Health Research and Development, ZonMw, and Netherlands Asthma Foundation supported the study. The funding sources had no role in the study design or conduct; collection, analysis, or interpretation of the data; or in the decision to submit the article for publication</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.110, Abstract
		QUOTE:

## Van der Meer 2010 (Continued)

"Participants were randomly assigned by using a computer-generated permuted block scheme to Internet-based self-management.."		
Allocation concealment (selection bias)	Low risk	see quote above
Were baseline outcome measurements similar?	Low risk	Baseline characteristics of the randomisation groups were similar (Table 2). Includes also baseline measures of outcomes.
Were baseline characteristics similar?	Low risk	Baseline characteristics of the randomisation groups were similar (Table 2)
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professional and the patient could not be blinded to the allocation into groups. Participants provided the Asthma Control Questionnaires, symptom-free days, and pre-bronchodilator FEV1 through the Internet (the UC group had limited access to the website for 2 weeks at baseline, 3 months, and 12 months). We collected the other outcomes by written questionnaires.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The analysis set included all randomly assigned patients who provided any data during the study. Analysis based on intention-to-treat.
Selective reporting (reporting bias)	Unclear risk	Results for most outcomes listed in the trial protocol were reported in the paper, except exhaled nitric oxide.
Other bias	Low risk	No other risk of bias identified.

## Wakefield 2008

Methods	<p><b>Study design:</b> RCT (3-armed)</p> <p><b>Inclusion criteria:</b> hospital admission for heart failure (HF), a telephone line in the home; absence of significant vision, hearing, or other communication deficits; enrolled in the ICVAMC Primary Care Clinic; and English speaking.</p> <p><b>Exclusion criteria:</b> cognitive impairment, residing in a long-term care facility, or discharged to a long-term care facility.</p> <p><b>Method of patient recruitment:</b> between July 2002 and September 2005 trained nurses screened patients within 24 hours of admission to identify potential participants. Patients were selected for screening based on documentation of possible HF exacerbation as the reason for admission (e.g., patients admitted for HF, volume overload, and pulmonary oedema).</p> <p><b>Study sample calculation:</b> for a two-tailed test, with a significance level set at 0.05, a sample size of 165 (55 participants in each of three groups) would be required to provide 80% power to detect a decrease of 0.23 in re-admission rates (from 43% to 20%).</p> <p><b>Data collection:</b> data on resource use (re-admission rate, time to first re-admission, hospital days, and urgent care clinic visits) were collected from the VA Patient Treatment File, which contains records of VA hospital stays, the VA Outpatient Clinic File, which contains records of ambulatory VA clinic visits, and the CPRS. These data sources were searched for 12 months prior to and 12 months following study enrolment for utilisation data. Mortality for the 12-month follow-up period was obtained using multiple methods, including attempts to contact participants for follow-up data collection; CPRS review; PTF data; and the Beneficiary Identification Records Locator Subsystem, which contains data on veterans known to be deceased.</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<b>Total no of eligible patients:</b> n = 344 eligible patients

## Wakefield 2008 (Continued)

**No of patients randomised to groups:** n = 101; Video-phone: n = 52; Control: n = 49. Note: a third group (telephone, n = 47) was not included in this review.

**No of patients lost to follow-up:** at 3 months, 85% (n = 126) completed follow-up; at 6 months, 74% (n = 109) completed follow-up.

### Patient baseline characteristics:

a) Clinical condition: heart failure (HF)

b) Age (mean, SD): Video-phone: 69.0 (9.6); Control: 67.2 (8.5)

c) Gender (% male): Video-phone: 98% (51); Control: 98% (48)

d) Ethnicity, % White (no): Video-phone: 88% (46); Control: 100% (49)

e) Severity of condition:

LVEF (mean, range) Video-phone: 38% (6% to 73%); Control: 43% (12% to 83%) > 41%: Video-phone: 36.5% (19); Control: 40.4 (23)

26% to 40%: Video-phone: 32.7 (17); Control: 31.9 (15) < 25%: Video-phone: 30.8 (16); Control: 19.2 (9)

Length of time diagnosed with HF: Video-phone: 3.1 years; Control: 1.9 years

NYHA class:

II: Video-phone: 21 (11); Control: 35% (17)

III: Video-phone: 71% (37); Control: 59 (29)

IV: Video-phone: 8 (4); Control: 6 (3)

f) Major co-morbidities: NA

**Setting** (hospital/community/residential care): the Iowa City Veterans Affairs Medical Center (ICVAMC), a 107-bed tertiary care referral centre affiliated with the University of Iowa.

**Location** (rural/urban etc.): urban

**Country:** USA

## Interventions

**Study objective:** to evaluate the efficacy of a telehealth-facilitated post-discharge support program in reducing resource use in patients with HF.

**Type of TM /mode of delivery (e.g. video-conference, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** i) video-phone; ii) telephone

**Delivery of intervention:** for the participants assigned to the telephone group, all intervention contacts were conducted using their personal telephone in their home. Two registered nurses conducted all intervention contacts. Intervention participants were given a symptom review checklist to help them report HF-related symptoms, a scale, blood pressure cuff, and tape measure and were instructed to measure daily weights, blood pressure, and ankle circumference to monitor fluid accumulation. Study nurses reviewed the discharge plan during the first intervention contact and reinforced it during subsequent contacts. During all intervention contacts, study nurses assessed participants using the symptom review checklist. When participants reported symptoms, nurses reviewed their data, reinforced the plan of care, and made referrals (e.g., dietitian) or contacted the participant's physician for care plan adjustments. During the contacts, study nurses had full access to participants' medical records through the Computerized Patient Record System. Study nurses also employed strategies to improve participants' compliance with prescribed treatment plans. This included behavioural skill training strategies (e.g., reviewing skills for monitoring blood pressure, and recommending use of a grocery list to purchase low-sodium food). Self-monitoring strategies were encouraged (e.g., keeping a daily record of weight and food intake). Self-efficacy enhancement strategies included encouraging use of community support groups; encouragement and feedback; and realistic goal setting. External cognitive strategies included encouraging use of aids such as meal plans and medication organisers. **Train-**

## Wakefield 2008 (Continued)

**ing:** The videophones were installed and removed by a research assistant, who trained participants on their use.

**Type of technology and its application:** a colour television–type monitor, camera, and remote control device. The remote control’s large green “Start” launched the system and large red “End call” button turned it off. To establish contact, the study nurse activated the system by entering a patient’s telephone number. The patient at home responded by pushing the “Start” button on the remote control. With the system activated on both ends, the nurse and patient saw and spoke to each other during the contact. At the end of the interaction, the patient pressed the “End call” button. During the enrolment period, CyberCare Technologies went out of business, and we contracted for newer, more reliable equipment. The TeleVyou 500SP videophone (distributed by Wind Currents Technology, Woodstock, NY) is a telephone with a built-in speaker phone, and a 5-inch colour video screen. Like the CyberCare model, this phone has a resolution of 176 × 144 pixels and transmits video at 15 FPS with full duplex audio. Establishing contact is the same as using a regular telephone. The videophones were installed and removed by a research assistant, who trained participants on their use. Intervention participants contacted their assigned study nurse if needed after discharge.

**Did the patient receive education about their condition?** Yes, all patients received pre-discharge education.

**Frequency of patient data transfer (monitoring studies only):** N/A

**Frequency/number of TM contacts between patient and healthcare personnel:** 14 times over 3 months (three times the first week after discharge, and then weekly for 11 weeks)

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** Two registered nurses.

**Duration of intervention:** 3 months

**Comparison intervention:** follow-up clinic appointments were scheduled in the usual manner for all participants. UC participants contacted their primary care nurse case manager by telephone if needed (all patients at the Medical Center are provided telephone numbers for their assigned nurse case manager).

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Re-admission rate</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Time to first re-admission</li> <li>Hospital days stayed</li> <li>Urgent care clinic visits</li> <li>Mortality (assessed 12 months after discharge)</li> <li>QOL (assessed with the Minnesota Living with Heart Failure instrument (MLHF) at 180 days)</li> </ul> <p><b>Follow-up time:</b> at 3, 6 and 12 months post randomisation</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p>

## Wakefield 2008 (Continued)

**Sources of funding:** the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development (VA HSR&D) Service (#NRI 99-345), a VA HSR&D Career Development Award to Dr. Wakefield, the VA HSR&D

Center for Research in the Implementation of Innovative Strategies in Practice (CRIISP) at the Iowa City VA Medical Center, Iowa City, IA, and by the Harry S. Truman Memorial Veterans Hospital.

**Conflict of interest:** No competing financial interest.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.754, col.1, Para.5  QUOTE:  "The project coordinator prepared sealed envelopes containing group assignments in blocks of 24. Following informed consent and baseline data collection, study nurses opened the envelope to assign subjects to one of three treatment conditions"
Allocation concealment (selection bias)	Unclear risk	p.754, col.1, Para.5  QUOTE:  "The project coordinator prepared sealed envelopes containing group assignments"
Were baseline outcome measurements similar?	Unclear risk	For most outcomes no baseline outcome measure could be reported, and for QOL the baseline scores were similar in the three groups.
Were baseline characteristics similar?	Unclear risk	p.755, Col.2, Para.2  No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. Primary outcome and most secondary outcomes were objective and retrieved from VA registers (re-admission, length of stay, clinic visits and mortality).
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. Patient-reported quality of life may be affected by patient non-blinding. No information on whether or not outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	At 3 months, 85% (n = 126) completed follow-up; at 6 months, 74% (n = 109) completed follow-up.
Selective reporting (reporting bias)	Low risk	No selective reporting.
Other bias	Low risk	No evidence of other risk of bias.

## Waldmann 2008

Methods

**Study design:** multicentre RCT

**Interactive telemedicine: effects on professional practice and health care outcomes (Review)**

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**Waldmann 2008** (Continued)

**Inclusion criteria:** Angiographically proven coronary artery disease (CAD) (ICD-10:120 (angina pectoris) company), 121 (acute myocardial infarction), 122 (recurrent myocardial infarction), 125 (chronic ischaemic heart disease) and age 18 and over, member of AOK Schleswig-Holstein (statutory health insurance), capable of cooperation, non-cardiac life-expectancy > 12 months, and provided written informed consent.

**Exclusion criteria:** Ending of health insurance, patients' cancellation (revocation or refusal) at baseline or at follow-up.

**Method of patient recruitment:** The patients were recruited at 11 hospitals in Schleswig-Holstein.

**Study sample calculation:** To test the primary hypothesis a sample size of 748 cases per group was needed (cardiac event rate: 19 % in intervention group and 25 % in the control group) during 12 month follow-up; alpha error 5%, power of 80%.

**Data collection:** At 12-months follow-up information on deaths, hospital stay (number, cause, intervention, duration), use of drugs and other direct costs were collected from the records of the AOK Schleswig-Holstein company. Data on telephone contacts, reasons for calling, diagnosis and advice given were documented at the call centre. A postal questionnaire was sent to the patient to assess QOL, depression and satisfaction at 12 months follow-up.

**Unit of analysis issues:** (yes/no):no

**Participants**

**Total no of eligible patients:** n = 2233, of which n = 692 declined participation (31%), n = 41 had to be excluded after enrolment

**No of patients randomised to groups:** n = 1541: Intervention: n = 774; Control: n = 767

**No of patients lost to follow-up:** Intervention: n = 19/774 (2%) post randomisation exclusions in the intervention group and n = 12/767 (1.5%) in the control group, n = 3 patients in the intervention group and n = 7 in the control group were excluded due to health insurance membership cancellations. At 12 months follow-up: Intervention: n = 10 deaths, n = 742 patients alive (including n = 59 withdrawals); Control: n = 23 deaths, and n = 725 patients alive (including n = 1 withdrawal).

**Patient baseline characteristics:**

a) Clinical condition: coronary artery disease (CAD)

b) Age: Intervention: 63 ± 10 years; Control: 64 ± 10 years

c) Gender, female sex no (%) ; Intervention: 174 (23); Control: 201 (27)

d) Ethnicity: no information

e) Severity of condition:

ST-Elevation Myocardial Infarction (STEMI, %) : Intervention: 57%; Control: 54%

Angina pectoris stable: Intervention: 131 (18%); Control: 126 (17%)

Angina pectoris unstable: Intervention: 178 (24%); Control: 178 (24%)

Artery disease: Intervention: 85 (11%); Control: 94 (13%)

Heart failure: Intervention: 245 (33%); Control: 226 (30%)

Arterial hypertension: Intervention: 585 (78%); Control: 584 (78%)

Hyperlipidaemia: Intervention: 564 (76%); Control: 584 (78%)

f) Major co-morbidities: More than 75% of the participating patients had hyperlipidaemia and arterial hypertension.

g) Medication: a greater number of patients in the intervention group (83% than in the control group (79%) took beta-blockers.

**Waldmann 2008** (Continued)

**Setting** (hospital/community/residential care): 11 hospitals

**Location** (rural/urban etc.): unclear

**Country:** Germany

**Interventions**

**Study objective:** To determine whether providing CAD patients with the opportunity to send a ECG trace and to consult with a physician whenever they felt they needed to, in addition to UC, would improve patient outcomes as compared to UC only.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** transtelephonic ECG

**Delivery of intervention:** On the day before discharge patients in the intervention group were equipped with a 12-lead event recorder . They were trained to use the device and send the CG by telephone to the call centre. Whenever the patients had symptoms they could call the call centre, transmit an ECG (without re-dialling) and consult a physician. A standardised, guideline-based clinical pathway was followed, which resulted in a mobile intensive care being sent to the patient, or a consultation with a general practitioner or a cardiologist, or a change of medication being recommended, or the patient being re-assured that the situation was not life-threatening.

**Type of technology and its application:** 12-lead event recorder (model CG 7100, Card Guard AG)

**Did the patients receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none; contact only if needed

**Clinician response to receipt of data (monitoring studies only):**

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** Physicians, cardiologists and GPs

**Duration of intervention:** 12 months

**Comparison intervention:** UC.

**Outcomes**

**Primary outcomes:**

- All-cause mortality
- Myocardial infarction
- Re-hospitalisation
- Re-vascularisation

**Secondary outcomes:**

- No and lengths of hospital stays
- QOL (only for intervention group)

**Follow-up time:** 12 months from randomisation

**Notes**

**Ethical approval and informed consent obtained (yes/no):** yes



**Waldmann 2008** (Continued)

**Sources of funding:** AOK Schleswig-Holstein, Card Guard Europe B.V. and Segeberger Kliniken GmbH.

**Conflict of interest:** Welch Allyn, Inc. Welch Allyn did not participate in the study design, implementation, or data analysis and had no role in the decision to publish the results.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.18, Col.2, Para.2 No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, outcomes are all objective and collected from register, by people not belonging to the study team. Qualitative data assessed via postal questionnaire (intervention group only).
Incomplete outcome data (attrition bias) All outcomes	Low risk	19/774 (2%) post randomisation exclusions in the intervention group and 12/767 (1,5%) in the control group, n = 3 patients in the intervention group and n = 7 in the control group were excluded due to health insurance membership cancellations
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

**Wallace 2002**
**Methods**

**Study design:** RCT (multi-centre)

**Inclusion criteria:** All patients referred by the participating general practitioners to specialists taking part were eligible.

**Exclusion criteria:** Patients requiring urgent assessment, patients wishing treatment outside the NHS, and those with significant difficulty communicating in English were excluded. Shortly after the start of the trial, the exclusion criteria were extended to patients referred for a specific investigation (such as a hearing test), but the small number of such patients who had already been recruited were retained in the final analysis.

**Method of patient recruitment:** General practitioners were, between March 1999 and September 2000, encouraged to seek consent from their patients when the decision was made to refer.

**Study sample calculation:** The sample size, was chosen to detect a reduction of 20% (from 60% to 40%) in follow-up outpatient appointments offered after the index consultation between the groups, both overall and separately for each of the five predefined specialty groups with 90% power and 5% significance. 250 patients were required in each specialty, and, allowing for imbalance in anticipated

## Wallace 2002 (Continued)

numbers between specialties and a potential 30% of missing outcome data, the study required a total of 1950 patients.

**Data collection:** Baseline measurements consisting of demographic variables and a QoL measure were collected on a questionnaire sent with the appointment letter. The referring GP completed a Duke Severity of Illness Inventory (DUSOI) for each patient. The outcome measures immediately after the index consultation included the Ware Specific Visit questionnaire (patient satisfaction) and the Patient Enablement Instrument (PEI). Research nurses reviewed the content of the letter written by the hospital specialist after the initial consultation to which patients were randomised (the index consultation) to determine whether or not a follow-up outpatient appointment in the same specialty had been offered, and the reasons for offering follow-up appointments.

**Unit of analysis issues:** (yes/no): no

### Participants

**Total no of eligible patients:** n = 3134 eligible patients referred by GP, of which 1040 failed to provide consent

**No of patients randomised to groups:** n = 2094 Intervention: n = 1051; Control: n = 1043

**No of patients lost to follow-up:** Intervention: n = 80 (7 withdrew, and n = 73 had no consultant letter available); Control: n = 75 (n = 8 withdrew, n = 67 had no consultant letter available)

#### Patient baseline characteristics:

a) Clinical condition: conditions patients requiring referral to a specialist

b) Age, years (SD) Intervention: 48.4 (20.8); Control: 48.1 (20.7)

c) Gender, male no (%) Intervention: 509 (48%); Control: 508 (49%)

d) Ethnicity, White: Intervention: 848 (90%); Control: 835 (88%)

e) Severity of condition: no information

f) Major co-morbidities: no information

**Setting** (hospital/community/residential care): the Royal Free Hampstead NHS trust and the Royal Shrewsbury trust in Shropshire; 29 practices (and 134 GPs) in London, and 20 hospital consultants at the Royal Free Hampstead NHS Trust and the Royal Shrewsbury Trust in Shropshire

**Location** (rural/urban etc.): inner city and urban setting (London) and small market towns and rural settings (Shropshire)

**Country:** UK

### Interventions

**Study objective:** To determine the effectiveness of virtual outreach (TM) on the frequency of follow-up, patients' satisfaction and welfare, the uses of health service facilities for investigation and treatment, and the economic implications for primary care.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing

**Delivery of intervention:** Patients randomised to virtual outreach underwent a joint tele-consultation, in which they attended the general practice surgery where they and their GP consulted with a hospital specialist via a video link between the hospital and the practice. To ensure comparability in the two arms of the trial, waiting times of no more than eight weeks were established for patients in both arms of the trial. In most cases, the specialists were unable to provide dedicated tele-consultation clinics, but generally offered appointments at the beginning or end of their routine outpatient clinics.

**Type of technology and its application:** Virtual outreach used PC-based technology (Intel Business Video Conferencing version 5) and ISDN2 links. No peripheral devices such as fiberoptic or other instrumentation were available for use within the tele consultations.

**Did the patient receive education about their condition?:** No information

**Wallace 2002** (Continued)

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** specialists, and GPs

**Duration of intervention:** one referral consultation.

**Comparison intervention:** Standard outpatient appointments.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• Offer of follow-up outpatient appointments</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• No of medical interventions and investigations</li><li>• No of contacts with primary and secondary care (i.e. contacts with general practice, outpatient visits, accident and emergency contacts)</li><li>• Patient satisfaction (assessed with SWQ, the Ware Specific Visit Satisfaction Questionnaire)</li><li>• Patient enablement (assessed with PEI, Patient Enablement Instrument)</li><li>• Health status/QOL (assessed with SF-12, and the CHQ, Child Health questionnaire)</li><li>• Costs</li><li>• Time spent attending index consultation (results reported in Jacklin 2003)</li></ul> <p><b>Follow-up time:</b> immediately after consultation for referrals and 6 months from index appointment for patient-reported outcomes</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> The study was funded by the National Health Service Research and Development Health Technology Assessment programme, with additional contributions from British Telecom and the Merck (MSD) Foundation.</p> <p><b>Conflict of interest:</b> None declared.</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	See.p.1962, Col.1, last para  QUOTE:  “ Computerised randomisation in permuted blocks of four and six (arranged unpredictably) was stratified by centre, practice, and specialty.”
Allocation concealment (selection bias)	Low risk	See comment above.

## Wallace 2002 (Continued)

Were baseline outcome measurements similar?	Low risk	N/A for primary outcome.
Were baseline characteristics similar?	Low risk	Adjustment for baseline characteristics was by logistic regression for binary outcomes and normal-errors regression for quantitative outcomes.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the allocation of patients, and neither could the patients. However, low risk for objective outcomes (follow-up appointments, resource use and costs) collected from medical records..
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	The participating patients could not be blinded to the group allocation. Non-objective patient-reported outcomes of satisfaction, enablement and health status. No information on how the patient-reported outcomes were assessed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p.1963, Col.2, Para.2  QUOTE:  "15% (155 of 1051) of those in the virtual outreach group compared with 7% (70 of 1043) in the standard group did not receive the index consultation, and, as a consequence, missing outcome data relating to the index consultation were generally more frequent in this group. In the case of outcome data extracted from medical records, the proportion of missing data was very low and did not differ between the groups"
Selective reporting (reporting bias)	Unclear risk	According to the trial protocol the authors intended to also report on anxiety, which also was done in a pilot study, but not in the main study. All other outcomes listed in the trial protocol were reported in the full text paper.
Other bias	Low risk	No evidence of other risk of bias.

## Weintraub 2010

### Methods

**Study design:** RCT, multicentre

**Inclusion criteria:** hospitalisation for heart failure (HF) within the prior 2 weeks.

**Exclusion criteria:** the presence of an illness other than HF deemed the principal limitation to either life expectancy or principal cause of disability; acute myocardial infarction during the index hospitalisation or within 30 days before enrolment; angina refractory to medical therapy or principal cause of limitation; coronary bypass surgery or percutaneous coronary intervention during the index hospitalisation or within 30 days before enrolment or planned within the subsequent 90 days; uncorrected valvular disease except where valvular regurgitation was considered to be secondary to severe left ventricular dilation; restrictive cardiomyopathy, constrictive pericardial disease, or hypertrophic cardiomyopathy; inability to independently perform a standing weight; and absence of a working phone line in the home.

**Method of patient recruitment:** no information

**Study sample calculation:** type I (alpha) error was set at 0.05 for testing the primary hypothesis with a 2-tailed test. The study was powered to detect a 50% reduction in the HF hospitalisation rate with 80% power.

**Data collection:** nurse managers contacted patients by telephone at 45 and 90 days post-randomisation to collect data on vital status, hospitalisations, mortality, compliance, and quality of life. They assessed compliance with standard HF medications including angiotensin converting enzyme inhibitors (ACE), angiotensin receptor blockers (ARB), b-blockers, aldosterone inhibitors, and digoxin. Health-re-

## Weintraub 2010 (Continued)

lated quality of life was assessed by administering the MLHF Questionnaire. Hospitalisations were adjudicated centrally by an experienced cardiologist blinded to group assignment and to intervention. The adjudicator was provided medical records for all events and classified hospitalisation by primary cause from: worsening HF, cardiovascular but not HF, or non-cardiovascular cause.

**Unit of analysis issues:** (yes/no):no

Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 188; Intervention: n = 95; Control: n = 93</p> <p><b>No of patients lost to follow-up:</b> n = 4, all from the TM group (hospitalisations)</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: heart failure</p> <p>b) Age (years), mean, (SD): TM: 69.5 (14.2); UC: 68.5 (12.8), P = 0 .59</p> <p>c) Gender: Male n (%): TM: 60 (63.2%); UC: 64 (68.8%), P = 0 .41</p> <p>d) Ethnicity:</p> <p>Race Black n (%): TM: 10 (10.5%); UC: 5 (5.4%) .45</p> <p>Hispanic n (%): TM: 3 (3.2%); UC: 6 (6.5%)</p> <p>Native n (%): TM: 1 (1.1%); UC: 1 (1.1%)</p> <p>White n (%): TM: 81 (85.3%); UC: 81 (87.1%)</p> <p>e) Severity of condition:</p> <p>LVEF% Mean (SD): TM: 32.1% (17.2%); UC: 27.2% (15.8%), P = 0 .05</p> <p>NYHA Class I n (%): TM: 1 (1.1%); UC: 2 (2.2%) .53</p> <p>II n (%): TM: 42 (44.2%); UC: 44 (47.3%)</p> <p>III n (%): TM: 48 (50.5%); UC: 46 (49.5%)</p> <p>IV n (%): TM: 4 (4.2%); UC: 1 (1.1%)</p> <p>f) Major co-morbidities:</p> <p>Ischemic CM Yes n (%): TM: 42 (44.2%); UC: 53 (57.0%), P = 0.08</p> <p>Hypertension Yes n (%): TM: 64 (68.1%); UC: 64 (69.6%), P = 0.83</p> <p>Diabetes Yes n (%): TM: 45 (47.4%); UC: 36 (38.7%), P = 0.23</p> <p><b>Setting</b> (hospital/community/residential care): 4 hospital sites</p> <p><b>Location</b> (rural/urban etc.): 3 sites in Massachusetts and 1 in Rhode Island</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b> to assess the incremental effect of automated health monitoring (AHM) technology over and above that of a nurse directed heart failure (HF) disease management program (usual care).</p> <p><b>Type of TM/ mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> remote monitoring (additional to usual care)</p> <p><b>Delivery of intervention:</b> the AHM technology that was provided to intervention patients was installed in the patient's home within 2 weeks of randomisation. Patients were trained in the use of the AHM</p>

## Weintraub 2010 (Continued)

equipment at the time of installation. Patients were expected to interact with the Health Buddy AHM daily. Data from both components of the AHM were stored in a central server that was accessible to the SPAN-CHF heart failure team. Nurse managers accessed and reviewed AHM data on a daily basis for all actively enrolled patients from Monday to Friday. Prespecified boundaries for weight, blood pressure, pulse, and symptoms were established. If the patient's data exceeded any of these boundaries, the HF nurse would call the patient to discuss the deviation and to initiate an intervention if necessary.

**Type of technology and its application:** The AHM device comprised measurement and communication components (i.e, transmission of body weight, blood pressure, and heart rate via a standard telephone line to a central server). Philips Telemonitoring Services provided the measurement devices that were used to collect patient vital sign data for automated home monitoring. Health Hero Network provided the Health Buddy appliance that delivered surveys for subjective assessments. The Health Hero Network text message component of the system entailed an interactive communication device designed to convey text information regarding symptoms, functional status, and compliance to medication. Patients' answers to the text messages were categorised into high-, intermediate-, and low-risk responses.

**Did the patient receive education about their condition?** Yes, before the start of the intervention.

**Frequency of patient data transfer:** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none

**Clinician response to receipt of data:**

- a) Who contacts the patient?: The nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): the same day (but not on weekends)
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): call the patient to discuss the deviation and to initiate an intervention if necessary

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses, and a HF physician

**Duration of intervention:** 90 days

**Comparison intervention** (e.g. face-to-face, telephone, none): Disease management over the 90-day study period consisted of: (1) weekly phone calls to all actively enrolled patients (i.e, both intervention and control patients) by the patient's nurse manager to review clinical status; (2) a weekly conference with the HF team, consisting of nurse managers from all clinical sites and a previously designated HF physician, to review all actively enrolled patients; and (3) 24/7 telephone access to a nurse manager. A HF cardiologist was available to nurse managers for clinical consultation subject to an on-call schedule. Specific recommendations regarding HF management were communicated frequently to the patients' primary care physicians.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>Heart failure hospitalisation rate</li></ul> <p>Secondary outcomes:</p> <ul style="list-style-type: none"><li>Time-to-event for death or HF hospitalisation and death or all-cause hospitalisations</li><li>Heart failure inpatient days</li><li>All-cause inpatient days</li></ul> <p><b>Follow-up time:</b> 90 days</p>
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> yes</p> <p><b>Sources of funding:</b> Funded in part from a research grant from GlaxoSmithKline, Inc, Philips Medical Systems, Inc, and Health Hero Network, Inc.</p>

## Weintraub 2010 (Continued)

**Conflicts of interest:**no information

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.286, Col.1, Para.4  "One hundred and eighty-eight eligible subjects were randomized between intervention and control groups in 1:1 ratio blocked at the site level"
Allocation concealment (selection bias)	Unclear risk	No information
Were baseline outcome measurements similar?	Unclear risk	p.287, Col.2 Para.2  Other than ejection fraction, there were no differences between intervention and control groups that were significant.
Were baseline characteristics similar?	Unclear risk	No baseline measures of outcomes
Blinding (performance bias and detection bias) Objective outcomes	Low risk	Objective outcomes of mortality and blinded objective adjudicator.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	Patient-reported outcomes of quality of life at unclear risk (assessed with validated tool) at unclear risk of bias due to non-blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 4 out of 95 people (4.2%) were lost to follow-up, all from the intervention group (hospitalisations). For quality of life, only 44% responded to the questionnaire.
Selective reporting (reporting bias)	Unclear risk	No trial protocol found
Other bias	Low risk	No other risk of bias identified.

## Whitlock 2000

### Methods

**Study design:** RCT

**Inclusion criteria:** HbA1c greater than or equal to 8.0, a diagnosis of Type II diabetes, and age greater than 18 years.

**Exclusion criteria:** HbA1c < 8.0% at initial assessment, inability to use equipment, pending surgery, documented psychiatric history,

**Method of patient recruitment:** Patients were recruited from the internal medicine, family practice, and primary care clinics at Eisenhower Army Medical Center. Hospital information systems were used to identify eligible patients with Type II diabetes from the clinics of the two primary care physicians. Physicians of the above mentioned settings were asked to identify potential patients for their patient panels.

**Study sample calculation:** no information



**Whitlock 2000** (Continued)

**Data collection:** At baseline and at 3 months. Both groups were then provided with the two quality of life questionnaires.

**Unit of analysis issues:** (yes/no):no

Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 28; Intervention: n = 15; Control: n = 13</p> <p><b>No of patients lost to follow-up:</b>no information</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: Type II diabetes</p> <p>b) Age, mean (range) years: Intervention: 61.5 (41-73); Control:59 (32-75)</p> <p>Total body weight, ib: BL: Intervention: 214.3 (110.0-386.0); Control:220.6 (148.0-371.0)</p> <p>c) Gender, male/female sex ; Intervention 6/9; Control:5/8</p> <p>d) Ethnicity: no information</p> <p>e) Severity of condition:</p> <p>HgA1c (%) BL: Intervention:9.5 (8.1-12.6) ; Control:9.5 (8.1-11.9)</p> <p>f) Major co-morbidities:no information</p> <p><b>Setting</b> (hospital/community/residential care): one Army Medical Center</p> <p><b>Location</b> (rural/urban etc.): no information</p> <p><b>Country:</b> USA</p>
Interventions	<p><b>Study objective:</b>To investigate whether home TM can improve patients' ability to self-manage diabetes as compared to UC.</p> <p><b>Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):</b> video-conferencing; and monitoring (the results from the previous week were reviewed during video-conferencing)</p> <p><b>Delivery of intervention:</b> A team including the case manager, clinical co-ordinator, and/or a technician visited each patient's home to install the unit and train the patient in its use.The case manager counselled the patient on the weekly schedule of visits and the information that would be recorded at each prearranged visit. The study group was followed by weekly tele-monitoring visits by the nurse case manager that included both voice and video interaction over a single telephone line. At each visit, the case manager reviewed the patient's blood glucose levels, weight, blood pressure, hypoglycaemic episodes, exercise and nutrition goals,and well-being from the previous week. The case manager recommended nutritional and exercise alternatives and reinforced medication adherence. E-mail contact was maintained between the case manager, the internist and the family practitioner on the patient's status, progress and medication. The two physicians contacted the TM patients once a month.</p> <p><b>Type of technology and its application:</b> The Aviva 20/20 and the Aviva 10/10 SL (American Telecare Institute.The Aviva 20/20 was initially installed in the treatment group homes: it incorporated a personal computer, a device that housed a blood pressure meter, controls for answering the communication system, and an electronic stethoscope (which was not used in this study). The system used one of telephone line for the video and voice connection. After the first month, an up-graded system, the Aviva 10/10 SL became available and was used by the patients, physicians and nurse case manager.</p> <p><b>Did the patients receive education about their condition?:</b> Multidisciplinary diabetic education classes.</p> <p><b>Frequency of patient data transfer (monitoring studies only):</b> unclear, but at least weekly</p>

**Whitlock 2000** (Continued)

**Planned/scheduled number of TM contacts between patient and healthcare personnel:**12  
telemedicine visits

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital):  
N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** internists, nurse case managers,  
primary care physicians

**Duration of intervention:**3 months

**Comparison intervention:** Standard care. They were encouraged at the start of the study to enrol in the multi-disciplinary diabetic education class at Eisenhower Army Medical Center. They were counselled to continue scheduling regular visits either with the family practice or internal medicine physician.

Outcomes	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"><li>• HbA1c</li></ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"><li>• Total body weight</li><li>• QOL (assessed with the DQOL and the SF-36)</li></ul> <p><b>Follow-up time:</b> within one month from the end of the 3-month study period</p>	
Notes	<p><b>Ethical approval and informed consent obtained (yes/no):</b> informed consent was obtained, but no information on whether ethical approval of the study was obtained</p> <p><b>Sources of funding:</b> A 1997 grant from the Office of the Assistant Secretary of Defense, Health affairs, to evaluate applications of telemedicine technology in the management of the high cost of chronic disease.</p> <p><b>Conflict of interest:</b> no information</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No differences reported.
Were baseline characteristics similar?	Unclear risk	No differences reported.

## Whitlock 2000 (Continued)

Blinding (performance bias and detection bias) Objective outcomes	Low risk	No blinding of healthcare professionals or patients. The two physicians made all diabetic management decisions for patients in the intervention and control groups. However, objective outcome of HbA1c.
Blinding (performance bias and detection bias) - Non-objective outcomes	Unclear risk	No blinding of healthcare professionals, patients and unclear if outcome assessors were blinded. The two physicians made all management decisions for patients in the intervention and control groups. Non-objective outcome of quality of life which may have been affected by non-blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

## Willems 2008

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients aged 7 and older with an asthma severity of stage I–III (as described in the Global Initiative for Asthma (GINA) guidelines), competent to use an asthma monitor, and in possess a household phone connection.</p> <p><b>Exclusion criteria:</b> Exclusion criteria were severe co-morbidity (such as chronic obstructive pulmonary disease (COPD) or heart failure (HF)), and structural defects in the upper airways or lungs.</p> <p><b>Method of patient recruitment:</b> From patient records of the departments of Respiratory medicine and Paediatrics eligible asthma outpatients were identified and approached by letter between January 2003 and January 2004.</p> <p><b>Study sample calculation:</b> One-sided testing, a power of 80%, and a significance level of 0.05 with a drop-out percentage of 10% resulted in a minimal inclusion of 51 patients in the intervention group and 51 patients in the control group.</p> <p><b>Data collection:</b> Clinical asthma symptoms and medical consumption were measured by using diaries (self-report). Asthma-specific quality of life was measured by the Paediatric Asthma QOL questionnaire at baseline, 4, 8 and 12 months. During the baseline visit the first questionnaire was collected and the first diary was handed out. From then on, all questionnaires and diaries were sent by mail every 3 months to all the participants (both control and intervention group). Lung function values concerned the PEF and FEV1, were registered at the start and at the end of the study.</p> <p><b>Clinical asthma symptom scores:</b> Clinical asthma symptoms were coughing, production of sputum, and shortness of breath/wheezing in the morning and the evening. Patients in both groups registered these symptoms in diaries (range of 0–3) along with their asthma-related medical consumption (four times for the duration of 1 month).</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> n = 274 of which 147 patients (54%) refused to participate; 18 patients (7%) did not have a telephone line</p> <p><b>No of patients randomised to groups:</b> n = 109; Intervention: n = 55 (n = 26 adults and n = 29 children); Control: n = 54 (n = 27 adults and n = 27 children)</p> <p><b>No of patients lost to follow-up:</b> Seven patients (five in the intervention group; two in the control group) were lost to follow-up. Six patients refused to continue the participation and one patient migrated.</p>

**Willems 2008** (Continued)

**Patient baseline characteristics:**

a) Clinical condition: mild to moderate asthma

b) Age, mean (SD) (years): Intervention (adults): 45.65 (11.3); Control (adults) 45.90 (15.9)

Intervention (children): 10.57 (2.1); Control (children): 10.85 (2.3)

c) Gender, male (%): Intervention (adults): 42.3%; Control (adults): 33.3%;

Intervention (children): 72.4%; Control (children): 55.6%

d) Ethnicity: NA

e) Severity of condition:

GINA classification: Intervention (adults): 2.96 (0.5); Control (adults): 2.74 (0.7); Intervention (children): 2.31 (0.8); Control (children): 2.07 (0.7)

f) Major co-morbidities: Patients with major co-morbidities were excluded.

h) Other relevant characteristics: it appeared that more patients in the control group were on sick leave (25.9% vs. 11.5%) and fewer were on paid salary (44.4% vs. 65.4%), as compared with in the intervention group. Also more people in the intervention group were married and lived together with someone than in the control group (92.3% vs. 77.4%).

**Setting** (hospital/community/residential care): secondary care (Medical Respiratory Department and the Department of Paediatrics at the University Hospital)

**Location** (rural/urban etc.): Maastrich, urban

**Country:** The Netherlands

**Interventions**

**Study objective:** to evaluate the effects on, and the relationship between, asthma symptoms, asthma-specific quality of life and medical consumption of a nurse-led tele-monitoring intervention compared with regular care in asthma

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** monitoring

**Delivery of intervention:** The asthma nurse educated the patients about the tele-monitoring protocol, lung function values and the asthma monitor during the baseline visit. Furthermore, the nurse gave instructions on the use of the monitor and the contacts with the asthma nurse. In this study the patients were asked to perform daily peak-flow measurements both in the morning and in the evening and more often if they were having complaints. Patients were asked to transfer the monitor data every month and more frequently if they were having asthma complaints. The transfer was performed by connecting the modem to the household phone connection. Monitor data were transferred to the computer of the asthma nurse. The nurse studied the data daily during working hours and classified the asthma following a stepwise intervention protocol. The protocol was based on the GINA guidelines and the Dutch College of General Practitioners. According to this protocol the asthma nurse was allowed to decrease (after 3 months of stable asthma) or increase asthma medication by one step. A physician was only consulted if necessary. This approach meant that the patients could be continuously monitored and that treatment could be immediately adjusted whenever indicated. The caregivers of patients aged younger than 18 years were also involved in the intervention.

**Type of technology and its application:** The monitor was a portable hand-held device with a matching modem. It was possible to register lung function values and symptoms on the monitor.

**Did the patient receive education about their condition?:** NA

**Frequency of patient data transfer (monitoring studies only):** monthly or more often if worsening condition

**Frequency/number of TM contacts between patient and healthcare personnel:** monthly or more often

**Willems 2008** (Continued)

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The asthma nurse
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): mostly by telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): the nurse reviewed the data the same day he or she received it (if received during office hours)
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): adjust or maintain the treatment, the physician was only contacted if necessary

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** asthma nurse practitioner

**Duration of intervention:** 12 months

**Comparison intervention:** The control group received regular outpatient care at the University Hospital Maastricht in The Netherlands. In case of stable asthma, these patients received three to six monthly medical check-ups by their lung specialist (18 years and older) at the Medical Respiratory Department or paediatrician (ages 7–18) at the Department of Paediatrics. In case of exacerbations, the patients received additional treatment as usual in The Netherlands.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Asthma-specific QOL (assessed with the AQLQ in adults, and the PAQLQ in children)</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>Clinical asthma symptoms (objective lung function values and self-reported symptoms)</li><li>Medical consumption (healthcare utilisation and medication use obtained from diaries)</li><li>Costs and cost-effectiveness (reported in Willems 2007)</li></ul> <b>Follow-up time:</b> 4, 8 and 12 months after randomisation	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes <b>Sources of funding:</b> The Dutch Health Care Insurance Board. <b>Conflict of interest:</b> NA	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	p.701, Col.1, Para.4  QUOTE:  “Randomization took place on patient level after stratification by age (ages 7–18 vs. 18 years and older), as regular care differs between these age groups. The asthma nurse used a list of random numbers to allocate the patients to one of the two treatment arms.”
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	The lung function baseline values are similar in both groups. No baseline disease specific QoL measure provided.
Were baseline characteristics similar?	Unclear risk	p.603, Col.1, Para.2

**Willems 2008** (Continued)

No differences reported. Table 1.

Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. However, lung function and costs are objective outcomes.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The participating patients and personnel could not be blinded to the group allocation. Non-objective outcomes of asthma symptoms and healthcare utilisation based on patient's self-report may in non-blinded trials be at risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	A similar number (in total around 6%) of participants were lost to follow-up in the intervention (n = 5) and control group (n = 2). Analysis was by intention to treat.
Selective reporting (reporting bias)	High risk	Results for lung function tests (PEF and FEV1) not reported in the paper.
Other bias	Low risk	No evidence of other risk of bias.

**Wojcicki 2001**

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> pregnant women with Type I diabetes; diabetes group B, C, and D according to White; duration of pregnancy less than 16 weeks; no diseases; an acceptable intelligence level according to the modified Wechsler-Bellevue Scale for Adults (i.e., Full-Scale Intelligence Quotient (IQ) . 85 points); and glycaemic control in the range of HbA1c &gt; 9.5%.</p> <p><b>Exclusion criteria:</b> none stated</p> <p><b>Method of patient recruitment:</b> no information</p> <p><b>Study sample calculation:</b> no</p> <p><b>Data collection:</b> no information</p> <p><b>Unit of analysis issues:</b> (yes/no): no</p>
Participants	<p><b>Total no of eligible patients:</b> no information</p> <p><b>No of patients randomised to groups:</b> n = 32; Intervention: n = 17; Control: n = 15</p> <p><b>No of patients lost to follow-up:</b> two patients in the intervention group were found to have a diagnosis that made them ineligible for participation (pneumonia and Meniere's disease)</p> <p><b>Patient baseline characteristics:</b></p> <p>a) Clinical condition: Type I diabetes</p> <p>b) Age, mean ± SD: Intervention: 25.3 ± 4.1; Control: 26.8 ± 4.8</p> <p>c) Gender, female (%); 100%</p> <p>d) Ethnicity, white no (%): no information</p> <p>e) Weeks of pregnancy at start of the project: Intervention: 11.3 ± 2.3; Control: 12.2 ± 2.4</p> <p>f) Weeks of delivery: Intervention: 37.0 ± 2.2; Control: 37.3 ± 1.7</p>

**Wojcicki 2001** (Continued)

g) Treatment::intensive insulin treatment by multi injection technique, with one or two injections of NPH insulin given before breakfast and at bedtime, and three or four injections of short-acting insulin given before main meals and at bedtime

**Setting** (hospital/community/residential care): one gastroenterology and metabolic disease clinic at the Medical Academy

**Location** (rural/urban etc.): Warsaw

**Country:** Poland

**Interventions**

**Study objective:**To examine the influence of the increased frequency of data reporting on metabolic control in patients with diabetes.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** remote monitoring

**Delivery of intervention:** The patients were instructed to perform 4 to 9 blood glucose measurements per day and to register their insulin doses, content of carbohydrates in meals, physical activity, symptoms of hypoglycaemia and other events that might influence their metabolic control. All data were stored in the memory of the glucometer, which was integrated with a simple electronic logbook. The results of the blood glucose tests were stored automatically, while the remaining information was entered by the patient manually. The data collected by the patient were automatically transmitted every night to a central control unit in the diabetologist's office. The downloaded data were stored in a database (DiaPre), software for monitoring of the intensive insuline treatment in pregnant diabetic patients. The diabetologist could perform a daily examination of the patient's metabolic state and to intervene, if necessary. In addition, as in the control group, each patient was examined during routine clinical visits every three weeks.

**Type of technology and its application:** A home telecare system (a transmission module consisting of a blood glucose meter/electronic logbook and a modem for connection to the telephone network) that stored blood glucose values.

**Did the patients receive education about their condition?** Patients from both groups were initially educated with a three-day training programme, which included 2 days hospitalisation.

**Frequency of patient data transfer (monitoring studies only):** daily

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** none scheduled

**Clinician response to receipt of data (monitoring studies only):**

- a) Who contacts the patient?: The diabetologist
- b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone):telephone
- c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): the following morning
- d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): insulin adjustments

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** diabetologist

**Duration of intervention:** 6 months

**Comparison intervention:** The control group was treated based on clinical examinations performed every three weeks. In this group no telephone contacts between the patients and the diabetologist were scheduled.

**Outcomes**

**Primary outcomes:**

- Mean blood glucose (mean weekly mean level)



## Wojcicki 2001 (Continued)

- HbA1c level (average of measurements performed every 6 weeks)
- Hypo- and hyperglycaemic events (% of measurements)
- Insulin dose adjustments (assessed using the mean absolute difference of the current daily insulin dose and its arithmetic mean calculated for the 21 days centred at the current day- results not included in this review)

**Follow-up time:** 180 days (SD 22) in TM group and 176 days (SD16) in the control group (around 6 months)

Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes	
	<b>Sources of funding:</b> This work was supported by the Research Grant no 4PO5B 101 09 from the State Committee for Scientific Research, and was sponsored by Bayer Diagnostic Division Warsaw Ltd and PTK Centertel Ltd.	
	<b>Conflict of interest:</b> no statement made.	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Unclear risk	No information.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The diabetologist treated patients in both the intervention and the control group. However, objective outcomes of HbA1c and hyperglycaemic and hypoglycaemic episodes and thus low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No other risk of bias identified.

## Wong 2006

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> 1) head injury group, patients with a Glasgow Coma Scale (GCS) score of 14 or below, and/or clinical or radiological evidence of cranial fracture or intracranial injury; 2) haemorrhagic stroke group, patients with evidence of intracranial haemorrhage, including subarachnoid haemorrhage; and 3) miscellaneous group, patients with symptoms and signs of increased intracranial pressure or focal neurological deficit, such as brain tumour, hydrocephalus, brain abscess, and chronic subdural haematoma.</p>
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**Wong 2006** (Continued)

**Exclusion criteria:** none stated

**Method of patient recruitment:** no information

**Study sample calculation:** Setting an anticipated outcome improvement of 30% as statistically significant and clinically relevant (i.e., a favourable outcome improvement from 50% to 65%), a significance level of P 0.05 and a power of 80%, and predicting a 10% patient loss, 187 patients for each consultation mode were required.

**Data collection:** Data regarding resources used were collected for each patient and included time spent in telehealth application, inpatient (ward and intensive care) days, operating room time, radiological and physiotherapy procedures, emergency room visits, and extended care days. Unit costs were obtained from the study hospitals, nursing homes, and the Hong Kong Hospital Authority.

**Unit of analysis issues:** (yes/no):no

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Participants

**Total no of eligible patients:** not stated

**No of patients randomised to groups:** n = 475; TM (Video-consultation): n = 239; Control (telephone consultation): n = 236. Note: a third group (teleradiology, n=235) was not included in this review.

**No of patients lost to follow-up:** no information

**Patient baseline characteristics:**

a) Clinical condition: patients with emergency neurosurgical conditions (head injury, stroke, and miscellaneous)

b) Age  $\pm$  SD (years): Video-consultation: 58.8  $\pm$  20.1; Usual care (telephone): 57.6  $\pm$  22.4

c) Gender, male sex (%): Video-consultation: 61.9; Usual care (telephone): 62.1

d) Ethnicity: no information

e) Severity of condition:

Head injury (n = 147): Video-consultation: 73; usual care (telephone): 74

Stroke (n = 216): Video-consultation: 110; usual care (telephone):106

Others (n = 108): Video-consultation: 53; usual care (telephone): 55

f) Major co-morbidities:no information

**Setting** (hospital/community/residential care): one large district general hospital and one tertiary neurosurgical centre in a teaching hospital

**Location** (rural/urban etc.): urban

**Country:** China (Hong Kong)

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Interventions

**Study objective:**This study aimed to determine the differences among three consultation methods (telephone (TP); Teleradiology (TR) and video-consultation) on the basis of their process-of-care indicators, clinical outcomes, and cost-effectiveness.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conference (tele-radiology only constituted the third arm which was not included in this review)

**Delivery of intervention:**

Patients and any relevant radiological images could be visualised at the same time, using the low-cost commercial real-time interactive video-conferencing equipment installed in the Accident and Emergency Departments of the two hospitals,

**Wong 2006** (Continued)

**Type of technology and its application:** video-conferencing equipment (Polycom view station; Polycom Inc., San Jose, CA) connected by one Integrated Services Digital Network line transmitting information at 256 kbps. Note: Approximate 30% failure rate for video-conferencing, most often due to technical errors and logistical difficulties at the referring institution.

**Did the patient receive education about their condition?:** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Frequency/number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** ED physicians; neurosurgical specialist

**Duration of intervention:** one consultation

**Comparison intervention:** Telephone consultation: The referring physician was required to telephone and discuss in detail with the on-call neurosurgical specialist the case history, physical signs, and relevant investigations.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Clinical outcomes (assessed by Glasgow Outcome Scale (GOS))</li><li>• Mortality</li><li>• Cost-effectiveness</li><li>• Process measures (time taken for the consultation process, adverse events during management, safety, necessity for transfer, and diagnostic accuracy)</li></ul> <b>Follow-up time:</b> one month and 6 months from initial consultation	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> Ethic committee's approval was obtained, unclear if informed consent was obtained from patients. <b>Sources of funding:</b> This study was supported by a grant from the Health Services Research Committee/ Health Care & Promotion Fund. <b>Conflict of interest:</b> no information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	p.608, Col.1, Para.3  QUOTE:  "..stratified into three diagnosis groups... patients were further randomized by double-sealed envelopes into three modes of consultation:"
Allocation concealment (selection bias)	Low risk	See quote above

### Wong 2006 (Continued)

Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcomes.
Were baseline characteristics similar?	Low risk	p.609, Col.1, Para.2 No differences reported.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation, and neither could the patients. Objective outcome of mortality and cost.
Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professionals delivering the intervention could not be blinded to the group allocation. Non-objective clinical outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information on number of patients lost to follow-up. Only that Intention-to-treat was applied.
Selective reporting (reporting bias)	Unclear risk	No trial protocol could be found.
Other bias	Low risk	No other risk of bias identified.

### Woodend 2008

Methods	<p><b>Study design:</b> RCT</p> <p><b>Inclusion criteria:</b> Patients were considered for admission to the study if they had symptomatic heart failure (HF) (NYHA Class II or greater) or angina (Canadian Cardiovascular Society [CCS] Class I or greater scheduled to return for revascularisation, or CCS Class II or greater angina being discharged on medical treatment). In addition, they had to be capable of reading and writing either English or French, live within 100 km (by road) of the University of Ottawa Heart Institute, and provide informed consent.</p> <p><b>Exclusion criteria:</b> Patients were excluded if they were being discharged from the hospital to another institution or long-term care facility.</p> <p><b>Method of patient recruitment:</b> Patients were identified in the hospital and approached during their hospital admission for consent to participate in this study.</p> <p><b>Study sample calculation:</b> The number of patients we planned to enrol in this study was fixed by the number of systems available (n = 20). Assuming that each patient would use the equipment for 3 months, we planned to enrol 160 patients (80 with chronic heart failure, 80 with angina) in the intervention arm of the trial. Assuming the analysis is done within each diagnostic group, and assuming that the family-wise alpha is maintained at .05, this would have yielded 80% power to detect a clinically significant decrease in admissions.</p> <p><b>Data collection:</b> Data on re-admission, healthcare resource use, and quality of life data were based on patient self-report and collected at one month, three months, and one year post-discharge.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated.</p> <p><b>No of patients randomised to groups:</b> n = 249, HF group: Intervention: n = 62; Control: n = 59; Angina group: Intervention: n = 62; Control: n = 66</p>

**Woodend 2008** (Continued)

**No of patients lost to follow-up:** Nine patients with HF and three patients with angina died during the study period; nine patients in the tele homecare arm of the study and six patients in the UC arm (not significant) were lost to follow-up at 1 year.

**Patient baseline characteristics:**

a) Clinical condition: heart failure and angina

b) Age, years (SD): HF: Intervention: 67 ± 13; Control: 66 ± 11; Angina: Intervention: 66 ± 12; Control: 65 ± 10

c) Gender, male (%): HF: Intervention: 74% ; Control: 70%; Angina: Intervention: 77% ; Control: 79%

d) Ethnicity: no information

e) Severity of condition:

Angina (yes): HF: Intervention: 57% ; Control: 68%; Angina: 100% both groups

Angina, CCS class (3+): HF: Intervention: 7%; Control: 22% Angina: Intervention: 55% ; Control: 58%

Heart failure, NYHA class (3+): HF: Intervention: Control;; Angina: Intervention: Control:

f) Major co-morbidities: HF: Previous MI: Intervention: 60%; Control: 53%; Angina: Previous MI: Intervention: 53%; Control: 53%

g) Other treatments received: HF: Previous CABG: Intervention: 37%; Control: 34%; Angina: Previous CABG: Intervention: 34% ; Control: 24%

**Setting** (hospital/community/residential care): one hospital

**Location** (rural/urban etc.): no information

**Country:** Canada

Interventions

**Study objective:** To test the impact of 3 months of tele home-monitoring on hospital re-admission, quality of life, and functional status in patients with heart failure or angina..

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing and phone line transmission of physical measures

**Delivery of intervention:** A technician visited the patient's home within 48 hours of discharge to set up the home-monitoring equipment and train the patient in its use. Video-conferences included an assessment of the patient's progress and self-care education by the tele homecare nurse. Electronic records, including nurses' notes, were maintained for each patient. Video-conferencing was done by standard telephone lines. Weigh scales and blood pressure and electrocardiogram machines for remote monitoring were all electronic, and data were transmitted by telephone lines to a central station that held the electronic patient record at the Heart Institute.

**Type of technology and its application:** not further described

**Did the patient receive education about their condition?** Yes, the educational content and timing of teaching for patients with HF and patients with angina were structured so that the content was covered within the first 8 weeks of monitoring. Patient knowledge and understanding were then reassessed, permitting a further 4 weeks to revisit content areas that were less well understood. Triage protocols were also developed to ensure that responses to clinical issues (e.g., shortness of breath, chest pain) were consistent across the two study groups

**Frequency of patient data transfer (monitoring studies only):** daily transmission of weight and blood pressure, and periodic transmission of 12-lead electrocardiogram

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** Protocols were developed to guide both the frequency and the content of each patient contact. Video-confer-

**Woodend 2008** (Continued)

ences were held at least once a week, conferences were more frequent in the first few weeks after discharge and tapered over the 3-month period.

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** nurses

**Duration of intervention:** 3 months

**Comparison intervention:** Patients in the control group received the UC provided to patients with angina or HF discharged from the hospital. Per the intervention group, they were discharged to the care of their community physician or cardiologist. Note: Some of these patients were referred to home care, as were eligible patients in the intervention group. All patients were given a 24-7 telephone number to access an advanced practice nurse with questions related to their care.

Outcomes	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• Hospital re-admissions,</li><li>• Days spent in the hospital,</li><li>• Functional status (Minnesota Living with Heart Failure Questionnaire, and the Seattle Angina Questionnaire)</li><li>• QOL (assessed with the SF 26)</li></ul> <b>Follow-up time:</b> 6 months from recruitment	
Notes	<b>Ethical approval and informed consent obtained (yes/no):</b> yes  <b>Sources of funding:</b> The Richard Ivey Foundation, The Change Foundation and an unrestricted educational grant from Merck-Frosst Canada.  <b>Conflict of interest:</b> no information	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	p.37, Col.1, Para.2  QUOTE:  “Randomization was stratified by primary discharge diagnosis; an equal number of patients with HF and patients with angina were randomly allocated to receive home monitoring, and equal numbers were allocated to UC.”
Allocation concealment (selection bias)	Unclear risk	No information.
Were baseline outcome measurements similar?	Unclear risk	No baseline measure of outcome.
Were baseline characteristics similar?	Unclear risk	p. 38, Col.2, last para  More participants with angina in the telehealth group.

## Woodend 2008 (Continued)

Blinding (performance bias and detection bias) - Non-objective outcomes	High risk	The healthcare professional delivering the intervention could not be blinded to the group allocation, and neither could the patients. All outcomes based on patients' self-report, which may be at risk of bias due to non-blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	p. 38, Col.2, last para  QUOTE:  “Nine patients with HF and three patients with angina died during the study period; nine patients in the tele home care arm of the study and six patients in the UC arm (not significant) were lost to follow-up at 1 year.”  Comment: A similar number of patients lost to follow-up in both groups.
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

## Wootton 2000

Methods	<p><b>Study design:</b> RCT (multi-centre)</p> <p><b>Inclusion criteria:</b> no information</p> <p><b>Exclusion criteria:</b> no information</p> <p><b>Method of patient recruitment:</b> Patients with dermatological conditions were invited to participate in the trial by their GP.</p> <p><b>Study sample calculation:</b>yes</p> <p><b>Data collection:</b> Patient's re-attendance to general practice or to hospital and the clinical outcome of the initial consultation were ascertained from a follow-up review of patient records.</p> <p><b>Unit of analysis issues:</b> (yes/no):no</p>
Participants	<p><b>Total no of eligible patients:</b> not stated</p> <p><b>No of patients randomised to groups:</b> n = 204; Intervention: n = 102; Control: n = 102</p> <p><b>No of patients lost to follow-up:</b> Since all outcomes were obtained from patient records one would assume that no data were missing.</p> <p><b>Patient baseline characteristics:</b></p> <ul style="list-style-type: none"> <li>a) Clinical condition:dermatological conditions</li> <li>b) Age, mean (SD): 38.6 (23.8) years (4 months to 89 years)</li> <li>c) Gender, male/female: 85 (42%)/119 (58%)</li> <li>d) Ethnicity: no information</li> <li>e) Severity of condition: no information</li> <li>f) Major co-morbidities:no information</li> </ul> <p><b>Setting</b> (hospital/community/residential care): two hospital dermatology departments and four health centres</p>



**Wootton 2000** (Continued)

**Location** (rural/urban etc.): two of the health centres were located in rural areas and two in urban areas; 125 (63%) were registered with an urban practice and 76 (37%) a rural practice.

**Country:** Northern Ireland

## Interventions

**Study objective:** To compare real-time tele-dermatology with outpatient dermatology in terms of clinical outcomes, cost benefits, and patient re-attendance.

**Type of TM /mode of delivery (e.g. video-conferencing, remote monitoring with healthcare professional responding to transferred data and alerts etc.):** video-conferencing

**Delivery of intervention:** Patients randomised to a tele-dermatology consultation attended their own health centre and, in the company of a general practitioner, were seen by a hospital dermatologist over the video-link. The dermatologist recorded a diagnosis, management plan, clinical outcome of consultation, and length of consultation time. All patients received an accelerated referral and were seen within 10 days.

**Type of technology and its application:** Standard commercial video-conferencing units (VC 7000, BT) connected by basic rate ISDN lines at 128 kbit/s were installed at each of the participating sites. An additional video camera was connected to the video-conferencing unit at each health centre to enable the general practitioner to transmit close up images to the dermatologist.

**Did the patient receive education about their condition?** No information

**Frequency of patient data transfer (monitoring studies only):** N/A

**Planned/scheduled number of TM contacts between patient and healthcare personnel:** N/A

**Clinician response to receipt of data (monitoring studies only):** N/A

a) Who contacts the patient?: N/A

b) Method of patient contact (e.g. e-mail, automated feedback (yes/no), telephone): N/A

c) Timing of response (e.g. reviewed immediately, reviewed in 24 hours, reviewed in a week): N/A

d) Action (e.g. referral, storing data for next consultation, changing treatment, admission to hospital): N/A

**Providers (e.g. no., profession, training, ethnicity etc. if relevant):** dermatologists, GPs

**Duration of intervention:** 12 months

**Comparison intervention:** Control patients were seen by the dermatologist in the outpatient department as normal.

## Outcomes

**Primary outcomes:**

- Reported clinical outcome of initial consultation
- Primary care and outpatient re-attendances
- Cost benefits

**Follow-up time:** a minimum of 3 months after the index consultation

## Notes

**Ethical approval and informed consent obtained (yes/no):** yes

**Sources of funding:** The UK Multicentre tele dermatology trial was funded by the NHS research and development programme (primary and secondary interface). We also received support from Southern Health and Social Services Board (Northern Ireland), Glaxo, and Steifel.

**Conflict of interest:** None declared.

**Risk of bias**

**Wootton 2000** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.1253, Col.1, Para.5  QUOTE:  “Prior randomisation of the referral forms had taken place using a table of random numbers. Each referral form had an assigned trial identification number for all subsequent patient communication between the dermatologist and general practitioner.”
Allocation concealment (selection bias)	Unclear risk	p.1253., Col.1, Para.4  QUOTE:  “Sealed envelopes containing a referral form and consent form were distributed at each health centre. The referral form contained details of the randomisation to either a tele dermatology consultation or traditional hospital consultation.”
Were baseline outcome measurements similar?	Unclear risk	No information.
Were baseline characteristics similar?	Unclear risk	No information.
Blinding (performance bias and detection bias) Objective outcomes	Low risk	The healthcare professionals delivering the intervention could not be blinded to the patient allocation, and neither could the patients. However, the outcomes (consultations and costs) were all objective and obtained from patient records.
Incomplete outcome data (attrition bias) All outcomes	Low risk	
Selective reporting (reporting bias)	Unclear risk	Trial protocol not found.
Other bias	Low risk	No evidence of other risk of bias.

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
<a href="#">Agha 2009</a>	RCT, but reports patient satisfaction with physician communication strategies only.
<a href="#">Ahmed 2008</a>	RCT, but only self-reported outcomes.
<a href="#">Andersson 2005</a>	Waiting list controls participated in an Internet discussion group. Minimal patient-provider interaction in the Internet intervention treatment group.
<a href="#">Andrade 2011</a>	Costs only. Not performed alongside an RCT.
<a href="#">Angermann 2012</a>	Telephone only.

Study	Reason for exclusion
<a href="#">Appel 2011</a>	No usual care group. Control group self-directed.
<a href="#">Arthur 2002</a>	Telephone only.
<a href="#">Artinian 2001</a>	Less than 10 participants in one or both arms.
<a href="#">Artinian 2003</a>	Less than 10 participants in one or both arms.
<a href="#">Baker 2011</a>	Not an RCT.
<a href="#">Balk 2008</a>	A subgroup of intervention patients received distal measuring devices in addition to the home TV-channel providing educational material. Results for intervention patients with and without monitoring were not reported separately.
<a href="#">Barnason 2009</a>	No patient-provider interaction.
<a href="#">Battaglia 2008</a>	Poster abstract only. No response to e-mails sent to corresponding author.
<a href="#">Benger 2004</a>	Diagnostic accuracy only.
<a href="#">Benhamou 2007</a>	Cross-over trial. Paired comparisons.
<a href="#">Bergenstal 2005</a>	Telephone versus modem data transmission comparison only.
<a href="#">Bergquist 2009</a>	Less than 10 participants in one or both arms. Cross-over study.
<a href="#">Bergrath 2012</a>	The plan was to conduct an RCT, but in the end this was not done.
<a href="#">Bischof 2010</a>	Control condition is no treatment.
<a href="#">Bishop 2002</a>	Less than 10 participants in one or both arms.
<a href="#">Boman 2012</a>	Compares the processing time of blood samples measured through the use of telemedicine (TM) and samples that are sent to the hospital for analyses.
<a href="#">Bosworth 2009</a>	Trial design altered from protocol.
<a href="#">Bowles 2009</a>	Three different types of monitors were used in the study and results were amalgamated. Contacted author but data for individual groups are not available.
<a href="#">Boyd 2003</a>	Evaluation of technical quality of web-based tool.
<a href="#">Brennan 1999</a>	Self-reported outcomes only.
<a href="#">Burbank 2012</a>	Education only. Self-reported outcomes only.
<a href="#">Burke 2011</a>	Both groups assigned a personal digital assistant (PDA), one group also received feedback. Control group was not usual care.
<a href="#">Bynum 2001</a>	Main focus is on educating how to use an inhaler, in both groups, and the main patient outcome is satisfaction.
<a href="#">Cadario 2007</a>	Cross-over trial and analysis.

Study	Reason for exclusion
<a href="#">Cargill 2003</a>	Insufficient data reported to judge the study eligibility. We contacted the authors for additional information but did not receive a reply.
<a href="#">Cartwright 1992</a>	Non-validated tool used after intervention.
<a href="#">Casas 2006</a>	No data were transferred and the education was delivered face-to-face at discharge, and not over telemedicine.
<a href="#">Chambers 2010</a>	Control group is minimal self-management.
<a href="#">Chambers 2013</a>	Peer support for people with prostate cancer.
<a href="#">Chambers 2013a</a>	Mindfulness over telemedicine (TM) vs. education for men with prostate cancer. Not the same clinical intervention- more an evaluation of the effectiveness of mindfulness intervention than TM intervention.
<a href="#">Cho 2011</a>	On-line monitoring of blood glucose- primary outcome physician's time on-line. N=79
<a href="#">Cho 2011a</a>	Specialized management of patients with diabetes, mediated by a primary care nurse who used a PDA blood glucometer. N=71
<a href="#">Chua 2001</a>	Not an RCT. Quasi-randomised study.
<a href="#">Ciemins 2011</a>	Rural patients non-randomised.
<a href="#">Coccolini 1995</a>	Two-group design, but no randomisation process and no baseline data are given for either group.
<a href="#">Colwell 2011</a>	Intervention is a decision aid to support treatment choices; outcome is patient knowledge.
<a href="#">Constantinescu 2011</a>	Feasibility trial only. No patient health outcomes. Only measures of transmission and satisfaction.
<a href="#">Cordova 2007</a>	Intervention group received algorithm-based treatment - appears to be no patient/provider interaction.
<a href="#">Cummings 2011</a>	Control is mentor and mentor plus self-help plus mobile phone.
<a href="#">Dansky 2001</a>	No clinical data, only cost data provided.
<a href="#">Dark 2012</a>	Not an RCT. Commentary only.
<a href="#">Datta 2010</a>	Telephone only. Not the same clinical intervention.
<a href="#">de Toledo 2006</a>	It seems that they could have used video-conference but did not. No patient-provider interaction, other than telephone only .
<a href="#">Demaerschalk 2010</a>	Feasibility study only.
<a href="#">Depp 2010</a>	Feasibility study, with unclear study design.
<a href="#">Dinesen 2012</a>	Control group did not receive usual care, just self-directed home exercise.
<a href="#">Dlugonski 2012</a>	Waiting list controls. No comparison with usual care.

Study	Reason for exclusion
<a href="#">Domingo 2012</a>	Both the intervention group and the control group received Motiva system (educational videos, motivational messages, and questionnaires), and the telemedicine (TM) group also received remote management (RM). No comparison with usual care.
<a href="#">Dorsey 2013</a>	Less than 10 patients in one or both arms.
<a href="#">Duncan 2012</a>	Self-management only. Self-reported outcomes.
<a href="#">Earle 2010</a>	No provider-patient real-time interaction. GP and patient provided with a letter of amalgamated HbA1c readings.
<a href="#">Egner 2003</a>	Less than 10 patients in two of the three arms.
<a href="#">Eisdorfer 2003</a>	Intervention aimed at caregivers only.
<a href="#">Elliott 2008</a>	Both groups received video-conferencing sessions. The intervention was problem-solving training rather than telemedicine.
<a href="#">Eng 2013</a>	Investigation of whether or not health literacy influence the effectiveness of the intervention in a recent clinical trial using IVRS (Interactive voice response system) to support chronic obstructive pulmonary disease (COPD) patients. Not an investigation of the effectiveness of telemedicine per se.
<a href="#">Ercan-Fang 2012</a>	Insufficient information to assess the eligibility of the study. Abstract only.
<a href="#">Escourrou 2012</a>	Describes plans for the development of a telemedicine intervention for sleep apnoea and plans for an RCT. No study protocol.
<a href="#">Eysenbach 2011</a>	Not an RCT. Describes an extension of the CONSORT.
<a href="#">Fairbrother 2012</a>	Not an RCT. Qualitative study.
<a href="#">Farmer 2005</a>	Patients recorded data daily, but nurses only reviewed data every 2 weeks making this a 'store and forward' project. Control patients also recorded data daily and their results were also transmitted to the server, but they received 'minimal feedback', i.e. the control condition was not usual care.
<a href="#">Farrer 2011</a>	Web-based cognitive behavioural therapy (CBT) intervention plus telephone vs. telephone alone vs. web-based CBT alone.
<a href="#">Fincher 2009</a>	Results presented for telephone and videophone groups only. No results for the face-to-face group.
<a href="#">Finkel 2007</a>	Intervention aimed at caregivers only.
<a href="#">Finkelstein 2004</a>	Technical feasibility and patient satisfaction only.
<a href="#">Finlayson 2011</a>	Waiting list controls.
<a href="#">Fortney 2007</a>	A trial of collaborative care in which intervention and usual care groups both received some care face-to-face, by telephone and by video-consultation. Clinic sites randomised and data presented at patient level.
<a href="#">Frangou 2005</a>	Three methods of measuring 'pill counting'. The intervention and the outcome were the same.
<a href="#">Franzini 2011</a>	Not an RCT. Based on an observational study.
<a href="#">Frederix 2012</a>	Only six patients in the control group.

Study	Reason for exclusion
<a href="#">Frederix 2013</a>	No patient-provider interaction. Automatic telemedicine intervention .
<a href="#">Friedman 1996</a>	No patient-provider interaction. Automated telecommunication only.
<a href="#">Frueh 2007</a>	Feasibility study.The therapist is delivering both the face-to-face and the telemedicine intervention at the clinic.
<a href="#">Gallar 2007</a>	Study design - patients who refused to take part were included in the control group.
<a href="#">Guendelman 2002</a>	HealthBuddy intervention with automated feedback.No patient-provider interaction.
<a href="#">Halpin 2011</a>	All patients completed a diary including the EXACT PRO questionnaire on a BlackBerry Smartphone each day, but only one group received alert calls.
<a href="#">Hanley 2013</a>	Perceptions only.
<a href="#">Harno 2006</a>	30% allocated to the home care link did not use it, and while the care team could access the patients' home diary it is not clear what if any, feedback was provided/received.
<a href="#">Hastings 1976</a>	Insufficient data. Unable to contact author.
<a href="#">Hawkins 2010</a>	Both groups received video phone calls.
<a href="#">Hayes, 2011</a>	Not an original paper.
<a href="#">Hayes, 2011a</a>	Not an original paper. Review.
<a href="#">Hayes, 2011b</a>	Not an original paper.Review.
<a href="#">Hayes, 2012</a>	Not an original paper. Review.
<a href="#">Hayes, 2012a</a>	Not an original paper.Review.
<a href="#">Hebden 2013</a>	Study protocol. Both intervention and control groups receives SMS- but few SMS in the control group. No comparison with face-to-face care/usual care.
<a href="#">Hebert 2012</a>	Not telemedicine, only home self-monitoring.
<a href="#">Heiney 2012</a>	Intervention (social support in story telling group) was delivered by a social worker (not a health-care professional), and was compared with any social support available/used (i.e. not with usual care).
<a href="#">Hilty 2007</a>	Control group patients also received tele-psychiatric consultation.
<a href="#">Himle 2012</a>	Only 10 patients in each arm.
<a href="#">Hoek 2012</a>	Comparison with waiting list controls.
<a href="#">Istepanian 2009</a>	No provider-patient real-time interaction. GP and patient provided with a letter of amalgamated HbA1c readings.
<a href="#">Jaatinen 2002</a>	Quasi-randomised by birth date.
<a href="#">Johnston 2000</a>	Not an RCT.Quasi-randomised.

Study	Reason for exclusion
Jones 2010	Not an RCT. Qualitative study.
Juan 2011	Non-randomised study.
Kerby 2012	Analysis involving intervention group only.
Kerr 2012	All groups receive the mobile food record, but the control group patients do not receive feedback.
Kerry 2013	Home blood pressure self-monitoring without data transfer. Not a telemedicine intervention.
Kesavadev 2012	Not an RCT. A retrospective study.
Kessing 2011	Methods only. This study has been withdrawn prior to enrolment.
Kielblock 2007	Quasi-randomised.
Kim 2013	Compares one week telephone (tele-monitoring) intervention + video education with video education only. No comparison with face-to-face usual care.
Kortke 2008	All participants received the intervention at the start. The effects of withdrawing the intervention was assessed.
Kortke 2012	Compares different anticoagulation dose ranges and INR (International Normalised Ratio) values.
Kraft 2012	Only five out of 13 intervention participants remained at follow-up. Intervention group received nutrition supplements and telemedicine and control participants received standard care (unclear what constituted standard care).
Krier 2011	Not an RCT. Quasi-randomised study.
Kroenke 2010	Controls were only told about their depressive symptoms but no further attempts were made to deal with them.
Kulshreshta 2010	Non randomised, allocated one week on and one week off.
LaFramboise 2003	For most outcomes data are not presented for the groups separately, and for SF-36 scores only the significant items are presented.
Langhorne 2010	Less than 10 participants in each arm.
Leichter 2013	Both groups transferred data.
Leu 2005	Patients in the control group also used a pager.
Levine 2006	No clinical outcomes. Only satisfaction in telemedicine group and process outcomes.
Logan 2012	The comparison is between monitoring with and without feedback, and not with usual care.
Lopes 2012	Quasi-randomised. Patients were selected to in-office visits and telemedicine depending on distance to hospital.
Luley 2011	The control patients attended for their second visit after the end of the intervention- so no care during the intervention. In the intervention group patients transmitted data, which were weekly put together in a report, which was sent by letter to the patient with advice. The patients paid for the intervention.



Study	Reason for exclusion
Lynga 2012	Comparison of two different ways of reporting weight change- through RM or telephone.
Man 2006	Not an RCT. Method of selecting control group and assigning patients to the three different treatment groups is unclear.
Marasinghe 2012	Telephone intervention only.
Marios 2012	Both groups received a six-month exercise programme, telemedicine group received weekly phone calls and transmitted heart rate data
Marsch 2012	Not an RCT. A review of therapeutic methods.
McGill 2012	Non-randomised study.
McKenzie 2011	Compares multiple daily insulin therapy with continuous delivery of insulin by a pump. Both groups provided data, via home PC, for continuous glucose monitoring.
McMahon 2012	No usual care comparison: usual care supplemented with online resources and Internet access.
McManus 2010	No patient-provider interaction. Self-management and self-titration of antihypertensive drugs. Follow-up at 6 and 12 months.
Meyer 2010	Not an RCT. Retrospective study design.
Miller 2007	HealthBuddy intervention with no direct patient-provider interaction.
Miloh 2011	Not an RCT. Non-randomised prospective design.
Moessner 2012	The 'treated as usual' group did not receive an aftercare program offer, and thus received no care.
Montori 2004	Both groups transferred glucometer data to the healthcare professional, only one group received feedback.
Moore 1975	Insufficient data on the numbers of patients included in the study and how patients receiving 'wrong consultation mode' were dealt with in the analysis. Unit of allocation was the nurse, but unit of analysis is the patient. Unable to contact author for further information.
Morey 2012	Telephone only.
Morgan 2008	Not an RCT. Quasi-randomisation based on availability of equipment.
Morgan 2011	Cross-over design for a tele-e-health memory clinic and primary outcome is satisfaction with service.
Mullan 2003	'Store and forward' project - team reviewed patient data weekly.
Narayanan 2012	Telephone only.
Nelson 2003	Feasibility study. Telemedicine equipment was all on one site, so psychiatrist and child were in the same building.
Pacaud 2012	All groups received a type of e-health Internet education.
Perings 2011	Not an RCT. Non-randomised study.

Study	Reason for exclusion
Persson 2011	Intervention is home-telephone support and coaching. No data transmitted.
Phillips 2001	Exploratory/preliminary analysis. Not all patients had reached the 1-year follow-up time point. No full report available.
Piette 2000	Automatic telephone intervention only.
Piette 2001	Automatic telephone intervention only.
Preschl 2011	On-line (Internet only) vs. face to face cognitive behavioural therapy (CBT).
Pronovost 2009	Cross-over trial.
Racine 2008	Telephone only.
Ramos 2009	Feasibility study - only five participants.
Regan 2011	Both groups received IVR (interactive voice response) but of different intensity.
Reijonsaari 2012	Physical activity intervention in the workplace. Not telemedicine.
Rein 2011	Not an RCT.
Rigla 2008	Less than 10 participants in each arm.
Roberts 2011	Outcomes: lessons learned.
Rogan 2012	Could not find but a descriptive paper on the study, but not the main study.
Rotheram-Borus 2012	Not an RCT.
Rotondi 2005	Web-based interactions only.
Russell 2003	Feasibility study with intervention group patients and physiotherapists on the same site but in different rooms.
Ruwaard 2010	Intervention involved web-based interactions only.
Sanders 2012	Qualitative study of non-participants in a telemedicine intervention.
Sanford 2006	Feasibility study- research assistant present at home with patient during telemedicine. Usual care control group received no therapy.
Schillinger 2009	Telephone only. No monitoring data transferred.
Seto 2010	Survey only.
Sheeran 2011	All patients received home tele-health.
Smith 2006	Less than 10 participants in each arm.
Smith 2008	The authors merged the outcome data for the intervention group that transmitted data for monitoring with that of the intervention group that did not transmit data.
Smith 2010	Telephone only.

Study	Reason for exclusion
Smith 2011	Telephone only.
Sohn 2012	Not an RCT.
Sorknaes 2011	Quasi-randomised study. Patients were consecutively allocated into two groups (telemedicine or control) depending on their home municipality.
Sparks 1993	Only 10 participants in each group.
Stone 2012	Evaluates the withdrawal of telemedicine.
Strath 2011	Intervention is a pedometer and telephone feedback.
Stricklin 2000	Only patient reported outcomes. Heart failure and hypertension patients are included in the same group. No characteristics of participants provided.
Stuckey 2011	Feasibility only.
Summerhayes 2012	Not an RCT.
Tan 2013	Not an RCT. Review.
Thokala 2013	Not an RCT.
Thorp 2012	Not an RCT. Descriptive.
Timmerberg 2009	Control and intervention groups both received some care by video-conferencing.
Timonen 2004	Patients who called in after hours were not appropriately randomised
Vanagas 2012	Not an RCT.
Varma 2013	Not an RCT.
Vitacca 2009	Participants were randomised to intervention and control groups, but only selected cases in the intervention group received the intervention.
Vuolio 2003	No clinical outcomes reported. No numerical data for main outcome: implementation of a management plan. Feasibility study.
Whitten 2007	No data reported. Authors contacted by e-mail. No response.
Wilkinson 2008	Feasibility study only. Less than 10 participants in each arm.
Woollard 2005	Feasibility only. Thrombolytic drug not actually given before arrival at hospital.
Wray 2010	Intervention delivered by telephone and aimed at caregivers only.
Xu 2010	Comparison between nurse telephone or e-mail support vs. IVRS (interactive voice response system) (automatic) vs. usual care. Telemedicine intervention does not involve patient-provider interaction.
Zutz 2007	Less than 10 participants in each arm.

## Characteristics of studies awaiting assessment *[ordered by study ID]*

### Abraham 2011

Methods	RCT
Participants	Patients (n = 550) with New York Heart Association (NYHA) class III heart failure and a wireless implantable haemodynamic monitoring (W-IHM) system
Interventions	Management with a wireless implantable haemodynamic monitoring (W-IHM) system
Outcomes	Rate of heart failure-related hospitalisations, freedom from device-related or system-related complications (DSRC), freedom from pressure-sensor failures.
Notes	

### Aharonovich 2012

Methods	RCT
Participants	Urban HIV adult clinic patients (n = 40) reporting $\geq 4$ days of NIDU in the past month
Interventions	A telephone-based Interactive Voice Response system, which provided data for subsequent personalised feedback
Outcomes	Days used primary drug
Notes	

### Aitken 2011

Methods	RCT
Participants	People with cystic fibrosis (CF) (n = 42)
Interventions	An early intervention in the recognition and hence treatment of adult CF acute exacerbations using home symptom monitoring with the CF Respiratory Symptom Diary (CFRSD) and home spirometry.
Outcomes	Feasibility and compliance of the intervention, nutritional status, lung function, exacerbations.
Notes	

### Antoniades 2012

Methods	RCT
Participants	People (n = 44) with chronic obstructive pulmonary disease (COPD).
Interventions	Standard best practice care (SBP) plus remote in-home telemonitoring (RM).
Outcomes	Primary outcomes: hospital admissions, inpatient bed-days, and quality of life

**Antoniades 2012** *(Continued)*

Secondary outcomes: 6-minute walk distance (6MWD), adherence to daily monitoring, reproducibility of the physiological measurements, and patient acceptance of RM.

Notes

**Blasco 2012**

Methods	RCT
Participants	Acute coronary syndrome (ACS) survivors (n = 203)
Interventions	A Web-based telemonitoring system, connecting patients provided with self-measurement devices and care managers via mobile phone text messages.
Outcomes	Blood pressure (BP), body mass index (BMI), smoking status, low-density lipoprotein-cholesterol (LDL-c), and glycated haemoglobin A1c (HbA1c)

Notes

**Bove 2013**

Methods	RCT
Participants	Urban underserved people (n = 241 ) with hypertension (systolic BP $\geq$ 140 mm Hg)
Interventions	An Internet- and telephone-based communication system.
Outcomes	Proportion of patients who reached goal systolic BP, absolute changes in BP

Notes

**Broekhuizen 2013**

Methods	RCT
Participants	Adults with Familial Hypercholesterolemia (n = 340).
Interventions	Web-based tailored lifestyle advice and face-to-face counselling.
Outcomes	Physical activity, fat, fruit and vegetable intake, smoking and compliance to statin therapy.

Notes

**Callender 2012**

Methods	RCT
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### Callender 2012 (Continued)

Participants	A sample (unknown number) hypertensive, inner-city African Americans in medically underserved communities.
Interventions	A provider-assisted online telehealth intervention.
Outcomes	Blood pressure (BP), body mass index (BMI) and regular physical activity.
Notes	

### Calo 2013

Methods	RCT
Participants	Patients (N = 233) after ICD implantation.
Interventions	Remote monitoring (RM) of implantable defibrillators (ICD)
Outcomes	Costs, frequency of scheduled in-hospital visits, time for follow-up.
Notes	

### Campos 2012

Methods	RCT
Participants	Hearing impaired people (n = 50) with mean audiometric thresholds between 30 and 68.75 dBHL
Interventions	Hearing aid fitting using synchronous teleconsultation with interactive video and remote applicative control.
Outcomes	Time for programming, verification and orientation, total consultation time, real ear measures' matching to their respective targets; HINT (silence and noise), daily amount of use of hearing aids in hours, and the IOI-HA scores.
Notes	

### Chambers 2012

Methods	RCT
Participants	People with psoriasis (n = 64)
Interventions	Patient-centered online healthcare delivery model.
Outcomes	Psoriasis disease severity (assessed with the Psoriasis Area and Severity Index (PASI)), Investigator's Global Assessment (IGA), Dermatology Life Quality Index (DLQI)
Notes	

### **Chau 2012**

Methods	RCT
Participants	Older people (n = 53) with chronic obstructive pulmonary disease (COPD).
Interventions	A telecare device kit enabling remote monitoring and an online network platform.
Outcomes	User satisfaction, health-related quality of life, pulmonary function, hospital re-admission and use of emergency room services.
Notes	

### **Choudhuri 2012**

Methods	RCT
Participants	Participants (N = 71) following an ICD implantation who were at low risk for complications (not pac-ing-dependent or requiring bridging heparin anticoagulation)
Interventions	Same-day discharge with remote monitoring for 24 hours after ICD implant.
Outcomes	Acute complications.
Notes	

### **Chumbler 2012**

Methods	RCT
Participants	Veterans (n = 52) with stroke from three Veterans Affairs Medical Centers.
Interventions	The STeleR intervention consisted of home visits, telephone calls, and an in-home messaging device provided to instruct patients in functionally based exercises and adaptive strategies.
Outcomes	Improvement in function (measured by both the motor subscale of the Telephone Version of Functional Independence Measure and by the function scales of the Late-Life Function and Disability Instrument).
Notes	

### **Conroy 2011**

Methods	RCT
Participants	Overweight adults (n = 210)
Interventions	Palm Tungsten E2i PDA with self-monitoring software that tracked energy and fat consumption, displayed current intake related to daily goals, and provided easily accessed nutrition information (Dietmate Pro (5,6) and CalcuFit; PICS, Reston, VA).



**Conroy 2011** (Continued)

Outcomes	Change in body weight and PA levels
Notes	

**de Niet 2012**

Methods	RCT
Participants	Overweight and obese children (n = 141).
Interventions	A short message service maintenance treatment (SMSMT) via mobile phones with personalised feedback positively effects weight, lifestyle behaviours and psychological well-being in obese children.
Outcomes	Primary treatment outcomes: weight, eating behaviour and psychological well-being, i.e. competence, self-esteem and quality of life. Secondary outcome: adherence to the SMSMT.

Notes	
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**Deschildre 2012**

Methods	RCT
Participants	Children with severe uncontrolled asthma (n = 50)
Interventions	Daily home spirometry and medical feedback.
Outcomes	Number of severe exacerbations, unscheduled visits, lung function, Paediatric Asthma Quality of Life Questionnaire scores, daily dose of inhaled corticosteroids.

Notes	
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**Eberl 2006**

Methods	RCT
Participants	Patients (n = 23) after surgical intervention by arthroplasty in posttraumatic contracture of the elbow.
Interventions	Televisit system.
Outcomes	Duration of stay in hospital and the costs for treatment.

Notes	
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**Fortney 2013**

Methods	RCT
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### Fortney 2013 *(Continued)*

Participants	Patients (n = 364) who screened positive for depression at federally qualified health centres serving medically underserved populations.
Interventions	Telemedicine-based collaborative care i.e. evidence-based care from an on-site primary care provider and an off-site team: a nurse care manager and a pharmacist by telephone, and a psychologist and a psychiatrist via video-conferencing.
Outcomes	Treatment response, remission, and change in depression severity.
Notes	

### Foster 2011

Methods	RCT
Participants	Low-income (overweight) participants (n = 363) in urban and rural areas
Interventions	A combined church-based and telemedicine program.with group leader interaction via a study website
Outcomes	Weight loss
Notes	

### Fox 2012

Methods	RCT
Participants	Patients (n = 75) with moderate to severe obstructive sleep apnoea.
Interventions	Positive airway pressure (PAP) machine that transmitted physiologic information (i.e., adherence, air leak, residual AHI) daily to a website.
Outcomes	PAP adherence, subjective sleep quality, and side effects
Notes	

### Gupta 2013

Methods	RCT
Participants	People with advanced heart failure (n = 40) .
Interventions	Telemonitoring-facilitated discharge (at the point when they were switched from intravenous to oral diuretics).
Outcomes	Early decompensation, time to discharge, quality of life, mortality
Notes	

### Gustafson 2012

Methods	RCT
Participants	Parent-child dyads (n = 301); children with asthma
Interventions	Combined web-based e-health and telephone nurse case management.
Outcomes	Asthma control, medication adherence, social support, information competence, and self-efficacy
Notes	

### Heudebert 2013

Methods	RCT
Participants	People with type 2 diabetes mellitus (n = 134) in a predominantly poor African American cohort.
Interventions	Telemedicine.
Outcomes	Hemoglobin A1C (HgbA1C); compliance of self-monitored blood glucose
Notes	

### Howlett 2011

Methods	RCT
Participants	People with heart failure (n = 122) and at least one hospitalisation within the previous six months.
Interventions	A telephone-based monitoring system with or without video and with involvement of primary care providers.
Outcomes	A composite endpoint of total mortality and hospitalisation.
Notes	

### Jodar-Sanchez 2013

Methods	RCT
Participants	Patients (n = 45) with severe chronic obstructive pulmonary disease (COPD) treated with long-term oxygen therapy.
Interventions	Telemonitoring of vital signs.
Outcomes	Number of accident and emergency department visits; number of hospital admissions, health-related quality of life, patients and healthcare professionals satisfaction.
Notes	

### Kamei 2011

Methods	RCT
Participants	Patients with chronic obstructive pulmonary disease (COPD) (n = 37) and home oxygen therapy
Interventions	Home monitoring-based telenursing practice.
Outcomes	Acute exacerbations, time to onset of acute exacerbation, readmissions
Notes	

### Kamel 2013

Methods	RCT
Participants	Patients (n = 40) with cryptogenic ischaemic stroke or high-risk transient ischaemic attack.
Interventions	A Cardionet mobile cardiac outpatient telemetry monitor.
Outcomes	Rate of AF detection, incidental arrhythmias, compliance with monitoring
Notes	

### Kasckow 2011

Methods	RCT
Participants	Suicidal patients with schizophrenia (n = 38).
Interventions	A telehealth intervention using the Health Buddy device,
Outcomes	Depression ratings.
Notes	

### Kashem 2011

Methods	RCT
Participants	Hypertensive people (n = 242, JNC VII- Stage I and II, 16% white, 80% African American, 4% others, 62% female, age 60 ± 12 years) with systolic blood pressure (SBP) >140 mmHg from two medical centres.
Interventions	An Internet or IVR (interactive voice response) phone system.
Outcomes	Blood pressure.
Notes	

### Klocek 2010

Methods	RCT
Participants	Hypertensive patients (n = 80) never treated.
Interventions	Telemonitoring (comparison home monitoring)
Outcomes	Blood pressure, quality of life (QoL).
Notes	

### Kokubu 1999

Methods	RCT
Participants	Patients with asthma and a high risk for hospitalisation.
Interventions	An asthma telemedicine system, involving feedback from a nurse under physician supervision.
Outcomes	Hospitalisation rate, peak expiratory flow and asthma symptoms.
Notes	Paper in Japanese.

### Landolina 2012

Methods	RCT
Participants	Heart failure patients (n = 200) with implantable cardioverter–defibrillators (ICD) or an ICD for re-synchronisation therapy.
Interventions	Remote monitoring.
Outcomes	Rate of emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events.
Notes	

### Mabo 2012

Methods	RCT
Participants	People with pacemaker (n = 538)
Interventions	Long-term remote monitoring.
Outcomes	Proportion of patients who experienced at least one major adverse event (MAE), including all-cause death and hospitalisations for device-related or cardiovascular adverse events, MAE-free survivals and quality of life

**Mabo 2012** (Continued)

Notes

**Margolis 2013**

Methods	RCT
Participants	Adults with uncontrolled blood pressure (BP) (n = 450)
Interventions	Home blood pressure telemonitoring and pharmacist management.
Outcomes	Control of systolic BP to less than 140mmHg and diastolic BP to less than 90mmHg (<130/80mmHg in patients with diabetes or chronic kidney disease). Secondary outcomes :change in BP, patient satisfaction.

Notes

**McDowell 2012**

Methods	RCT
Participants	Patients (n = 110) with moderate or severe chronic obstructive pulmonary disease (COPD) in a district general hospital.
Interventions	Home-based healthcare with telehealth monitoring.
Outcomes	Quality of life, anxiety and depression, healthcare utilisation, exacerbations of COPD

Notes

**McKinstry 2013**

Methods	RCT
Participants	People with uncontrolled hypertension (n = 401) (mean daytime ambulatory measurement $\geq$ 135/85 mm Hg but $\leq$ 210/135 mm Hg)..
Interventions	Telemonitoring and supervision by usual primary care clinicians of home self-measured blood pressure and optional patient decision support.
Outcomes	Mean daytime systolic ambulatory BP, costs and cost-effectiveness.

Notes

**Moattari 2013**

Methods	RCT
Participants	Patients with insulin-dependent diabetes (n = 48)

**Moattari 2013** (Continued)

Interventions	A specially designed electronic education programme which included a consultation service, quick answers to patients' questions, contact with the healthcare team and educational materials.
Outcomes	Serum concentrations of HbA1c, fasting blood sugar, triglycerides and high-density (HDL) and low-density lipoprotein (LDL) cholesterol.
Notes	

**Moss-Morris 2012**

Methods	RCT
Participants	People with multiple sclerosis (n = 40).
Interventions	Internet-based cognitive behavioural therapy self-management programme (MS Invigor8), and interaction with a clinical psychologist..
Outcomes	Fatigue severity, mood, quality of life and health service use.
Notes	

**Neumann 2013**

Methods	RCT
Participants	Patients (n = 120) with end-stage renal failure on haemodialysis
Interventions	Telemetric body weight measurement (TBWM)
Outcomes	Interdialytic weight gain (IWG), ultrafiltration rate, and blood pressure
Notes	

**Nicolucci 2011**

Methods	RCT
Participants	Pople with Type 2 diabetes (n = 291)
Interventions	Telecare for optimising Insulin Glargine Plus One Injection of Insulin Glulisine.
Outcomes	Functional health status and treatment satisfaction.
Notes	

**Nield 2012**

Methods	RCT
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### Nield 2012 (Continued)

Participants	People with chronic obstructive pulmonary disease (COPD) (n = 22)
Interventions	Real-time telehealth for COPD self-management using Skype.
Outcomes	Medical Outcomes Study Social Support Survey and dyspnoea assessment (visual analogue scales for intensity and distress, modified Borg after six-minute walk distance, and Shortness of Breath Questionnaire for activity-associated dyspnoea).
Notes	

### Osmera 2013

Methods	RCT
Participants	Patients (n = 198) with implantable cardioverter defibrillators (ICD).
Interventions	Continuous remote monitoring system using Home Monitoring (HM)™ (BIOTRONIK).
Outcomes	Planned and emergency visits, hospitalisation for events related to ICD, delivered shock therapies and their adequacy.
Notes	

### Patrick 2013

Methods	RCT
Participants	Obese adolescents at risk for Type 2 diabetes (n = 101).
Interventions	Website and SMS (WSMS) supporting intervention goals and behavioural strategies and communicated via SMS with a case manager.
Outcomes	Treatment effects for anthropometric, behavioural, and behavioral change strategy outcomes.
Notes	

### Pedone 2013

Methods	RCT
Participants	Elderly people with chronic obstructive pulmonary disease (COPD) (n = 99) aged 65 or older with COPD in GOLD stages II and III enrolled in a pulmonary medicine outpatient facility
Interventions	A multiparametric remote monitoring system.
Outcomes	Number of exacerbations and exacerbation-related hospitalisations.
Notes	

### Pekmezaris 2012

Methods	RCT
Participants	People with heart failure (n = 168) who are Medicare Beneficiaries (receiving home care).
Interventions	A combination of live nursing visits and video-based nursing visits.
Outcomes	Hospital utilisation and Medicare costs.
Notes	

### Pinnock 2013

Methods	RCT
Participants	Adults (n = 256) with at least one admission for chronic obstructive pulmonary disease (COPD) in the year before randomisation
Interventions	Telemonitoring integrated into existing clinical services.
Outcomes	Time to hospital admission due to COPD exacerbation; number and duration of admissions, health-related quality of life, anxiety or depression (or both), self-efficacy, knowledge, and adherence to treatment.
Notes	

### Rifkin 2013

Methods	RCT
Participants	Veterans with stage 3 or greater chronic kidney disease and uncontrolled hypertension (n = 43)
Interventions	A telemonitoring device pairing a Bluetooth-enabled BP cuff with an Internet-enabled hub, which wirelessly transmitted readings.
Outcomes	Improved data exchange and device acceptability (feasibility only). Secondary endpoint was BP change.
Notes	

### Sabatier 2013

Methods	RCT
Participants	Elderly patients (n = 90) with heart failure.
Interventions	Educational telemedicine was based on an original and interactive user-friendly interface on a touch-sensitive screen tablet installed at home

**Sabatier 2013** (Continued)

Outcomes	Number of days of hospitalisation for acute heart failure, time to death or hospitalisation for acute heart failure.
Notes	

**Segrelles 2014**

Methods	RCT
Participants	Participants (n = 60) with a prior diagnosis of chronic obstructive pulmonary disease (COPD) with a post-bronchodilator forced expiratory volume (FEV1)% predicted <50%, age 50 years, were on long-term home oxygen therapy, and non-smokers.
Interventions	Home telehealth. Patients measured their vital signs on a daily bases, and data were transmitted automatically to a Clinical Monitoring Center for follow-up, and who escalated clinical alerts to a Pneumologist.
Outcomes	Emergency department visits, hospitalisations, length of hospital stay, need for non-invasive mechanical ventilation, time to the first severe AECOPD.
Notes	

**Spaniel 2012**

Methods	RCT
Participants	Relapse-prone outpatients (n = 146) with schizophrenia or schizoaffective disorder.
Interventions	information technology-aided program of relapse prevention (ITAREPS)..
Outcomes	Hospitalisations, number of inpatient days and costs.
Notes	

**Steventon 2012**

Methods	RCT
Participants	People with diabetes, chronic obstructive pulmonary disease (COPD), or heart failure (n= 3230).
Interventions	Telehealth involved remote exchange of data between patients and healthcare professionals as part of patients' diagnosis and management.
Outcomes	Proportion of patients admitted to hospital.
Notes	

### Stickland 2011

Methods	RCT
Participants	Patients (n = 147) with chronic obstructive pulmonary disease (COPD).
Interventions	Pulmonary rehabilitation delivered via Telehealth (Telehealth-PR).
Outcomes	Change in quality of life as evaluated by the St George's Respiratory Questionnaire (SGRQ).
Notes	

### Takahashi 2012

Methods	RCT
Participants	Older adults with multiple co morbid conditions (n = 205), of which some also received home care.
Interventions	Telemonitoring and communicating with the patient via phone or video-conferencing.
Outcomes	A composite end point of hospitalisations and ED visits, hospitalizations,emergency department (ED) visits, total hospital days, hospice referral, and time-to-event
Notes	

### van Os-Medendorp 2012

Methods	RCT
Participants	Patients (n = 199) with atopic dermatitis.
Interventions	An e-health portal for patients with atopic dermatitis (AD), consisting of e-consultation, a patient-tailored website, monitoring and self-management training.
Outcomes	Disease-specific quality of life, severity of AD and intensity of itching, costs.
Notes	

### Varma 2010

Methods	RCT
Participants	Patients (n = 1339) with implantable cardioverter-defibrillator (ICD).
Interventions	Remote home monitoring with automatic daily surveillance (HM) for ICD follow-up.
Outcomes	Scheduled office visits and unscheduled evaluations, incidence of morbidity, and time elapsed from first event occurrence.
Notes	

### Venter 2012

Methods	RCT
Participants	Māori with congestive heart failure and chronic obstructive pulmonary disease (COPD).
Interventions	Tele-health enabled chronic care management.
Outcomes	Quality of life, hospitalisations, acceptability of telemedicine (TM).
Notes	

### Wakefield 2012

Methods	RCT
Participants	Patients with co-morbid diabetes and hypertension (n=302)
Interventions	A nurse-managed home telehealth intervention comparing two remote monitoring intensity levels (and usual care).
Outcomes	HbA1c and systolic blood pressure (SBP); adherence.
Notes	

### Walter 2012

Methods	RCT
Participants	Patients with stroke (n = 100).
Interventions	Prehospital stroke treatment in a specialised ambulance (equipped with a CT scanner, point-of-care laboratory, and telemedicine connection).
Outcomes	Time from alarm to therapy decision, times from alarm to end of CT and to end of laboratory analysis, number of patients receiving intravenous thrombolysis, time from alarm to intravenous thrombolysis, and neurological outcome
Notes	

### Welch 2003

Methods	RCT
Participants	Patients (n = 52) with tTpe 1 diabetes.
Interventions	A modem-equipped blood glucose meter system augmented with bi-weekly diabetes educator phone calls.
Outcomes	HbA1c, patient satisfaction.

## Welch 2003 (Continued)

Notes

## White 2011

Methods	RCT
Participants	Patients (n = 40) under renal dialysis.
Interventions	An interactive device that asks patients a series of questions, on a daily basis, related to their therapy [continuous ambulatory PP (CAPD) or automated PD (APD)] and diabetic status, and a health coach and nursing staff communicates with the patients.
Outcomes	Individual case studies related to timely assessment and intervention related to blood glucose, pulse, fluid status, and exit-site condition, as well as nurse and patient satisfaction data.
Notes	

## Zabel 2013

Methods	RCT
Participants	Patients (n = 180) with implantable cardioverter-defibrillator (ICD)
Interventions	Wireless fluid monitoring and remote ICD management using OptiVol alert-based predefined management and ICD remote monitoring
Outcomes	Time to first hospitalisation due to worsened heart failure; time from event to clinical decision, rate of health care utilisation, quality of life.
Notes	

## Zugck 2008

Methods	RCT
Participants	Patients (n = 90) with chronic heart failure.
Interventions	Remote monitoring with regular follow-up by well-trained nurses. Physicians could be contacted at any time at the monitoring centre in case of an emergency or for advice.
Outcomes	Cardiac hospitalisations and hospital days stayed
Notes	

## Characteristics of ongoing studies [ordered by study ID]

### Antypas 2012

Trial name or title	E-Rehabilitation - an Internet and mobile phone based tailored intervention to enhance self-management of cardiovascular disease: study protocol for a randomized controlled trial.
Methods	RCT
Participants	The study population is adult participants of a cardiac rehabilitation programme in Norway with home Internet access and mobile phone.
Interventions	E-Rehabilitation – an Internet and mobile phone-based tailored intervention to enhance self-management.
Outcomes	Level of physical activity.
Starting date	January 2012
Contact information	Norwegian Centre for Integrated Care and Telemedicine, University Hospital of North Norway, Tromsø, N-9038, Norway. Konstantinos.Antypas@telemed.no
Notes	

### Carlisle 2012

Trial name or title	Randomised controlled trial of an in-home monitoring intervention to improve health outcomes for type 2 diabetes: study protocol.
Methods	RCT
Participants	Pople with Type 2 diabetes in Australia (N = 210).
Interventions	Additional diabetes care from a care co-ordinator nurse via an in-home broadband communication device that can capture clinical measures, provide regular health assessments and video-conference with other health professionals when required.
Outcomes	Biomedical, psychological, self-management and quality of life measures. Data on utilisation rates and satisfaction with the technology will be collected and cost-effectiveness data.
Starting date	No information
Contact information	Townsville-Mackay Medicare Loca, Queensland, Australia. kcarlisle@tmml.com.au
Notes	

### Duncan 2011

Trial name or title	PDA+: A Personal Digital Assistant for obesity treatment - An RCT testing the use of technology to enhance weight loss treatment for veterans.
Methods	RCT
Participants	Veterans enrolled in the MOVE! group at the Hines Hospital VAMC with BMI $\geq 25$ and $\leq 40$ and weigh $< 400$ pounds, experience chronic pain ( $\geq 4$ on the NRS-I scale for $\geq 6$ months prior to enrolment) and are able to participate in a moderate intensity exercise program.



### Duncan 2011 (Continued)

Interventions	PDA+: A Personal Digital Assistant for Obesity Treatment.
Outcomes	Weight loss, change in pain level intensity, quality of life, greater treatment adherence, care utilisation, patient satisfaction, mood, and waist circumference.
Starting date	October 2007
Contact information	Center for Management of Complex Chronic Care, Hines VA Medical Center, Hines, IL, USA Department of Preventive Medicine, Northwestern University, Chicago, IL, USA Jennifer M Duncan <a href="mailto:jennifer-duncan@northwestern.edu">jennifer-duncan@northwestern.edu</a>
Notes	

### Egede 2011

Trial name or title	Effectiveness of technology-assisted case management in low income adults with Type 2 diabetes (TACM-DM): study protocol for a randomized controlled trial
Methods	RCT
Participants	Low income adults with Type 2 diabetes (n = 200)
Interventions	Technology-assisted case management.
Outcomes	Glycaemic control.
Starting date	October 2011
Contact information	Center for Disease Prevention and Health Interventions for Diverse Populations, Ralph H, Johnson Veterans Affairs Medical Center, 109 Bee Street, Charleston, South Carolina 29401, USA. <a href="mailto:egedel@muscl.edu">egedel@muscl.edu</a>
Notes	

### Grau 2013

Trial name or title	Evaluation of the efficacy and costs impact of a tele monitoring and tele intervention trough video conference program for patients with chronic heart failure: a randomized controlled trial
Methods	RCT
Participants	People with heart failure (n = 74 in preliminary analysis)
Interventions	Telemonitoring of vital signs were transmitted to a central station controlled by HF nurses, and replacing the physical appointments by video conference.
Outcomes	Non-fatal HF events requiring hospital attention (decompensations requiring parenteral treatment); combined endpoint (all-cause death or HF non-fatal events), costs.
Starting date	No information

**Grau 2013** (Continued)

Contact information	C. Enjuanes Grau, Hospital del Mar, Department of Cardiology, Heart Failure Program, Barcelona, Spain
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**Jahanshahi 2012**

Trial name or title	A multi-centre controlled pilot study to evaluate a telemedicine system for the assisted living of people with dementia and their carers
Methods	RCT
Participants	People with dementia (PwD).
Interventions	'Telemedicine' for remote monitoring of the cognitive and behavioural state of PwD and detection of carer burden.
Outcomes	PwDs' cognition, mood and quality of life, and the carers' burden, mood and quality of life.
Starting date	No information
Contact information	M. Jahashahi. Sobell Department of Motor Neuroscience & Movement Disorders, UCL Institute of Neurology & The National Hospital for Neurology and Neurosurgery, London, UK

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**Jakobsen 2013**

Trial name or title	Hospital-admitted COPD patients treated at home using telemedicine technology in The Virtual Hospital Trial: methods of a randomized effectiveness trial.
Methods	RCT
Participants	COPD patients with acute exacerbation.
Interventions	Telemedicine technology (that is, a video-conference system with a touch screen and web cam and monitoring equipment (spirometer, thermometer, and pulse oximeter) intervention..
Outcomes	Treatment failure defined as re-admission due to exacerbation in COPD, death from any cause, prescription of additional antibiotics or steroids, need of intubation or non-invasive ventilation, emergency room visits, visits to the GP, lung function, bed days, health-related quality of life, healthcare costs and user satisfaction.
Starting date	June 2010
Contact information	Anna S Jakobsen <a href="mailto:annasvarre@gmail.com">annasvarre@gmail.com</a> . Research Unit of Clinical Nursing, Bispebjerg & Frederiksberg University Hospital, Bispebjerg Bakke 23a, DK 2400, Copenhagen, NV, Denmark

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### Kroenke 2013

Trial name or title	Stepped Care to Optimize Pain care Effectiveness (SCOPE) trial study design and sample characteristics.
Methods	RCT
Participants	Primary care veterans with persistent (3 months or longer) musculoskeletal pain of moderate severity (n = 250).
Interventions	A telemedicine collaborative care approach, the intervention couples automated symptom monitoring with a telephone-based, nurse care manager/physician pain specialist team to treat pain.
Outcomes	Pain severity/disability, pain beliefs and behaviours, psychological functioning, health-related quality of life and treatment satisfaction.
Starting date	October 2009
Contact information	Regenstrief Institute, 5th Floor, 1050 Wishard Blvd, Indianapolis, IN 46202, United States. Tel.: +1 317 630 7447; fax: +1 317 630 8776. E-mail address: kkroenke@regenstrief.org (K. Kroenke).
Notes	

### Lechtzin 2013

Trial name or title	Rationale and design of a randomized trial of home electronic symptom and lung function monitoring to detect cystic fibrosis pulmonary exacerbations: the early intervention in cystic fibrosis exacerbation (eICE) Trial
Methods	RCT
Participants	People (n = 320) with cystic fibrosis (CF) age 14 years and older
Interventions	Home monitoring of both lung function measurements and symptoms for early detection and subsequent early treatment of acute CF pulmonary exacerbations
Outcomes	Change in FEV1, time to first acute protocol-defined pulmonary exacerbation, number of acute pulmonary exacerbations, number of hospitalisation days for acute pulmonary exacerbation, time from the end of acute pulmonary exacerbation to onset of subsequent pulmonary exacerbation, change in health-related quality of life, change in treatment burden, change in CF respiratory symptoms, and adherence to the study protocol
Starting date	October 2011
Contact information	Corresponding Author: Noah Lechtzin, MD, MHS Johns Hopkins University School of Medicine Division of Pulmonary and Critical Care Medicine 1830 E. Monument Street, 5th Floor Baltimore, MD 21205 Telephone: (410) 502-7047 Fax: (410) 502-7048, nlechtz@jhmi.edu.
Notes	

### Margolis 2012

Trial name or title	Design and rationale for home blood pressure telemonitoring and case management to control hypertension: A cluster randomized trial
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### Margolis 2012 (Continued)

Methods	RCT
Participants	Hypertensive patients (n = 450) with uncontrolled BP from 16 primary care clinics.
Interventions	A home BP tele-monitor that internally stores and transmits BP data to a secure database. Pharmacist case managers adjust antihypertensive therapy based on the home BP data under a collaborative practice agreement with the clinics' primary care teams.
Outcomes	BP control, maintenance of BP control, patient satisfaction with their health care, and costs of care.
Starting date	March 2009
Contact information	Karen Margolis, HealthPartners Research Foundation, PO Box 1524, MS 21111R, Minneapolis, MN 55440-1524, United States, Karen.l.margolis@healthpartners.com Phone: 952-967-7301, Fax: 952-967-5022.
Notes	

### Parati 2013

Trial name or title	Blood pressure control and treatment adherence in hypertensive patients with metabolic syndrome: protocol of a randomized controlled study based on home blood pressure tele monitoring vs. conventional management and assessment of psychological determinants of adherence (TELEBPMET Study)
Methods	RCT
Participants	Patients (n = 252) with high cardiovascular risk (treated or untreated essential arterial hypertension).
Interventions	Automated tele-transmission of home blood pressure values, followed by manual transmission of self-measured blood pressure data to the HBPT centre immediately before each office visit, with regular doctor's visit every 3 months,
Outcomes	Rate of participants achieving normal daytime ambulatory blood pressure targets (< 135/85 mmHg), psychological determinants of adherence and persistence to drug therapy, clinical and economic outcomes (number of additional medical visits, direct costs of patient management, number of antihypertensive drugs prescribed, level of cardiovascular risk, degree of target organ damage and rate of cardiovascular events, regression of the metabolic syndrome).
Starting date	November 2007
Contact information	Correspondance:gianfranco.parati@unimib.it Department of Cardiology, IRCCS Ospedale San Luca, Istituto Auxologico Italiano and Department of Clinical Medicine and Prevention, University of Milano Bicocca, Milano, Italy
Notes	

### Saywell 2012

Trial name or title	Telerehabilitation to improve outcomes for people with stroke: study protocol for a randomised controlled trial
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## Saywell 2012 (Continued)

Methods	RCT
Participants	People will be eligible if they have had their first ever stroke, are over 20 and have some physical impairment in either arm or leg, or both
Interventions	ACTIV programme uses readily available technology, telephone and mobile phones, combined with face-to-face visits from a physiotherapist, to help people with stroke resume activities they enjoyed before the stroke.
Outcomes	Physical function and quality of life, costs and preferences for rehabilitation options
Starting date	April 2012
Contact information	Correspondence: nsaywell@aut.ac.nz Health and Rehabilitation Research Institute, AUT University, Private Bag 92006, Auckland 1142, New Zealand
Notes	

## Shah 2011

Trial name or title	Secondary Prevention Risk Interventions Via Telemedicine and Tailored Patient Education (SPRITE)
Methods	RCT (3-armed)
Participants	Patients (n = 450) with a recent myocardial infarction and hypertension.
Interventions	Home blood pressure monitors plus a nurse-delivered, telephone-based tailored patient education intervention and will be enrolled into HealthVault, a Microsoft electronic health record platform or BP monitors plus a tailored patient education intervention and be enrolled in HeartVault but patient education will be delivered by a Web-based program.
Outcomes	Systolic BP , LDL cholesterol, body weight, glycosylated haemoglobin, adherence to evidence-based therapies, health behaviours.
Starting date	June 2009
Contact information	Correspondence to Bimal R. Shah, MD, MBA, Duke Clinical Research Institute, 2400 Pratt St, Durham, NC 27705. E-mail bimal.shah@duke.edu
Notes	

## Strachan 2012

Trial name or title	Home-based tele health to deliver evidence-based psychotherapy in veterans with PTSD
Methods	RCT
Participants	Veterans (n = 226) with PTSD in the catchment area of a large Veterans Affairs Medical Center (VAMC) in the Southeastern United States.

**Strachan 2012** (Continued)

Interventions	Prolonged exposure therapy delivered via their choice of two video-conferencing modalities: (a) encrypted Internet-based tele video software to their home computer, or (b) an analogue “plug-and use” videophone with built-in camera and video screen that operates using plain old telephone service (POTS line).
Outcomes	Clinical, quality of life, and process outcomes.
Starting date	No information
Contact information	Corresponding author at: Department of Psychiatry, MUSC, 67 President Street, 2-S, Charleston, SC 29425, United States. Tel.: +1 843 792 2949; fax: +1 843 792 3388.
Notes	

**Villani 2007**

Trial name or title	Disease management for heart failure patients: role of wireless technologies for telemedicine. The ICAROS project.
Methods	RCT
Participants	People with heart failure (unclear final number)
Interventions	Use of a portable computer to get in touch daily with the heart failure clinic and receive feedback instruction for the management of drug therapy and daily problems.
Outcomes	feasibility and appropriateness of intervention (preliminary results)
Starting date	No information
Contact information	Cardiologia, Ospedale San Luca, Istituto Auxologico Italiano IRCCS, Milano.
Notes	

COPD: chronic pulmonary obstructive disease; HF: heart failure; LDL: low-density lipoprotein; PTSD: post-traumatic stress disorder; RCT: randomised controlled trial; VAMC: Veterans Affairs Medical Center

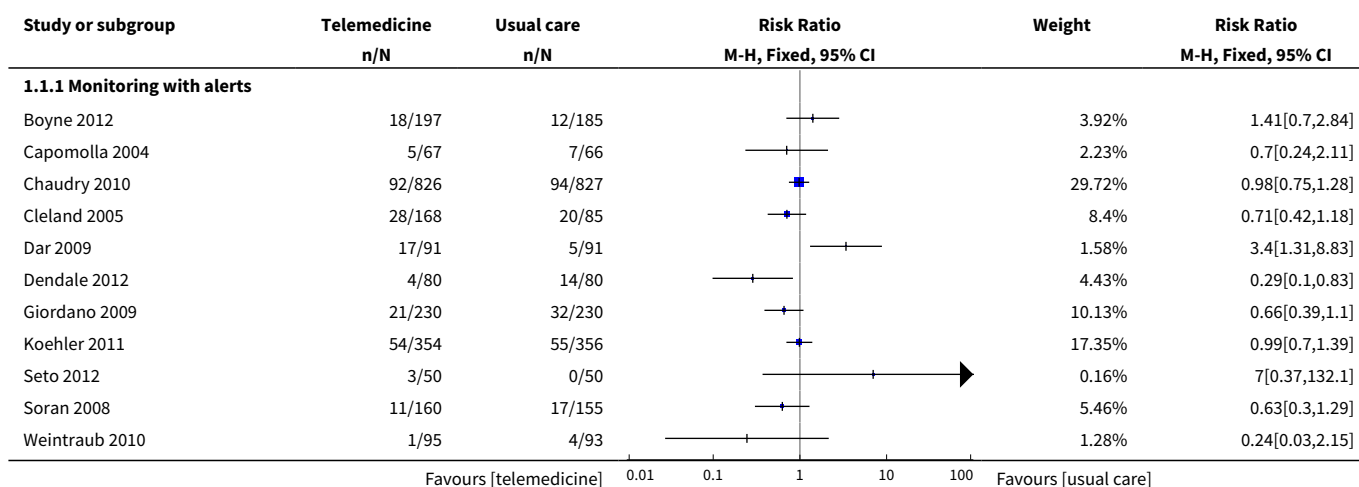
## DATA AND ANALYSES

**Comparison 1. Telemedicine with and without usual care vs. usual care only-Heart failure**

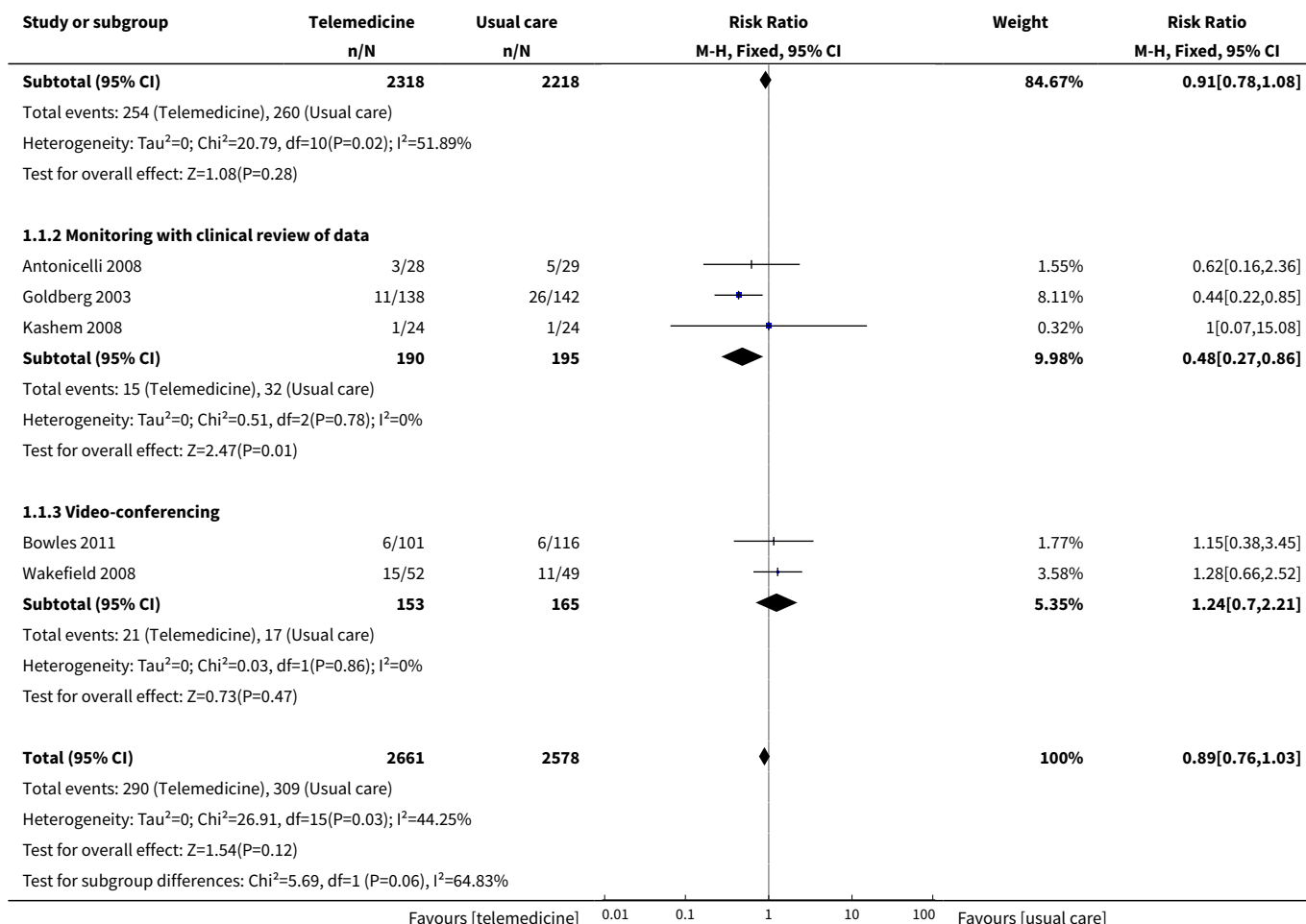
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All-cause mortality at median 6 months follow-up	16	5239	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.76, 1.03]
1.1 Monitoring with alerts	11	4536	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.78, 1.08]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 Monitoring with clinical review of data	3	385	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.27, 0.86]
1.3 Video-conferencing	2	318	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.21]
2 Disease-specific quality of life at median 3 months follow-up	5	482	Mean Difference (IV, Fixed, 95% CI)	-4.39 [-7.94, -0.83]
2.1 Monitoring with alerts	3	382	Mean Difference (IV, Fixed, 95% CI)	-5.03 [-8.81, -1.24]
2.2 Video-conferencing	2	100	Mean Difference (IV, Fixed, 95% CI)	0.31 [-9.95, 10.58]
3 All-cause hospital admissions at median 8 months follow-up	11		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3.1 Monitoring with clinical review of data	2		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Monitoring with alerts	9		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 ED and urgent care visits at median 4 months follow-up	3	689	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.74, 1.17]
5 Length of stay at median 6 months follow-up	5	2688	Mean Difference (IV, Fixed, 95% CI)	-0.12 [-0.79, 0.55]
6 Length of stay related to heart failure at median 6 months follow-up	5	2920	Mean Difference (IV, Fixed, 95% CI)	-0.16 [-0.85, 0.53]

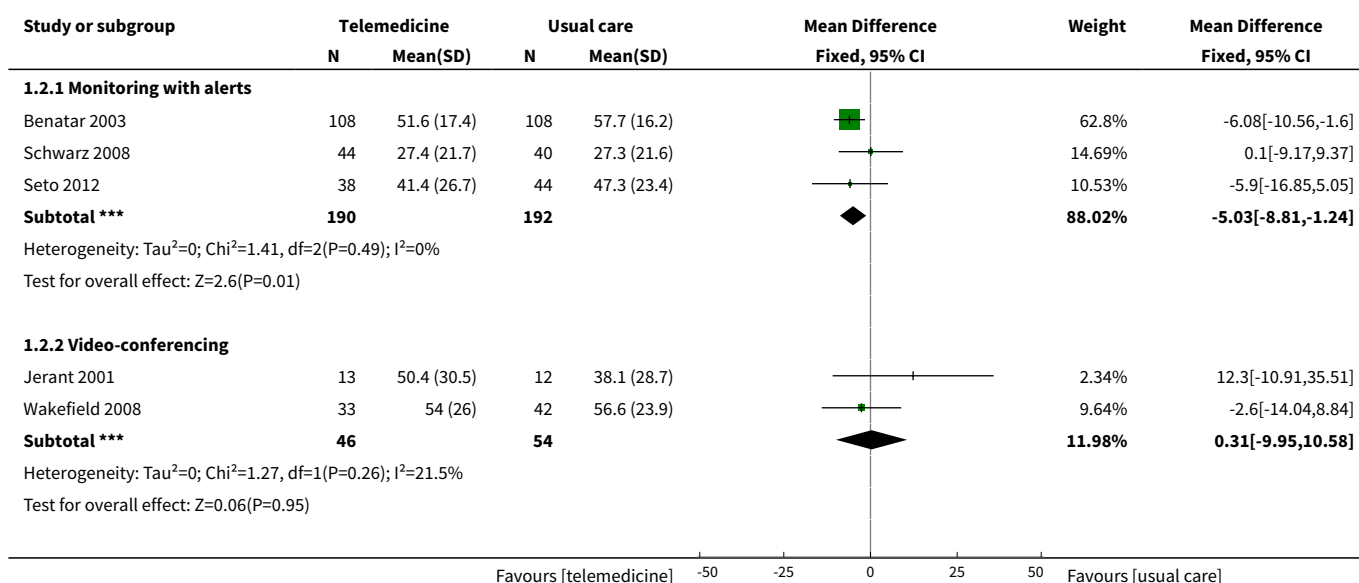
### Analysis 1.1. Comparison 1 Telemedicine with and without usual care vs. usual care only-Heart failure, Outcome 1 All-cause mortality at median 6 months follow-up.

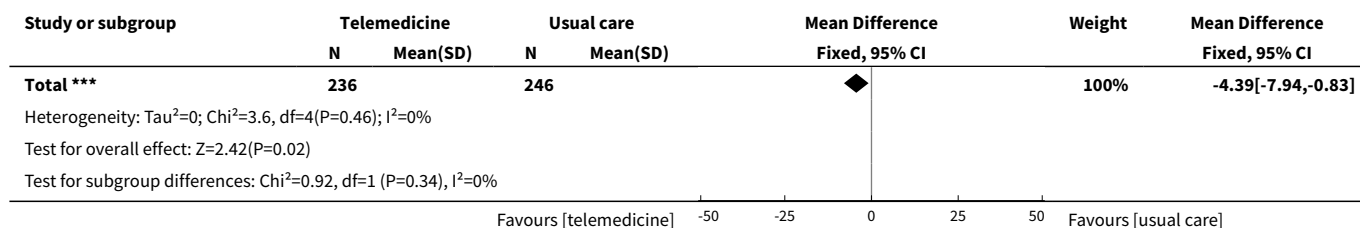




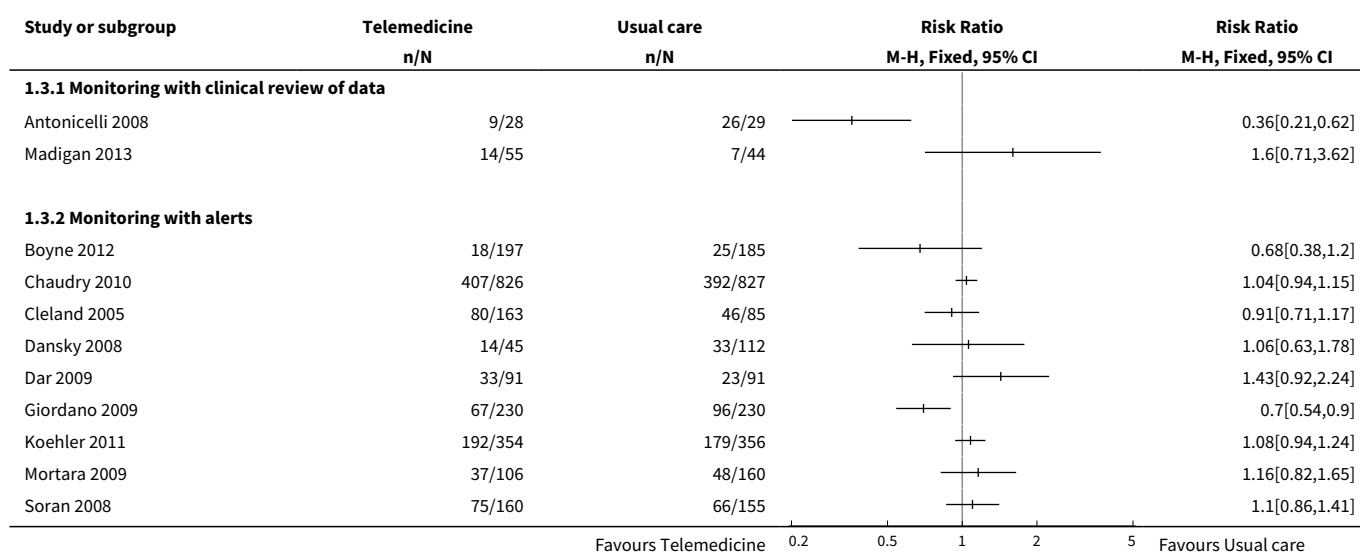


### Analysis 1.2. Comparison 1 Telemedicine with and without usual care vs. usual care only- Heart failure, Outcome 2 Disease-specific quality of life at median 3 months follow-up.

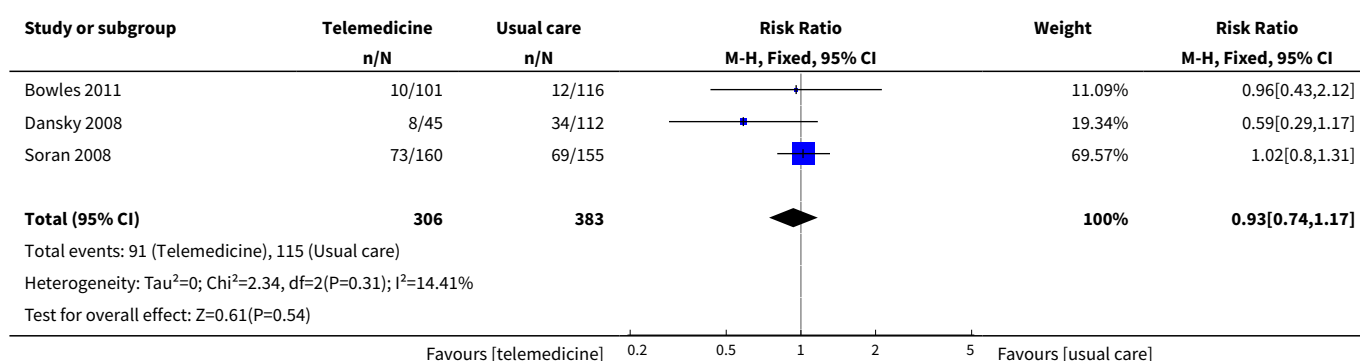




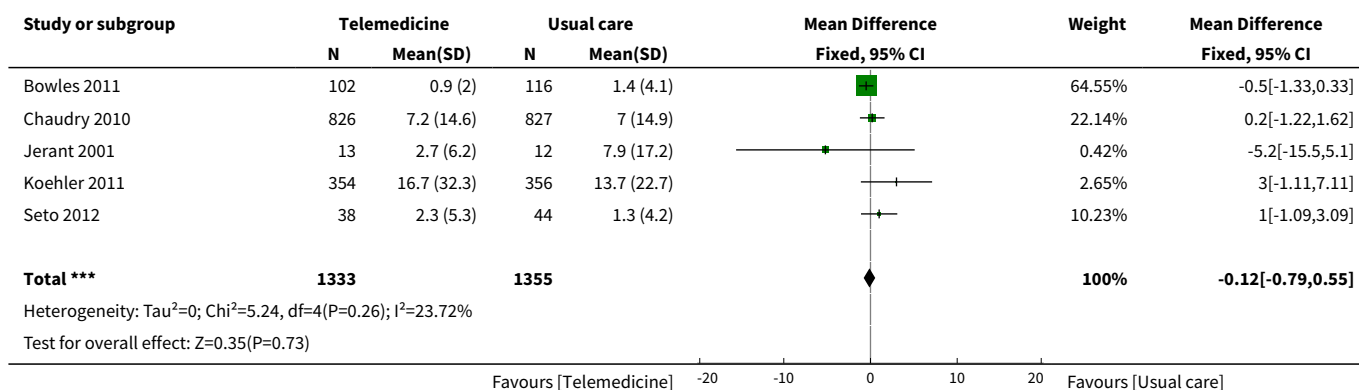
### Analysis 1.3. Comparison 1 Telemedicine with and without usual care vs. usual care only-Heart failure, Outcome 3 All-cause hospital admissions at median 8 months follow-up.



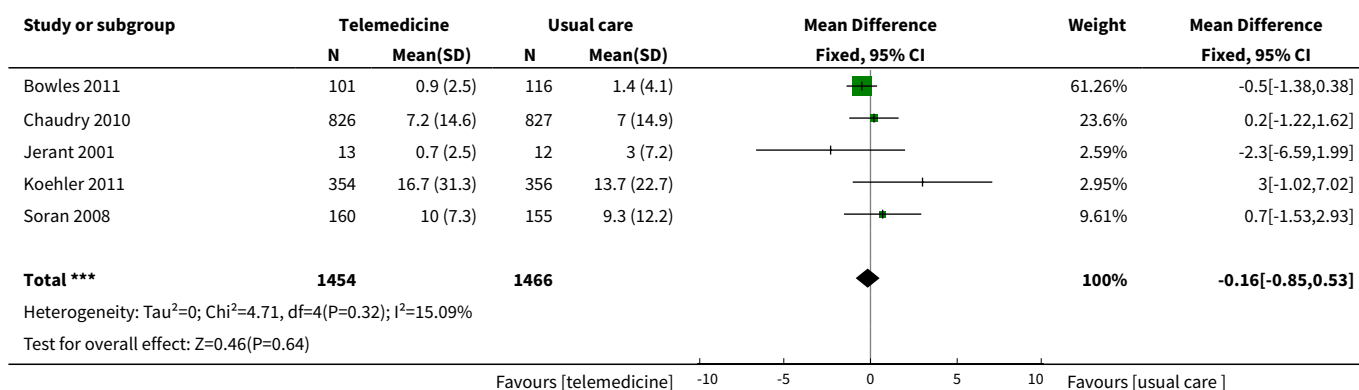
### Analysis 1.4. Comparison 1 Telemedicine with and without usual care vs. usual care only-Heart failure, Outcome 4 ED and urgent care visits at median 4 months follow-up.



### Analysis 1.5. Comparison 1 Telemedicine with and without usual care vs. usual care only-Heart failure, Outcome 5 Length of stay at median 6 months follow-up.



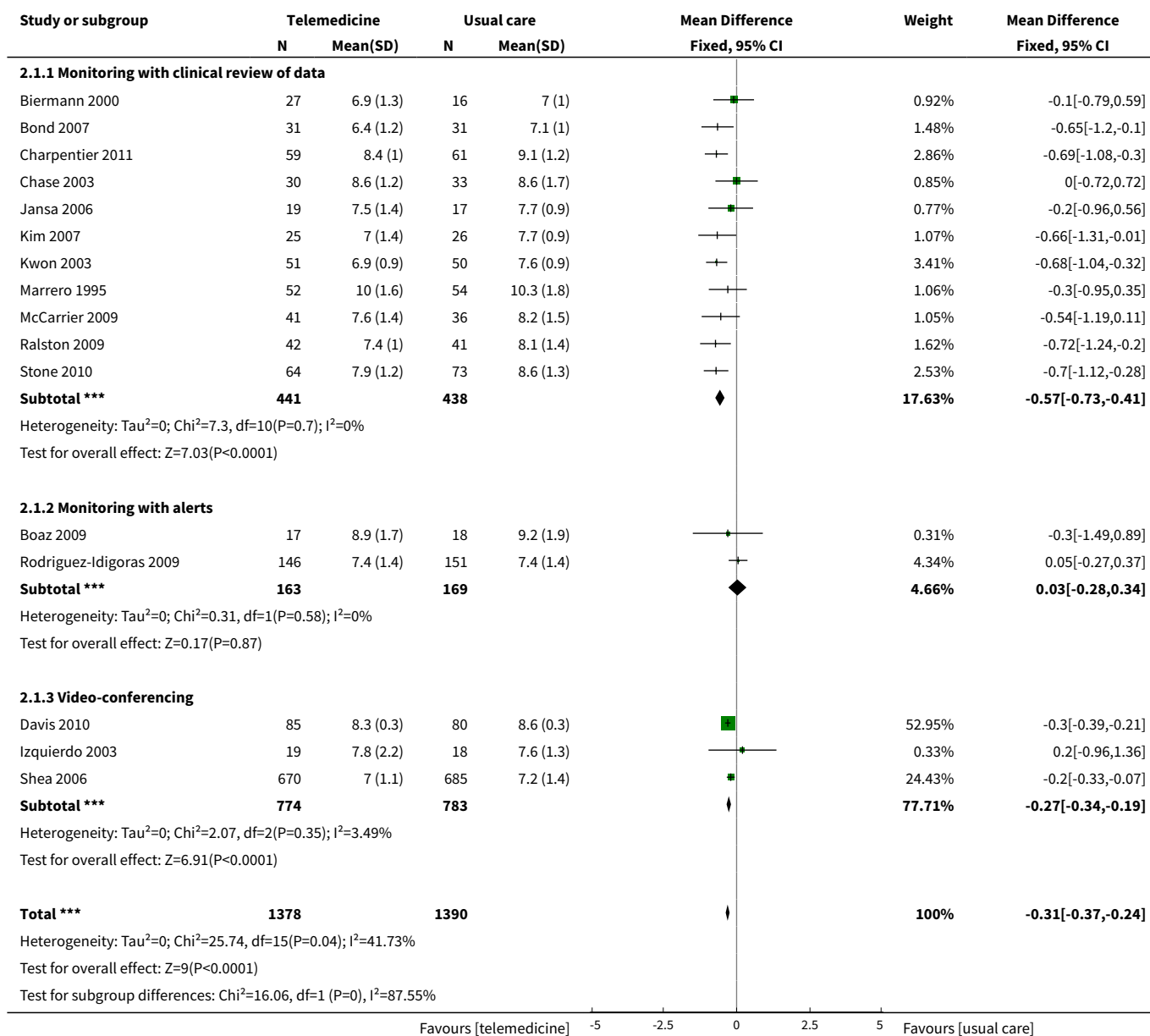
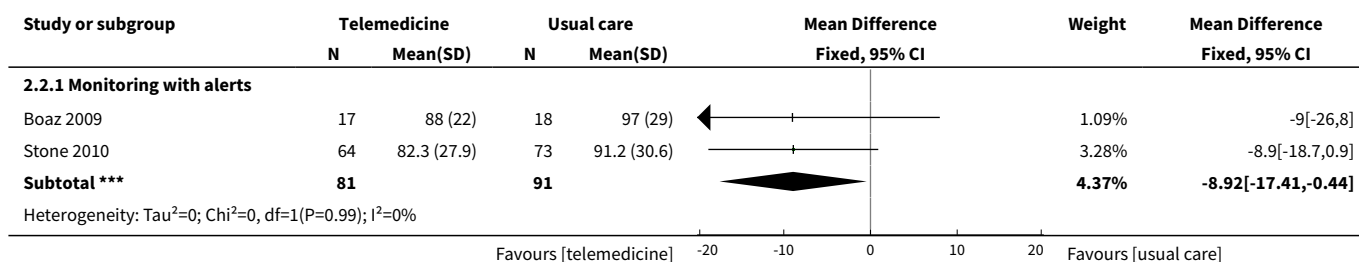
### Analysis 1.6. Comparison 1 Telemedicine with and without usual care vs. usual care only-Heart failure, Outcome 6 Length of stay related to heart failure at median 6 months follow-up.

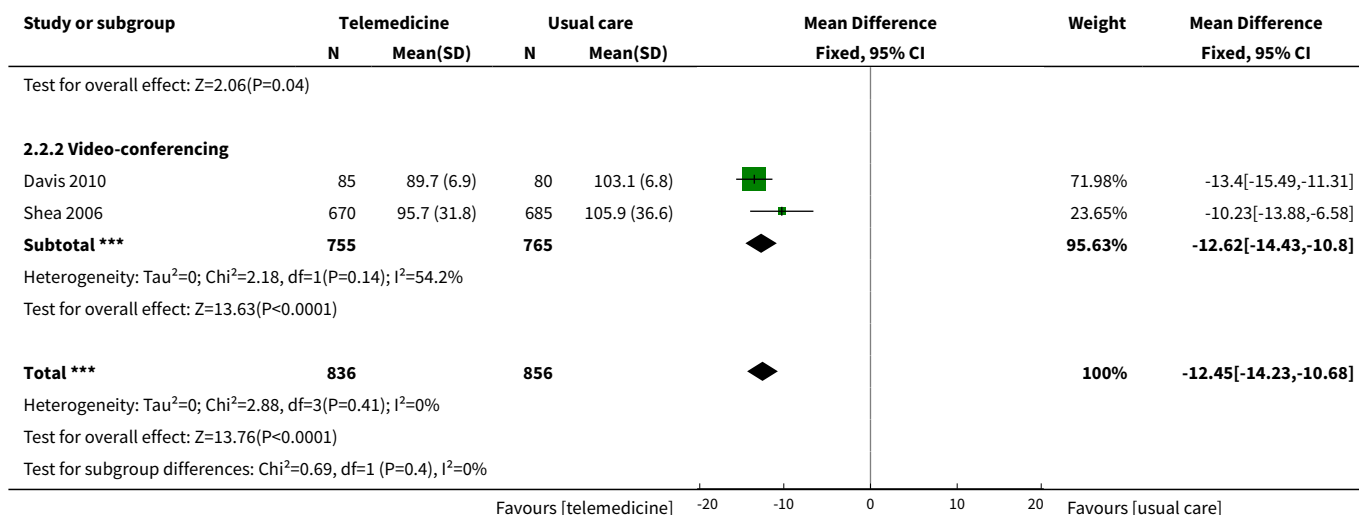


## Comparison 2. Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus

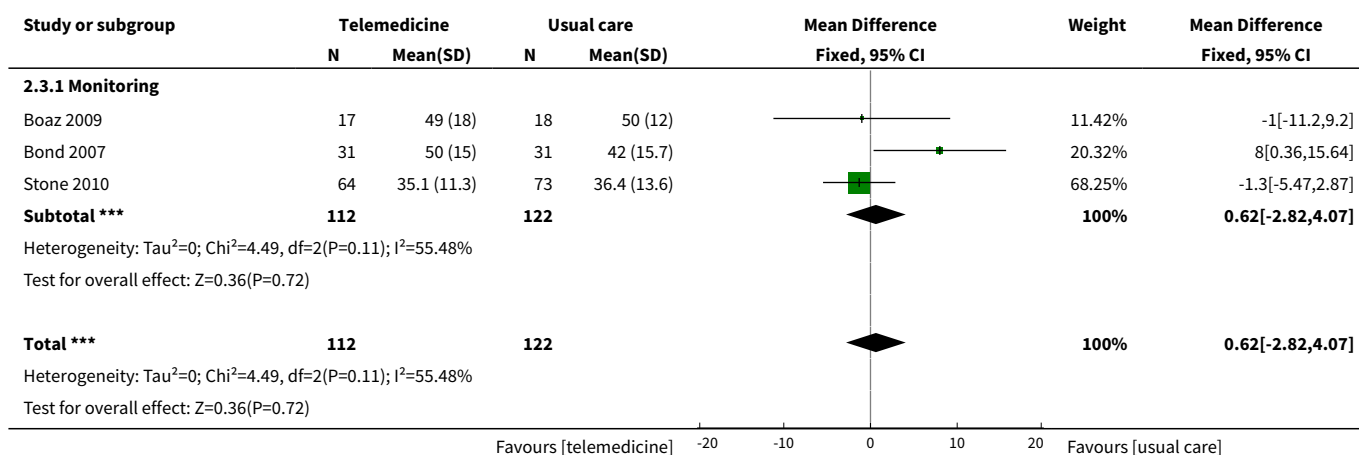
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 HbA1c at median 9 months follow-up	16	2768	Mean Difference (IV, Fixed, 95% CI)	-0.31 [-0.37, -0.24]
1.1 Monitoring with clinical review of data	11	879	Mean Difference (IV, Fixed, 95% CI)	-0.57 [-0.73, -0.41]
1.2 Monitoring with alerts	2	332	Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.28, 0.34]
1.3 Video-conferencing	3	1557	Mean Difference (IV, Fixed, 95% CI)	-0.27 [-0.34, -0.19]
2 LDL-cholesterol at median 6 months follow-up	4	1692	Mean Difference (IV, Fixed, 95% CI)	-12.45 [-14.23, -10.68]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Monitoring with alerts	2	172	Mean Difference (IV, Fixed, 95% CI)	-8.92 [-17.41, -0.44]
2.2 Video-conferencing	2	1520	Mean Difference (IV, Fixed, 95% CI)	-12.62 [-14.43, -10.80]
3 HDL-cholesterol at median 6 months follow-up	3	234	Mean Difference (IV, Fixed, 95% CI)	0.62 [-2.82, 4.07]
3.1 Monitoring	3	234	Mean Difference (IV, Fixed, 95% CI)	0.62 [-2.82, 4.07]
4 Total cholesterol at median 6 months follow-up	3	234	Mean Difference (IV, Fixed, 95% CI)	-7.63 [-17.36, 2.09]
5 Triglycerides at median 6 months follow-up	2	172	Mean Difference (IV, Fixed, 95% CI)	-11.15 [-43.39, 21.09]
5.1 Monitoring with alerts	2	172	Mean Difference (IV, Fixed, 95% CI)	-11.15 [-43.39, 21.09]
6 Systolic blood pressure at median 9 months follow-up	4	1770	Mean Difference (IV, Fixed, 95% CI)	-4.33 [-5.30, -3.35]
6.1 Monitoring with clinical review or with alerts	2	199	Mean Difference (IV, Fixed, 95% CI)	-2.22 [-6.82, 2.37]
6.2 Video-conferencing	2	1571	Mean Difference (IV, Fixed, 95% CI)	-4.42 [-5.42, -3.42]
7 Diastolic blood pressure at median 9 months follow-up	4	1770	Mean Difference (IV, Fixed, 95% CI)	-2.75 [-3.28, -2.22]
7.1 Monitoring with clinical review or alerts	2	199	Mean Difference (IV, Fixed, 95% CI)	-3.18 [-6.00, -0.36]
7.2 Video-conferencing	2	1571	Mean Difference (IV, Fixed, 95% CI)	-2.73 [-3.28, -2.19]
8 Total body weight at median 6 months follow-up	4	276	Mean Difference (IV, Fixed, 95% CI)	0.54 [-3.55, 4.63]
8.1 Monitoring with clinical review of data	2	104	Mean Difference (IV, Fixed, 95% CI)	-2.05 [-8.52, 4.42]
8.2 Monitoring with alerts	2	172	Mean Difference (IV, Fixed, 95% CI)	2.26 [-3.02, 7.54]

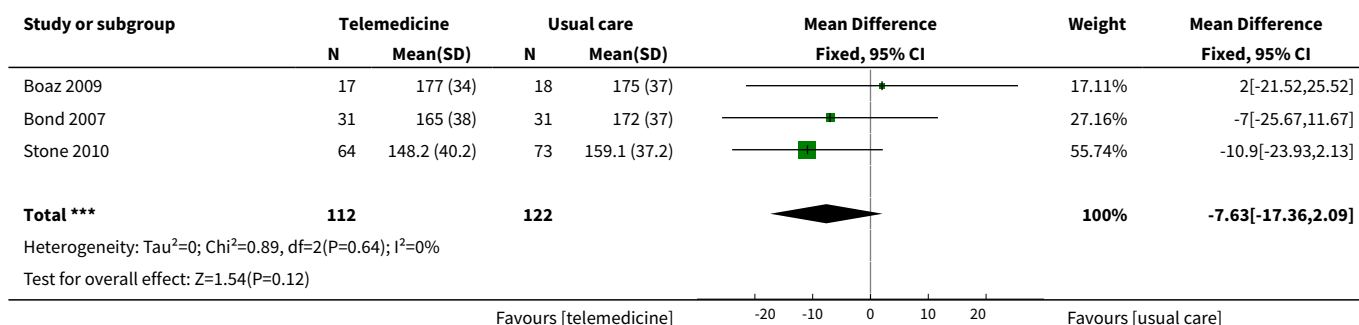
**Analysis 2.1. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 1 HbA1c at median 9 months follow-up.****Analysis 2.2. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 2 LDL-cholesterol at median 6 months follow-up.**



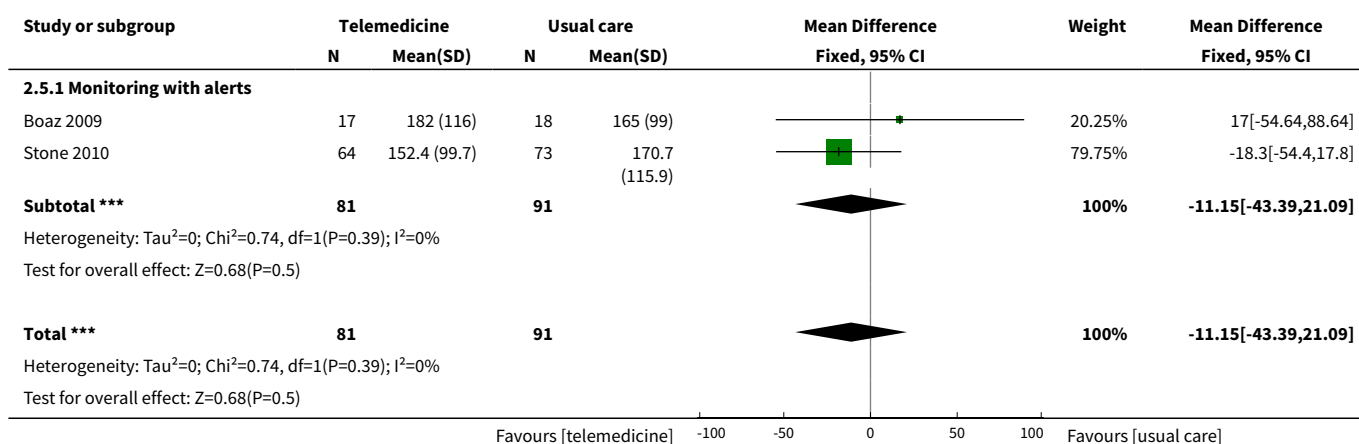
### Analysis 2.3. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 3 HDL-cholesterol at median 6 months follow-up.



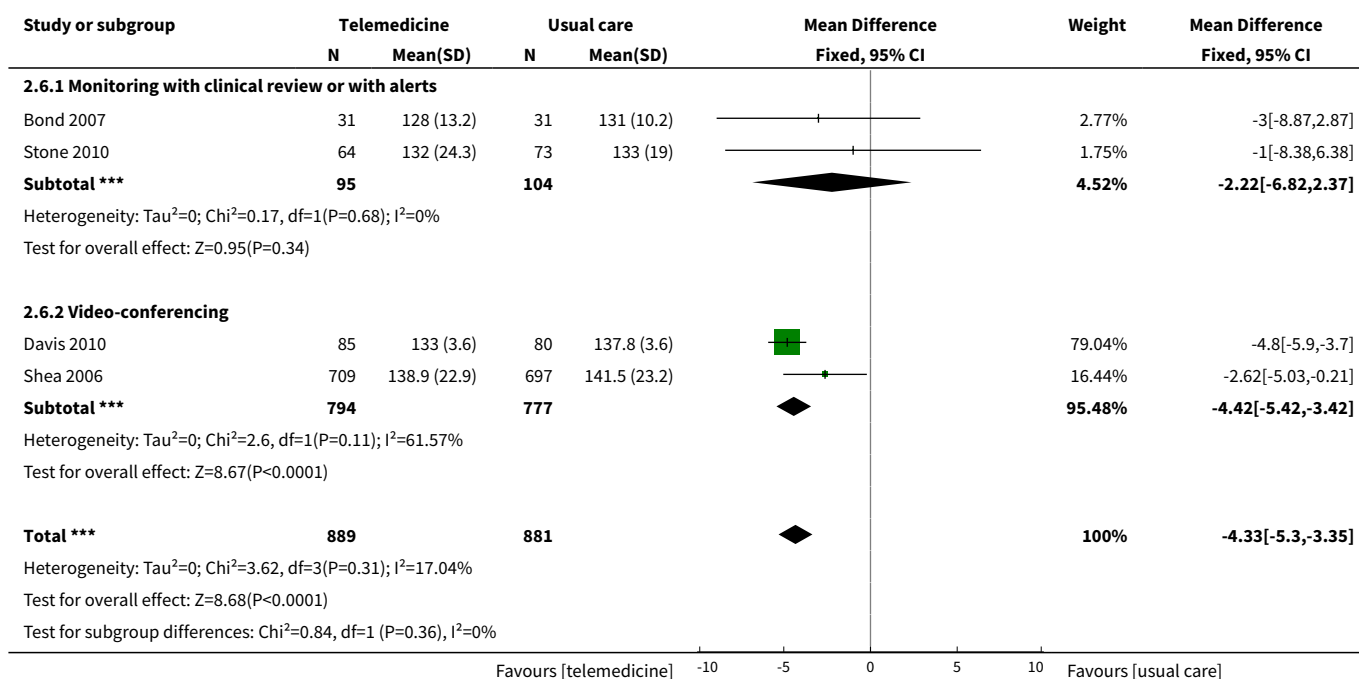
### Analysis 2.4. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 4 Total cholesterol at median 6 months follow-up.



### Analysis 2.5. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 5 Triglycerides at median 6 months follow-up.



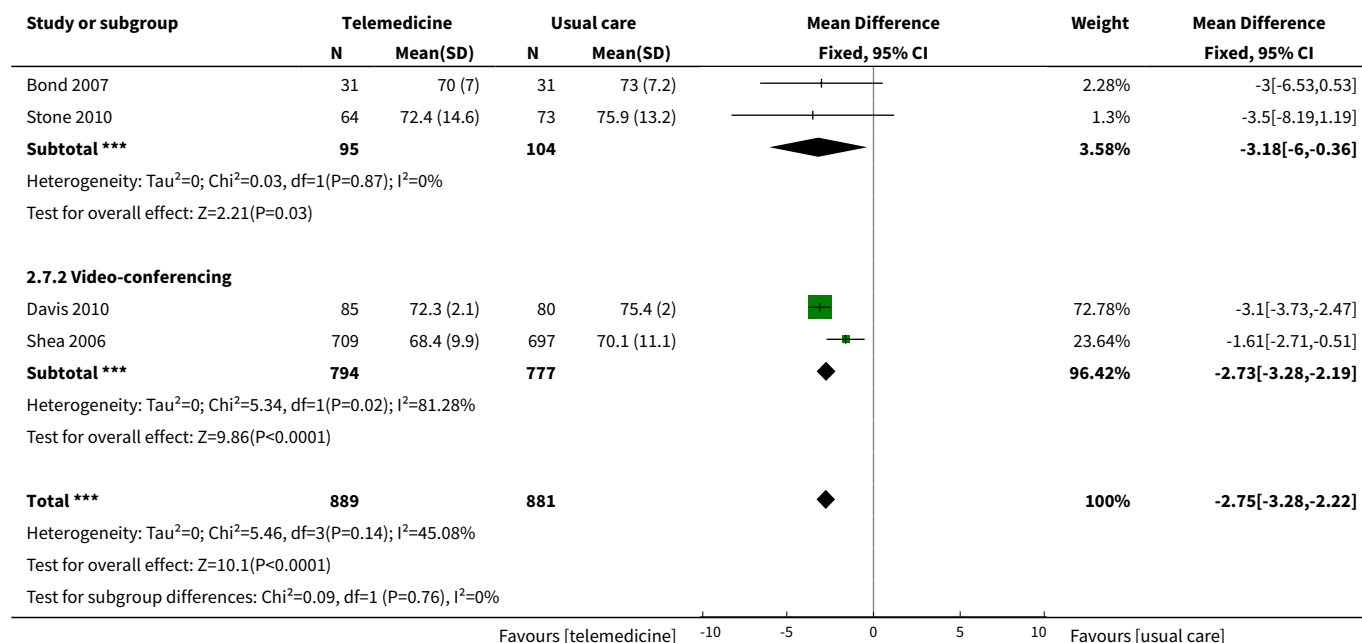
### Analysis 2.6. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 6 Systolic blood pressure at median 9 months follow-up.



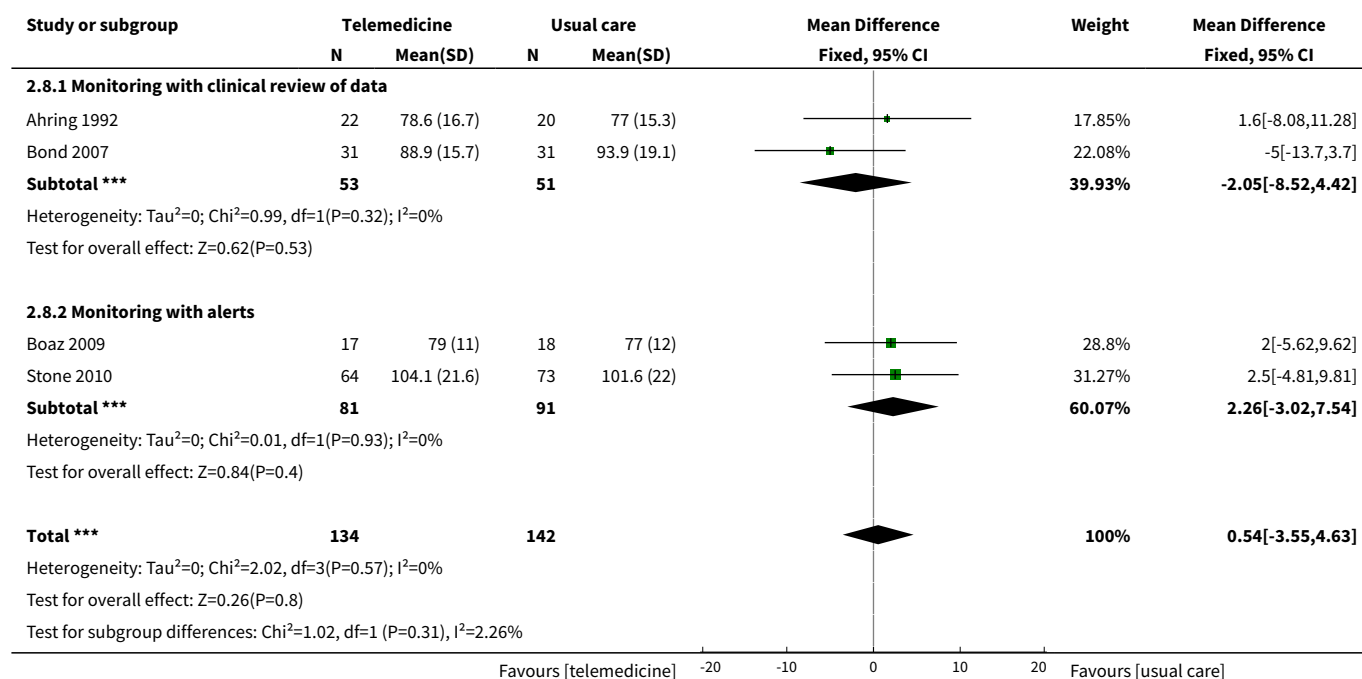
### Analysis 2.7. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 7 Diastolic blood pressure at median 9 months follow-up.







### Analysis 2.8. Comparison 2 Telemedicine with and without usual care vs.usual care only - Diabetes Mellitus, Outcome 8 Total body weight at median 6 months follow-up.



## ADDITIONAL TABLES

**Table 1. Summary of Characteristics of Cardiovascular disease studies**

Author Year Setting Country	Clinical condition/ Char- acteristics of Partici- pants	TM system and Characteristics of interven- tion	Function	Comparison	Outcomes
<b>HEART FAILURE</b>					
<b>ANTONICELLI 2008</b>	Heart failure Total N=57  <b>Setting:</b> one (National Re- search on Age- ing) hospital  <b>Country:</b> Italy :  Gender, male sex (%) ; TM: 57%; UC: 66%  Ethnicity: N/A  NYHA class <sup>1</sup> , %  Class II: TM:54%; UC:62%  Class III: TM:43%; UC:31%  Class IV: TM:1 (4%); UC:2(7%)  LVEF <sup>2</sup> , % (SD): TM:35(6); UC: 37(7)	<b>TM equipment:</b> a trans-tele- phonic ECG <sup>3</sup> recording system  <b>Data transfer:</b> weekly  <b>Review of data:</b> unclear  <b>Type and timing of response:</b> weekly telephone calls  <b>Actions:</b> changing treatment, clinic visits and admission to hospital  <b>Duration of intervention:</b> 12 months  <b>Follow-up:</b> 12 months from ran- domisation	Remote moni- toring.  <b>Data trans- ferred:</b> ECG  Information on symptoms and adher- ence to pre- scribed treat- ment as well as BP <sup>4</sup> , HR <sup>5</sup> , weight, and 24 hours urine output were collected at weekly inter- vals.	TM + UC vs. UC	<b>Primary out- comes:</b>  • Mortality • Hospitali- sations  <b>Secondary outcomes:</b>  • Compli- ance with treatment • QOL <sup>6</sup> • Costs (not reported)
<b>BENATAR 2003</b>	Heart failure patients receiving home health care.  <b>Setting:</b>  2 Medical cen- tres; 3 HCAs <sup>7</sup> (shared caHre)  <b>Country:</b> USA	<b>TM equipment:</b> a trans-tele- phonic home monitoring device  <b>Data transfer:</b> daily  <b>Review of data:</b> unclear  <b>Type and timing of response:</b> telephone, unclear timing.  <b>Actions:</b> the advanced practice nurse conducts telephone as- sessments, titrates medication therapy; conducts patient edu- cation as needed to achieve the goal of the medical plan  <b>Duration of intervention:</b> 3 months  <b>Follow-up:</b> 12 months after ran- domisation	Remote moni- toring,  assessment, education and titration of medication  <b>Data trans- ferred:</b>  BP, HR, arteri- al oxygen sat- uration, and weight	TM vs. UC  UC= home nurse visits	<b>Primary out- comes:</b>  • Hospitali- sations • LoS <sup>8</sup> • QoL • Costs

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

UC: 38.83±13.97

<b>BOWLES 2011</b>  <b>Setting:</b> one (not-for-profit) HHCA  <b>Country:</b> USA	Heart failure  All patients receiving home health care.  Total:N=218;  TM: n=102; UC: n=116  Age (years), mean, (SD):  TM: 71.3 (10.2); UC:73.5 (9.6)  Gender, male no (%): TM:36 (35.6); UC:39 (33.6)  Ethnicity:white, no (%):  TM:33 (32.7); UC:39 (33.6)  black, no (%):  TM:66 (65.3); UC:75 (64.7)  Severity of condition:  CHF (months): TM:60.7 (67.7); UC: 61.5 (71.6)  Comorbid Conditions : TM: 6.8 (4.0), n=101: UC: 6.0 (4.0), n=116  Concomitant Medications: TM (n=95): 11.3 (4.6), n=95; UC: 10.0 (3.4), n=113	<b>TM equipment:</b> was based on patient need. e.g. if they had diabetes or COPD in addition to HF, they received a glucometer and pulse oximeter, respectively. All patients received a video phone, blood pressure cuff, and a weight scale (all wireless) for automatic data transfer via a hub that connected to the Internet via a telephone line.  <b>Data transfer:</b> daily  <b>Review of data:</b> clinical review of data by nurses  <b>Type and timing of response:</b> reviewed daily (unclear if also during weekends)  <b>Actions:</b> changes in the treatment plan, or confirm the accuracy with another reading, notify physician if judged needed  <b>Duration of intervention:</b> one episode of home care (30-60 days)  <b>Follow-up:</b> up to 180 days (but at least 90 days)  <b>Note:</b> the type and number of visits were guided by a standardised study protocol that defined minimal expectations of at least 4 video visits and daily use of the device during the home care period, and at least 5 in-person home visits for each group.	Remote monitoring and consultation  <b>Data transferred:</b> BP and weight (unclear if data on blood glucose and oxygenation was also transferred)	TM (45% substituting for UC) vs. UC	<b>Primary outcomes:</b>  <ul style="list-style-type: none"> <li>• All-cause re-admissions</li> <li>• HF re-admissions,</li> <li>• Hospital days stayed</li> <li>• Time to re-admission or death</li> </ul> <b>Secondary outcomes:</b>  <ul style="list-style-type: none"> <li>• Access to care,</li> <li>• ED use</li> <li>• Satisfaction with care (using a validated tool )</li> </ul>
<b>BOYNE 2012</b>  <b>Setting:</b> 3 hospitals  <b>Country:</b> The Netherlands	Heart failure  Total N=382;  TM: n=197; UC: n=185  Age (years), mean ± SD: TM:71.0±11.9; UC: 71.9±10.5  Gender, male no (%): TM::115 (58); UC: 111 (60)  Ethnicity: N/A  Severity of condition:	<b>TM equipment:</b> a device, with a liquid crystal display and four keys, connected to a land line phone. Automatic transfer of vital signs was not part of the system.  <b>Data transfer:</b> daily  <b>Review of data:</b> automatically analysed and risk categorised  <b>Type and timing of response:</b> immediate responses to alerts (probably over telephone)  <b>Actions:</b> N/A	Remote monitoring  <b>Data transferred:</b> answers to health-related questions	TM (partly substituting UC; two follow-up visits were skipped) vs. UC	<b>Primary outcomes:</b>  <ul style="list-style-type: none"> <li>• Time to first heart failure hospitalisation</li> <li>• Costs and cost-effectiveness</li> </ul> <b>Secondary outcomes:</b>  <ul style="list-style-type: none"> <li>• Combined endpoint of</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	History of HF, months: TM:19 (6–41); UC: 17 (6–40)	<b>Duration of intervention:</b> 12 months			heart failure admission and all-cause death,
	NYHA classification/n (%): NYHA II :	<b>Follow-up:</b> 12 months			• Number of re-admissions for heart failure,
	TM:110 (56); UC: 109 (59) NYHA III :				• All hospitalisations,
	TM:79 (40); UC: 74 (40) NYHA IV:				• Days in hospital for heart failure, cardiovascular or heart failure therapy-related
	TM: 8 (4); UC: 2 (1)				• Other-cause hospitalisations
	LVEF (%): TM:36 (28–50); UC: 35 (26–42)				• Mortality
	Pacemaker: TM: 59 (29.9); UC: 53 (28.6)				• Number of visits to the heart failure clinic.
	Major co-morbidities				
	Charlson index: TM:2 (2–3); UC: 2 (1–3)				
<b>CAPOMOLLA 2004</b>	Heart failure Total N=133	<b>TM equipment:</b> IVR <sup>9</sup> system, with dedicated software, alerts.	Remote monitoring	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> 1 HF unit at a day-hospital	TM: n=67; UC: n=66	<b>Data transfer:</b> low-risk patients every 60 days, medium-risk patients every 30 days and high-risk patients every 15 days.	<b>Data transferred:</b> weight, SBP, heart rate, dyspnoea, asthma, oedema, therapy		• Hospitalisations
<b>Country:</b> Italy	Age, mean ± SD (yrs): TM: 57±10 yrs; UC: 57±10 yrs	<b>Review of data:</b> unclear	changes, blood urea nitrogen, creatinine, sodium, potassium, bilirubin.		• Mortality
	Gender, male (%): TM:92%; UC:83%:	<b>Type and timing of response:</b> nurses and/or physicians contacts the patients at least monthly, and In case of a receipt of a voice message or an alert			• ED room visits
	Ethnicity: N/A	<b>Actions:</b> counselling or triage, integration or changes in the therapy, to require further examinations, or to manage unexpected access			<b>Compliance outcomes:</b>
	NYHA II/III-IV	<b>Duration of intervention:</b> 12 months			• Number of accesses
	TM: 45/22 ; UC: 44/22	<b>Follow-up:</b> 12 months after randomisation			• Amount of transmitted data
	LVEF %: N/A				• Data entry errors
					• Transmission errors
					• Compliance to strategy

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

<b>CHAUDHRY 2010</b>	Heart failure	<b>TM equipment:</b> IVR system	Remote mon- itoring with alerts	TM vs. UC	<b>Primary out- comes:</b>
<b>Setting:</b> 33 cardiology practices	Total N=1653; TM: n=826; UC: n=827	<b>Data transfer:</b> daily			<ul style="list-style-type: none"> <li>• Re- admission for any rea- son</li> <li>• Death from any cause within 180 days after enrolment.</li> </ul>
<b>Country:</b> USA	Age (years), median, IQR: TM:61 (51–73); UC: 61 (51– 73)	<b>Review of data:</b> automatic with alerts	<b>Data trans- ferred:</b> an- swers to health-related questions		<b>Secondary outcomes:</b>
	Gender, female sex, no (%): TM:359 (43.5); UC: 336 (40.6)	<b>Type and timing of re- sponse:</b> directly in case of an alert			<ul style="list-style-type: none"> <li>• Hospitali- sation for heart fail- ure</li> <li>• Number of days in the hospital</li> <li>• Number of hospitali- sations.</li> </ul>
	Ethnicity:	<b>Actions:</b> N/A			
	White: TM: 413 (50.1); UC: 402 (48.6)	<b>Duration of intervention:</b> 6 months			
	Black: TM: 314 (38.0); UC: 330 (39.9)	<b>Follow-up:</b> 6 months			
	Severity of condition:				
	NYHA class — no. (%)				
	I: TM: 48 (5.8); UC: 52 (6.3)				
	II: TM: 301 (36.4); UC: 306 (37.0)				
	III : TM:416 (50.4); UC: 423 (51.1)				
	IV: TM: 61 (7.4); UC: 46 (5.6)				
	LVEF% <40% — no./to- tal no. (%): TM: 572/806 (71.0); UC: 563/802 (70.2)				
	Major co-morbidities:				
	Chronic kidney disease — no./total no. (%): TM:370/814 (45.5);UC: 378/813 (46.5)				
	COPD — no. (%): TM: 169 (20.5); UC: 177 (21.4)				
	Diabetes mellitus — no. (%): TM: 394 (47.7); UC: 378 (45.7)				
	Hypertension — no. (%):TM: 632 (76.5); UC: 639 (77.3)				
	Coronary artery disease — no. (%):TM: 432 (52.3); UC: 403 (48.7)				
	Medications; no (%):				
	ACE inhibitor or ARB: TM: 549 (66.5); UC: 557 (67.4)				

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Beta-blocker: TM: 668 (80.9); UC: 641 (77.5)				
	Loop diuretic: TM: 646 (78.2); UC: 646 (78.1)				
	Digoxin: TM: 214 (25.9); UC: 198 (23.9)				
	Aldosterone-receptor antagonist: TM: 266 (32.2); UC: 277 (33.5)				
<b>CLELAND 2005</b>	Heart failure patients with a recent admission for HF and LVEF	<b>TM equipment:</b> A TM system with a low-profile, electronic, weighing scale, an automated sphygmomanometer, and a single-lead ECG using wrist-band electrodes and trans- telephonic data transmission.	Remote monitoring	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b>	<40%)	<b>Data transfer:</b> twice daily	<b>Data transferred:</b> BP, HR, weight and heart rhythm	Note: a third study arm (nurse telephone support, n=173) was not included in this review	<ul style="list-style-type: none"> <li>• Mortality</li> <li>• Hospitalisation</li> </ul>
4 main and 4 satellite hospitals (acute care):	Total N= 253	<b>Review of data:</b> clinical			<b>Secondary outcomes:</b>
<b>Country:</b> Italy	TM: n=168; UC: n=85	<b>Type and timing of response:</b> the study nurse reviewed the information and contacted the patient directly or after consultation with the physician (telephone?)			<ul style="list-style-type: none"> <li>• Optimisation of medication treatment</li> </ul>
	Age. mean yrs: TM: 67(13); UC: 68(10)	<b>Actions:</b> short-term advice or through the primary care physician if long-term changes in therapy were required. Nurses also could scan patient data manually to identify any trends that they considered as requiring action).			
	Gender, female sex (%) ; TM: 20 %; UC: 18 %	<b>Duration of intervention:</b> unclear			
	Ethnicity: N/A	<b>Follow-up:</b> 240 days (reduced from 460 days after inter-rim analysis)			
	Severity of condition:				
	NYHA class, %: Class I:				
	TM: 22%; UC: 18%				
	Class II: TM: 46%; UC: 36%				
	Class III: TM: 23%; UC: 42%				
	Class IV: TM: 8%; UC: 4%				
	LVEF %: NA				
	Previous MI: TM: 94 (56%); UC: 57 (67%)				
<b>DANSKY 2008</b>	Heart failure patients receiving Homecare	<b>TM equipment:</b> a two-way (synchronous) monitoring system with video- conferencing and digital stethoscope	Remote monitoring and assessment	TM+UC vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b>	Total N=157	<b>Data transfers:</b> 2-3 times per week	<b>Data transferred:</b> blood pressure, pulse, weight	Note: a third study arm (monitor only, n=127) was not included in this review.	<ul style="list-style-type: none"> <li>• Mortality</li> <li>• Hospitalisations</li> <li>• ED visits</li> </ul>
3 HHCA's (community care)	TM : n=45; UC: n=112	<b>Review of data:</b> in real time			<b>Other outcomes:</b>
<b>Country:</b> USA	Age, mean:	<b>Type and timing of response:</b> during video-conferencing			<ul style="list-style-type: none"> <li>• Self-reported symptoms related to</li> </ul>
	77.0 (9.83) yrs	<b>Actions:</b> the nurse reviews and discusses the data and healthy			
	Gender: N/A				
	Ethnicity: N/A				
	Severity of condition:				

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	NYHA class: N/A	living with patient during video-conferencing			diet (sodium and fluid intake), medication and physical activity
	LVEF %: N/A	<b>Duration of intervention:</b> 120 days			
		<b>Follow-up:</b> 120 days from randomisation			
<b>DAR 2009</b>	Heart failure	<b>TM equipment:</b> TM system which included an electronic weighing scale, automated blood pressure cuff, pulse oximeter and a control box connected to the telephone line.	Remote monitoring	TM +UC vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> 3 large acute care hospitals	Total N=182				• Days alive and out of hospital
	TM: n=91; UC: n=91		<b>Data transferred:</b>		
(acute care)	Age, mean (SD) years:		weight, BP, HR, oxygenation		<b>Secondary outcomes:</b>
<b>Country:</b> UK	TM: 70 (12.8); UC: 72(10.4)	<b>Data transfer:</b> daily			• HF hospitalisations
	Gender, female sex no (%); TM: 32%; UC: 35%	<b>Review of data:</b> automatic (alerts) and on a daily basis			• Duration of HF hospitalisations
	Ethnicity, south Asian (%); TM: 20%; UC: 21%	<b>Type and timing of response:</b> nurse contact patient by telephone; unclear timing, but probably in case of an alert			• HF clinic visits
	Severity of condition:	<b>Actions:</b> nurse gave life style advice, advice regarding medication, recommendations if needed to contact primary care, or early review in secondary care			• QOL
	NYHA class: all patients had class II–IV	<b>Duration of intervention:</b> 6 months			• Costs
	LVEF>40%: normal function available for 168/182 patients, (%): TM: 39%; UC: 40%	<b>Follow-up:</b> 6 months from randomisation			
<b>DENDALE 2012</b>	Heart failure	<b>TM equipment:</b> a TM system consisting of a electronic scale and sphygmomanometer connected by Bluetooth to a dedicated cell phone,	Remote monitoring	TM (partly substituting for UC) vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> 7 hospitals	Total N=160; number randomised to each group not stated but we assume equal distribution				• All-cause mortality.
<b>Country:</b> Belgium	TM: n=;80; UC: n=80	<b>Data transfer:</b> daily	<b>Data transferred:</b> body weight, blood pressure, and heart rate		<b>Secondary outcomes:</b>
	Age, mean, (SD) years:	<b>Review of data:</b> unclear			• Days lost to death, hospitalisation, or dialysis
	TM: 75.9 (9.6); UC: 75.6 (9.8)	<b>Type and timing of response:</b> 1-3 days after an alert (by nurses), GP after receiving the alert			• Number of hospitalisations
	Gender (male) no (%):	<b>Actions:</b> GP to adapt the treatment; GP could ask the HF specialist for advice on the website			• Costs
	TM: 50 (62%); UC: 54 (67%)	<b>Duration of intervention:</b> 6 months			
	Ethnicity: N/A	<b>Follow-up:</b> 6 months			
	Severity of condition:				
	Heart rhythm (sinus rhythm):				
	TM: 45 (56%); UC: 45 (56%)				

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

Hospitalisations before inclusion: TM: 1.7 (2.5); UC: 1.4 (1.7)

Body weight (kg):TM: 77 (17);UC: 75 (16)

Blood pressure

Systolic (mmHg):

TM: 125 (23); UC: 124 (23)

Diastolic (mmHg):

TM: 73 (12);UC: 70 (12)

Heart rate (beats per minute):TM: 72 (15); UC: 75 (16)

NYHA class, mean (SD):

TM: 3.0 (0.5); UC: 3.0 (0.5)

LVEF (%):TM: 34.9 (15.0); UC: 35.9 (15.1)

NT-proBNP (pg/mL) on discharge:TM: 4994 (6836); UC:6818 (7456)

6 min walking test (min):TM: 273 (123); UC: 288 (114)

<b>GIORDANO 2009</b>  <b>Setting:</b> 5 cardiovascular rehabilitation departments  <b>Country:</b> Italy	Heart failure	<b>TM equipment:</b> Data transfer by telephone, a one-lead trace to a receiving station where a nurse was available for interactive tele-consultation.  <b>Data transfer:</b> every week or every 15 days for patients with severe (III-V NYHA) or moderate (II NYHA)  <b>Review of data:</b> in real time at a receiving station, where a nurse or doctor were available 24 hours, 7 days/week  <b>Type and timing of response:</b> telephone; unclear timing  <i>Scheduled appointments</i> (tele monitoring), were done every week or every 15 days for patients with severe (III–IV NYHA) or moderate HF (II NYHA).  <i>Occasional appointments</i> (tele assistance) were done when	Consultation/  Remote monitoring  <b>Data transferred:</b> ECG trace (one lead)	TM vs. UC (by PCP and cardiologist)	<b>Primary outcomes:</b>  <ul style="list-style-type: none"> <li>Hospital re-admissions for cardiovascular reasons</li> </ul> <b>Secondary outcomes:</b>  <ul style="list-style-type: none"> <li>Hospitalisations for HF</li> <li>Costs</li> <li>Episodes of haemodynamic instability</li> <li>Mortality due to a cardiovascular cause</li> </ul>
	N=460				
	TM: n=230				
	UC: n=230				
	Age, mean± SD, years :				
	TM: 58±10; UC: 56±10				
	Gender, female sex (%) ;				
	TM:16%; UC: 14%				
	Ethnicity: N/A				
	Severity of condition:				
	NYHA class, no (%)				
	II: TM: 124 (54%); UC:150 (65%)				
	III-IV:				
	TM:106 (46%); UC:80 (35%)				



**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	<p>LVEF (%): TM:28±7; UC:26±8</p> <p>LVEF&lt;25%: TM:42%; UC:52%</p>	<p>the patient, in the presence of symptoms or signs of possible decompensation</p> <p><b>Actions:</b> a) in presence of stable conditions, fixed a new scheduled appointment, determine drug modification pre-planned with the cardiologist or with general practitioner – asked for further investigations or scheduled cardiological consultation, b) in presence of ECG trace modifications or of signs or symptoms of haemodynamic instability- contacted the GP and or the cardiologist of the patients.</p> <p><b>Duration of intervention:</b></p> <p>12 months</p> <p><b>Follow-up:</b> 12 months from randomisation</p>			
<p><b>GOLDBERG 2003</b></p> <p><b>Setting:</b> 8 cardiac transplant centres and 8 community- based cardiology practices</p> <p><b>Country:</b> USA</p>	<p>Heart failure</p> <p>Total N=280;</p> <p>TM: n=138 ; UC: n=142</p> <p>Age, mean (SD) years:TM: 57.9 (15.7); UC: 60.2 (14.9)</p> <p>Gender, female sex:</p> <p>TM: 42 (30.4); UC: 49(34.5)</p> <p>Ethnicity; white:TM 92 (66.7); UC: 87 (61.3);</p> <p>Severity of condition:</p> <p>Duration of CHF (months): TM: 42.3 (48.0); UC: 45.4 (59.7)</p> <p>NYHA class</p> <p>III:TM:100 (75.8); UC:106 (75.2)</p> <p>IV: TM: 32 (24.2); UC: 35 (24.8)</p> <p>LVEF%: TM:21.6 (6.8); UC: 21.8 (6.8)</p> <p>Major co-morbidities:</p> <p>Hypertension: TM:84 (60.9); UC:93 (65.5)</p>	<p><b>TM equipment:</b> symptom response system with electronic scale</p> <p><b>Data transfer:</b> twice daily</p> <p><b>Review of data:</b>daily manual review of data by trained cardiac nurses (employed by Alere)</p> <p><b>Type and timing of response:</b>the nurse contacted the patient if necessary by telephone</p> <p><b>Actions:</b>reported changes to the physician (sent summary fax and contacted the physician directly)</p> <p><b>Duration of intervention:</b>6 months</p> <p><b>Follow-up:</b> 6 months after randomisation</p>	<p>Remote monitoring</p> <p><b>Data transferred:</b> weight and responses to health-related questions</p>	<p>TM + UC vs. UC</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Hospital re-admission rate</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Mortality rate</li> <li>Heart failure hospitalisations</li> <li>ED visits</li> <li>QoL</li> <li>Patient Satisfaction (single item) with HF care</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Myocardial infarction: TM:53 (38.4); UC:56 (39.4)				
	Medications				
	Diuretic: TM:134 (97.1); UC: 135 (95.1)				
	ACE Inhibitor: TM:102 (73.9); UC:104 (73.2)				
	Digoxin : TM:123 (89.1); UC: 112 (78.9)				
	Beta-Blocker: TM:53 (38.4); UC: 52 (36.6)				
<b>JERANT 2001</b> (Jerant 2003)	Heart failure  Total N=25  TM: n=13; UC: n=12  Age, years (%): TM: 66.6 (10.9); UC:72.7 (11.4)  Gender, male (%):  TM: 46%; UC: 50%  Ethnicity (%):  TM: 8 (62) Afro-Americans, 4 (31) Caucasians;  UC: 4 (33) Afro-Americans; 7(58) Caucasians  Severity of condition:  NYHA class  II: TM: 9 (69%); UC: 7 (58%) III: TM:3 (23%);UC: 5 (42%) IV: TM: 1 (8%); UC: 0 (0)  Functional impairment (%) Intermediate:  TM:23%; UC: 42% High:  TM:77%; UC: 58%	<b>TM equipment:</b> Videoconfer- encing unit, with a small cam- era on an extension cable allow- ing observation of facial expres- sions, respiratory effort, lower extremity oedema, and digital scale displays. Combined with a voice signal transmitted via a microphone, and an integrated electronic stethoscope.  <b>Data transfer:</b> data transferred during 9 scheduled tele-care sessions  <b>Review of data:</b> in real time  <b>Type and timing of response:</b> N/A  <b>Actions:</b> the nurse reviewed her assessment with the principal investigator and, if appropri- ate, then sent a letter contain- ing non-urgent recommenda- tions for improving HF care to the PCP. Urgent recommenda- tions were conveyed immedi- ately by telephone.  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 6 months after ran- domisation	Real time as- sessment of vital signs and education.  <b>Data trans- ferred:</b> real time transfer of patients da- ta at the time of the video- conference	TM vs.UC  Note: a third study arm (telephone only; n=12), was not in- cluded in this review	<b>Primary out- comes:</b> <ul style="list-style-type: none"><li>• HF-related re- admission charges</li><li>• HF-related emergency visits</li><li>• Self-care adherence</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>• Medica- tions</li><li>• Health sta- tus</li><li>• Satisfac- tion</li></ul>
<b>KASHEM 2008</b> (Kashem 2006)	Heart failure  Total N=48  TM: n=24; UC: n=24  Age, mean (SD): TM:54 (10); UC: 53 (11)  Gender, female (%): TM: 27%; UC: 23%	Web-based TM intervention with standard or tailored replies from the healthcare provider.  <b>TM equipment:</b> The TM sys- tem comprised a secure Inter- net server and a database with web-based access by patients and providers, allowing patients to send data directly to the database via the Internet, and	Remote mon- itoring en- abling fre- quent sur- veillance and communica- tion between patient and providers.	TM+UC vs. UC	<b>Primary out- comes:</b> <ul style="list-style-type: none"><li>• Hospitali- sations</li><li>• Hospital days stayed</li><li>• ED visits</li><li>• Scheduled clinic visits</li></ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Ethnicity: Caucasians (%): TM: 61%; UC: 71%  Severity of condition:  NYHA class (%):  II: TM:42%; UC:43%  III: TM:58%; UC:52%  IV: TM:0%; UC:5%  LVEF(%): TM:25 ± 3; UC:26 ± 3	to receive data for disease management from the database.  <b>Data transfer:</b> 3 times per week  <b>Review of data:</b> usually within a day  <b>Type and timing of response:</b> Internet-based text messaging or telephone (by nurse)  <b>Actions:</b> advice on medication or dietary changes, or instructions to call or visit the office.  <b>Duration of intervention:</b> 12 months  <b>Follow-up:</b> 12 months after randomisation	<b>Data transferred:</b> BP, HR, steps/day, weight and symptoms.		
<b>KOEHLER 2011</b>  <b>Setting:</b> 165 cardiology, internal medicine, or general medicine practices  <b>Country:</b> Germany	Heart failure  Total N=710; TM: n=354; UC: n=356  Age (years), mean, (SD):  TM: 66.9(10.8); UC: 66.9 (10.5)  Gender, male sex, no. (%) : TM:285 (80.5); UC: 292 (82.0);,  Ethnicity: N/A  Severity of condition:  NYHA class, no. (%)  II: TM: 176 (49.7); UC: 180 (50.6)  III : TM:178 (50.3); UC: 176 (49.4)  LVEF %:  TM:26.9(5.7); UC: 27.0 (5.9)  Duration of heart failure, years : TM:6.7(6.6); UC: 6.8 (6.4)  Ischemic cause of heart failure, No. (%) : TM:202 (57.1; UC:) 194 (54.5)  Body weight, kg: TM: 84.7(18.9); UC: 84.7 (18.3)	<b>TM equipment:</b> a wireless Bluetooth device, together with a personal digital assistant, and distal measuring devices (a 3-lead ECG, a blood pressure device, and a weighing scale)  <b>Data transfer:</b> daily  <b>Review of data:</b> N/A  <b>Type and timing of response:</b> N/A  <b>Actions:</b> to verify measurements, to give consultation, or to institute treatment  <b>Duration of intervention:</b> 12 months  <b>Follow-up:</b> median 26 months follow-up (minimum 12 months)	Remote monitoring  <b>Data transferred:</b> ECG, BP and weight	TM vs. UC	<b>Primary outcomes:</b>  <ul style="list-style-type: none"> <li>Death from any cause</li> </ul> <b>Secondary outcomes:</b>  <ul style="list-style-type: none"> <li>Composite of cardiovascular death and hospitalisation for HF</li> <li>Days lost because of death or HF hospitalisation,</li> <li>Duration of hospitalisation for HF</li> <li>Rate of hospitalisation for a cardiovascular reason</li> <li>Rate of hospitalisation for HF</li> <li>NYHA functional classification (no numerical data)</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	<p>Body mass index, kg/m<sup>2</sup>*: TM: 28.4 (5.4); UC: 28.2 (5.3)</p> <p>BP, mm Hg;SBP: TM: 121 (16 ); UC:122 (17)</p> <p>DBP: TM: 74 (10); UC: 74 (10)</p> <p>Major co-morbidities:</p> <p>Hypertension: TM: 241 (68.1); UC: 235 (66.0)</p> <p>Hyperlipidemia : TM:262 (74.0); UC: 266 (74.7)</p> <p>Diabetes mellitus:TM: 141 (39.8); UC: 140 (39.3)</p>				<p>ta provided by authors)</p> <ul style="list-style-type: none"> <li>Physical functioning (assessed with SF-36 physical functioning score; no total scores reported)</li> <li>Depression (assessed with PHQ-9 depression score) (no numerical data provided by authors)</li> </ul>
<b>MADIGAN 2013</b>	<p>Heart failure</p> <p>Total N=99</p> <p>TM: n=55; UC: n=44</p> <p>Age, mean (yrs): TM: 75.2 ± 12.0; UC:74.4 ± 11.3</p> <p>Female (%): TM:72.7%; UC: 61.4%</p> <p>Ethnicity: African American race (%): TM: 16.4%; UC: 34.1%</p> <p>NYHA Class, n (%)</p> <p>Class II: TM: 23 (42.6);UC: 18 (42.9)</p> <p>Class III: TM: 28 (51.9); UC: 20 (47.6)</p> <p>Class IV: TM: 3 (5.6); UC: 4 (9.5)</p> <p>Preserved systolic function: 60.3%</p>	<p><b>TM equipment:</b> a trans-telephonic home monitoring device</p> <p><b>Data transfer:</b> daily</p> <p><b>Review of data:</b> clinical review of data (within a couple of hours)</p> <p><b>Type and timing of response:</b> unclear</p> <p><b>Actions:</b> the nurse contacts the physician, not further described</p> <p><b>Duration of intervention:</b> 30 days (or until discharge from HHA)</p> <p><b>Follow-up:</b> 90 and 180 days post-HHA discharge</p>	<p>Remote monitoring</p> <p><b>Data transferred:</b> BP, HR, oxygen saturation and weight</p>	<p>TM+UC vs. UC</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Hospitalisations</li> <li>ED visits</li> <li>Urgent care visits</li> <li>Home visits</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Health status</li> </ul>
<b>MORTARA 2009</b>	<p>Heart failure</p> <p>Total N=261</p> <p>TM:n=101; UC: n=160</p> <p>Age, mean± SD:</p> <p>TMI: 59±11;</p> <p>UC: 60±12</p>	<p><b>TM-equipment:</b></p> <p>tele-monitoring equipment and 24-h NICRAM<sup>10</sup> equipment</p> <p><b>Data transfer:</b> see above</p> <p><b>Review of data:</b> Each submitted vital sign parameter was subjected to an automatic range check.</p>	<p>Remote monitoring</p> <p><b>Data transmitted:</b> weight; HR; systolic arterial pressure; dyspnoea score; asthma score; ede-</p>	<p>TM +UC vs. UC</p> <p>UC=follow-up according to usual clinical practice plus pre-discharge NICRAM</p> <p>TM=UC + remote monitor-</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Bed-days occupancy for HF</li> <li>Cardiac death</li> <li>HF hospitalisation</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

<b>Country:</b> Italy, Poland, UK	Gender, female (%):	<b>Type and timing of response:</b>	ma score;	ing using con-
	TM: 16;UC: 17	Any suspect data elicited a re-	changes in	ventional tele-
	Ethnicity: N/A	request for checking by the moni-	therapy;	phone contact
	Severity of condition:	toring	blood sam-	and intermit-
	NYHA class	nurse or attending physician.	ples	tent tele-mon-
	TM: 2.5±0.6;UC: 2.3±0.6	<b>Actions:</b> best action to re-estab-	if obtained.	itoring of vital
	NYHA≥3 (%)	lish the haemodynamic balance		signs and 24-h
	TM: 49;UC: 34	following modern guidelines		NICRAM
	LVEF (%)	<b>Duration of intervention:</b>		<b>Note:</b> this was
	TM:28 ±8;UC: 30 ±7	<b>Follow-up:</b> 12 months after ran-		a 4-armed tri-
		domisation		al of which on-
		.		ly the com-
				parison be-
				tween the in-
				tervention de-
				scribed above
				and the usu-
				al care arm
				was included
				in this review.
				Interventions
				not includ-
				ed were 1)
				monthly mon-
				itoring using
				convention-
				al telephone
				contacts and
				pre-discharge
				NICRAM
				(n=104); and
				2) monitor-
				ing using con-
				ventional tele-
				phone contact
				and intermit-
				tent tele-mon-
				itoring of vital
				signs (n=96),
				both delivered
				in addition to
				UC.

<b>SCHERR 2009</b>	Heart failure	<b>TM equipment:</b>	Remote moni-	TM +UC vs UC	<b>Primary out-</b>
<b>Setting:</b> un-	Total n=120	a mobile phone, a weight scale	toring	UC=phar-	<b>comes:</b>
clear	TM:n=66; UC:n=54	with 0.1 kg accuracy and elec-		macological	• Hospitali-
<b>Country:</b>	Median age, years (IQR):	tronic display, and a sphygmo-	<b>Data trans-</b>	treatment	sation for
Austria	TM: 65 (62-72); UC: 67	manometer for fully automated	<b>ferred:</b>		worsening
	(61-72)	measurement of blood pressure	weight, blood		CHF
	Gender, male, no. (%);TM:	and heart rate.	pressure heart		• Cardiovas-
	40 (74); UC: 39 (72)	<b>Data transfer:</b>	rate and heart		cular mor-
	Ethnicity: N/A	daily	failure med-		tality
	Severity of condition:	<b>Review of data:</b>	ication dose		<b>Process out-</b>
		e- mail alerts were sent to physi-			<b>comes:</b>
		cians in the case of data being			• System
		out of range (sophisticated pre-			availability

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Median LVEF% (IQR): TM: 25 (20-38); UC: 29 (21-36)	analysis of data was not implemented)			<ul style="list-style-type: none"> <li>Cumulative transmissions</li> <li>Transmissions per patient.</li> </ul>
	NYHA class II, no. (%): TM: 7 (13); UC: 7 (13)	<b>Type and Timing of response:</b> unclear timing, directly after receiving the e-mail alert (unclear if this was only the case during office hours); mobile phone			
	NYHA class III, no. (%): TM: 33 (61); UC: 37 (68.5)				
	NYHA class IV, no. (%): TM: 14 (26); UC: 10 (18.5)	<b>Actions:</b> medication adjustments, advice and education			
	Median number of HF hospitalisations in past 12 months, no. (IQR): Intervention: 1 (1-2); Control: 1 (1-2)	<b>Duration of intervention:</b> 6 months (stopped early)			
	Median length of stay for HF hospitalisations, days (IQR): TM: 12 (9-15); UC: 11 (7-17)	<b>Follow-up:</b> 6 months from randomisation			
	Major co-morbidities:				
	Ischemic heart disease, no. (%): TM: 20 (37); UC: 23 (43)				
	Hypertension, no. (%): TM: 29 (54); UC: 24 (44)				
	Medications at BL:				
	ACE inhibitor, no. (%): TM: 45 (83); UC: 41 (76)				
	ARB, no. (%): TM: 9 (17); UC: 13 (24)				
	Diuretic, no. (%): TM: 49 (91); UC: 44 (81)				
	Beta-blocker, no. (%): TM: 47 (87); UC: 42 (78)				
	Spironolactone, no. (%): TM: 21 (39); UC: 23 (43)				
<b>SCHWARTZ 2008</b>	Heart failure Total N=102 TM: n=51; UC: n=51 Age, mean $\pm$ SD, years : TM: 77.1 $\pm$ 7.3; UC: 79.1 $\pm$ 6.9 Gender, female sex (%) ; TM: 43%; UC: 61% Ethnicity, white, (%): TM: 80%; UC: 82% NYHA class (%):	<b>TM equipment:</b> Cardiocom EHM system (Cardiocom, LLC, Chanhassen, MN) programmed to measure weight on a daily basis, and to prompt the patients to daily respond to a set of health-related questions.  <b>Data transfer:</b> daily  <b>Review of data:</b> automatic. The HF care manager was responsible for daily monitoring of received data.	Remote monitoring	TM + UC vs. UC  UC= usual post-hospital discharge care	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>Hospital re-admissions for HF</li> <li>ED visits for HF</li> <li>Time to re-admission</li> <li>Costs</li> </ul> <b>Secondary outcomes:</b>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	<p>Class II:</p> <p>TM: 24%; UC: 18%</p> <p>Class III (%):</p> <p>TM: 45%; UC: 51%</p> <p>Class IV (%):</p> <p>TM: 31%; UC: 31%</p> <p>LVEF%: N/A</p>	<p><b>Type and timing of response:</b> the nurse called the patient/caregiver in case of abnormal values</p> <p><b>Actions:</b> further assessment, up-date of medication regimen, and if necessary contact the primary physician or cardiologist</p> <p><b>Duration of intervention:</b> 3 months</p> <p><b>Follow-up:</b> 3 months after randomisation</p>	<p>fort, urination, exercise, dizziness, medication use or sodium intake)</p>	<ul style="list-style-type: none"> <li>• Depressive symptomatology</li> <li>• QOL</li> <li>• Caregiver mastery</li> <li>• Social support</li> </ul>
<p><b>SETO 2012</b></p> <p><b>Setting:</b> one UHN Heart Function Clinic</p> <p><b>Country:</b> Canada</p>	<p>Heart failure</p> <p>Total n=100; TM: n=50; UC: n=50</p> <p>Age (years), mean, (SD): TM:55.1 (13.7); UC: 52.3 (13.7)</p> <p>Gender, male no (%):</p> <p>TM:41 (82%); UC: 38 (76%)</p> <p>Ethnicity:white Caucasian no (%):TM:39 (78%); UC: 33 (66%)</p> <p>Severity of condition:</p> <p>NYHA class, no (%)</p> <p>II : TM: 21 (42%); UC: 22 (44%)</p> <p>II/III: TM: 6 (12%); UC: 5 (10%)</p> <p>III: TM: 21 (42%); UC: 21 (42%)</p> <p>IV: TM: 2 (4%); UC: 2 (4%)</p> <p>LVEF, % (SD): TM: 27.1 (7.8);UC: 27.0 (9.9)</p> <p>Major co-morbidities: N/A</p>	<p><b>TM equipment:</b> A mobile phone based TM system with wireless distal measuring devices, and alerts.</p> <p><b>Data transfer:</b> daily</p> <p><b>Review of data:</b> automatic with alerts</p> <p><b>Type and timing of response:</b>in a couple of minutes after an alert</p> <p><b>Actions:</b> calling the patient, modification of medications, etc.</p> <p><b>Duration of intervention:</b> 6 months</p> <p><b>Follow-up:</b> 6 months</p>	<p>Remote monitoring</p> <p><b>Data transferred:</b>weight, blood pressure, heart rate, and single lead ECG (only a subgroup of participants)</p>	<p>TM + UC vs. UC</p> <p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• QOL</li> <li>• Brain Natriuretic Peptide (BNP) values</li> <li>• Self-care</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Hospitalisation rate</li> <li>• Number of nights in hospital</li> <li>• Number of ED visits</li> <li>• Number of Heart Function Clinic visits.</li> <li>• Mortality</li> <li>• In addition, LVEF, NYHA class, medication prescriptions, and blood test results (specifically creatinine, sodium, potassium, haemoglobin, and urate values) were also subsequently analysed.</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

<b>SORAN 2008</b>  <b>Setting:</b> 3 academic sites with affiliations to a major academic medical centre  <b>Country:</b> USA	Heart failure  Total N=315  TM: n=160; UC: n=165  Age, mean±SD : TM: 76.9 ± 7.1; UC: 76.0 ± 6.8  Gender, female sex(%): TM: 68.7%; UC: 60.6%  Ethnicity: White/Black (%): TM:57.5/41.9%; UC: 47.7/52.3%  NYHA class (%)  II : TM: 57.5; UC: 59.3  III: TM: 42.5; UC: 40.7  LVEF %, mean: TM:24.3±8.8 ; UC:23.8±8.7	<b>TM equipment:</b> A computer-based telephonic monitoring system which included an electronic scale and an individualized symptom response system linked via a standard phone line to a computerized database.  <b>Data transfer:</b> daily  <b>Review of data:</b> automatic  <b>Type and timing of response:</b> in case of an alert the nurses immediately contacted the patients  <b>Actions:</b> the nurse confirmed with patient notified the physician about worsening symptoms; the physician could adjust medications, schedule an office visit, or initiate other therapeutic changes with the goal being to prevent further deterioration and to stave off the need for a hospitalisation.  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 6 months from randomisation	Remote monitoring (for detection of early signs and symptoms of heart failure)  <b>Data transferred:</b> weight and responses to health-related questions	TM +UC vs..UC	<b>Primary outcomes:</b>  <ul style="list-style-type: none"> <li>• Treatment failure= a composite of cardiovascular death or re hospitalisation for HF within 6 months of enrolment</li> <li>• Length of hospital stay (among patients re-hospitalised for HF)</li> </ul> <b>Secondary outcomes:</b>  <ul style="list-style-type: none"> <li>• All-cause re-hospitalisations</li> <li>• HF-related re-hospitalisations</li> <li>• QOL (will be reported separately in another publication)</li> <li>• Costs (will be reported separately in another publication)</li> </ul>
<b>SPAEDER 2006</b>  <b>Setting:</b>  2 Hospital Outpatients CHF clinics  <b>Country:</b> USA	Heart failure  Total N=49  TM: n=24; UC: n=25  Age, mean (SD): TM: 56.4 (14.4); UC: 52.7 (17.2)  Gender, male sex, (%): TM: 72%; UC: 63%	<b>TM equipment:</b> a telephone-based, automated, voice interactive, 2-way store and forward TM system, with alerts.  <b>Data transfer:</b> daily  <b>Review of data:</b> automatic analysis  <b>Type and timing of response:</b> immediately in case of an alert  <b>Actions:</b> treatment changes	Remote monitoring for Medication therapy  Data transferred:	TM + UC vs. UC	<b>Primary outcome:</b>  <ul style="list-style-type: none"> <li>• Time to reach final carvedilol dose</li> </ul> <b>Secondary outcomes:</b>



**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Ethnicity: white, (%): TM: 76%; UC: 54%  NYHA class  II: TM:11 (44%); UC: 14 (58%)  III: TM:14 (56%); UC: 10 (42%)  LVEF(%)  TM: 22.1 (7.9); UC:22.3 (6.0)	<b>Duration of intervention:</b> 3 months  <b>Follow-up:</b> 3 months from randomisation			<ul style="list-style-type: none"> <li>• Mean carvedilol dose</li> <li>• Adverse events</li> </ul>
<b>WAKEFIELD 2008</b>  (Wakefield 2009)  <b>Setting:</b> one VAMC, one tertiary care referral centre  <b>Country:</b> USA  :	HF patients recently discharged from hospital  N=101  TM: n=52; UC: n=49  Age (mean, SD): TM: 69.0 (9.6); UC: 67.2 (8.5)  Gender, male sex (%):TM: 98% ; UC: 98%  Ethnicity, White: TM:88% ; UC: 100%  NYHA class (%): II: TM: 21 (11);  UC:35% (17)  III: TM:71% (37);  UC:59 (29)  IV: TM:8 (4); UC:6(3)  LVEF% (mean, range): TM: 38% (6-73%);  UC:43% (12-83%)  LVEF > 41%: TM:36.5%(19);  UC:40.4(23)  LVEF 26-40%: TM:32.7(17)  UC:31.9 (15)  LVEF < 25%: TM:30.8 (16)  UC:19.2 (9)	<b>TM equipment:</b> Video-phone +electronic blood pressure monitor & scale +use of check-list  <b>Data transfer:</b> three times the first week after discharge, and then weekly for 11 weeks (14 contacts over 3 months)  <b>Type and timing of response:</b> N/A  <b>Actions:</b> N/A  <b>Duration of intervention:</b> 3 months  <b>Follow-up:</b> 12 months after randomisation	Assessment and self-care education.  <b>Data transferred:</b> N/A	TM vs. UC  UC= Follow-up clinic appointments scheduled in the usual manner.  Note: a third study arm (telephone only, n=47) was not included in this review	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>• Re-admissions</li> <li>• Urgent care visits</li> <li>• Mortality</li> <li>• QOL</li> <li>• Self-efficacy</li> <li>• Medication adherence</li> </ul>
<b>WEINTRAUB 2010</b>	Heart failure	<b>TM equipment:</b> The TM system comprised measurement and communication compo-	Remote monitoring	TM+UC vs. UC	<b>Primary outcomes:</b>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

<b>(and Kon-stam 2010)</b>	Total n=188; TM: n=95; UC: n=93	nents (i.e., transmission of body weight, and vital signs via a standard telephone line to a central server), and an interactive communication device designed to convey text information regarding symptoms, functional status, and compliance to medication.	<b>Data transferred:</b> body weight, blood pressure, and heart rate, and	<ul style="list-style-type: none"> <li>HF hospitalisation rate</li> </ul>
<b>Setting:</b> 4 hospital sites	Age (years), mean, (SD): TM: 69.5 (14.2); UC: 68.5 (12.8)		answers to health / symptom-related questions	<b>Secondary outcomes:</b>
<b>Country:</b> USA	Gender: Male n (%): TM: 60 (63.2%); UC: 64 (68.8%)	<b>Data transfer:</b> daily		<ul style="list-style-type: none"> <li>Time-to-event for death or HF hospitalisation and death or all-cause hospitalisations</li> <li>Heart failure inpatient days</li> <li>All-cause inpatient days</li> </ul>
	Ethnicity: Race Black n (%): TM: 10 (10.5%); UC: 5 (5.4%) .45	<b>Review of data:</b> clinical review of patient data; Monday-Friday; automated review of the answers to the health-related questions		
	Hispanic n (%): TM: 3 (3.2%); UC: 6 (6.5%)	<b>Type and timing of response:</b> the same day but not on weekends; telephone		
	Native n (%): TM: 1 (1.1%); UC: 1 (1.1%)	<b>Actions:</b> call the patient to discuss the deviation and to initiate an intervention if necessary		
	White n (%): TM: 81 (85.3%); UC: 81 (87.1%)	<b>Duration of intervention:</b> 90 days		
	Severity of condition:	<b>Follow-up:</b> 90 days		
	LVEF% Mean (SD): TM: 32.1% (17.2%); UC: 27.2% (15.8%)			
	NYHA Class I n (%):			
	TM: 1 (1.1%); UC: 2 (2.2%)			
	II : TM: 42 (44.2%); UC: 44 (47.3%)			
	III : TM: 48 (50.5%); UC: 46 (49.5%)			
	IV: TM: 4 (4.2%); UC: 1 (1.1%)			
	Major co-morbidities:			
	Ischemic CM Yes n (%): TM: 42 (44.2%); UC: 53 (57.0%)			
	Hypertension Yes n (%): TM: 64 (68.1%); UC: 64 (69.6%)			
	Diabetes Yes n (%): TM: 45 (47.4%); UC: 36 (38.7%)			
<b>WOODEND 2008</b>	Heart failure or angina (at high risk of readmission)	<b>TM-equipment:</b>	Remote monitoring, assessment and self-care education.	<b>Primary outcomes:</b>
	Total N=249	Video-conferencing in combination with phone line transmission of vital signs. Weigh scales and BP and ECG machines were all electronic, and data were transmitted by telephone lines to a central station that held the electronic patient record.	<b>Data transferred:</b> weight, BP, and ECG	<ul style="list-style-type: none"> <li>Hospital readmission</li> <li>Days spent in hospital</li> <li>QOL</li> <li>Functional status</li> </ul>
<b>Setting:</b> one hospital	Heart failure			
<b>Country:</b> Canada	TM: n=62; UC: n=59			
	Angina			

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

TM: n=62; UC: n=66	<b>Data transfer:</b> daily transmission of weight and blood pressure, and periodic transmission of 12-lead ECG
Age, mean (SD): HF: TM: 67 ±13; UC: 66 ±11; Angina: TM: 66 ±12; UC: 65 ±10	<b>Review of data;</b> unclear
Gender, male (%): HF:	<b>Type and timing of response:</b> N/A
TM: 74% ; UC: 70%; Angina:	<b>Actions:</b> at least weekly video-conferences; more frequent in the first few weeks after discharge and tapered over the 3-month period)
TM: 77% ; UC: 79%	<b>Duration of intervention:</b> 3 months
Ethnicity: N/A	<b>Follow-up:</b> 6 months from randomisation
NYHA class: N/A	
LVEF%: N/A	

# PATIENTS RECOVERING FROM CARDIAC EVENT, SURGERY OR PROCEDURE.

<b>CHIANTERA 2005</b>	Recent acute coronary syndrome.	<b>TM equipment:</b> A portable device which enabled a 12 -lead ECG to be recorded and transmitted to the service centre by fixed or mobile telephone	Remote monitoring	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> 1 coronary care unit (acute care)	Total N=200; TM: n=99;UC: n=101	<b>Data transfer:</b> at least once weekly	<b>Data transferred:</b> ECG trace		<ul style="list-style-type: none"> <li>Hospitalisations</li> <li>Occurrence of angina</li> </ul>
<b>Country:</b> Italy	Age, mean yrs:61 years (SD 12)	<b>Review of data:</b> unclear			
	Gender, male sex (%):80.5%	<b>Type and timing of response:</b> unclear			
	Ethnicity: N/A	<b>Actions:</b> The nursing staff and the cardiologist issued a medical report and eventually proceeded to an interactive consultation with the patient.			
	Risk score: TM:16.6 (SD12.8); UC: 15.9 (SD12.4)	<b>Duration of intervention:</b> 4 weeks			
		<b>Follow-up:</b> one month after end of the intervention			
<b>WALDMANN 2008</b>	Patients with cardiovascular disease	<b>TM equipment:</b> trans-telephonic ECG system	Consultation	TM + UC vs. UC	<b>Primary outcomes</b>
(Katalinic 2008)	Total N=1541	<b>Data transfer:</b> Whenever the patients had symptoms they could call the call centre, transmit an ECG (without re-dialling) and consult a physician.	<b>Data transferred:</b> ECG trace		<ul style="list-style-type: none"> <li>A composite end point of all-cause mortality, myocardial infarction, re-hospitalisation or re-</li> </ul>
<b>Setting:</b> 11 hospitals	TM: n=774; UC: n=767	<b>Review of data:</b> real time			
	Age, mean ± SD : TM:63 ± 10 years; UC: 64± 10 years	<b>Type and timing of response:</b> N/A			
<b>Country:</b> Germany	Gender, female sex (%) ; TM: 23%; UC: 27%				
	Ethnicity: N/A				

Interactive telemedicine: effects on professional practice and health care outcomes (Review)

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**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Severity of condition:	<b>Actions:</b> a mobile intensive care being sent to the patient, or a consultation with a general practitioner or a cardiologist, or a change of medication being recommended, or the patient being re-assured that the situation was not life-threatening.			vascularisation
	NYHA class: N/A				
	LVEF%:N/A				<b>Secondary outcomes:</b>
	ST-Elevation Myocardial Infarction (STEMI, %): TM: 57%; UC:54%	<b>Duration of intervention:</b> 12 months			<ul style="list-style-type: none"> <li>No and lengths of hospital stays</li> <li>QOL</li> <li>Depression</li> <li>Satisfaction</li> </ul>
		<b>Follow-up:</b> 12 months from randomisation			
<b>PATIENTS RECOVERING FROM IMPLANTATION OR REPLACEMENT OF CARDIAC MEDICAL DEVICE (ICD, PM)</b>					
<b>AL KHATIB 2010</b>	Heart disease patients after Implantation of a Cardioverter Defibrillator (ICD)	<b>TM equipment:</b> Medtronic CareLink transmission monitor.	Remote monitoring/ Surveillance of ICDs	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> 1 Medical Centre:	N= 151	<b>Data transfer:</b> every 3 months		UC= quarterly device interrogations in clinic.	<ul style="list-style-type: none"> <li>Hospitalisations due to cardiovascular reasons</li> <li>ED visits for a cardiac cause</li> <li>Unscheduled visits to the electrophysiology clinic (for a device-related issue)</li> </ul>
<b>Country:</b> USA	TM: n=76; UC: n=75	<b>Review of data:</b> within 48 hours, or directly if abnormal data	<b>Data transferred:</b>		
	Age, mean (yrs):	<b>Type and timing of response:</b> patient only contacted if abnormal data	information from the ICD		
	TM: 63 (54, 70); UC: 63 (54, 72)	<b>Actions:</b> further evaluation			
	Gender, male sex (%);	<b>Duration of intervention:</b> 12 months			
	TM: 72%;UC: 73%	<b>Follow-up:</b> 12 months from randomisation			
	Ethnicity, white race (%):				<b>Secondary outcomes:</b>
	TM: 62%;UC: 64%				<ul style="list-style-type: none"> <li>Use of evidence-based medications</li> <li>HRQOL</li> <li>Patient satisfaction</li> <li>Costs, cost-effectiveness</li> </ul>
	Severity of illness:				
	NYHA class, %				
	I: TM:20%; UC:20%				
	II: TM:80%; UC:75%				
	III:TM:0; UC: 5				
	IV:TM:0; UC: 0				
<b>CROSSLEY 2011</b>	Heart disease patients after implantation of a cardioverter-defibrillator (ICD)	<b>TM equipment:</b> Home monitor with automatic alerts and advanced diagnostics. Not further described.	Remote monitoring/ Surveillance of ICD	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b>	Total N=1 997	<b>Data transfer:</b> automatic alerts	<b>Data transferred:</b> alerts and advanced diagnostics		<ul style="list-style-type: none"> <li>Time to clinical decision</li> </ul>
136 clinical sites	TM: n=1 094; UC: n=983				<b>Secondary outcomes:</b>
<b>Country:</b> USA					

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	Age, mean (SD)yrs: TM: 65.2 (12.4); UC: 64.9 (11.9) Gender, male sex (%): TM:70.5%; UC: 71.7% Ethnicity: N/A NYHA class, % Class I : TM:3.9%; UC:4.7% Class II: TM: 40.9%; UC:39.5% Class III: TM:48.5%; UC:47.5% Class IV: TM: 1.5%; UC: 1.5% LVEF, % (SD) TM: 28.6(10.0); UC: 29.2 (10.3)	<b>Review of data:</b> a clinician viewed the data within 1.5 days (70% of the time).  <b>Type and timing of response:</b> unclear  <b>Actions:</b> Echo, ECG, change in CV oral medication ,device interrogation, device testing, system modification, blood test, chest x-ray, cardioversion, and TEE  <b>Duration of intervention:</b> 15 months  <b>Follow-up:</b> 15 months from randomisation	<ul style="list-style-type: none"><li>CV-related hospitalisations</li><li>CV-related ED</li><li>Visits</li><li>CV-related clinic office visits</li></ul>	
<b>HALIMI 2008</b>  <b>Setting:</b>  38 French and 1 Belgian medical centre  <b>Country:</b> France and Belgium	Heart disease patients after implantation or replacement of a dual-chamber pacemaker (PM)  Total N=379  TM: n=184; UC: n=195  Age:75±9.8 years  Gender, male (%):61%  Ethnicity: N/A  NYHA class: N/A  LVEF %: N/A	<b>TM equipment:</b> A tele cardiology system capable of automatically transmitting the data stored in implantable devices.  <b>Data transfer</b> automatic transfer of data from PM  <b>Review of data:</b> the data transmitted were analysed daily  <b>Type and timing of response:</b> unclear  <b>Actions:</b> In the event of an alert the cardiologist was notified by e-mail, facsimile, or text message, allowing the rescheduling of the next follow-up visit.  <b>Duration of intervention:</b> 24 days  <b>Follow-up:</b> one month after randomisation	Remote monitoring/ Follow-up after pacemaker implantation/ or replacement.  <b>Data transferred:</b> parameters of device function	TM vs. UC (FTF nurse visits optional)  <b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Major adverse events</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>Hospital length of stay</li><li>Putative cost savings</li><li>QOL</li></ul>
<b>HYPERTENSION</b>				
<b>ARTINIAN 2007</b>  (Artinian 2001)	Hypertension  Total: n=387  TM: n=194; UC: n=193  Age, M ± SD (years):	<b>TM-equipment:</b>  BP monitors and a trans-telephonic BP Link Communicator  <b>Data transfer:</b>	Self-Care Education  <b>Data transferred:</b> BP	TM+UC vs. UC  UC: Enhanced UC for participants included visits to  <b>Primary outcomes:</b> <ul style="list-style-type: none"><li>SBP</li><li>DBP</li></ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

<b>Setting:</b> unclear (participants were recruited at community centres, thrift stores, drug stores, and grocery stores)	TM: 59.1±13.0;	BP monitoring 3 times per week; patients sent their BP readings	their primary care provider (PCP) scheduled at intervals requested by the PCP. Participants who did not have a PCP were provided with a list of locations where they could obtain a PCP and free or low-cost healthcare. Participants who could not afford their medications were enrolled in a pharmacy assistance program.
	UC: 60.2 ±12.3		
	Gender, female sex no (%); TM: 114 (59); UC: 135 (70)	once a week during the first 3 months of the study, then once a month between the 4- and 12-month follow-ups.	
	Ethnicity: Afro Americans 100%		
<b>Country:</b> USA	Severity of condition:		
	Mean Number of antihypertension medications taken 7.87	<b>Type and timing of response:</b> Once the nurses received the BP reports, they telephoned each participant.-weekly between baseline and 3-month follow-up, monthly between 4 and 6 months, and then	
	SBP, mmHg: TM:156.8 (19.6); UC:155.9 (19.2)	once at 8 months.	
	DBP, mmHg: TM:89.5 (14.0); UC:88.4 (13.0)		
		<b>Actions:</b> the nurse provided telephone counselling about lifestyle modifications and medication adherence	
		<b>Duration of intervention:</b> 8 months	
		<b>Follow-up:</b> 12 months after randomisation	

<b>MADSEN 2008</b>	Hypertension	<b>TM-equipment:</b>	Remote monitoring of chronic condition for improved medication treatment.	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> GP practices (unclear number)	Total: n=236 TM: n=113;UC: n=123	A semi-automatic BP measuring device connected to a PDA. Automatic registration and transfer of BP data to a server, over which patient and provider can be in contact. For patients with no Internet access, the PDA could record and send spoken messages to the GP, who could respond by written messages to the PDA.	<b>Data transferred:</b> BP	UC: patients were instructed to visit their GP as often as needed.	<ul style="list-style-type: none"> <li>Systolic daytime ABPN (reported in Madsen 2008 a)</li> </ul>
<b>Country:</b>	Age, years (SD):				
Denmark	TM: 54.5(11.5); UC: 56.7 (11.5)				
	Body mass index (SD): TM: 28.0 (6.6); UC: 29.5 (12.5)				
	Gender, female sex no, % (SD): TM: 54 (51.4); UC: 59 (50.0)	<b>Data transfer:</b> 3 times per week for the first 3 months and once a week for the last 3 months of monitoring.			<b>Secondary outcomes:</b>
	Ethnicity: N/A	<b>Type and timing of response:</b> the physician contacted the patients through e-mail or the PDA			
	Severity of condition:				
	Years since diagnosis of hypertension: TM: 3.1 (5.9); UC: 3.3 (5.9)				
	No of antihypertensive drugs :TM: 1.3 (0.9); UC: 1.5 (1.2)	<b>Actions:</b> contact patients if BP measurements were not performed, and to institute or change antihypertensive treatment at their own discretion, (and to instruct patients in correct technique to measure BP)			<ul style="list-style-type: none"> <li>HRQOL (reported in another Madsen 2008 paper)</li> <li>Diastolic daytime ABPM</li> <li>Systolic and diastolic nighttime ABPM</li> <li>Number of patients who achieved</li> </ul>

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

		<b>Duration of intervention:</b> 6 months			normal daytime ABPM and target BP (home BP in the intervention group, office BP in the control group)
		<b>Follow-up:</b> 6 months from randomisation			
<b>PARATI</b>	Hypertension	<b>TM-equipment:</b> An oscillometric device equipped with a built-in modem permanently plugged to the house phone.	Remote monitoring	TM vs. UC	<b>Primary outcomes</b>
<b>2009</b>	Total: n=329			UC: of-fice-based BP management, treatment aimed at reducing of-fice BP to less than 140/90 mmHg.	
<b>Setting:</b> probably PCPs as 12 primary care physicians were included	TM: n=216;UC: n=113 Age, mean SD (years): TM: 57.2(10.7); UC: 58.1(10.8)	<b>Data transfer:</b> unclear (regularly transmitted)	<b>Data transferred:</b> BP		<ul style="list-style-type: none"> <li>Percentage of patients who reached normalisation of day-time ambulatory SBP and DBP (i.e. &lt;130/80 mmHg) at the end of the follow-up period</li> </ul>
<b>Country:</b> Italy	Gender, male sex, n (%): TM: 102 (54.5); UC: 60 (54.1) Ethnicity: N/A Severity of condition: N/A	<b>Type and timing of response:</b> in case of an alarm a nurse called the patient			
		<b>Actions:</b> to check the clinical status of patient and the possibility of artefactual measurements.			
		Whenever needed, the physician in charge was immediately alerted, and an additional office visit was scheduled.			<b>Secondary outcomes:</b>
		<b>Duration of intervention:</b> 24 weeks			<ul style="list-style-type: none"> <li>Rate of normalisation of office SBP/DBP</li> <li>Frequency of treatment changes originated either by the physician or by the patient</li> <li>QOL</li> <li>Costs.</li> </ul>
		<b>Follow-up:</b> 24 weeks after randomisation.			
<b>ROGERS</b>	Hypertension	<b>TM-equipment:</b> Trans-telephonic automatic home BP monitor.	Remote monitoring	TM vs. UC	<b>Primary outcomes:</b>
<b>2000</b>	(patients with essential hypertension being considered for a change in treatment)			UC= Patients assigned to usual care were treated for hypertension according to the guidelines of	
<b>Setting:</b> university affiliated primary care outpatient clinics	Total: n=121 TM: n=60; UC: n=61	<b>Data transfer:</b> at least 3 times per week	<b>Data transferred:</b> BP		<ul style="list-style-type: none"> <li>Change in mean arterial pressure (measured as diastolic pressure 1</li> </ul>
		<b>Type and timing of response:</b> the physician contacted the pa-			

**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

(unclear number)	Age, mean $\pm$ SD:	tient through telephone, office visit or both telephone and visit	the Joint national Committee on Prevention, Detection, and Treatment of High Blood Pressure.	1/3 [systolic pressure - diastolic pressure]].
<b>Country:</b> USA	TM: 62.6 $\pm$ 10.0 years; UC: 60.3 $\pm$ 11.9 years	<b>Actions:</b> The results were weekly converted to a report form and faxed to the patient's physician. where after s/he could take actions in case of elevated pressure		<b>Secondary outcomes:</b>
	Gender, female sex no (%); TM: 34 (56.7); UC: 27 (44.3)	<b>Duration of intervention:</b> at least 8 weeks		<ul style="list-style-type: none"> <li>Changes in systolic pressure, diastolic pressure, and heart rate (by using 24-hour ABPM).</li> <li>Percentage of readings above target levels</li> </ul>
	Ethnicity, white no (%): TM:46 (80.7); UC: 52 (91.2)	<b>Follow-up:</b> at least 8 weeks from randomisation		
	Severity of condition:			
	Mean BMI $\pm$ SD, kg/m <sup>2</sup> : TM: 31.5 $\pm$ 7.6; UC: 28.9 $\pm$ 5.2			

## STROKE

<b>MEYER 2008</b>	Suspected Stroke	<b>TM equipment:</b> a video-conferencing system with two way audio and video, and digital imaging and communication in medicine (DICOM) enabling interpretation of CT images	Hub stroke team and consultants	TM vs. UC (telephone)	<b>Primary outcomes:</b>
<b>Setting:</b> four remote spoke sites (acute care)	Total N= 234; TM:111; UC (telephone): 111	<b>No of sessions:</b> one index appointment			<ul style="list-style-type: none"> <li>Correct decision to treat with thrombolytics</li> </ul>
<b>Country:</b> USA	Age, years, mean $\pm$ SD: TM: 70.4 $\pm$ 14.5; UC:69.0 $\pm$ 14.9	<b>Follow-up:</b> 90 days			<b>Secondary outcomes:</b>
	Gender, female sex no (%); TM:57 (51); UC:57 (51)				<ul style="list-style-type: none"> <li>Rate of Intravenous thrombolytic use</li> <li>90 day functional outcomes</li> <li>Intracerebral haemorrhage</li> <li>Data completeness</li> <li>Technical observations</li> </ul>
	Ethnicity, white no (%): TM:106 (96); UC:105 (95)				<b>Follow-up time:</b> 90 days after index consultation
	Severity of condition:				
	Baseline mRS <sup>11</sup> (Complete Scale) n (%),dichotomised (0-1): TM:78 (72); UC: 86 (78)				
	Baseline NIHSS (National Institute of Health stroke Score), mean (SD) TM: 11.4 (8.7); UC: 7.7 (7.0) (S)				
	mNIHSS <sup>12</sup> Mean $\pm$ SD (Median): TM:8.8 $\pm$ 7.4 (8); UC: 5.9 $\pm$ 5.9 (4)				
	CT scan normal, no (%): TM:29(26); UC:49 (45)				
	Major co-morbidities:				
	Coronary disease, n (%):TM; 37 (33) (3% un-				



**Table 1. Summary of Characteristics of Cardiovascular disease studies** (Continued)

	known); UC: 24 (22) (10% unknown)				
	MI <sup>13</sup> , n (%): TM:12 (11) (12% unknown); UC: 5 (5) (15% unknown)				
	Prior CVA, no (%): TM:40 (36) (5% unknown); UC: 41 (37) (5% unknown)				
	Hypertension, no (%): TM:83 (75) (5% unknown); UC: 81 (73) (2% unknown)				
PIRON 2009	Stroke	TM-equipment	Rehabilitation	TM vs UC	Primary outcomes:
<b>Setting:</b> one rehabilitation facility	Total N=36 TM: n=18; UC: n=18	A combined virtual-reality TM (video-conferencing) intervention delivered via the Internet, which provided motor tasks to the patients.	<b>Data transferred:</b> N/A	UC: traditional physical therapy for the upper limb	<ul style="list-style-type: none"> <li>• Motor performance</li> <li>• Functional activity of the upper extremity</li> <li>• Spasticity</li> </ul>
<b>Country:</b> Italy	Age, mean (SD): TM: 66.0 (7.9); UC: 64.4 (7.9)	<b>Data transfer:</b> N/A			
	Gender, men/women: TM: 11/7; UC: 10/8	<b>Review of data:</b> N/A			
	Ethnicity: N/A	<b>Type and timing of response:</b> real time feedback about the tasks' exactness			
	Severity of condition: N/A (check)	<b>Actions:</b> N/A			
		<b>Duration of intervention:</b> 4 weeks			
		<b>Follow-up:</b> 4 weeks after the end of intervention			

1 NYHA class: the New York Heart Association functional classification according to the severity of symptoms. Four categories based on how much they are limited during physical activity (I to IV- lower is better).

2 LVEF %: percent left ventricular ejection fraction. Represents the fraction of blood within the left ventricle pumped out with each heartbeat. A typical normal value is 58% (range 55 to 70 % is considered normal).

3 ECG- Electrocardiography

4 BP = Blood Pressure

5 HR= Heart Rate

6 QOL= Quality of Life

7 HHCA= Home Health Care Agency

8 LoS= Length of (hospital) Stay

9 IVR system= Interactive Voice Response System

10 NICRAM= a system to record cardiorespiratory and physical activity signals usually during a 24 hours period.

11 rMS = modified Rankin scale. A scale used for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability.

12 mNIHSS = modified National Institutes of Health stroke scale score

13 MI= Myocardial Infarction

**Table 2. Summary of Characteristics of Diabetes studies**

Author Year Setting Country	Clinical condition/ Characteristics of Par- ticipants	Type of TM system and Characteristics of intervention	Function	Comparison	Outcomes
<b>TYPE 1 DIABETES (N=9)</b>					
<b>AHRING 1992</b>  <b>Setting:</b> 2 hospital en- docrine clinics  <b>Country:</b> Canada	Type 1 diabetes (insulin dependent)  Total N= 42  TM: n=22; UC :n=20  Age, mean± SD, yrs:  TM: 41.60 ± 16.93; UC 41.25 ± 13.90  Body weight, kg:77.8 kg  Gender, men/women:  22 /20  Ethnicity: N/A  Severity of condition:  Duration of diabetes, mean (SD): TM:11.93 ± 11.43 years; UC: 11.19 ± 4.51 years  Major co-morbidities: N/ A	<b>TM-equipment</b>  Glucofacts data-link telephone modem and glucometer M.  <b>Data transfer:</b> stored blood-glu- cose values transferred using a modem once a week  <b>Review of data:</b> clinical review  <b>Type and timing of response:</b> Weekly advice given to the pa- tients over the phone if needed  <b>Actions:</b> advice given on how to adjust insulin dosage or food in- take  <b>Duration of intervention:</b> 12 weeks  <b>Follow-up:</b> 12 weeks from ran- domisation	Remote moni- toring  and adjust- ment of med- ication thera- py.  <b>Data trans- ferred:</b> blood glucose	TM vs. UC  UC= patients took results of glucose mea- surements to routine clin- ic visit at 0, 6, and 12 weeks.	<b>Primary out- comes:</b> <ul style="list-style-type: none"><li>• HbA1c<sup>1</sup> (%)</li><li>• Random blood glu- cose</li><li>• No of hypo- glycaemic episodes</li><li>• Weight</li><li>• Satisfac- tion of pa- tients, car- ers and healthcare profession- als (inter- vention group only)</li></ul>
<b>BIERMANN 2000</b>  <b>Setting:</b> one diabetes hos- pital centre  <b>Country:</b> Ger- many	Type 1 diabetes (patients on intensified insulin therapy)  .  Total N= 48  TM: n=30; UC :n=18  Age, mean years (SD): TM: 30.5 (11); UC: 30.0 ( 8.6)  Gender: N/A  Ethnicity: N/A  Severity of condition:  Unstable metabolic con- trol: TM: 9 patients; UC: 3 patients  Duration of diabetes, yrs:TM: 10.9; UC: 8.1	<b>TM-equipment</b>  A TM system for transmission of self-monitored and stored blood glucose values using a combined modem-interface and ordinary telephone lines.  <b>Data transfer:</b> Every 1 to 3 weeks  <b>Review of data:</b> unclear  <b>Type and timing of response:</b> every 2 to 4 weeks depending on the extent of specific problems, or the day after if urgent  <b>Actions:</b> advice on insulin dose were given over the phone  Note: For urgent consultations, patients were able to contact the centre via a 24-hour voice recorder system and a consulta- tion with the physician was es- tablished the following day	Remote moni- toring and ad- justment of medication therapy.  <b>Data trans- ferred:</b>  blood glucose	TM vs. UC	<b>Primary out- comes:</b> <ul style="list-style-type: none"><li>• HbA1c</li><li>• Patient time ex- penditure</li><li>• Physician time ex- penditure</li><li>• No of hypo- glycaemic events (da- ta present- ed in graph)</li><li>• Costs (no data re- ported)</li></ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	Major co-morbidities: N/A	<b>Duration of intervention:</b> 4-8 months			
		<b>Follow-up:</b> 4-8 months after randomisation			
<b>CHARPENTIER 2011</b>	<p>Type 1 diabetes</p> <p>Total n= 120; Intervention:n=59;</p> <p>Usual care: n=61</p> <p>Age (years), mean, (SD): TM: 31.6 (12.5); UC:36.8 (14.1)</p> <p>Gender: Male, TM: 22 (37.3%); UC:21 (34.4%)</p> <p>Ethnicity: N/A</p> <p>Severity of condition:</p> <p>Retinopathy: TM: 12/56 (21.4%); UC:17/58 (29.3%)</p> <p>Nephropathy: TM: 7 (11.9%); UC: 4/58 (6.9%)</p> <p>Clinical neuropathy: TM: 7 (11.9%); UC: 9/59 (15.3%)</p> <p>Insulin pump: TM: 36.7% (22); UC: 36.1% (22)</p> <p>HbA1c at baseline: TM: 9.11 (1.14); UC: 8.91 (0.90)</p> <p>Duration of diabetes, years, mean (SD): TM:14.7 ( 9.1); UC:16.9 (10.5)</p> <p>BMI kg/m2: TM: 25.8 (5.0); UC:25.1 ( 6.8)</p> <p>Major co-morbidities:N/A (young population)</p>	<p><b>TM equipment:</b>a smart phone with a software which calculates insuline doses Participant SMPG, diet, and insulin treatment data were automatically uploaded by the smart phone to a secured website, where they were available to investigators at any time, including during the tele consultations.</p> <p><b>Data transfer:</b>daily</p> <p><b>Review of data:</b>tele consultations every 2 weeks</p> <p><b>Type and timing of response:</b>telephone every two weeks</p> <p><b>Actions:</b>support and dose adjustments</p> <p><b>Duration of intervention:</b> 6 months</p> <p><b>Follow-up:</b> 6 months after recruitment</p>	<p>Remote monitoring/ consultation and adjustment of medication therapy.</p> <p><b>Data transferred:</b> blood glucose</p>	<p>TM (partly substituting for UC) vs. UC</p> <p>Note: a third study arm (Diabeo without telephone consultations, n=60) was not included in this review.</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>HbA1c levels</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Change in the HbA1c level</li> <li>Proportion of patients reaching the HbA1c target of &lt; 7.5%</li> <li>Change in SMBG<sup>2</sup> frequency</li> <li>Change in QoL</li> <li>Time spent by investigators conducting face-to-face visits or tele consultations, and by the participants coming for hospital visits</li> <li>Major hypoglycaemia episodes</li> <li>Minor hypoglycaemia episodes</li> </ul>
<b>CHASE 2003</b>	<p>Type 1 diabetes</p> <p>Total N=70;</p> <p>TM: n=35 ;UC: n=35</p> <p>Age, mean (SD) years: TM:17.4 (1.7); Control:17.2 (1.5)</p>	<p><b>TM equipment:</b> Acculink Modem, not further described</p> <p><b>Data transfer:</b>every two weeks</p> <p><b>Review of data:</b>clinical review of data</p>	<p>Remote monitoring</p> <p><b>Data transferred:</b> blood glucose</p>	<p>TM (intervention replacing one of three face-to-face visits) vs. UC</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>HbA1c</li> <li>Hypo- and hyper- glycaemic events</li> <li>Costs</li> </ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	Gender, male/female sex:TM:14/16; UC: 16/17	<b>Type and timing of response:</b> unclear, but probably every two weeks			
	Ethnicity: all Caucasian and Hispanic	<b>Actions:</b> to discuss the data and make medication adjustments			
	Severity of condition:	<b>Duration of intervention:</b> 6 months			
	Duration of diabetes, years (mean): TM:8.4 (4.6); UC: 7.4 (3.1)	<b>Followup:</b> 6 months after randomisation			
	BL HbA1c: TM:9.0 (1.2); UC:8.9 (1.1)				
	Major co-morbidities:N/A				
<b>IZQUIERDO 2009</b>	Type 1 diabetes (children)	<b>TM-equipment</b> Video-conferencing system. A TM system with a centrally managed Internet-based portal connecting the school and diabetes centre, enabling clinical data exchange and school-based care diabetes-related education.	Consultation/treatment and education (mostly through web-based resources)	TM+UC vs. UC	<b>Primary outcomes:</b> • HbA1c (e-mailed author for raw-data 26/02/13)
<b>Setting:</b> school nurses offices and diabetes hospital centre	Total N= 41 TM: n=23; UC :n=18 Age, mean years (SD): TM:9.74 (2.2); UC: 10.56 (2.5)	<b>Data transfer:</b> N/A	<b>Data transferred:</b> N/A		<b>Secondary outcomes:</b> • Paediatric QOL <sup>3</sup> (e-mailed author for raw-data 26/02/13) • Urgent encounters • Urgent calls • Treatments needed
<b>Country:</b> USA	Mean BMI kg/m2: TM:18,2 kg/m2; UC: 20 3 kg/m2 Gender: N/A Ethnicity: most subjects were white Severity of condition:: HbA1c levels: TM: 8.53% (1.86); UC: 8.67% (1.05) Mean duration of diabetes, years: TM:5.1 (3.3); UC: 4.7 (3.4)	<b>Review of data:</b> N/A <b>Type and timing of response:</b> N/A <b>Actions:</b> N/A <b>Duration of intervention:</b> 12 monthly sessions; 12 months <b>Follow-up:</b> 12 months after randomisation			
<b>JANSA 2006</b>	Type 1 Diabetes (patients with poor metabolic control)	<b>TM-equipment</b> GlucoBeep glucose monitoring system with trans-telephonic patient data transfer, and a server which also invites the patient to leave a 1-min vocal message concerning insulin doses and events.	Remote Monitoring and self-management education	TM vs. UC UC=12 outpatient appointments	<b>Primary outcomes:</b> • Metabolic control • Self-management • QOL • Costs
<b>Setting:</b> one Diabetes Unit of the Hospital Clinic	Total N= 40 TM: n=20; UC :n=20	<b>Data transfer:</b> 12 telematic appointments with the GlucoBeep system + 3 ambulatory appointment	<b>Data transferred:</b> blood glucose		
<b>Country:</b> Spain	Age, mean (SD): TM: 27(11); UC: 23(5) Weight, kg (SD): TM: 68.4 (10.5); UC: 69.3 (9.6) BMI (kg/m2): TM: 23.3 ±2.6; UC: 23.5 ±2.5	<b>Review of data:</b> unclear <b>Type and timing of response:</b> unclear			

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	Gender, Sex, male/female: TM: 10/9; UC:11/5	<b>Actions:</b> appropriate counselling and therapeutic adjustments			
	Ethnicity: N/A	<b>Duration of intervention:</b> 6 months			
	Severity of condition:	<b>Follow-up:</b> 6 months after the end of intervention			
	Insulin (IU/kg/day):				
	TM: 0.8± 0.2; UC:0.8± 0.2				
	DM evolution (years):				
	TM: 12.6; UC: 10.6				
	Major co-morbidities: N/A				
<hr/>					
<b>MARRERO 1995</b>	Type 1 and Type 2 diabetes.	<b>TM-equipment:</b> Remote monitoring system with stored data transferred over a modem and ordinary telephone lines, with telephone feedback.	Monitoring and adjustment of medication therapy.	TM+UC vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> one out-patient diabetes clinic	Total N= 106 young people with their families	<b>Data transfer:</b> once every two weeks	<b>Data transferred:</b> blood glucose		<ul style="list-style-type: none"> <li>• HbA1c.</li> <li>• Total no of hospital visits,</li> <li>• Total no of ED visits,</li> <li>• Nursing time on task</li> <li>• Psychological status</li> <li>• Family dynamics</li> <li>• DQOL</li> <li>• Responsibility for diabetes care</li> <li>• Attitudes about the diabetes regimen.</li> </ul>
<b>Country:</b> USA	TM: n=52; UC: n=54	<b>Review of data:</b> unclear			
	Age, mean (SD): TM: 13.3 (4.5); UC: 13.3 (4.9)	<b>Type and timing of response:</b> in case the values are out of range the nurse calls the patient, otherwise s/he sends a postcard saying how well the blood glucose values are kept within range			
	Gender, male (%): TM: 59.6%; UC: 59.2%	<b>Actions:</b> to discuss possible regimen adjustments, the need for a clinic visit, or the initiation of referral to dietary services, social work or physical therapy			
	Ethnicity, white (%): TM: 98%; UC: 94%	<b>Duration of intervention:</b> 12 months			
	Severity of condition:	<b>Follow-up:</b> 12 months after randomisation			
	HbA1c: TM: 9.4 (1.9); UC: 9.9 (1.6)				
	Duration of diabetes: TM: 4.3 (3.4); UC: 8.0 (4.7)				
	Major co-morbidities: N/A				
<hr/>					
<b>MCCARRIER 2005</b>	Type 1 diabetes	<b>TM equipment:</b> web-application consisting of 5 modules, a health record; an upload meter; a diabetes daily diary; an action planner and an educational module	Monitoring and adjustment of medication therapy.	TM+ UC vs. UC	<b>Primary outcome:</b>
<b>Setting:</b> one Diabetes Care Center	Total N=77; TM: n= 41; UC: n=36	<b>Data transfer:</b> unclear, but probably weekly	<b>Data transferred:</b> blood glucose		<ul style="list-style-type: none"> <li>• Change in HbA1c values</li> </ul>
<b>Country:</b> USA	Age, mean years: TM: 36.8 (8.5); UC: 137.8 (7.67)	<b>Review of data:</b> weekly clinical review of data			<b>Secondary outcome:</b>
	Gender, % female sex: TM: 36.60%; UC: 27.80%	<b>Type and timing of response:</b> the nurse contacted the patient weekly (the first month and after			<ul style="list-style-type: none"> <li>• Change in self-efficacy (DES scores)</li> </ul>
	Ethnicity, % Caucasian: TM: 95.10%; UC: 97.20%				
	Severity of condition:				

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	Mean PHQ-9 severity score: TM: 4.85 (4.9); UC: 5.26 (5.3) Mean (SD) BL HbA1c: TM: 7.99 (1.05); UC: 8.05 (1.32) Glycemic control at baseline HbA1c 7–8%: TM: 63.40%; UC: 66.70% HbA1c >8%: TM: 36.60%; UC: 33.30% Major co-morbidities: N/A	this once a month) by e-mail or web-resources  <b>Actions:</b> discussed patients' goal based actions; provide feedback on uploaded data  <b>Duration of intervention:</b> 12 months  <b>Follow-up time:</b> 12 months from randomisation			
<b>WOJCICKI 2001</b>  <b>Setting:</b> one gastroenterology and metabolic diseases clinic  <b>Country:</b> Poland	Pregnant women with Type 1 diabetes (with intensive insulin treatment)  Total N: n=32; TM: n=17; UC: n=15  Age, mean $\pm$ SD: TM: 25.3 $\pm$ 4.1; UC: 26.8 $\pm$ 4.8  Gender, female (%): 100%  Ethnicity, white no (%): N/A  Weeks of pregnancy at start of the project: TM: 11.3 $\pm$ 2.3; UC: 12.2 $\pm$ 2.4  Weeks of delivery: TM: 37.0 $\pm$ 2.2; UC: 37.3 $\pm$ 1.7	<b>TM-equipment:</b> Remote monitoring system with stored data automatically transferred over a modem and ordinary telephone lines each night, with telephone feedback.  <b>Data transfer:</b> daily  <b>Review of data:</b> the following morning  <b>Type and timing of response:</b> the diabetologist contacts patients if necessary  <b>Actions:</b> adjustment of insuline dose  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 3 years after randomisation (why?)	Monitoring and adjustment of medication therapy.  <b>Data transferred:</b> blood glucose, and patient reported insulin doses, markers of meals, physical activity, symptoms of hypoglycaemia and special events	TM+UC vs. UC	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>Mean blood glucose (weekly average)</li> <li>HbA1c level (average of measurements performed every 6 weeks)</li> <li>Hypo- and hyperglycaemic events (% of measurements)</li> <li>Insulin dose adjustments</li> <li>indices</li> </ul>
<b>TYPE 2 DIABETES (n=6)</b>					
<b>KIM 2007</b>  <b>Setting:</b> out-patients departments  <b>Country:</b> South Korea	Type 2 diabetes.  Total N= 60; TM: n=30; UC: n=30  Age, years, SD, IQR: TM: 46.8 $\pm$ 8.8 (43.2, 50.5); UC: 47.5 $\pm$ 9.1 (43.8, 51.2)  Gender, male/female: TM: 11/14; UC: 11/15  Ethnicity: N/A  Severity of condition:  Diabetes duration, years: TM: 5.2 $\pm$ 5.9 (2.6, 7.8); UC: 8.0 $\pm$ 4.9 (5.9, 10.1)	<b>TM-equipment:</b> A cellular phone and the Internet were used to provide a short messaging service (SMS) relating to plasma glucose levels.  <b>Data transfer:</b> daily  <b>Review of data:</b> unclear  <b>Type and timing of response:</b> After the integration of the received information the nurse sent optimal recommendations to each patient, weekly by an SMS, a cellular phone or wired Internet.	Education and monitoring  <b>Data transferred:</b> blood glucose	TM vs. UC  UC= Participants in the control group met the endocrinologist specialist once or twice during the 12 weeks. the patients were provided with recommendations  about medication, medica-	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>HbA1c</li> <li>Fasting blood glucose</li> <li>2HPMG<sup>4</sup>-two hours post meal glucose</li> </ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

Note: Patients with major co-morbidities: were excluded		<b>Actions:</b> continuous education and reinforcement of diet, exercise, medication adjustment		tion dosage and lifestyle
		<b>Duration of intervention:</b> 6 months		modification by the endocrinologist specialist. When the doctor chose to consult with the patient to disclose particular information, or if the patient wished, the nurse or dietitian came to aid with more individualized and detailed information relating to lifestyle modification.
		<b>Follow-up:</b> 3 and 6 months after randomisation		
<b>KWON 2004</b>	Type 2 diabetes	<b>TM equipment:</b> a website to which patient data could be uploaded and the healthcare professional could assess it	Remote monitoring	TM vs. UC
<b>Setting:</b> one outpatient clinic at a diabetes centre	Total N=110; TM: n= 55; UC: n=55	<b>Data transfer:</b> at least once a week	<b>Data transferred:</b> blood glucose (unclear if BP, weight, and other data were also uploaded)	<b>Primary outcome:</b>
<b>Country:</b> South Korea	Age, mean years: TM:53.5 (8.8); UC: 54.7 (9.4)	<b>Review of data:</b> daily (no automated algorithm; no alerts);2 endocrinology fellows checked in with the system daily.		<ul style="list-style-type: none"> <li>• HbA1c</li> </ul>
	Gender, male/female sex:: TM:35/16; UC: 32/18	<b>Type and timing of response:</b> nurses and endocrinology fellows contacted the patient over Internet (through the patient's own individual chart system)		<b>Secondary outcomes:</b>
	Ethnicity:N/A	<b>Actions:</b> to give optimal recommendations according to guidelines;If there was any need to change the patient's medication or dosage the follows referred the case to the professor. Three nurses mainly commented upon lifestyle modification, including exercise, and the two dietitians supplied individually modified medical nutrition therapy.		<ul style="list-style-type: none"> <li>• Fasting blood glucose</li> <li>• Triglycerides</li> <li>• Total cholesterol</li> <li>• LDL<sup>5</sup> cholesterol</li> <li>• HDL<sup>6</sup> cholesterol</li> </ul>
	Severity of condition:	<b>Duration of intervention:</b> 12 weeks		
	Diabetes duration (years): TM: 7.0 (6.3); UC:6.6 (5.7)			
	HbA1c (%):TM: 7.59 (1.43); UC:7.19 (1.17)			
	Major co-morbidities:			
	Diagnosis of hypertension (n):TM: 17; UC: 13			



**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

**Follow-up:** 12 weeks from randomisation

<b>RALSTON 2009</b>  <b>Setting:</b> one general internal medicine clinic  <b>Country:</b> USA	Type 2 diabetes  Total N=83;  TM: n=42; UC: n=41  Age, mean years: TM: 57.0; UC: 57.6  Gender, % female sex: TM: 47.6; UC: 51.2  Ethnicity, Non-Hispanic white (%): TM: 89.7; UC: 73.0  Severity of condition:  Insulin use (%): TM: 38.1; UC: 39.0 Baseline values of outcomes GHb (%): TM: 8.2; UC: 7.9	<p><b>TM equipment:</b> Web-based program with patient access to electronic medical records, secure e-mail with providers, feedback on blood glucose readings, an educational website, and an interactive online diary for entering information about exercise, diet, and medication.</p> <p><b>Data transfer:</b> once a week</p> <p><b>Review of data:</b> clinical review of data at least once a week</p> <p><b>Type and timing of response:</b> unclear, care manager contacted patients once a week (telephone or e-mail)</p> <p><b>Actions:</b> adjusted hypoglycaemic medications and conferred with the primary care physician as needed.</p> <p><b>Duration of intervention:</b> 12 months</p> <p><b>Follow-up time:</b> 12 months after randomisation (data were collected at between 9 and 15 months follow-up)</p>	Remote monitoring and medication adjustment  <b>Data transferred:</b> blood glucose	TM+UC vs. UC	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>HbA1c</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Proportion of participants with HbA1c &lt; 7%</li> <li>Total cholesterol (no raw-data provided)</li> <li>Blood pressure (no raw-data provided)</li> <li>Outpatient visits</li> <li>Inpatient days</li> </ul>
<b>RO-DRIGUEZ-IDI-GORAS 2009</b>  <b>Setting:</b> community health centres (unknown number)  <b>Country:</b> Spain	Type 2 diabetes (adults)  Total N= 328  TM: n=161; UC: n=167  Age (years): TM : 63.32 (61.60, 65.04); UC: 64.52 (62.96, 66.09)  Gender (male/female) (% male): TM: 87/74 (54.04); UC: 82/85 (49.10)  Ethnicity: N/A  Severity of condition:  Duration of diabetes (years): TM: 11.32 (10.16, 12.50); UC: 10.18 (9.11, 11.25)  Note: Patients with major co-morbidities: were excluded	<p><b>TM equipment:</b> a glucometer and a mobile phone. Patients and physicians' mobile phones, together with the call centre, made up the tele assistance system.</p> <p><b>Data transfer:</b> no information (probably daily), just that it was real time data transfer</p> <p><b>Review of data:</b> automatic review of data with alerts to call centre if values were out of range; answered using a standard protocol, with immediate response when necessary</p> <p><b>Type and timing of response:</b> by mobile phone</p> <p><b>Actions:</b> Standard protocol used to decide on interventions</p> <p><b>Duration of intervention:</b> 12 months</p>	Remote monitoring and medication adjustment  <b>Data transferred:</b> blood glucose	TM vs. UC	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>HbA1c</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>SBP, DBP<sup>7</sup></li> <li>Total cholesterol,</li> <li>LDL cholesterol</li> <li>BMI<sup>8</sup></li> </ul>



**Table 2. Summary of Characteristics of Diabetes studies** (Continued)  
**Follow-up time:** 12 months from start of intervention

<b>STONE 2010</b>  <b>Setting:</b> one outpatient VAC <sup>9</sup>  <b>Country:</b> USA	Type 2 diabetes (veterans with entry HbA1c 7.5%.)  Total N= 150  TM: n=73; UC :n=77  Age, no (%): <45 years : TM (ACM+HT): 3 (4.7); UC (CC): 4 (5.5)  45-65 years: TM (ACM+HT): 38 (59.4); UC (CC): 43 (58.9);  ≥65 years: TM (ACM+HT): 23 (35.9); UC (CC): 26 (35.6)  Gender, male sex no (%) ; TM (ACM+HT): 64(100); UC (CC): 71 (97.3)  Ethnicity: white race no (%) : TM (ACM+HT):46 (71.9) ; UC (CC): 59 (80.8)  Severity of condition: N/A  Major co-morbidities: coronary artery disease: TM(ACM+HT): 25 (39.1); UC (CC): 24 (32.9)	<b>TM equipment:</b> a home tele monitoring device with reminders and education;  <b>Data transfer:</b> daily  <b>Review of data;</b> reviewed immediately (non-automatic review of data)  <b>Type and timing of response:</b> the nurse practitioner called the patient  <b>Actions:</b> medications for glycaemic, blood pressure, and lipid control were adjusted by the nurse practitioner supervised by the study endocrinologist without prior approval of the PCP who was informed retrospectively of all changes.  <b>Duration of intervention:</b> 6 months  <b>Follow-up time:</b> 6 months after randomisation	Remote monitoring, medication adjustment and self-management education  <b>Data transferred:</b> blood glucose, BP, weight	TM+UC vs.UC.  TM= active care management with home tele monitoring  UC=CC= a monthly care coordination telephone call	<b>Primary outcome:</b>  • HbA1c  <b>Secondary outcomes:</b>  • BP • Lipids • Weight
<b>WHITLOCK 2000</b>  <b>Setting:</b> one army medical centre  <b>Country:</b> USA	Type 2 diabetes  Adult patients with HbA1c >8.0.  Total N=28;  TM: n=15; UC: n=13  Age, years, mean (range): TM: 61.5 (41-73); UC:59 (32-75)  Gender, male/female sex ; TM 6/9; UC:5/8  HbA1c (% of blood):T-M:9.5 (8.1-12.6) ; UC:9.5 (8.1-11.9)  Total body weight, lbs: TM: 214.3 (110.0-386.0); UC:220.6 (148.0-371.0)	<b>TM-equipment:</b> Video-conferencing system; and real time assessment of signs and symptoms (using a check list)  <b>Data transfer:</b> N/A  <b>Review of data:</b> N/A  <b>Type and timing of response:</b> N/A  <b>Actions:</b> N/A  <b>Duration of intervention:</b> 3 months (12 visits)  <b>Follow-up:</b> within one month from the end of the 3 months study period	Education  <b>Data transferred:</b> blood glucose, weight, blood pressure, hypoglycaemic episodes, exercise (nutrition goals, and well-being)	TM vs. UC  UC= control patients were encouraged to enrol in the multi-disciplinary diabetic education class at Eisenhower Army Medical Centre, and were counselled to continue scheduling regular visits either with the family practice or internal medicine physician.	<b>Primary outcomes:</b>  • HbA1c  Secondary outcomes:  • Total body weight • QOL (no raw-data reported)

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

**TYPE 1 AND TYPE 2 DIABETES (n=6)**

<b>BOAZ 2009</b>  <b>Setting:</b> one hospital medical centre  <b>Country:</b> Israel	Type 1 and Type 2 diabetes  Adult, insulin-treated patients  Total N= 35 TM: n=18; UC :n=17  Age, mean years (SD): TM: 63 (10);UC: 63 (15)  Weight, kg, mean (SD): TM:78 (11); UC:77 (12)  Gender, female sex no (%) ;TM: 10 (59); UC: 12 (67)  Ethnicity: N/A  Severity of condition:  HBA1c % (SD): TM:8.4 (1.4); UC:9.3 (1.6)  Major co-morbidities: N/A	<b>TM-equipment:</b> a transmitter that automatically transferred data to the information server in real time to a computerised medical file.  <b>Data transfer:</b> unclear  <b>Review of data:</b> automatic review of data (audio alarm at the diabetes clinic computer and generated a text message to the cellular phone of the caregiver)  <b>Type and timing of response:</b> a specialised diabetes nurse contacted the patient over the phone  <b>Actions:</b> provide medical advice regarding titration of insulin dose, oral medications etc/ verify the diabetes care physician  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 6 months after start of intervention	Remote monitoring and medication adjustment  <b>Data transferred:</b> blood glucose	TM vs. UC.	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>• HbA1c</li> <li>• FBG10</li> <li>• Total Cholesterol</li> <li>• HDL cholesterol</li> <li>• LDL cholesterol</li> <li>• Triglycerides</li> </ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"> <li>• Hypoglycaemic events (self-report)</li> <li>• Hyperglycaemic events (self-report)</li> <li>• Clinically symptom free (self-report)</li> <li>• QOL (assessed with the patient satisfaction questionnaire)</li> </ul>
<b>BOND 2007</b> (and Bond 2010)  <b>Setting:</b> one diabetes hospital clinic  <b>Country:</b> USA	Type 1 and Type 2 diabetes  Total N=62; TM: n=31 ; UC: n=31  Age, mean years:TM: 66.2 (5.7); UC: 68.2 (6.2)  Gender, % female sex: TM:42%; UC: 48%  Ethnicity,Caucasian race (%):TM:87%; UC: 86%  Severity of condition:	<b>TM-equipment:</b> web/Internet based monitoring system allowing both synchronous communication (instant messaging and chat) and asynchronous communication (e-mail)  <b>Data transfer:</b> patient entered the blood sugar readings on study website, unclear if daily  <b>Review of data:</b> clinical review of data by nurses, unclear if daily  <b>Type and timing of response:</b> a nurse contacted the patient through via e-mail or instant messaging and/or direct chat, messaging or e-mail when there	Self-management education and remote monitoring  <b>Data transferred:</b> blood glucose, exercise programs, weight changes, blood pressure, and medication data	TM +UC vs. UC	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>• HbA1c</li> <li>• BP</li> <li>• Weight</li> <li>• Total cholesterol</li> <li>• HDL cholesterol</li> </ul> Qualitative data from Bond 2010: <ul style="list-style-type: none"> <li>• QoL</li> <li>• Depression</li> </ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	<p>Years with diabetes:(mean): TM:16.1 (10.5); UC:17.8 (11.7)</p> <p>HbA1c (%): TM: 7.1 (0.18); UC:7.1 (0.20)</p> <p>Major co-morbidities: N/A</p>	<p>were changes in blood sugar patterns (= weekly educational discussion on line or through e-mail by the principal investigator)</p> <p><b>Actions:</b> 'problem solving'</p> <p><b>Duration of intervention:</b> 6 months</p> <p><b>Follow-up:</b> 6 months after recruitment</p>			<ul style="list-style-type: none"> <li>• Social support</li> <li>• Self-efficacy</li> </ul>
<p><b>DAVIS 2010</b></p> <p><b>Setting:</b> one academic health centre and three primary care clinics</p> <p><b>Country:</b> USA</p>	<p>Type 1 and Type 2 diabetes (adult patients)</p> <p>Total N= 165</p> <p>TM: n=85; UC :n=80</p> <p>Age, mean (SD): TM: 59.9 (9.4); UC:59.2 (9.3)</p> <p>Weight, mean (SD): TM:101.3 (21.7) Kg; UC:96.6 (22.3)</p> <p>BMI (kg/m<sup>2</sup>): TM: 37.1 (8.1); UC: 35.9 (7.6)</p> <p>Gender, % females: TM:72.9%; UC:76.3%</p> <p>Ethnicity- black Afro-Americans %: TM: 75.3%; UC: 72.5%</p> <p>Severity of condition:</p> <p>Duration of diabetes (years): TM:8.5 (6.6); UC: 10.3 (8.1)</p> <p>Oral medication &amp; insulin (%): TM:32.5%; Control: 29.1%</p> <p>Major co-morbidities: N/A</p>	<p><b>TM-equipment:</b>an interactive video-conference system, telephone (both cellular and land lines), a fax line, and a tele health-enabled retinal camera constituted the TM system.</p> <p><b>Data transfer:</b> N/A</p> <p><b>Review of data:</b> N/A</p> <p><b>Type and timing of response:</b> N/A</p> <p><b>Actions:</b> N/A</p> <p><b>Duration of intervention:</b> 12 months; 13 sessions curriculum</p> <p><b>Follow-up:</b>12 months from start of the intervention</p>	<p>Education</p> <p><b>Data transferred:</b> blood glucose</p>	<p>TM vs. UC</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• LDL cholesterol</li> <li>• Albumin-to-creatinine ratio</li> <li>• No of eye examinations (reported also in two conference abstracts by Davis from 2003)</li> </ul>
<p><b>IZQUIERDO 2003</b></p> <p><b>Setting:</b> one diabetes centre, and three satellite offices</p> <p><b>Country:</b> USA</p>	<p>Type 1 and Type 2 diabetes</p> <p>Total N= 46; TM: n=24</p> <p>UC :n=22</p> <p>Age, mean years (SD): TM: 53.95 (10.08) (36.3–70.0); UC: 61.37 ( 8.95) (44.8–80.2)</p>	<p><b>TM-equipment:</b>Real time teleconferencing session with a document camera to enlarge brochures and text.</p> <p><b>Data transfer:</b> N/A</p> <p><b>Review of data:</b> N/A</p> <p><b>Type and timing of response:</b> N/A</p> <p><b>Actions:</b> N/A</p>	<p>Education</p> <p><b>Data transferred:</b> N/A</p>	<p>TM vs. UC</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> </ul> <p><b>Secondary outcomes</b></p> <ul style="list-style-type: none"> <li>• Psychosocial functioning (assessed by PAID scale)</li> </ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

	<p>BMI (kg/m<sup>2</sup>): TM:35.95 (9.22) (22.41–56.80); UC: 31.34 (6.20) (20.57–44.15)</p> <p>Gender, (M/F): TM: 8/16; UC: 13/9</p> <p>Ethnicity: mostly Caucasian</p> <p>Severity of condition:</p> <p>Diabetes type (type 1/ type 2) TM:3/21; UC:2/20</p> <p>Duration of diabetes, years (SD): TM: 15.78 ±11.54 (1.75–49.03); UC: 11.72 ± 8.2 (1.42–35.02)</p> <p>Major co morbidities: N/A</p>	<p><b>Duration of intervention:</b> 3 months; 3 educational sessions (the 1st included a 1 hour consultation with the diabetes nurse educator and dietician, followed up by 2 30 minute appointments at 4 to 6 weeks and 8 to 12 weeks.)</p> <p><b>Follow-up:</b> 3 months after recruitment</p>		<p>and ADS scale)</p> <ul style="list-style-type: none"> <li>• DQOL (assessed with the Diabetes Quality of Life questionnaire)</li> </ul>
<p><b>MCMAHON 2005</b></p> <p><b>Setting:</b>one VAHS<sup>11</sup></p> <p><b>Country:</b>USA</p>	<p>Type 1 and 2 Diabetes (poorly controlled)</p> <p>Total N=104; TM: n= 52; UC: n=52</p> <p>Age, mean years:TM: 64 ± 7; UC: 63 ± 7</p> <p>Gender,% male:TM: 99%; UC: 100%</p> <p>Ethnicity: N/A</p> <p>Severity of condition:</p> <p>Diabetes Medication (n, %)</p> <p>Oral medication only: TM: 27 (52%) ; UC:26 (50%)</p> <p>Insulin: TM: 25 (48%) ; UC:26 (50%)</p> <p>HbA1c (mean %): TM: 10.0 ± 0.8; UC: 9.9 ± 0.8</p> <p>BP (mm Hg): SBP: TM: 141 ± 21; UC: 139 ± 20</p> <p>DBP: TM: 81± 7; UC: 80 ± 7</p> <p>Lipids (mg/dl)</p> <p>LDL cholesterol: TM: 100 ± 35; UC: 97 ± 21</p> <p>HDL cholesterol: TM: 43 ± 14; UC: 40 ± 8</p> <p>Triglycerides: TM: 178 ±112; UC: 204 ± 140</p> <p>BMI (kg/m<sup>2</sup>): TM:32.3 ± 5.6 ; UC: 34.1 ± 7.0</p> <p>Major co-morbidities:N/A</p>	<p><b>TM-equipment:</b> a computer, a glucose meter and a blood pressure monitor constituted the TM system. The computer was programmed to connect to a diabetes education and management website using complimentary toll-free dial-up Internet.</p> <p><b>Data transfer:</b> unclear; patients were encouraged to measure BP three times per week, B-glucose measurements frequency were individualised</p> <p><b>Review of data:</b> unclear</p> <p><b>Type and timing of response:</b> messaging system and occasionally telephone contact; unclear timing</p> <p><b>Actions:</b> provide recommendations to the primary care provider and to the participants</p> <p><b>Duration of intervention:</b> 12 months</p> <p><b>Follow-up:</b> 12 months after recruitment</p>	<p>Self-management education and monitoring</p> <p><b>Data transferred:</b> blood glucose and BP</p> <p>TM +UC vs. UC</p>	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>• HbA1c</li> <li>• SBP, DBP (only a subgroup of patients)</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Fasting triglycerides</li> <li>• LDL cholesterol</li> <li>• HDL cholesterol</li> </ul>

**Table 2. Summary of Characteristics of Diabetes studies** (Continued)

<b>SHEA 2006</b> (Shea 2007; Shea 2009; Palmas 2010)	Type 1 and Type 2 diabetes  Ethnically Diverse, Medically	<b>TM-equipment:</b> a home telemedicine unit (HTU) (American Telecare Inc., Eden Prairie, Minnesota) with four main functions: synchronous videoconferencing, self-monitoring of fingerstick glucose and blood pressure, messaging, and Web access. The device is a Web-enabled computer with modem connection to an existing telephone line a TM unit consisting of a video-conferencing system, a Web-enabled computer with modem connection to an existing telephone line enabling remote monitoring, access to a web portal and the patient data (the data was uploaded by the patient), secure messaging with nurse case managers and an educational webpage. Some subjects also received glucose test strips for the specific glucose monitor provided by the study.	Education, monitoring, consultation	TM vs. UC	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>• HgbA1c,</li><li>• BP</li><li>• LDL cholesterol</li></ul>
<b>Setting:</b> primary care practices (unclear number)	Underserved Patients  Total N= 1665  TM: n=844; UC :n=821	<b>Data transfer:</b> unclear	<b>Data transferred:</b> blood glucose, blood pressure	<b>Other outcomes:</b>	<ul style="list-style-type: none"><li>• Depression, diabetes distress, self efficacy (reported in Trief 2007)</li><li>• Costs (reported in Moreno 2009)</li></ul>
<b>Country:</b> USA	Age:55–64 yrs: TM: 12.1; UC: 11.9; 65–69 yrs: TM: 33.2; UC: 34.0; 70–74yrs: TM: 26.9; UC: 25.1; 75–79 yrs: TM: 17.7; UC: 18.0; >80 yr: TM: 10.2; UK: 11.0  Gender, male (%): TM: 36.5;  UC: 37.9  Ethnicity:African-American (non-Hispanic): TM: 15.3; UC: 14.5; Hispanic: TM: 35.8; UC: 34.6; White (non-Hispanic): TM: 48.2; UC: 50.6	<b>Review of data:</b> unclear			
	Severity of condition:	<b>Type and timing of response:</b> unclear			
Duration of diabetes (yrs):	<5: TM: 30.8;UC: 29.7  5–9;TM: 19.0;UC: 21.3  10–14;TM:18.1;UC: 15.8  >15;TM: 30.8;UC: 32.2	<b>Actions:</b> When a case manager believes that a change in management is indicated, he or she contacts the primary care physician (by email, fax, or phone)			
Major co-morbidities: N/A		<b>Duration of intervention:</b> 12 months			
Other treatments received:		<b>Follow-up:</b> 12 months from randomisation			
Pills alone: TM: 65.3; UC: 65.4					
Insulin alone: TM: 14.5; UC: 14.4; Insulin and pills : TM:14.8 ; UC: 15.3; Diet alone : TM:5.1; UC: 4.9					

1 HbA1c= Glycated haemoglobin

2 SMBG= Self Measured Blood Glucose

3 QOL= Quality of Life

4 2 HPMG= 2 Hours Post Meal Glucose reading

5 LDL= Low Density Lipoprotein cholesterol  
6 HDL= High Density Lipoprotein cholesterol  
7 SBP and DBP = Systolic and Diastolic Blood Pressure  
8 BMI= Body Mass Index (kg/m<sup>2</sup>)  
9 VAC= Veteran Affairs Clinic  
10 FBG= Fasting Blood Glucose  
11 VAHS= Veteran Affairs Health System

**Table 3. Summary of Characteristics of Respiratory conditions studies**

Author Year	Clinical condition/ Setting	Type of TM	Function	Comparison	Outcomes
Country	Participants	Description of intervention			
<b>ASTHMA (n=5)</b>					
<b>CHAN 2007</b>	Asthma (children)	<b>TM equipment:</b> a home computer system, camera, and access to a customized educational and monitoring website, which allowed for secure interactive asthma education and secure e-mail contact between patients and case managers, as well as the capability for digital video uploads.	Monitoring and Education/ consultation	TM (partly substituting UC) vs. UC	<b>Primary outcome:</b>
<b>Setting:</b> one VAC <sup>1</sup>	Total N=120				<ul style="list-style-type: none"> <li>Therapeutic and diagnostic adherence</li> <li>Disease control (QOL<sup>5</sup>, lung function, utilisation of services, rescue therapy, symptom control, patient education, and satisfaction)</li> </ul>
<b>Country:</b> USA	TM: n=60; UC: n=60				
	Age, mean years: TM: 10.23 (3.1); UC: 9.03. (3.0)		<b>Data transferred:</b> videos of inhalation technique, symptom scores (in electronic diary)		
	Gender, male sex: TM: 37; UC 38	<b>Data transfer:</b> patients sent videos of inhalation technique 2 times per week for 6 weeks and then once-weekly thereafter; and completed electronic symptom diaries daily			
	Ethnicity: N/A	<b>Review of data:</b> 2 times per week for 6 weeks and then once-weekly thereafter			
	Severity of condition:	<b>Type and timing of response:</b> e-mail contact as per above			
	Mild persistent asthma, n: TM:7; UC: 15	<b>Actions:</b> to provide education/feedback on inhalation technique; to recommend an appointment with the study paediatrician and case manager if one was needed for closer observation or intervention			
	Moderate asthma, n: TM:41; UC:40S	<b>Duration of the intervention:</b> 12 months			
	Severe asthma, n : TM:12; UC:5	<b>Follow-up time:</b> 12 months after randomisation			
	FVC <sup>2</sup> , mean±SD, % predicted: TM: 103.7±17.4; UC:104.5±15.4				
	BL FEV <sup>3</sup> <sub>1</sub> , mean ±SD, % predicted: TM: 104.1±19.9; UC: 96.8±13.04				
	FEV <sup>4</sup> <sub>25-75</sub> , mean ±SD, % predicted: TM: 83.8±25.6 UC: 84.3±23.5				
<b>JAN 2007</b>	Asthma (children)	<b>TM-equipment:</b>	Monitoring and education to assist disease self-management.	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> one paediatric allergy and asthma clinic	Total N=196	An Internet-based interactive asthma educational and monitoring system/program which consisted of i) basic information regarding		UC: received a traditional asthma care	<ul style="list-style-type: none"> <li>Disease control (weekly av-</li> </ul>
	TM: n=97; UC: n=99				
	Age, mean ± SD (years):				

**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

ic at a univer- sity medical centre (outpa- tient clinic)	TM: 10.9 (2.5); UC: 9.9(3.2)	the care of the asthmatic child, ii) an electronic diary, iii) an action plan for the patients and iv) a re- trieval analysis system to review the accumulated data on symp- toms score and PEF <sup>6</sup> variability	<b>Data trans- ferred:</b>	plan consist- ing of a writ- ten asthma diary supple- mented with instructions for self-man- agement.	eraged PEF values, symptom scores)
<b>Country:</b> Tai- wan	Gender, male sex no (%): TM: 35(39.7); UC: 28 (36.8)		PEF values and symp- tom scores (in electronic di- ary)		<ul style="list-style-type: none"> <li>• Asthma control tests</li> <li>• Adherence (therapeu- tic and di- agnostic monitor- ing)</li> <li>• QOL</li> <li>• Retention of asthma knowledge</li> </ul>
	Ethnicity: N/A	<b>Data transfer:</b> daily			
	Severity of condition: <i>Mild:</i> TM:33 (37.5); UC: 33 (43.4);	<b>Review of data:</b> daily clinical re- view of patient data			
	<i>Moderate:</i> TM: 43 (48.9); UC: 35 (46.1);	<b>Type and timing of response:</b> dai- ly contact either through e-mail or phone			
	<i>Severe:</i> TM: 12 (13.6); UC: 8 (10.5)	<b>Actions:</b> the physician advised the patient to increase, decrease or continue medication all depending on the data received.			
		<b>Duration of intervention:</b> 12 weeks			
		<b>Follow-up:</b> 12 weeks after ran- domisation			
<b>RASMUSSEN 2005</b>	Asthma (adults)	<b>TM equipment:</b> Internet-based monitoring system/tool with auto- matic feedback and alerts+ physi- cian feedback. The tool comprised an electronic diary, an action plan for the patients, and a decision support system for the physician.	Medication	TM vs. GP care (+UC)	<b>Primary out- comes:</b>
	Total N=200		therapy man- agement +		
<b>Setting:</b> GP clinics and an outpatient clinic (shared care)	TM: n=100		assist pa- tients' self- management..	<b>Note:</b> one study group (specialist care, n=100) was not in- cluded in this review	<ul style="list-style-type: none"> <li>• Asthma symptoms (from self-reported symptoms diary)</li> <li>• AQOL (asthma quality of life questionnaire)</li> <li>• Lung function (objective measure)</li> <li>• Airway responsiveness (objective measure)</li> <li>• Hospitalisations (self-reported)</li> <li>• Adverse reactions (self-reported)</li> </ul>
<b>Country:</b> Den- mark	UC:= GP care n=100	<b>Data transfer:</b> daily			
	Age, mean ± SD (years):	<b>Review of data:</b> unclear when, but probably before Internet consulta- tion or in case of an alert	<b>Data trans- ferred:</b> asth- ma symptoms (electronic di- ary), need for rescue med- ication, and PEF values		
	TM: 28 (18-44); GP care: 30 (20-45)	<b>Type and timing of response:</b> 4 scheduled Internet consultations 1 month apart (plus one additional if needed) to check asthma control and adjust pharmaceutical treat- ment			
	Gender/Sex (F/M):TM: 58/27; GP care:58/30	<b>Actions:</b> changing medication treatment			
	Ethnicity: N/A	<b>Duration of intervention:</b> 6 months			
	Severity of condition: FEV1, % predicted: TM:91 (14) ; GP group:92 (12)	<b>Follow-up:</b> 6 months from ran- domisation			
	AHR log DRS: TM:1.03 (0.5); GP group:1.02 (0.5)				
	Symptoms grading:				
	<i>Very mild</i> (%): TM: 1; GP care: 1				
	<i>Mild</i> (%): TM: 49; GP care: 50				
	<i>Moderate</i> (%): TM: 25; GP care: 24				



**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

Severe (%): TM: 25; GP  
care: 25

<p><b>VAN DER MEER 2010</b></p> <p><b>Setting:</b> 37 general practices and one pulmonology outpatient clinic at a medical centre (shared care)</p> <p><b>Country:</b> Germany</p>	<p>Asthma (adults)</p> <p>Total: N=200; TM: n=101; UC: n=99</p> <p>Age, mean years (range): TM:36 (19–50); UC:37 (18–50)</p> <p>Gender, % male sex: TM:32; UC:29</p> <p>Ethnicity: N/A</p> <p>Severity of condition:</p> <p>Mean asthma duration (range), years : TM:15 (1–47); UC:18 (0–47)</p> <p>Mean FEV<sub>1</sub> (pre bronchodilator) (range), L TM:3.08 (1.14–5.19); UC:3.13 (1.56–5.23)</p> <p>Mean predicted FEV<sub>1</sub> (pre bronchodilator) (range), % TM:88 (34–133); UC:90 (53–118)</p> <p>f) Medication:</p> <p>Mean daily inhaled corticosteroid dose (range), g TM:497 (0–1000); UC: 517 (0–2000)</p> <p>Inhaled long-acting 2-agonist use, % TM:59; UC:60</p> <p>Leukotriene modifier use, % TM:3; UC:2</p> <p>f) Major co-morbidities: no information</p> <p>g) Baseline measures of outcome:</p> <p>Mean educational outcomes (range):</p> <p>Asthma knowledge: TM:8.74 (2–12); UC:8.32 (3–12)</p> <p>Inhaler technique: TM:4.34 (3–5); UC:4.11 (1–5)</p> <p>Self-reported medication adherence: TM:6.46 (0–7); UC:6.19 (0–7)</p> <p>Clinical outcomes:</p>	<p><b>TM equipment:</b> The Internet-based self-management program which consisted of 4 principal components was accessed through the specially designed website, which allowed monitoring through the website (or text message on a mobile telephone), use of an Internet-based treatment plan, online education, and Web communications with a specialized asthma nurse.</p> <p><b>Data transfer:</b> weekly</p> <p><b>Review of data:</b> unclear (immediate)</p> <p><b>Type and timing of response:</b> N/A</p> <p><b>Actions:</b> change of medication if needed</p> <p><b>Duration of intervention:</b> 12 months; 2 group based educational sessions</p> <p><b>Follow-up time:</b> 12 months after randomisation</p>	<p>Education and remote monitoring</p> <p><b>Data transferred:</b></p> <p>responses to the Asthma control questionnaire <sup>7</sup></p>	<p><b>Primary outcome:</b></p> <ul style="list-style-type: none"> <li>Asthma QoL</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>Asthma control (self-reported)</li> <li>Symptom-free days</li> <li>Lung function (pre bronchodilator FEV<sub>1</sub>)</li> <li>Daily inhaled corticosteroid dose (calculated daily as fluticasone equivalents)</li> <li>Exacerbations (defined as deterioration in asthma that required emergency treatment or hospitalisation)</li> <li>Process outcomes (i.e. educational outcomes, inhaler technique; self-reported medication adherence; health-care provider contacts for asthma, use of Internet</li> </ul>
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**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

	Mean Asthma Quality of Life Questionnaire score (range) TM:5.73 (3.66–6.94); UC:5.79 (3.03–7.00) Mean Asthma UC Questionnaire score (range): TM: 1.12 (0.07–3.22); UC:1.11 (0–3.86) Symptom-free days (range), % TM:44.9 (0–100); UC:44.5 (0–100)				tool, medication changes);
<b>WILLEMS 2008</b>	Asthma (adults and children)  Total no: n=109 TM: n=55;UC: n=54  Age, years, mean $\pm$ SD:Adults:TM:45.65 (11.3); UC: 45.90 (15.9); Children TM: 10.57 (2.1); UC:10.85 (2.3)  Gender, Male (%):  Adults: TM: 42.3% ; UC : 33.3%;Children TM: 72.4%; UC :55.6%  Ethnicity: N/A  Severity of condition:  GINA classification:  Adults TM: 2.96 (0.5); UC:2.74 (0.7);  Children TM: 2.31 (0.8); UC: 2.07 (0.7)  Note: Patients with severe co-morbidities were excluded.	<b>TM-equipment:</b> A portable handheld remote monitoring device (for registering lung function values and symptoms), connected to a modem for data transmission.  <b>Data transfer:</b> monthly or more often if worsening condition  <b>Review of data:</b> clinical review of data  <b>Type and timing of response:</b> mostly by telephone  <b>Actions:</b> the nurse classified the asthma following a stepwise intervention protocol based on the GINA guidelines and the Dutch College of GPs According to this protocol the asthma nurse was allowed to decrease (after 3 months of stable asthma) or increase asthma medication by one step. A physician was only consulted if necessary.  <b>Duration of intervention:</b> 12 months  <b>Follow-up:</b> 12 months from randomisation	Medication adjustments.  <b>Data transferred:</b> lung function values and symptoms	TM vs. UC  UC: regular outpatient care	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Asthma-specific QOL</li></ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"><li>Clinical asthma symptoms (lung function values and self-reported symptoms)</li><li>Medical consumption (healthcare utilisation and medication use)</li><li>Costs and cost-effectiveness</li><li>Health state utilities</li></ul>
<b>CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), n=3</b>					
<b>KOFF 2009</b>	COPD  Total N=40 TM: n=20; UC: n=20  Age, years, mean(SD) :	<b>TM-equipment</b>  A small telecommunication device that connects directly to a home telephone with an interactive dialogue reinforcing disease- specific	Assist self-management, through remote monitoring and education	TM (pro-active integrated care) + UC vs. UC  UC= continued on the	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>QOL</li></ul> <b>Secondary outcomes:</b>

**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

Table 6: Summary of characteristics of respiratory conditions studies (continued)					
<b>Country:</b> USA	TM: 66.6 (9.1); UC: 65.0 (8.2)	education (and monitoring) on a daily basis.	<b>Data transferred:</b>	treatment regimen prescribed by their health-care provider	<ul style="list-style-type: none"><li>Healthcare costs (included visits to clinics and ED room, hospitalisations, radiology services and other diagnostic tests, and blood tests)</li><li>Identification of unreported exacerbations</li></ul>
	Gender, female sex (%) ; TM:55; UC:50	<b>Data transfer:</b> Monday to Friday	symptoms, oxygen saturation, FEV <sub>1</sub> , and steps in 6-min walk distance (6MWD)		
	Ethnicity, no whites: TM: n=17 ; UC: n=19	<b>Review of data:</b> the following morning but only on weekdays (algorithm-based data analysis with colour coding of patient data according to the risk )			
	Severity of condition:				
	FEV1 % predicted:	<b>Type and timing of response:</b> in case of a red alert or persistent yellow alert, the healthcare provider telephoned the patient the next morning			
	TM: 33.6±9.1;				
	UC: 31.1±10.2				
	Long-term oxygen therapy %: TM: 95; UC: 95	<b>Actions:</b> to help facilitate the resolution of a clinical problem by calling the patients' primary care physician. In the event of an important non clinical problem, the coordinator would help the patient make the appropriate contacts			
	Resting oxygen saturation %: TM:92.5±2.6; UC: 93.2±2.5				
	Major co-morbidities: N/A	<b>Duration of intervention:</b> 3 months			
		<b>Follow-up:</b> 3 months from randomisation			
<b>LEWIS 2010</b>	COPD	<b>TM-equipment:</b> A handheld monitor with a pulse oximeter connected to the hub, was used for automatic transfer of symptoms over ordinary (Freephone) telephone lines. The patient obtained physical data and typed the result into the HUB.	Remote monitoring to permit timely intervention.	TM+UC vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> unclear	(moderate or severe COPD; optimised condition)			UC: continued chronic disease management team and hospital / primary care support at the discretion of their clinical teams for 12 months	<ul style="list-style-type: none"><li>Hospital admissions</li></ul>
<b>Country:</b> Wales	Total N=40				<b>Secondary outcomes:</b>
	TM: n=20;UC: n=20	<b>Data transfer:</b> once a day at 2 a.m.			<ul style="list-style-type: none"><li>ED attendances for COPD</li><li>Hospital days stayed</li><li>Primary care contacts (chest and non-chest)</li><li>Chronic disease management team phone calls</li><li>Chronic disease management team home visits</li></ul>
	Age, years mean (SD):TM: 67 (9);	<b>Review of data:</b> daily during office hours, or in case of an alert			
	UC:70 (10)				
	Gender, male,%: TM: 50%;UC: 50%	<b>Type and timing of response:</b> in case of an alert the healthcare professional called the patient the following morning (only during office hours)			
	Ethnicity: N/A	<b>Actions:</b> in case of an alert the provider calls the patient- not further described			
	Severity of condition:				
	MRC dyspnoea score:	<b>Duration of intervention:</b> 6 months			
	TM: 4.0 (0.7);				
	UC: 3.4 (0.8)				
	Major co-morbidities:	<b>Follow-up:</b> 6 months after the end of the intervention			
	TM: 92%; UC: 88%				

**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

<b>NGUYEN</b>	<b>COPD</b>	<b>TM-equipment</b>	Assist self-management, through monitoring and education.	TM vs. UC	<b>Primary outcomes:</b>
<b>2008</b>	(moderate to severe)	A web-based tool for dyspnoea self-management which allowed patients to daily transmit real time information on symptoms and exercise, via a PDA or a website, and to receive E-mail alerts were sent to the study nurses based on real-time worsening of symptoms from usual and reports of not performing exercise for at least 3 consecutive days. The tool also included patient access to an educational website,	<b>Data transmitted:</b> COPD symptoms and exercise	UC: control group participants completed paper diaries and mailed them back weekly to the study office. Exercise goals were set during the telephone calls. The nurses reviewed this information to provide individualized feedback and reinforcement to participants regarding their use of dyspnoea management strategies and exercise progress via telephone, weekly for the first month and then bi-weekly for the next 5 months.	<ul style="list-style-type: none"> <li>Dyspnoea with ADL</li> </ul>
<b>Setting:</b> 2 academic medical centres	Total: N=50 TM: n=26; UC: n=24				<b>Secondary outcomes:</b>
<b>Country:</b> USA	Age, years, mean (SD): TM: 68.0 (8.3); UC: 70.9 (8.6)	<b>Data transfer:</b> over a PDA or website			<ul style="list-style-type: none"> <li>Exercise behaviour</li> <li>Exercise performance</li> <li>COPD exacerbations</li> </ul>
	Gender, female no (%): TM: 8 (39); UC: 9 (45)	<b>Review of data:</b> daily			
	Ethnicity, Caucasian no (%): TM: 18 (95); UC: 20 (100)	<b>Type and timing of response:</b> prompt individualised feedback and reinforcements by nurses via email, weekly for the first month and then biweekly for the next 5 months. In case of an alert the nurses then contacted the patient,			
	Severity of condition: FEV <sub>1</sub> /FVC (mean ± SD): TM: 0.49±0.14; UC: 0.46±0.11	<b>Actions:</b> to provide individualised feedback and reinforcements for self-management of the disease			
	Major co-morbidities: Cardiovascular (HTN and CAD): TM: 9(50); UC: 10(50)	<b>Duration of intervention:</b> 3 months			
		<b>Follow-up:</b> 3 months after randomisation			
<b>OBSTRUCTIVE SLEEP APNEA SYNDROME (OSAS), n=1</b>					
<b>TAYLOR 2006</b>	<b>OSAS</b>	<b>TM-equipment:</b>	Self-management, education and monitoring.	TM vs. UC	<b>Primary outcomes:</b>
<b>Care sector:</b> one university-affiliated sleep disorders centre	Total N=160 TM: n=56 UC: n=58 (number who completed the study)	A computer that provided daily Internet-based informational support and feedback for problems experienced with CPAP <sup>8</sup> use, involving an IVR <sup>9</sup> system.	<b>Data transferred:</b> responses to a series of health-related questions		<ul style="list-style-type: none"> <li>CPAP use</li> <li>Functional status (assessed using the Modified Functional Outcomes of Sleep Questionnaire)</li> <li>Client satisfaction (non-validated questionnaire)</li> </ul>
<b>Country:</b> USA	Age, mean years ±SD: TM: 45.8±10; UC: 44.6±8.5	<b>Data transfer:</b> daily			
	Gender, male (n, %): TM: 39 (66); UC: 44 (71)	<b>Review of data:</b> automated risk classification of patient data			
	Ethnicity: African-Americans, no, (%): TM: 25 (42); UC: 25 (40)	<b>Type and timing of response:</b> Patients with responses that resulted in a high-risk (red) category for more than 3 days			
	Caucasians, no, (%): TM: 29 (49); UC: 37 (60)				

**Table 3. Summary of Characteristics of Respiratory conditions studies** (Continued)

Severity of condition:	were contacted by telephone by the sleep medicine practitioner within 24 hours.
OSAS severity no, (%)	
Mild: TM: 17 (31); UC: 15 (25)	<b>Actions:</b> Consultation on improving CPAP use, or provision of different mask
Moderate: TM: 19 (35); UC: 16 (27)	<b>Duration of intervention:</b> 30 days
Severe: TM: 19 (34); UC: 28 (48)	<b>Follow-up:</b> 30 days after randomisation
Major co-morbidities:	
N/A	

1 VAC= Veteran Affairs Clinic

2 FVC= Forced Vital Capacity

3 FEV<sub>1</sub>= Forced Expiratory Volume (FEV) at timed intervals of 1.0 (FEV<sub>1</sub>) seconds

4 FEV<sub>25-75</sub>= Forced Expiratory Flow 25–75% (FEF 25–75)

5 QOL= Quality of Life

6 PEF= Peak Expiratory Flow: The highest forced expiratory flow measured with a peak flow meter.

7 Asthma Control Questionnaire=ACQ is a 7-item questionnaire that has been validated to measure asthma control. The items refer to asthma symptoms, rescue bronchodilator use and FEV<sub>1</sub>% of predicted normal. Responses are given on a 7-point scale and the overall score is the mean of the responses where 0 = totally controlled and 6 = severely uncontrolled.

8 CPAP= Continuous Positive Airway Pressure (CPAP) is the use of continuous positive pressure to maintain a continuous level of positive airway pressure in a spontaneously breathing patient.

9 IVR system= Interactive Voice Response system

**Table 4. Summary of Characteristics of Mental disorders studies**

Author Year	Clinical condition/ Setting Country	Participants	Description of TM	Function	Comparison	Outcomes
<b>CHONG 2012</b>	Major Depression.					
<b>Setting:</b> one community health centre	Total N=167; TM: n=80; UC: n=87		<b>TM equipment:</b> video web cam and a Web application to create a virtual meeting room that can be entered using a software-generated URL specific to that meeting.	Psychotherapy consultation	TM vs. UC	<b>Primary outcome:</b>
<b>Country:</b> USA	Age, mean (SD): TM: 42.8 (12.0); UC: 43.2 (11.9)					• Depression severity
	Gender, male no; TM: 7/80; UC: 12/87					<b>Secondary outcome:</b>
	Ethnicity, Hispanic or of Mexican origin: 100%		<b>No of sessions:</b> 6 times 30 min sessions (first session 1 hour)			• No of days lost,
	Severity of condition: Moderate depression at least (PHQ-9 <sup>1</sup> score of 10 or more)		<b>Duration of intervention:</b> 6 months			• No of unproductive days,
	Major co-morbidities: over 50% of participants did not have a chronic illness.		<b>Follow-up:</b> 6 months after randomisation			• Acceptability of tele psychiatry (intervention group only)
						• Resource use (appointment keeping)
						• Antidepressant use

**Table 4. Summary of Characteristics of Mental disorders studies** (Continued)

<b>DE LAS CUEVAS 2006</b>	Mental disorders (for details on diagnoses see below)	<b>TM-equipment:</b> a video-conferencing system	Psychotherapy consultation	TM vs. UC	<b>Primary outcomes:</b>
<b>Care sector:</b> one community mental health centre	Total N=140	<b>Number of sessions:</b>		UC: 8 times 30 min face-to-face consultations	<ul style="list-style-type: none"><li>Clinical changes in psychiatric test scores</li></ul>
<b>Country:</b> Spain	TM: n=70; UC: n=70	8 times 30 min sessions			
	Age:	<b>Duration of intervention:</b> 6 months			
	<25 years: TM: 12(17.1); UC:13 (18.6); 25–45 years: TM: 37(52.9); UC:33 (47.1)	<b>Follow-up:</b> 6 months after randomisation			
	45–65 years: TM: 16(22.9); UC: 21 (30); >65 years: TM: 5 (7.1); UC:3 (4.3)				
	Gender, Male sex, n (%): TM: 22 (31.4); UC: 25 (35.7)				
	Ethnicity: N/A				
	CGI <sup>2</sup> severity of illness, no (%)				
	Moderately ill: TM: 8(11.4); UC:5( 7.1); Markedly ill: TM: 61(87.1); UC: 65(92.9)				
	Severely ill: TM: 1 (1.4); UC: 0 (0)				
	Major co-morbidities: N/A				
	Diagnoses ICD-10:				
	Mental and behavioural disorders due to psychoactive substance abuse: TM: 5 (7.1); UC: 6 (8.5)				
	Schizophrenia, schizotypal, and delusional disorders: TM: 5(7.1) ; UC: 6 (8.5)				
	Mood (affective) disorders: TM: 23(32.9); UC: 25 (35.7)				
	Neurotic, stress-related and somatoform disorders: TM: 31(44.3); UC: 25 (35.7)				
	Disorders of the adult personality and behaviour: TM: 6 (8.6); UC:8 (11.4)				

<b>KING 2009</b>	Substance abuse	<b>TM-equipment:</b> an Internet-based videoconferencing platform	Psychotherapy/ Counselling	TM+ UC vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> outpatients in the Addiction Treatment	Total N=37	<b>Number of sessions:</b> 2 video-sessions per week for 6 weeks (12 in total), including 8 group sessions		UC= Participants received daily methadone and were required to attend weekly individual counselling with their pri-	<ul style="list-style-type: none"><li>Treatment satisfaction</li><li>Response to treatment (counselling adherence, drug use, step completion)</li></ul>
Services (community care)	TM: n=20; UC: n=17				
	Age, mean years:				
	TM: 42.7; UC: 41.4				
<b>Country:</b> USA	Gender: Female sex (%):				
	TM: 65%; UC: 47%				

**Table 4. Summary of Characteristics of Mental disorders studies** (Continued)

	Ethnicity: Minority (%):  TM: 40%; UC: 41%  Severity of condition:N/A	<b>Duration of intervention:</b>  6 weeks  <b>Follow-up:</b> 6 weeks from randomisation		mary counsellor. Participants were also required to submit one observed urine sample per week on a random schedule.	
<b>MITCHELL 2008</b> (costs in Crow 2009)  <b>Setting:</b> one regional healthcare system facility  <b>Country:</b> USA	Bulimia nervosa or other binge eating disorder  Current diagnosis: Bulimia nervosa, no (%): TM: 33 (53.2); UC: 38 (57.6);  Eating disorder not otherwise specified, no (%): TM: 29 (46.8); UC: 28 (42.4)  Total N=128  TM: n=62; UC: n=66  Age, mean (SD):TM: 28.4 (10.4); UC: 29.6 (10.9)  Gender, female sex no (%) ;TM:62 (100); UC: 64 (97.0)  Ethnicity, Caucasian no (%): TM:n=61 (98.4) ;UC: n=62 (93.9)  Condition specific characteristics:  Body mass index (kg/m2), mean (SD): TM: 23.5 (5.4); UC: 23.3 (5.0)  Objective binge episodes previous 28 days, mean (SD) TM:19.1 (24.7); UC: 21.9 (27.3)  Vomiting episodes previous 28 days, mean (SD) TM: 28.5 (28. 3); UC: 31.3 (34.3)  Major co-morbidities: lifetime mood disorder, lifetime anxiety disorder	<b>TM equipment:</b> a tele-video-conferencing system  <b>Number of sessions:</b> 20 CBT <sup>3</sup> sessions delivered over a 16 weeks period  <b>Duration of intervention:</b>  16 weeks  <b>Follow-up:</b> at the end of the intervention and at 3 and 12 months	Psychotherapy/  Counselling	TM vs. UC  UC= 20 face-to-face CBT sessions for bulimia nervosa	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>• Abstinence rates for objective binge eating, purging (vomiting, laxative abuse and diuretic abuse)</li> <li>• Combined objective binge eating and purging</li> <li>• Secondary outcomes:</li> <li>• EDE <sup>4</sup>(restraint, eating concerns, shape concerns, weight concerns)</li> <li>• Depression (Hamilton depression tool)</li> <li>• Self-esteem (Rosenberg self-esteem tool)</li> <li>• QOL (SF-36)</li> <li>• Costs (reported in Crow 2009)</li> </ul>
<b>MORLAND 2010</b>  <b>Setting:</b> 3 VAC <sup>5</sup> clinics and 3 VAC centres  <b>Country:</b> USA	Posttraumatic stress disorder (PTSD)  Rural population of combat veterans  Total N=125  TM: n=61; UC: n=64  Age: TM: 54.8± 9.3 years; UC:54.7 ± 9.7 years  Gender: 100% male	<b>TM-equipment:</b> video- conferencing equipment  <b>Number of sessions:</b> 12 manual based sessions AMT protocol, with 2 sessions per week  <b>Duration of intervention:</b>	Psychotherapy/ Counselling	TM (group therapy) vs. UC (group therapy)  UC: Face-to-face delivered manual based 12 sessions AMT <sup>6</sup> protocol, with 2 sessions per	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>• Anger severity (anger expression, trait anger, anger disposition)</li> </ul> <b>Secondary outcomes:</b> <ul style="list-style-type: none"> <li>• PTSD symptom reduction</li> </ul>

**Table 4. Summary of Characteristics of Mental disorders studies** (Continued)

	Ethnicity, no (%):  Asian: TM: 13 (21.3) ; UC: 21 (32.8)  White: TM: 21 (34.4); UC: 22 (34.8)  Pacific Islander: TM: 22 (36.1) ; UC: 19 (29.7)  PTSD severity (CAPS total score): TM: 80.2 (17.1) ; UC: 77.8 (15.4)  Combat exposure: TM: 55 (90.2) ; UC: 60 (93.8)	6 weeks  <b>Follow-up:</b> 6 months post-treatment		week over a 6 week period.	<ul style="list-style-type: none"> <li>Attrition</li> <li>Treatment adherence</li> <li>Satisfaction</li> </ul>
<b>POON 2005</b>  <b>Care sector:</b> one social centre for the elderly and one outpatient hospital clinic (shared care)  <b>Country:</b> China	Mild cognitive impairment or dementia  Total N=22  TM: n=11; UC: n=11  Age: N/A  Gender: N/A  Ethnicity: N/A  Severity of condition: mild cognitive impairment/ dementia  Major co-morbidities: no information	<b>TM-equipment:</b> a video-conferencing system  <b>Number of sessions:</b> 12 sessions  <b>Duration of intervention:</b> 6 weeks  <b>Follow-up:</b> 6 weeks from randomisation	Therapy for cognitive improvement	TM vs. UC  UC= A total of 12 CI face-to-face sessions were conducted over 6 weeks	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>Cognitive improvement (cognitive status; behavioural memory; dementia grade)</li> <li>Acceptability and adherence (fidelity) with intervention</li> </ul>
<b>RUSKIN 2004</b>  <b>Care sector:</b> 3 mental health clinics within the VAHC <sup>7</sup> system  <b>Country:</b> USA	Depression.  Total N: 119 (131)  TM: n=59; UC: n=60  Age, mean $\pm$ SD: 49.7 years (12.8)  Gender, male/female: 105/14  Ethnicity, white %: 61%  Severity of condition: N/A  Major co-morbidities: N/A	<b>TM equipment:</b> a video-conferencing system  <b>No of sessions:</b> 8 sessions  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 6 months after randomisation	Psychotherapy/  Counselling for depression.	TM vs. UC  UC patients received the same no of sessions face-to-face (by the same psychiatrists)	<b>Primary outcomes:</b> <ul style="list-style-type: none"> <li>Treatment outcomes (depressive symptoms, response to treatment/ degree of improvement, remissions, other measures of depression and health status)</li> <li>Treatment adherence</li> <li>Medication adherence</li> <li>Resource consumption/costs</li> <li>Satisfaction (assessed with non-validated scale, results not included in the review)</li> </ul>



1 PHQ-9: The PHQ-9 is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). It has been validated for use in primary care. It is a tool to be used to monitor the severity of depression and response to treatment.

2 CGI-S: The Clinical Global Impression - Severity scale (CGI-S) is a 7-point scale that requires the clinician to rate the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Considering total clinical experience, a patient is assessed on severity of mental illness at the time of rating 1, normal, not at all ill; 2, borderline mentally ill; 3, mildly ill; 4, moderately ill; 5, markedly ill; 6, severely ill; or 7, extremely ill.

3 CBT: Cognitive Behavioural Therapy

4 EDE: Eating Disorder Examination interview

5 VAC: Veteran Affairs Clinic

6 AMT: Anger Management Therapy

7 VAHC system: Veterans Affairs Health Care system

**Table 5. Summary of Characteristics of Complex co-morbidities studies**

Author Year Setting Country	Clinical condition/ Participants	Description of TM	Function	Comparison	Outcomes
<b>Finkelstein 2006</b>  <b>Care sector:</b> 4 rural and urban HHC <sup>1</sup> agencies (community care)  <b>Country:</b> USA	CHF <sup>2</sup> , COPD <sup>3</sup> and wound care patients receiving home care  Total: n=68  TM: n=unclear  UC: n=unclear  Age, years: 74.3 years (range of 60–96)  Gender, female/male: TM: 9/11; UC: 9/10  Ethnicity: N/A  Severity of condition: N/A  Major co-morbidities: N/A	<b>TM-equipment:</b> a combined monitoring and video-conferencing system including an eyeball camera which could be moved to transmit real-time pictures of wounds, swollen ankles, etc. Distal measuring devices: CHF: pulse oximeters and automatic BP cuffs; COPD: pulse oximeters, and electronic spirometers, and automatic BP cuffs.  <b>Data transfer:</b> in real time during virtual visits, twice weekly  <b>Type and timing of response:</b> N/A  <b>Actions:</b> N/A  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> up to 6 months after HHC discharge	Consultation and  real time monitoring	TM+ UC vs. UC  UC=received standard HHC as determined by their underlying condition  <b>Note:</b> one study arm (video-conferencing +UC) was not included in this review	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Discharge to a higher level of care</li><li>Mortality</li><li>Morbidity</li><li>Costs</li></ul>
<b>Hopp 2006</b>  <b>Care sector:</b> one Veterans Affairs Medical Centre (community care)  <b>Country:</b> USA	Home care patients at high risk of hospital resource utilisation  Total N=37  TM: n=18; UC: n=19  Age, mean (SD): TM: 69.8 (11.6); UC: 69.5 (12.7)  Gender: 100% male  Ethnicity:	<b>TM-equipment:</b>  A IVR <sup>4</sup> unit with video technology, and a video camera allowing the patients to be seen by the nurses in the home care program. Some patients were also given units with peripheral attachments, such as BP monitors, stethoscopes, and glucose monitors.  <b>Data transfer:</b> N/A  <b>Type and timing of response:</b> N/A  <b>Actions:</b> N/A  <b>Duration of intervention:</b> 6 months	Consultation and  real time monitoring	TM + UC vs. UC  UC= nursing services at home and periodic telephone contact with the clinical staff concerning their home care services.	<b>Primary outcomes:</b> <ul style="list-style-type: none"><li>Resource utilisation</li><li>HRQOL<sup>5</sup></li><li>Patient satisfaction</li></ul>



**Table 5. Summary of Characteristics of Complex co-morbidities studies** (Continued)

	<p>Caucasian, % (no): TM: 56% (10); UC: 47% (9)</p> <p>African American % (no): TM: 33% (6); UC: 37% (7)</p> <p>Severity of condition:</p> <p>Baseline measures of HRQOL, including both the PCS (mean 24.83; SD 7.47) and MCS (mean 40.52; SD 11.98), were below norms established for a general popula- tion.</p> <p>Major co-morbidities:</p> <p>Hypertension TM:78% (14); UC: 84% (16)</p> <p>Diabetes TM: 50% (9); UC: 58% (11)</p>	<p><b>Follow-up:</b> 6 months after randomi- sation</p>			
<p><b>Noel 2004</b></p> <p><b>Care sector:</b></p> <p>one Veterans Affair's health- care system (community care)</p> <p><b>Country:</b>USA</p>	<p>Patients with com- plex HF, chronic lung disease, and/or dia- betes</p> <p>Total N=104</p> <p>TM: n=47; UC: n=57</p> <p>Age, years: TM: 72 years; UC: 70</p> <p>Gender, Male no (%): TM: 44(42%); UC: 57 (55%)</p> <p>Ethnicity: N/A</p> <p>Severity of condition: N/A</p> <p>Major co-morbidities: CHF (n=59), COPD (n=35), DM (n=58)</p>	<p><b>TM-equipment:</b>A TM system support- ing on-screen hospital-to-home mes- saging, scheduling, and advice from providers to patients. Peripheral de- vices were plugged into the TM unit and collected data (for temperature, blood pressure, pulse, blood glucose, 3-lead ECG, stethoscope for heart and lung sounds, pulse oximetry, and weight).</p> <p>A digital camera was used to monitor wound care Disease- specific patient education modules.</p> <p><b>Data transfer:</b> Data were transmitted (daily) over telephone lines to a Web- based Intranet system and directly in- to the facility's electronic database.</p> <p><b>Review of data:</b> Automatic review of patient data; out-of range data trig- gered alerts via the Web to nurse case managers.</p> <p><b>Type and timing of response:</b> un- clear, but all vital sign data were available for clinicians within 10 min- utes of being received; immediate re- sponse in the case of an alert</p> <p><b>Actions:</b> intervention strategies and patient education,</p>	<p>Monitoring and consulta- tion</p> <p><b>Data trans- ferred:</b></p> <p>temperature, BP, pulse, blood glu- cose, ECG, heart and lung sounds, pulse oximetry, and weight</p>	<p>TM+ nurse case manage- ment</p> <p>vs. UC + nurse case manage- ment</p> <p>UC= usual</p> <p>HHC services</p>	<p><b>Primary out- comes:</b></p> <ul style="list-style-type: none"> <li>• Subjective and objec- tive QOL measures</li> <li>• Health re- source use</li> <li>• Costs</li> </ul>

**Table 5. Summary of Characteristics of Complex co-morbidities studies** (Continued)

**Duration of intervention:** 6 to 12 months

**Follow-up:** 6 to 12 months

- 1 HHC agencies: Home Health Care agencies  
2 CHF: Congestive Heart Failure  
3 COPD: Chronic Pulmonary Disease  
4 IVR: Interactive Voice Response system  
5 HRQOL: Health Related Quality of Life

**Table 6. Summary of Characteristics of Conditions requiring a specialist consultation**

Author Year Setting Country	Clinical condition/ Participants	Description of TM	Function	Comparison	Outcomes
<b>DERMATOLOGICAL CONDITIONS (n=3)</b>					
<b>BERGMO 2009</b>	Atopic dermatitis (children)	<b>TM equipment:</b> a secure web-based messaging system.	Consultation (patient- specialist)	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> one university hospital clinic	Total N=98, TM: n=50; UC: n=48	<b>Data transfer:</b> when felt needed, parents of children with atopic dermatitis could send pictures of the affected area/s with a description of the severity and seek advice			<ul style="list-style-type: none"> <li>Severity scoring atopic dermatitis</li> <li>Resource use (self-reported GP visits etc.)</li> </ul>
<b>Country:</b> Norway	Age, mean (range) yrs: TM: 4.6 (3.7–5.5); UC 5.3 (4.3–6.3)	<b>Review of data:</b> clinical review of data by dermatologist			
	Gender, female sex no (%); TM: 26 (52); UC: 28 (58)	<b>Type and timing of response:</b> respond within 24 hours with advice, or the next day by secure messaging			
	Ethnicity: N/A	<b>Actions:</b> advice on how to handle the condition			
	Severity of condition: SCORAD <sup>1</sup> : TM: 22.3 (19.1–25.6); UC: 22.3 (18.7–25.8)	<b>Duration of intervention:</b> 12 months			
		<b>Follow-up:</b> 12 months after recruitment			
<b>OAKLEY 2000</b>	Dermatologic conditions	<b>TM equipment:</b> a video-conferencing system with an additional camera to capture good quality close up pictures of affected areas for diagnosis and treatment decisions	Consultation (physician- specialist)	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> a local health centre and one hospital (shared care)	Total N=203; TM: n=109; UC: n=94	<b>No of session:</b> One index appointment only			<ul style="list-style-type: none"> <li>Total time involved in attending appointment, including waiting, consultation and travel time</li> </ul>
	Age, mean yrs: 41 years				
	Gender, male/female sex (%); 48/42%				
<b>Country:</b> New Zealand	Ethnicity: N/A				

**Table 6. Summary of Characteristics of Conditions requiring a specialist consultation** (Continued)

	Severity of condition: N/A	<b>Follow-up:</b> one to 12 months			<ul style="list-style-type: none"> <li>Proportion of follow-up appointments</li> </ul>
	Major co-morbidities: N/A				
<b>WOOTTON 2000</b>	<p>Dermatological conditions</p> <p>Total N=204; TM: n=102; UC: n=102</p> <p>Age, mean (SD) and range: 38.6 (SD 23.8) years (range 4 months to 89 years)</p> <p>Gender: Male: 85 (42%); Female: 119 (58%)</p> <p>Ethnicity: N/A</p> <p>Severity of condition: N/A</p> <p>Major co-morbidities: N/A</p>	<p><b>TM equipment:</b> a video-conferencing system with an additional camera to capture good quality close up pictures of affected areas for diagnosis and treatment decisions</p> <p><b>No of session:</b> One index appointment only</p> <p><b>Follow-up:</b>a minimum of 3 months after the index consultation</p>	Consultation (physician-specialist)	TM vs. UC	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Reported clinical outcome of initial consultation</li> <li>Primary care and outpatient re-attendances</li> <li>Costbenefits</li> </ul>
<b>ACUTE INJURIES AND CONDITIONS (patients visiting the ED ; n=1)</b>					
<b>WONG 2006</b>	<p>Patients with emergency neurosurgical conditions (head injury, stroke, and miscellaneous)</p> <p>Total N=475; TM (Video-consultation): n=239; UC (telephone): n=236</p> <p>Age <math>\pm</math> SD (yr): TM: 58.8 <math>\pm</math>20.1; UC: 57.6 <math>\pm</math> 22.4</p> <p>Gender, male sex (%): TM: 61.9; UC: 62.1</p> <p>Ethnicity: N/A</p> <p>Severity of condition:</p> <p><i>Head injury</i> (n = 224): TM: 73; UC: 74</p> <p><i>Stroke</i> (n= 327): TM: 110; UC:106</p>	<p><b>TM equipment:</b> real-time interactive video-conferencing equipment used for video-consultation with the specialist: both the patients and any relevant radiological images could be visualized at the same time, using ...</p> <p><b>No of sessions:</b> one index appointment only</p> <p><b>Follow-up:</b>6 months after index consultation</p>	Consultation (physician-specialist)	<p>TM (video-conferencing and tele-radiology) vs. telephone only</p> <p>Note: one of the study arms (telera-diology only; n=235) was not included in this review</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Favourable outcome (health status/recovery)</li> <li>Mortality</li> </ul> <p><b>Process measures:</b></p> <p>time taken for the consultation process, adverse events during management, safety, necessity for transfer, and diagnostic accuracy</p>
<b>NON-ACUTE CONDITIONS (patients visiting the GP, N=2)</b>					
<b>HARRISON 1999</b>	<p>Patients referred by the GPs for outpatient consultation.</p> <p>Total N=132; TM: n=62; UC: n=70</p> <p>Age: N/A</p>	<p><b>TM equipment:</b> PC-based video- conferencing equipment</p> <p><b>No of sessions:</b> One index appointment only.</p>	Consultation (physician-specialist)	TM vs. UC	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>Patient satisfaction</li> <li>Patient time taken for the visit.</li> </ul>

**Table 6. Summary of Characteristics of Conditions requiring a specialist consultation** (Continued)

<b>Country:</b> UK	Gender, female sex no (%) : N/A	<b>Follow-up:</b> 3 months after index visit			• QOL (SF-12 scores)
	Ethnicity: N/A				
	Severity of condition: N/A				
	Major co morbidities: N/A				
<b>WALLACE 2004</b>	Conditions patients requiring referral to a specialist	<b>TM equipment:</b> PC-based video-conferencing system No peripheral devices.	Consultation (physician-specialist)	TM vs. UC  UC=Standard outpatients appointments	<b>Primary outcome:</b>  • Offer of follow-up hospital appointments.
<b>Setting:</b> GP practices and the Royal Free Hampstead NHS Trust and the Royal Shrewsbury Trust (shared care )	Total N=2094; TM: n=1051;  UC: n=1043  Age, years (SD) TM: 48.4 (20.8); UC: 48.1 (20.7)	<b>No of sessions:</b> One video-conference referral consultation.			<b>Secondary outcomes:</b>
<b>Country:</b> UK	Gender, male no (%) TM:509 (48%) ; UC:508 (49%)  Ethnicity, White: TM: 848 (90%); UC: 835 (88%)  Severity of condition: N/A  Major co-morbidities: N/A	<b>Follow-up:</b> directly after consultation  for referrals; six months from index appointment for patient outcomes			• Number of medical interventions and investigations • Patient satisfaction (assessed with the Ware Specific Visit Satisfaction questionnaire) • Patient enablement (assessed with PEI) • Health status and QOL (assessed with SF12 or the Child Health Questionnaire)

1 SCORAD: is a clinical tool used to assess the extent and severity of eczema (SCORing Atopic Dermatitis). Dermatologists may use this tool before and after treatment to determine whether the treatment has been effective. A representative area of eczema is selected. In this area, the intensity of each of the following signs is assessed as none (0), mild (1), moderate (2) or severe (3). Redness; Swelling; Oozing / crusting; Scratch marks; Skin thickening (lichenification); Dryness (this is assessed in an area where there is no inflammation) The intensity scores are added together to give 'B' (maximum 18).

**Table 7. Summary of Characteristics of Gastro-intestinal conditions studies**

Author Year	Condition/ Characteristics of participants	Description of TM	Function	Comparison	Outcomes
<b>Setting</b>					
<b>Country</b>					
<b>CHAMBERS 2006</b>	Home parenteral nutrition	<b>TM equipment:</b>	Support/Consultation	TM vs. UC	<b>Primary outcomes:</b>
	Total N=30	Video-phone equipment		UC: telephone consultation	• QOL
<b>Setting:</b> 9 home	TM: n=15; UC: n=15	<b>Number of sessions:</b>	(no data transfer)		

**Table 7. Summary of Characteristics of Gastro-intestinal conditions studies** (Continued)

parental nutrition centres	TM: 42.1 (29–62); UC: 37.5 (22–59)	2 times /month for the next month,once monthly for the next 4 months,and at least once every 3 months			<b>Secondary outcomes:</b>
<b>Country:</b> UK	Gender, male/female:  TM: 8/7; UC: 5/10  Ethnicity: N/A  Severity of condition: N/A  Major co morbidities: N/A  Length of index hospital admission, days (SD):  TM: 75 (44); UC: 60 (30)	for the remaining of the study (Total no of video-phone sessions:11)  <b>Duration of intervention:</b>  12 months  <b>Follow-up:</b> 12 months from randomisation			<ul style="list-style-type: none"> <li>• Outpatients re-attendances</li> <li>• Hospital re-admissions</li> <li>• Hospital anxiety</li> <li>• Depression</li> <li>• No of central lines required</li> </ul>
<b>CROSS 2012</b>	Ulcerative colitis	<b>TM equipment:</b>	Remote monitoring	TM vs. UC	<b>Primary outcomes:</b>
<b>Setting:</b> one gastro- enterology clinic of the VAHC <sup>1</sup> system	Total N=47  TM: n=25; UC: n=22  Age, mean ±SD:	A TM system with a Web-based care management portal with customized clinical alerts and action plans.	<b>Data transferred:</b>	UC= control patients underwent routine follow-up, received written action plans, and were given educational fact sheets.	<ul style="list-style-type: none"> <li>• Clinical Disease activity</li> <li>• Disease specific Quality of life</li> <li>• Medication Adherence</li> </ul>
<b>Country:</b> USA	TM: 41.7± 13.9 years ; UC:40.3± 14.4 years  Gender, female no (%) ; TM:15 (60); UC:15 (68)  Ethnicity, white no (%): TM:16 (64) Control:15 (68)  Disease extent::  Proctitis/Left:  TM: 12 (48); UC:10 (45)  Sised pan colitis: TM:113 (52); UC:2 (55)  Medications:  Steroid use:TM:3 (12); UC:2 (9)  Immunosuppressant use:TM:14 (56); UC:6 (27)  Infliximab use:TM: 7 (28); UC:7 (32)	An educational curriculum was delivered after each session.  <b>Review of data:</b> automatic generation of alerts and action plans based on the results  <b>Duration of intervention:</b>  12 months.  <b>Follow-up:</b> 12 months after randomisation	Patients responses to questions regarding disease activity, adherence, side effects, and patients also measured their weight weekly		

<sup>1</sup> VAHC = Veterans Affairs Health Care system

**Table 8. Summary of Characteristics of Urological conditions studies**

Author Year	Condition/Participants	Description of TM	Function	Comparisons	Outcomes
<b>Setting</b>					

**Table 8. Summary of Characteristics of Urological conditions studies** (Continued)

Country					
<b>ELLISON 2004</b>	Patient post op minimally invasive surgical procedure	<b>TM equipment:</b> a web based video conference system mounted on a remotely controlled service robot. The robot was driven into the patient room by a remote workstation, and a joystick interface was used to steer the robot and operate the camera.	Consultation/assessment	TM vs. UC UC: face-to-face post op assessment  Note: one study group (telerounds, n = 29) was not included in the review.	<b>Primary outcome:</b>  • Patient satisfaction with post-operative care
<b>Setting:</b> one urologic clinic	Total N=56; Robotic tele rounds: n=27; Standard rounds: n=29				
<b>Country:</b> UK	Age, mean years: Robotic tele rounds: 58.8; Standard rounds: 57.0				
	Gender, male (%): Robotic tele rounds: 58; Standard rounds: 59				
	Ethnicity: N/A	<b>No of sessions:</b> <i>Robotic tele rounding:</i> participants were seen at the bedside by the attending on the first postoperative day. A resident accompanied the service robot on subsequent days.			
	Severity of condition:				
	Cancer: Robotic tele rounds: 22; Standard rounds: 19				
	Major co-morbidities: N/A	<b>Follow-up:</b> 2 weeks after discharge			
<b>ELLISON 2007</b>	Patients post op elective urologic surgical procedure	See description of the intervention above	Consultation/assessment	TM (partly substituting for UC) vs. UC  UC: face-to-face post op assessment	<b>Primary outcomes:</b>  • Morbidity (major, and minor)  <b>Secondary outcomes:</b>  • Patient satisfaction • LoS
<b>Setting:</b> one urologic clinic	Total N=270;				
<b>Country:</b> UK	TM: n=134; UC: n=136				
	Age, mean, years: Telerounds: 53.6 ; Standard rounds: 54.3, p				
	P = 0.71				
	Gender, male sex, % Telerounds: 62.0; Standard rounds: 60.0, P = 0.90				
	Ethnicity: no information				
	Severity of condition:				
	Surgical distribution (%): Upper urinary tract resection: Telerounds: 63.9; Standard rounds: 59.3				
	Upper urinary tract reconstruction: Telerounds: 6.5; Standard rounds: 15.0				
	Radical prostatectomy: Telerounds: 29.6; Standard rounds: 25.7				
	Major co-morbidities: no information				
<b>HUI 2006</b>	Patients with urinary incontinence	<b>TM equipment:</b> A video-conferencing system	Rehabilitation/	TM vs. UC	Primary outcome:

**Table 8. Summary of Characteristics of Urological conditions studies** (Continued)

<b>Setting :</b>	Total N=64;	with dual video output allowed the subjects to see the nurse specialist and PowerPoint slides on two separate TV screens.	Treatment	UC: face-to-face re-hab-training	• Number of incontinence episodes
one hospital outpatient clinic, one community centre (shared care)	TM: n=32; Control: n=32 Age (SD): TM: 73.6 (5.5); UC: 73.5(3.8) Gender, female sex 100%			TM partly substituting usual care.	
<b>Country:</b>	Ethnicity: N/A	<b>Duration of intervention/No of sessions:</b> Once a week for 8 weeks (8 times in total)			
Hongkong	<i>Severity of incontinence symptoms:</i>  Severe: TM: 8 (30%) ; UC: 5 (17%); Moderate TM: 14(52%) ; UC:15(52%)  Mild TM:5(19%) ; UC:8(28%)  None TM:0 ; UC:1(3%)  Missing TM:0 ; UC: 2	<b>Follow-up:</b> 8 weeks			

**Table 9. Summary of Characteristics of Non-acute neurological conditions studies**

Author Year	Condition/ Participants	Description of TM	Function	Comparison	Outcomes
<b>Setting</b>					
<b>Country</b>					
<b>DALLOLLIO 2008</b>	Spinal cord injury (SCI)  Total N=137; TM: n=69; UC: n=68  Age: 40 years (range, 18–85y)  Gender, male sex: 107 (84.2%)  Ethnicity: N/A  Severity of condition:  Tetraplegia:Bologna: 17-40%  Paraplegia:Bologna:54-83%  Major co morbidities: N/A	<b>TM equipment:</b> A video-conferencing platform powered by software specifically designed to allow operation by people with limited manual skills which allowed the sending and storage of video messages.  <b>No of sessions:</b> one weekly TM session during the first two months, and bi-weekly sessions for 4 months.  <b>Duration of intervention:</b> 6 months  <b>Follow-up:</b> 6 months from recruitment	Consultation/rehabilitation	TM+UC vs. UC  UC=standard care provided to patients discharged to their homes or to non-specialized institutions (hospitals or nursing homes)	<b>Primary outcomes:</b>  • Functional status • Clinical complications • Patient satisfaction (non-validated questionnaire)  <b>Secondary outcomes:</b>  • Medications prescribed • Number and length of any re-admissions to the spinal cord unit • Number and length of emergency admissions to other hospitals

**Table 9. Summary of Characteristics of Non-acute neurological conditions studies** (Continued)

<b>HERMENS 2007</b>	Multiple Sclerosis (MS), Traumatic Brain Injury (TBI) or stroke	<b>TM equipment:</b> A home care activity desk for training of hand/arm function and a video-conferencing system was used.	Rehabilitation	TM vs. UC  UC=usual care and general exercises prescribed by their physician	<b>Primary outcome:</b>  • Arm/hand function  <b>Secondary outcomes:</b>  • Average exercise time per day • User satisfaction
<b>Setting:</b> 3 rehabilitation centres	Total N=81; TM: n=55; UC: n=26	<b>No of sessions:</b> one 30 min training session a day for 5 days a week.			
<b>Country:</b> Italy, Spain and Belgium	Age, years, mean±SD: TM: 46.5± 17.7; UC: 50.1± 18.2	<b>Duration of intervention:</b> one month			
	Gender, male/female: 47/34	<b>Follow-up:</b> one month from recruitment			
	Ethnicity: no information				
	Severity of condition:				
	Stroke: TM: n=11; UC:n=5				
	TBI: TM: n=20; UC:n=10				
	MS: TM:n=24 ; UC:n=11				
	Major co-morbidities: no information				

**Table 10. Summary of results - Heart failure**

Author Year	Mortality	Admission to hospital	Length of stay	ED /Urgent care visits/ Clinic visits	Quality of Life (QoL), Self-esteem Depression Self-care	Costs/ Access to care Satisfaction
<b>ANTONI-CELLI 2008</b>	All-cause mortality  at 12 months:  TM: 3 (10.7%), n=28;  UC: 5 (17.2%),n=29, P = NS  Combined end-point of mortality and hospital admission rate at 12 months:  TM: 12, n=28; UC:31, n=29  Mean incidence rate/events/patient/month:	All-cause hospital admissions at 12 months:  TM: 9, n=28; UC:26, n=29; P < 0.001			General QoL (assessed with the SF-36 <sup>1</sup> ) at 12 months:  Physical component summary, mean (SD): TM:39 (11); UC:39 (11), P = NS  Mental component summary, mean (SD): TM:53 (12); UC:48 (9)	



**Table 10. Summary of results - Heart failure** (Continued)

TM:0.043;  
UC:0.107,  
p=0.006

BENATAR 2003	Total no of HF-related hospital admissions		Total no of HF-related hospital days at 3 months	Disease specific QoL (assessed with the ML-HFQ <sup>2</sup> ): at 3 months: TM:51.64 (17.36), n=108; UC:57.72 (16.24), n=108, P = 0.47	HF hospitalisation charges (US \$) <sup>6</sup> :
	at 3 months:				
	TM:13, n=108; UC:24, n=108, P < 0.01		TM: 49.5 days, n=108; UC: 105 days, n=108; P < 0.001	QLI cardiac version <sup>3</sup> at 3 months: TM: 20.93 (3.35); UC:18.34 (3.73), P = 0.63	At 3 months:
	At 6 months:				TM: 65023;UC: 177365, P < 0.02
	TM:38; UC:63, P = 0.05			HADS <sup>4</sup> score at 3 months: TM:12.53 (5.08); UC:15.52 (5.97), p P = 0.03	Cumulative re-admission charges
	At 12 months			Heart Failure Self-efficacy scale <sup>5</sup> scores at 3 months: TM:35.90 (2.73); UC:32.74 (3.53), P = 0.43	at 6 months:
	TM:75;UC:103,P = 0.12				TM: 223 638;UC: 500 343, P < 0.03
					at 12 months:
					TM: 541 378;UC: 677 710, P = 0.16
BOWLES 2011	All-cause mortality at 6 months:TM:4, n=102; UC:5, n=116, P = 0.822  Combined end-point of time to re-admission:or death; (log- rank P = 0.319)	At least one all-cause re-admission by 30 days: TM:16% (16); UC:19%(22) , P = 0.546	Mean no of all-cause hospital days by 30 days (after index visit): TM:0.91 (2.49); UC:1.41 (4.05), P = 0.260	At least one ED <sup>7</sup> visit by 30 days (after index visit):TM:10% (10); UC:10% (12), P = 0.939	Mean no of in-person home visits (during the initial home care episode, including certification):
		At least one HF-related admissions by 30 days:			
		TM:8% (8); UC: 9% (10), NS	Mean no of HF-related hospital days by 30 days: TM:0.48 (1.75) ; UC: 0.38 (1.38), P = 0.523	Time to first ED re-admission (adjusted for age and no of medications). No data provided, P = 0.231.	TM:5.0 (1.8); UC:4.2 (1.1), P = 0.013
		Time to first re-admission. No difference between groups, P = 0.319			Proportion patients who were re certified for an additional episode of

**Table 10. Summary of results - Heart failure** (Continued)

					home care: TM:24%; UC:9%, P < 0.003
					Length of initial home care episode: TM:54 days (41); UC:35 days (23), P < 0.001
					Satisfac- tion:  Enough home vis- its (agree): TM:84%; UC: 89%, NS
					Discharge (too soon): TM:25 %; UC: 75%, P = 0.03
					Not know- ing how to con- tact nurses (agree): TM: 0%; UC:7%, P = 0.02
<b>BOYNE 2012</b>	Mortality (all- cause) at 12 months: TM: 18 (9,1%), n=197; UC:12 (6.5%), n=185, P = 0.34  Combined end- point of all- cause mortal- ity and HF ad- missions at 12 months: HR <sup>8</sup> : 0.89, 95% CI: 0.69 to 1.83, P = 0.641	Mean time (days) to first HF readmission:  TM:161 (range 344; median 170); UC:139 (range 296; medi- an126), P = 0.151  No of patient with at least one HF-relat- ed readmission at 12 months: TM:18 (9.1%); UC:25 (13.5%) HR:0.65; 95% CI 0.35-1.17, P = 0.151  All-cause readmis- sions not reported.	Total no of days in hos- pital at 12 months: TM:1128; UC: 866; P = 0.40  No of HF-re- lated hospital days stayed at 12 months: TM:253 (22%); UC:330 (38%),P = 0.18  No of CV <sup>9</sup> re- lated days stayed (not HF): TM:155 (14%); UC:101 (12%), P = 0.28  No of days stayed for oth-	Disease-specific knowl- edge at 12 months (as- sessed with the Dutch Heart Failure Knowl- edge Scale <sup>10</sup> ): TM:BL: 12.6 (1.7); 12 months: 13.5 (1.2); UC: BL:12.3 (1.8); 12 months: 12.6 (1.8), P < 0.0001  Self-care at 12 months (assessed with EHFSCB Scale <sup>11</sup> ): TM:BL: 18.9 (5.3); at 12 months: 17.4 (4.5); UC: BL:20.9 (6.1); at 12 months :20.8 (5.8), P < 0.001 (corrected for BL differences)  Self-efficacy at 12 months (assessed with the Barnason Efficacy Expectation Scale <sup>12</sup> ): TM:53.2 (7.1); at 12	Total costs (in Euros): TM:16,687 (CI 14,041– 19,114); UC: 16,561 (CI 13,635– 20,218).The difference between groups was 126 Euros, indicating no signif- icant dif- ference (CI 24374– 3763).  The ICER <sup>14</sup> for TM ver- sus UC amounted to E40,321

**Table 10. Summary of results - Heart failure** (Continued)

		er causes: TM:720 (64%); UC:435 (50%), P = 0.21	months:54.9 (6.5); UC:BL: 51.2 (9.6); at 12 months:52.3 (8.9), P = 0.192	per QALY <sup>15</sup> gained.
		Mean dura- tion of HF-re- lated admis- sions: TM:9.9 (0-36); UC: 8.0 (0-39),p value not given	Adherence at 12 months (assessed with the Heart Failure Com- pliance Scale <sup>13</sup> ):	
		Mean dura- tion of non HF admissions: TM:8.8 (0-112); UC:7.7 (0-69), p value not given	Medication:T- M:100 :UC:98.7, P = 0.107	
		Planned and unplanned face to face contacts with the HF nurse TM: 1.36 (range 0-11); UC: 1.74 (0- 8) , P <0.001	Weighing:TM:87.2 : UC:72.8, P < 0.0001	
		No difference in the number of telephone contacts with the nurse be- tween groups.	Diet:TM:81.7 : UC:80.9, P = 0.724	
			Fluid:TM: 84.8: UC:81, P = 0.086	
			Activities:TM:65.8 : UC:64.1, P = 0.61	
			Smoking:TM:92.2: UC:92.4, P = 0.918	
			Alcohol:TM:90.3 : UC:92.5, P = 0.311	
<b>CAPOMOL- LA 2004</b>	All-cause mor- tality at 12 months:  TM: 5 (7.5%), n=67;  UC: 7 (10.6%),n=66, NS  CV-related mor- tality  at 12 months:  TM: 4 (6 %);UC: 7 (11%), NS	Total no of hospi- tal admissions at 12 months:  TM: 22, n=67;  UC: 77, n=66, P < 0.009	Total no of CV-related ED visits at 12 months:  TM: 1, n=67; Control: 12, n=66, 0 .05	
<b>CHAUDHRY 2010</b>	Readmission for any reason or death from any cause with-	All-cause readmis- sion at 180 days: TM: 49.3% ; UC: 47.4%. Dif- ference, 1.9 percent-	Mean No of days in hos- pital at 180 days: TM:7.2	

**Table 10. Summary of results - Heart failure** (Continued)

	in 180 days : TM:52.3% , n=820; UC: 51.5%, n=827 . Difference, 0.8 percent- age points; 95% confidence in- terval [CI], -4.0 to 5.6; P = 0.75	age points; 95% CI, -3.0 to 6.7; P =0.45	(14.6); UC:7.0 (14.9), P = 0.27	
	Death at 180 days: TM:11.1% ; UC:11.4% . Dif- ference, -0.2 percentage points; 95% CI, -3.3 to 2.8; P = 0.88	Admission for HF,no (%) at 180 days: TM:227 (49.3); UC:223 (27.0), P = 0.81		
<b>CLELAND 2005</b>	All-cause mor- tality at 240 days <sup>16</sup>  TM: 28, n=168; UC:20, n=85, p =0.032  Days dead or hospi- talised at 240 days month- s:TM: 4,898 (12.7%) ;UC: 3,885 (19.5%); Diff. in means and 95% CI: 16 (37 to 6), NS  Days lost due to death: TM:3,119 (8.1%); UC:3,072 (15.4%); Diff. in means and 95% CI: 17 (36 to 2)	Patients admitted to hospital (all-causes) at 240 days:  TM: 80 (47%), n=163  UC: 46 (54%), n=85  Note: not analysed  Patients admitted to hospital for HF at 240 days: TM:40 (25%); UC: 24 (28%)  Note: not analysed  Total no of hospital admissions at 240 days: TM:155; UC: 69  Note: not analysed  Total no of HF-related hospitalisations:  TM: 67; UC: 33  Note: not analysed	All-cause LoS, median (IQR) at 240 days:  TM: 9 (4 to 15), n=163; UC:7 (4 to 12), n=85, Diff. between means and 95% CI: 0 (7 to 6)  HF-related LoS at 240 days: Medi- an (IQR): TM: 11 (6 to 19); UC:11 (6 to 20), Diff. be- tween means and 95% CI:1 (13 to 11)	Total no of ED visits <sup>17</sup>  at 240 days:TM; 60 ; n=168; UC: 8; n=86  Note: not analysed
<b>DANSKY 2008</b>		Proportion (no) one or more hospital admis- sions at 60 days (dur- ing HHC <sup>18</sup> episode of care):  TM (monitor and video):31.1% (14), n=45; UC:29.1% (32), n=112, NS	Proportion (no) one or more ED vis- its at 60 days (during HHC episode of care):  TM (mon- itor and video):18.2% (8), n=45;	There was no difference in general or disease specific QoL between groups (P > 0.5 for EQ -5D <sup>19</sup> and P > 0.6 for ML- wHF).  No data reported for the respective groups separately.

**Table 10. Summary of results - Heart failure** (Continued)

		<p>The average number of hospital admissions, controlling for the number of days in home care (HHC days), was similar for the control and TM groups for both periods (60 and 120 days).</p>		<p>UC:30.3% (34), n=112, NS</p> <p>We did not include the 120 days results as some participants had their TM equipment removed at 60 days, while some participants received a second period of home care.</p>		
<b>DAR 2009</b>	<p>All-cause mortality at 6 months<sup>20</sup>:</p> <p>TM:17 (18.7%), n=91; UC:5 (5.5%),n=91</p> <p>Not analysed.</p> <p>Median no of days alive and out of hospital : TM:178 days (IQR:90–180);UC:180 days (IQR: 165–180), p =0.30</p>	<p>Patients hospitalised (all-cause), n (%) at 6 months: TM:33 (36); UC:23 (25), no p value or CI given</p> <p>Number of hospitalizations (all-cause): TM: 44; UC: 39</p> <p>Patients hospitalised (HF), n (%):TM: 17 (19); UC:10 (11)</p> <p>Number of hospitalizations (HF) : TM: 22; UC:16</p> <p>No difference in the time to first HF-related hospital admission in the two groups (P = 0.11)</p>	<p>Duration of hospitalisation</p> <p>Median (IQR):</p> <p>TM: 17 (6–25), n=91; UC:13 (8–34), n=91, P = 0.99</p> <p>HF-related LoS at 6 months:</p> <p>Median (IQR):</p> <p>TM: 17 (8–25); Control: 9 (7–33), P = 0.62</p>	<p>Total no of ED visits at 6 months::</p> <p>TM:20 ; UC: 32</p> <p>TM: n=91; UC: n=91</p> <p>Proportion emergency HF admissions at 6 months:TM: 8/22 (36%); UC: 13/16 (81%) , P &lt;0.01</p> <p>Total no of secondary care outpatients visits at 6 months: TM:622; UC: 733, n=91, p value or CIs not given</p> <p>Total no of Primary care visits at 6 months:T- M:421; UC: 403, n=91, p value or CIs not given</p>	<p>Disease specific QoL (assessed with EQ 5D and the MLwHF)</p> <p>No significant differences between the groups (P &gt; 0.5 for EQ 5D and P &gt; 0.6 for MLwHF).</p> <p>No raw data reported.</p>	<p>Mean total health service cost/patient (GBP)<sup>21</sup>:</p> <p>TM: £4610 (SD £7377); UC: £3006 (SD £3847), P &lt; 0.20</p>
<b>DENDALE 2012</b>	Mortality (all-cause) at 6	Mean no of all-cause hospital admissions	Total no of days lost to			Total costs (in Euros)

**Table 10. Summary of results - Heart failure** (Continued)

	months:TM: 4 (5%); UC: 14 (17.5%), P < 0.01.	per patient (SD): TM: 0.8 (0.97); UC: 0.82 (0.93), P = 0.93	all hospital admissions: TM: 7.1 (13.0); UC:8.0 (12.8), P = 0.65	for hospital admissions per patient: TM :2557 (4094); UC:2643 (4642), P = 0.90
	Note: no of participants randomised to each group not stated; we assume equal distribution of patients in TM and UC group (180 patients in total)	Mean no of HF-related hospital admissions per patient (SD): TM: 0.24 (0.51); UC:0.42 (0.70), p= 0.06	Total no of follow-up days lost to all HF-related hospital admissions, dialysis, or death at 6 months:  TM:13.1 (37.6) ; UC: 30.2 (56.0) days, p <0.02	
<b>GIORDANO 2009</b>	All-cause mortality at 12 months:  TM: 21 (9%) ,n=230:  UC: 32 (14%), n=230,no P value or CI given  Cardiovascular mortality at 12 months: TM:8% (18 patients); UC: 13% (29 patients) ,RR=0.44, 95% [CI]: 0.20–0.97; P = 0.04  In multivariate Cox-proportional hazard models including baseline variables; HR=0.45, 95% [CI]: 0.19–1.03; P = 0.06	All-cause hospital admissions at 12 months:  TM:67, n=230; UC: 96, n=230, not analysed  At least one re-admission due to cardiac event:TM: 55 pts (24%); UC: 83 pts (36%); RR=0.56; 95% CI: 0.38–0.82; P = 0.01  HF-related readmission at 12 months: TM:19% (43 patients); UC:32% (73 patients), RR=0.49, 95% [CI]: 0.31–0.76; P < 0.0001		Mean cost for hospital admissions (Euro) <sup>22</sup> :  TM: 843±1733; UC: 1298±2322, Diff: –35%, P < 0.01.  According to estimated  NNT the annual cost to prevent one readmission was € 638 (95% [CI]: 850–1913).
<b>GOLDBERG 2003</b>	Overall time to death or first re-hospitalisation only graphically presented.	Time to first re-hospitalisation only graphically presented.	Time to first ED visit only graphically presented.	General QoL (assessed with the SF-12 <sup>23</sup> ) at 6 months;  change from BL:  Physical summary score : TM:6.7 (10.4), n=138; UC:4.3 (11.4), n=142; P = 0.15

**Table 10. Summary of results - Heart failure** (Continued)

					<p>SF-12 Mental summary score; TM:5.9 (10.6); UC:5.2 (13.2), P = 0.73</p> <p>Disease specific QoL at 6 months:</p> <p>Heart Distress Score<sup>24</sup> at 6 months: TM: 4.8 (8.3); UC:5.5 (8..8), P = 0.57</p> <p>MLwHF change scores from BL to 6 months: TM:27.8 (23.8); UC: 23.3 (26.9), P = 0.22</p>	
<b>JERANT 2001</b>	<p>All-cause mortality at 6 months: TM: 0, n=13, UC:0, n=12</p>	<p>Total no of hospital admissions at 6 months:</p> <p>TM: 9, n=13; UC: 15, n=12, p value not given</p>	<p>All-cause LoS at 6 months:</p> <p>Mean (SD): TM 2.7 (6.2), n=13; UC: 7.9 (17.2), n=12, no P value provided</p> <p>HF-related LoS at 6 months:</p> <p>Mean (SD) TM: 0.7 (2.5); UC:3.0 (7.2), P value not given</p>	<p>All-cause ED visits at 6 months:</p> <p>Mean (SD): TM: 0.7 (1.4); UC: 1.8 (2.5), P = 0.178</p> <p>Total no all-cause ED visits at 6 months</p> <p>TM: 9, n=13; UC: 22, n=12</p> <p>HF-related ED visits at 12 months:</p> <p>Mean (SD): TM: 0.1 (0.3); UC:0.7 (0.9), P = 0.0342</p>	<p>General QoL (assessed with the SF-36) at 60 days:</p> <p>Physical component summary, mean score (SD): TM:35.1 (10.5); UC:33.7 (15.7); P = 0.4826</p> <p>Mental component summary, mean score (SD): TM:44.6 (9.9); UC:48.9 (9.5), P = 0.1185</p> <p>Disease specific QoL (assessed with the MLHFQ) at 60 days: TM:50.4 (30.5); UC:38.1 (28.7), P = 0.3922</p> <p>CSQ scores: TM:29.8 (3.5); UC:27.8 (4.5), P = 0.4095</p>	<p>Hospital re-admission charges (\$)<sup>25</sup>:</p> <p>TM: 19,087 ±42,822; UC: 85,176±190,405, P = 0.2188</p> <p>Total care, mean charges:</p> <p>TM:29,701±42,219 UC:93,686±192,976, P = 0.7144</p>
<b>KASHEM 2008</b>	<p>All-cause mortality at 12 months:</p> <p>TM: 1 (4.2%), n=24;</p> <p>UC: 1(4.2%), n=24, NS</p>	<p>Total no of hospital admissions at 6 months:</p> <p>TM: 24, n=24; UC: 40, n=24, P = 0.025</p> <p>Time to hospital admission: reduced risk for hospitalisation in TM group as compared with UC, P = 0.017</p>	<p>All-cause total LoS (days) at 8 months:</p> <p>TM: 84 days, n=24; UC: 226 days, n=24, p &lt; 0.05.</p>	<p>Total no of ED visit at 12 months: TM:5, n=24 ; UC:12, n=24 , P &lt; 0.05</p> <p>Unscheduled visits:</p> <p>TM: 13; UC: 13, NS</p> <p>Scheduled clinic visits:</p> <p>TM: 78, n=24; UC: 94, n=24; NS</p>		

**Table 10. Summary of results - Heart failure** (Continued)

				Total no of phone calls at 12 months: TM: 88 (+ 1887 TM data messages), n=24; UC: 74, n=24, NS
<b>KOEHLER 2011</b>	<p>All-cause mortality at median 26 months: TM:54; UC: 55, P = 0.87</p> <p>Mortality due to cardiovascular cause: TM:40; UC: 46; P = 0.49</p> <p>Combined endpoint of days lost because of death or HF hospital admissions: TM:32.8 (82.1); UC:38.9 (97.0), P = 0.66</p>	<p>Total no of hospitalisation due to HF or death due to cardiovascular cause: TM:153; UC: 160, P = 0.44</p> <p>Any hospital admission: TM:486; UC:394, P = 0.29</p> <p>Hospital admission for any cardiovascular cause:TM:290; UC: 248, P = 0.58</p> <p>Hospital admissions for HF: TM:113, UC: 114, P = 0.32</p>	<p>Mean duration of all-cause hospital admissions: TM:16.7 (32.3); UC:13.7 (22.7), P = 0.15</p> <p>Mean duration of HF-related hospital admissions: TM:5.3 (18.1); UC:4.9 (13.2), P = 0.71</p>	<p>General QOL: Note: No overall score provided.</p> <p>(SF 36): Physical functioning: at 12 months TM:54.3 (1.2); UC:49/9 (1.2), P = 0.01</p> <p>at 24 months: TM:53.8 (1.4); UC:51.7 (1.4), P = 0.30</p> <p>NYHA functional class<sup>26</sup>:No difference between groups. at 12 and 24 months. No data provided.</p> <p>Depression (assessed with the PHQ-9 depression scale<sup>27</sup>). No difference between groups at 12 and 24 months.No data provided (see online material)</p>
<b>MADIGAN 2013</b>	<p>Mortality not reported separately.90 and 180 days results data a composite of hospital admissions and ED visits</p>	<p>Admission to hospital first 30 days of HHC n (%): TM:14 (25.5),n=55; UC: 7 (15.9), n=44; P = 0.25</p>	<p>Median time to combined endpoint (all-cause hospital admission, ED visits, and death)</p> <p>TM: 60 days; UC: 62 days;p=0.5</p> <p>Nurse visits:</p> <p>TM: 12.7±7.9, n=55 ; UC: 9.5±4.1, n=44 (P = 0.01)</p> <p>Note: longer HHC period for TM patients</p>	<p>Disease specific QoL (assessed with the KCCQ<sup>28</sup>) at HHC discharge:: TM:72.5 (20.3), n=55; UC:63.8 (26.6), n=44, p- value not provided for overall summary scores. Significantly higher scores in the TM group as compared with controls.</p>



**Table 10. Summary of results - Heart failure** (Continued)

<b>MORTARA 2009</b>	All-cause mortality at 12 months:No result data reported - authors just state no statistical differences between groups.	Patients hospitalised for all causes at 12 months:  TM: 35 (35%), n=101; UC: 48 (30%), n=160), NS  (P value not reported)	All-cause LoS at 12 months:  Total counts (% of potential days)  TM:544 (1.6%), n=101; UC: 975 (1.7%), n=160, NS (P value not reported)  HF-related Total counts (% of potential days)  at 12 months:  TM:324 (1.0%), n=101; UC: 584(1.0%), n=160, NS  (P value not reported)		
<b>SCHERR 2009</b>	CV-related mortality at 6 months:  TM:0/66  UC:1/54  Combined end point:  (death or hospital admission),  TM:11 (17%, 0 deaths, 11 hospital admissions); UC: 18 (33%, 1 death, 17 hospital admissions); Relative risk reduction 50%, 95% CI 3-74%, P =0 .06)	CV-related hospital admissions only:  At 6 months:  TM: 11, n=66  UC:17, n=54	Median HF-related LOS (IQR) at 6 months  TM: 6.5 days; (5.5-8.3) : UC: 10.0 days, (7.0-13.0); P = 0.04		
<b>SCHWARTZ 2008</b>		Mean no of hospital admissions at 3 months  TM: 0.32 (SD 0.6), n=44; UC: 0.33 (SD 0.6),n=40, NS	Mean no ED visits at 3 months :  TM: 0.34 (0.6); n=44;	Disease specific QoL (assessed with the MLHFQ) at 3 months: TM:27.4 (21.7); UC:27.3 (21.6), P = 0.98	Hospital charges (US \$) <sup>31</sup> :  TM:10,996.86±29,230.05; UC:5.462.58±9,825.00,  P = 0.26

**Table 10. Summary of results - Heart failure** (Continued)

		Days to readmission: TM: 40.6 (31.3); UC:41.2 (24.0), NS	UC:0.38 (0.5); n=40, P = 0.73	CES-D22 <sup>29</sup> scores at 3 months: TM:8.2 (11.2); 6.6 (6.7), P = 0.44	Costs of care (US \$): TM: 12 017,99 (SD 29 405,65); UC: 6673,29 (SD 10 258,28), P = 0.28
<b>SETO 2012</b>	All-cause mortality at 6 months: TM:3; UC: 0, P value not reported	Mean no of hospital admissions at 6 months: TM:0.5 (0.8), UC:0.2 (0.4), P = 0.1	Mean number of nights in hospital; TM:2.3 (5.3); UC:1.3 (4.2), P = 0.2	Mean no of ED visits at 6 months: TM:0.4 (0.4); UC:0.3 (0.5), P = 0.6	Disease specific QOL (assessed with the ML-wHF questionnaire) at 6 months: TM:41.4 (26.7), n=38; UC:47.3 (23.4), n=44, P = 0.20
				Mean no of Heart Function Clinic Visits at 6 months: TM:3.5 (3.6); UC:2.5 (2.5), P = 0.04	Self-care (assessed by the SCHFI <sup>32</sup> ) at 6 months: Self-care maintenance: TM:73.3 (11.6), n=38; UC:65.5 (15.8), n=44, P = 0.03
					Self-care management: TM:68.6 (16.0), n=18; UC:69.3 (18.3), n=21, P = 0.7
					Self-care confidence: TM:57.7 (19.5), n=37; UC:56.2 (21.8), n=43, P = 0.9;
					BNP <sup>33</sup> levels at 6 months:TM: 414 (604), n=44; UC:303 (460), n=44, P = 0.2
					LVEF% <sup>34</sup> at 6 months:TM:32.7 (11.8), n=41; UC:31.3 (12.5),n=35, P = 0.7
					NYHA class at 6 months: TM:2.1 (0.2), n=43; UC:2,2 (0.7), n=38, P = 0.8
<b>SORAN 2008</b>	All-cause mortality at 6 months TM: 11 (7.0%), n=160; UC: 17 (11.2%), n=155, P = 0.24	Any hospital admission at 6 months: TM: 75 (46.8%), n=160; UC: 66 (42.5%), n=155, P = 0.44	HF-related LoS at 6 months: Mean LoS, SD TM: 10.0 ± 7.3, n=160; UC: 9.3 ±12.2, n=155, P = 0.22	Any ED visit, no (%):at 6 months: TM: 73 (45.9), n=160; UC: 69 (44.4), n=155, P = 0.93	General QoL (assessed with SF-36) and disease specific QoL (assessed with KCCQ). No results reported.

**Table 10. Summary of results - Heart failure** (Continued)

No measure of dispersion.

<b>SPAEDER 2006</b>				Disease specific QoL (assessed with KCCQ) and depression (assessed with the Zung Depression Scale).No results reported.
<b>WAKE-FIELD 2008</b>	<p>All-cause mortality at 12 months:</p> <p>TM: 15 (28.9 %), n=52;</p> <p>UC: 11 (22.4%), n=49, NS</p> <p>Note: data received from the authors</p>	<p>Mean number of all-cause hospital admissions at 3 months TM:0.29 (0.72); UC:0.45 (0.84)</p> <p>at 6 months TM:0.69 (0.92); UC:0.71 (0.98)</p> <p>at 12 months TM:0.77 (1.21); UC:1.12 (1.48)</p> <p>Mean no of CV-related hospital admissions</p> <p>at 3 months: TM:0.02 (0.14); UC:0.04 (0.20)</p> <p>at 6 months TM:0.12 (0.32); UC:0.04 (0.20)</p> <p>at 12 months TM:0.12 (0.32); UC:0.14 (0.35)</p> <p>Mean no of HF-related hospital admissions at 3 months:</p> <p>TM: 0.02 (0.14), n=42; UC:0.04 (0.20), n=44</p> <p>at 6 months: TM:0.12 (0.32), n=33; UC:0.04 (0.20), n=42 at 12 months: TM:</p> <p>0.12 (0.32); UC:0.14 (0.35)</p> <p>Time to readmission (the 2 intervention groups combined): HR: 0.54; 95% CI: 0.33 to 0.90, P = 0.02. No difference for the separate intervention groups vs. UC.</p>	<p>Mean no of urgent care visits at 3 months TM: 0.04(0.19); n=52; UC:0.06 (0.24);n=49</p> <p>at 6 months TM:0.06 (0.24); UC:0.08 (0.34)</p> <p>at 12 months TM (Video-phone): 0.06(0.24); UC: 0.08(0.34),</p>	<p>Disease specific QoL (assessed with the MLHFQ) at 180 days:</p> <p>TM: 54.0 (26.0), n=33; UC:56.6 (23.9), n=42</p>
<b>WEIN-TRAUB 2010</b> (and Konstam 2010)	<p>All-cause mortality at 90 days, no (%): TM: 1(1.1), n=95; UC: 4</p>	<p>The relative event rate of HF hospitalisation at 90 days: 0.50 (95%CI [0.25 to 0.99], P &lt;0 .05).</p>	<p>All-cause inpatient days (ALOS<sup>1</sup>):TM: 24 98.45); UC:260</p>	<p>Disease specific QOL (assessed with the ML-wHFQ) at 90 days:(56% lost to follow-up).</p>

**Table 10. Summary of results - Heart failure** (Continued)

(4.3), n=93, P = 0.209,	(8.39); Event rate <sup>2</sup> : TM: 4.14 (0.68 to 25.13); UC: 3.61 (0.54 to 24.19)	BL: TM: n=46; 56.8 (23.1) (11.0, 95.0)
		UC: n=48; 54.7 (26.2) (6.0, 104.0), P = 0.679
	Heart failure inpatient days (ALOS): TM: 95 (9.50); UC: 150 (7.89); Event rate: TM: 4.73 (0.19 to 117.3); UC: 11.86 (0.36 to 396.0)	Change at 45 days
		TM: n=43; -17.8 (20.3), (-69.0, 26.0)
		UC: n=42, -14.8 (25.0) (-76.0, 34.0), P = 0.416
		Change at 90 days
		TM: n=43, -18.6 (18.7) (-66.0, 24.0)
	1 ALOS=average length of stay	UC: n=42, 20.8 (23.5) (-77.0, 40.0), P = 0.759
	2 Estimates of event rate per 90 days of patient follow-up generated by Poisson regression models	(data from Konstam 2011)

<b>WOODEND 2008</b>	Results on mortality not reported for the groups separately (n=9 patients with HF and n=3 patients with angina had died at 3 months).	Mean no of hospital admissions at 3 months; HF: TM: 0.46; UC: 0.49, NS Angina: TM: 0.34; UC: 0.69, P = 0.016 at 12 months HF: TM: 0.96; UC: 0.92, NS Angina: TM: 0.55; UC: 1.00, P = 0.02	Angina: Mean no of visits during first 3 months: TM: 0.15 ; UC: 0.35 (P = 0.012; P = 0.037) TM: n=62; UC: n=66 HF: no result data Angina: At 12 months: TM: 0.31; UC: 0.83 (p = 2.63, P = 0.012). TM: n=62; UC: n=66 HF: no result data No differences between	General QoL (assessed with SF-36). Results not reported for intervention and control groups separately. MLwHF scores :No differences between TM and UC groups in overall score at 1 month postdischarge (P = 0.18) when controlling for BL scores. TM group had significantly better the overall score (P = 0.003) at 3 months than patients receiving UC. At 1 year there were no differences between groups.. No numerical results reported.
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**Table 10. Summary of results - Heart failure** *(Continued)*

groups in  
the number  
of ED visits  
made in the  
first month,  
3 months,  
or 1 year af-  
ter study en-  
rolment for  
all patients  
combined or  
for patients  
with HF.

No result da-  
ta report-  
ed for no of  
physician  
(generalist  
or specialist)  
visits or no  
of home care  
visits.

1 SF-36: The Short Form (36) Health Survey is a patient-reported survey of patient health consisting of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability. The higher the score the less disability i.e., a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability

2 Minnesota Living with Heart Failure Questionnaire (MLwHF): a scale which is used to measure the effects of heart failure and treatments on quality of life. The suggested cut-off scores for the MLwHFQ (Belouhli 2009) are <24 good, 24-45 moderate, >45 poor; i.e. a lower score indicates a better quality of life.

3 Quality of Life Index (QLI) cardiac version: a scale which is used to measure quality of life in terms of satisfaction with life (part 1) and importance regarding various aspects of life (part 2). Scores from parts 1 and 2 are combined so that higher scores represent higher satisfaction and importance. Scores for each sub scale are transformed to a scale of 0-30.

4 Hospital Anxiety and Depression Scale (HADS): a self-assessment scale used to detect states of depression, anxiety and emotional distress amongst patients (Zigmond and Snaith 1983). The scale has a total of 14 items, with responses being scored on a scale of 0-3, with 3 indicating higher symptom frequencies. Scores for the entire scale (emotional distress) range from 0-42, with higher scores indicating more distress.

5 Heart Failure Self-Efficacy Scale: a questionnaire which contains 5 sub scales designed to measure self-efficacy with medications, diet, symptom control, activity, and HF readmissions. Higher scores are indicative of higher self-efficacy.

6 Heart failure hospitalisation charges calculated for each admission according to discharge summary data and totaled for each group.

7 ED: Emergency Department

8 HR: Hazard Ratio

9 CV: Cardio Vascular

10 Dutch Heart Failure Knowledge Scale: is a 15-item, self-administered questionnaire that covers items concerning HF knowledge in general, knowledge on HF treatment (including diet and fluid restriction) and HF symptoms and symptom recognition. Higher scores indicate more knowledge.

11 European Heart Failure Self-Care Behavior Scale (EHFSCB): a 12-item scale to measure self-care behaviour. The items are rated on a 5-point scale between 1 (completely agree) and 5 (completely disagree), with lower scores indicating that the patient performs more self-care behaviour.

12 Barnason Efficacy Expectation Scale: is a 15-item scale used to assess self-efficacy. Items are rated from on a 5-point scale between 0 (completely disagree) to 4 (completely agree), with higher scores indicating patients had more confidence.

13 Heart Failure Compliance Scale: a scale used to assess compliance with therapy (identifying six health behaviours; appointment keeping, medication, sodium restriction, fluid restriction, daily weighing and exercise). First patients state the importance of the health behaviour by using a 5-point scale ranging from 0 (not at all important) to 4 (highly important). Finally, compliance is measured on a 5-point Likert scale (0, never; 1, seldom; 2, half of the time; 3, mostly; and 4, always). Higher scores indicate better adherence.

14 ICER: Incremental Cost Effectiveness Ratio (incremental costs divided by incremental effects): the extra monetary resources needed for the TM strategy to gain one extra QALY compared to UC.

15 QALY: The quality-adjusted life year or quality-adjusted life-year (QALY) is a measure of disease burden including both the quality and the quantity of life lived.

16 Note: Stopped early because of a large difference in mortality rate between the UC group and those assigned randomly to NTS or HTM and because it was unlikely that the primary end point would be reached: 4 patients did not reach 240 days. Results for 450 days follow-up are not reported here.

17 The outcome was assessed monthly in the TM group but every 4 months in the UC group.

18 HHC: Home Health Care

19 EQ -5D:

20 The study stopped early due to funding reasons.

21 We calculated the costs of home tele monitoring vs. UC over the 6 month period of the study. The analysis was undertaken at the individual (patient) level. The costs included in the analysis were tele monitoring equipment cost, hospital readmission costs, drug costs, primary care visit costs, secondary care visit costs, and hospital transport costs. Costs for each component were computed by multiplying the volume of resources used in each component by their unit costs. Resource use data were obtained directly from the trial. The unit costs were obtained from published national sources

22 Cost of readmissions during the follow-up was calculated using Medicare Diagnosis-Related-Group (DRG) reimbursement. In the programme the costs were classified as either fixed or variable. Fixed costs included equipments purchase and installation, installation of telecommunication lines, monthly line charges, maintenance costs. The annual equivalent costs of equipments were calculated incorporating depreciation and opportunity cost over a period of 5 years. Variable costs included Call Center services, nurses and cardiologist's costs and telecommunication costs. The average annual salaries for nurse and cardiologist were obtained from Salvatore Maugeri Foundation and reduced to a wage per minute. This wage per minute value was multiplied by the recorded duration of consultations to calculate the total costs of health service staff. Total costs (fixed and variable) were then divided by the duration (days) of follow-up in order to calculate the daily cost and the mean cost per patient of the intervention. The costs are expressed in Euro.

23 SF-12: short version of the SF 36 tool to assess health status and quality of life

24 Heart Distress Score

25 Total care charges were also determined for each group by adding together hospitalisations, ED visits, and nursing intervention charges. Nursing intervention charges included visit charges and, for the home tele care group, equipment charges. Nursing visit charges were determined for each group by multiplying the standard UCD charge per home visit, \$176.50, by the total number of nursing visits (in-person, telephone, and tele care) received. The total intervention cost for the home tele care group was then determined by calculating the manufacturer's charge to our institution for the 11 home tele care units (\$5,500 each) and single nursing base unit (\$10,000) and adding that figure to the total nursing visit charges for that group.

26 NYHA functional class: The NYHA classifies heart failure into 4 classes based on functional limitations and severity: Class I (Normal); Class II (Mild); Class III (Moderate); Class IV

(Severe); Patient Symptoms: Few observable symptoms, no limitation in ordinary physical activity. Mild observable symptoms and slight limitation during ordinary activity. Comfortable at rest.

Marked limitation in physical activity due to symptoms even during less than-ordinary activity. Comfortable only at rest. End-stage heart failure. Severe limitations. Experience symptoms even while at rest.

27 PHQ-9 depression scale: is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day). Depression Severity: 0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe.

28 Kansas City Cardiomyopathy Questionnaire (KCCQ): a self-administered, 23-item questionnaire that quantifies physical limitations, symptoms, self-efficacy, social interference and quality of life. Overall Summary Score % 0 = worst health status to 100 = best health status.

29 CES-D: Center for Epidemiologic Studies Depression Scale. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

30 Caregiver mastery scale

31 Costs of care were calculated for the 90 day period post-initial hospitalisation. Charges post-hospitalisation were calculated by tracking billing charges for re hospitalisation, emergency department visits, and charges for usual home care from the provider of home health care. Costs for the EHN group included the former charges plus the additional monthly charge of renting the monitoring system. Charges for usual home care were calculated by multiplying the standard charge data times the number of visits by the RN (at \$155 per visit), home health aide (at \$85 per visit), social worker (at \$165 per visit), and physical therapist, dietician, or speech therapist (at \$140 per visit). Supply costs averaged \$38.50 per episode of care. Charges for EHM were calculated for direct costs of placement of the Cardiocom unit (\$165). Data for reimbursement for the tele monitoring specialist were not available and therefore not included. In addition, out of pocket expenses for services post-hospitalisation were determined by calculating the number of physician office visits and instances of laboratory work and assigning a co-pay of \$12.

32 Self-care Heart Failure Index [SCHFI]

33 BNP: Brain Natriuretic Peptide

34 LVEF%: Left Ventricular Ejection Fraction %

**Table 11. Summary of results - Heart failure: Clinical outcomes**

Author Year	SBP, DBP, HR	Metabolic markers	BMI and Weight	Cardiac function	Therapy adherence
				(% LVEF; NYHA class (I-V)	Optimisation of medication
					Symptoms related to medication

**Table 11. Summary of results - Heart failure: Clinical outcomes** (Continued)

<b>ANTONICELLI 2008</b>	<p>SBP<sup>1</sup>, mmHg (supine) at 12 months: TM:129 (9), n=28; UC:132 (14), n=29</p> <p>DBP<sup>2</sup>, mmHG (supine) at 12 months: TM:77 (5); UC: 78 (6)</p> <p>HR (supine)at 12 months: TM:67 (7); UC:70 (6).</p> <p>No between group comparisons reported (other than no differences between groups in diastolic function).</p>	<p>Serum sodium (mmol/L): TM:138 (2); UC:138 (2), Serum potassium (mmol/L): TM:4.2 (0.3),</p> <p>24 hours urine output (ml/24h):</p> <p>TM:1532 (321); UC:1486 (464)</p> <p>Plasma cholesterol (mg/dL): TM:193 (14); UC:226 (27)</p> <p>No between group comparisons reported.</p>	<p>% LVEF<sup>3</sup> (SD) at 12 months follow-up:</p> <p>TM: 37 (7); UC: 37 (7).</p> <p>No difference between groups.</p>	<p>Patients compliant with prescribed treatment:</p> <p>TM: 26 (91%); UC:10 (46%), P &lt; 0.03</p>
<b>CLELAND 2005</b>			<p>NYHA<sup>4</sup> class (I-IV) at 120 days:</p> <p>I: TM:35 (23%); UC: 14 (18%); II: HTM: 71 (46%);UC: 27 (35%); III:TM: 27 (18%); UC: 16 (21%); IV:TM: 5 (3%); UC: 4 (5%);</p> <p>At 240 days:</p> <p>I:TM: 36 (24%); UC:13 (17%)</p> <p>II: TM: 53 (35%); UC:20 (26%)</p> <p>III: TM:27 (18%); UC:15 (19%)</p> <p>iv: TM: 9 (6%);UC: 8 (10%)</p> <p>TM: 27 (18%); UC:15 (19%)</p> <p>The NYHA class was similar among surviving patients in both groups at 120 days and 240 days. P values not provided.</p>	<p>Optimisation of medication treatment:</p> <p>ACE inhibitors</p> <p>BL: TM:BL:130 (94%): UC: 61(91%)</p> <p>120 d: TM 116 (96%); UC:42(78%), P &lt; 0.05</p> <p>240 d: TM: 93 (85%); UC: 40(70%)</p> <p>ARB</p> <p>BL: TM: 2 (25%); UC: BL 6 (50%)</p> <p>120 d: TM:3 (38%); UC: 6 (75%)</p> <p>240 d: TM: 4 (50%); UC: 4 (57%)</p> <p>Beta-blockers:</p> <p>BL: TM: 87 (86%); UC: 44 (77%)</p> <p>120 d:TM: 84 (93%); UC:34 (72%), P &lt; 0.05</p> <p>240 d: TM:75 (92%); UC:34 (77%)</p> <p>Spironolactone:</p> <p>BL:TM: 81 (80%); UC: 37 (74%)</p> <p>120 d:TM: 69 (81%); UC:27 (71%)</p> <p>240 d:TM:63 (80%); UC: 27(75%)</p>

**Table 11. Summary of results - Heart failure: Clinical outcomes** (Continued)

	<p>At 120 days patients in the TM group were more likely to receive ACE inhibitors and beta-blockers than those assigned to UC (<math>P &lt; 0.05</math>). These differences were not evident at 240 days.</p>
<b>DANSKY 2008</b>	<p><i>Omaha System problem Rating Scale (PRSO)<sup>5</sup></i></p> <p><i>Diet Sodium and fluid symptoms:</i></p> <p>TM(Monitor and Video) :2.89 (1.08);</p> <p>UC: 3.43 (1.27)</p> <p><i>Physical activity symptoms:</i></p> <p>TM(Monitor and video):2.47 (0.87) ;</p> <p>UC:2.87 (1.06)</p> <p><i>Medication effectiveness symptoms:</i></p> <p>TM (Monitor and video):4.00 (0.59)</p> <p>UC:4.02 (0.52).</p>
<b>JERANT 2001</b>	<p>Medication use/compliance : TM:0.93 (0.06); UC: 0.96 (0.14). <math>P = 0.3932</math></p>
<b>DENDALE 2012</b>	<p>Medication prescription</p> <p>Diuretics (mg):</p> <p>TM: BL:1.9 (1.5); at 6 months: 1.8 (2.2) ; Changes in dose: 0.0 (1.7)* ; No of changes:1.6 (1.9)*</p> <p>UC: BL: 2.0 (2.0); at 6 months: 1.2 (2.0) ; Changes in dose:-0.8 (2.1)*, <math>P &lt; 0.05</math>; No of changes: 0.9 (0.9)* (<math>P &lt; 0.001</math>)</p> <p>Thiazides (mg):</p> <p>TM: BL:3.3 (13.4); at 6 months: 2.3 (9.1); Changes in dose: -0.9 (14.0); No of changes: 0.1 (0.3)</p> <p>UC: BL:2.0 (8.8); at 6 months: 1.2 (6.8), Changes in dose: -0.8 (8.0), No of changes: 0.1 (0.3), NS</p> <p>ACE inhibitors (% target dose)</p> <p>TM: BL: 28 (24); at 6 months: 25 (27); Changes in dose: -3 (26)* ; No of changes:0.4 (0.5)UC: BL:30 (32); at 6 months: 17 (29); Changes in dose: -13 (35)* ; No of changes:0.4 (0.5), <math>P &lt; 0.05</math></p> <p>Angiotensin II antagonists (% target dose):</p>



**Table 11. Summary of results - Heart failure: Clinical outcomes** (Continued)

TM: BL:7 (18); at 6 months: 8 (22);  
Change in dose: 1 (14); No of changes:  
0.2 (0.4)

UC: BL: 7 (21), at 6 months 5 (16);  
Change in dose: -3 (14), No of  
changes: 0.1 (0.4), NS

Beta-blockers (% target dose):

TM: BL:27 (28); at 6 months: 28  
(30); Change in dose:1 (28)\*; No of  
changes: 0.6 (0.8)

UC:BL: 33 (36); at 6 months: 19 (30);  
Change in dose: -13 (26)\*; No of  
changes:0.5 (0.8)

Aldosterone antagonists (% target  
dose):

TM:BL: 24 (34); at 6 months: 16  
(31); Change in dose: -9 (39); No of  
changes: 0.3 (0.4)

UC:BL: 26 (35); at 6 months: 19  
(29); Change in dose: -7 (33); No of  
changes: 0.3 (0.5), NS

Total no of medication changes:  
TM:3.2 (2.8); UC:2.3 (2.1), P < 0.05

<b>KASHEM 2008</b>	<p>SBP mmHg at BL/12 months:</p> <p>TM:111/109; UC: 111/115</p> <p>DBP mmHg at BL/12 months:</p> <p>TM:72/69; UC:67/69</p> <p>HR (beats/ min ) at BL/12 months:</p> <p>TM: 76/76; UC: 74/74</p> <p>No differences between groups.</p>	<p>Total body weight (lbs) at BL/12 months:</p> <p>TM::213/217</p> <p>UC: 200/201lb</p> <p>No differences between groups. P val- ues not pro- vided.</p>
<b>KOEHLER 2011</b>	<p>NYHA class % (no) at 12 months:</p> <p>Class I:TM:11% (37);UC:8% (27); Class II: TM:46 (160); UC:49 (170); Class III: TM:32 (111); UC:32 (112); Class IV:TM:3</p>	

**Table 11. Summary of results - Heart failure: Clinical outcomes** (Continued)

			(10); UC:3 (9); OR: 1.08 (95% CI: 0.81 to 1.44), P = 0.59
			at 24 months:
			Class I: TM:8% (21); UC:8% (19); Class II:45% (114); UC:49%(124); Class III: TM:35% (90); UC:30 (75); Class IV: TM:8 % (21); UC:11 (28); OR:0.94 (95% CI: 0.67 to 1.31), P = 0.72
<b>SCHERR 2009</b>			% LVEF at 6 months:
			BL: TM: 25% (IQR 20-38); UC: 29% (IQR 21-36)
			at 6 months: TM:35% (IQR 25-45), UC: 35% (IQR 24-40), No difference between groups.
			NYHA class at 6 months:
			TM: improved from class III to II
			UC: no change
<b>SCHWARTZ 2008</b>			No significant differences between groups for prescribed use of angiotensin-converting enzyme inhibitors, beta-blockers; digoxin or diuretics at 3 months.
<b>SETO 2012</b>	BNP <sup>7</sup> levels at 6 months:TM: 414 (604), n=44; UC:303 (460), n=44, P = 0.2	Blood tests	NYHA class, mean (SD) at 6 months:  TM: 2.1 (0.7); UC: 2.2 (0.7), P = 0.8  % LVEF , mean (SD) at 6 months:  TM:32.7 (11.8); UC:31.3 (12.5), P = 0.7

1 SBP: Systolic Blood Pressure

2 DBP: Diastolic Blood Pressure

3 HR: Heart Rate

4. LVEF %: Left Ventricular Ejection Fraction %

5 NYHA: New York Heart Association functional classification.

6 The blinded research assistant evaluated patient responses to probe questions in each area and assigned a numerical score ranging from 1 (extreme symptoms) to 5 (no symptoms). In this coding scheme, a higher score indicates more favourable status.

7 BNP: Brain Natriuretic Peptide

**Table 12. Summary of results - Patients after cardiac event/surgery/procedure including implantation/replacement of cardiac medical device**

Author Year	Mortality Morbidity Adverse Clinical Events	Hospital admissions, Length of Stay (LoS), ED <sup>1</sup> and urgent care visits, other clinic visits	Quality of Life (QoL) Cardiac function Time from cardiac event to clinical decision	Costs
<b>Patients recovering from cardiac event, cardiac procedure or surgery</b>				
<b>CHIANTERA 2005</b>	Angina occurred within 15 days after discharge in 68% of patients and between the 16th day and the end of the first month of follow-up in 32% (with an incidence of angina of 65% in Group Tele cardiology and 72% in the usual care group within the first two weeks).	Hospital admissions, at one month :  TM: 7 (44%), n=99; UC: 9 (56%),n=101,p  P value or CIs not given		
<b>WALDMANN 2008</b>	All-cause mortality at 12 months: TM:10 (1.3%); n=752 :  UC: 23 (3.1%); n=748, OR (95% CI):0.43 (0.21-0.90), P = 0.021  Revascularisations at 12 months: TM: 40 (5%), n=752; UC:33 (4%), n=748  Myocardial infarction at 12 months: TM:38 (5%), n=752; UC:37 (5%), n=748  Composite endpoint (all-cause mortality, myocardial infarction, re-hospitalisation or re-vascularisation) : TM:40% : UC: 38%, NS  <b>Note:</b> The majority of intervention patients (n=581) did not send an ECG trail, and thus did not receive the intervention/consultation with the physician and/ or other clinical interventions.	Hospital admissions at 12 months:  TM; 297 (40%); n=752; UC: 279 (37%), n=748,OR (95%CI): 1.06 (0.93-1.20), P = 0.382  Mean cumulative LoS at 12 months:  TM: 17.8 (SD 20.1), n=752; UC:20.3 (SD 22.1), n=748, P = 0.139		
<b>Patients recovering from implantation/replacement of cardiac medical device</b>				
<b>AL KHATIB 2010</b>	All-cause mortality at 12 months: TM: 4 (5%), n=76; UC:3 (4%), n=75, P = 0.99  Composite endpoint of hospital admission and ED visits for a cardiac	CV <sup>2</sup> related hospitalisations at 12 months:  TM: 17 (23%), n=76; UC: 18 (24%), n=75, P = 0.88	QOL at 12 months (assessed with the EuroQoL <sup>3</sup> hermometer);  TM:80; UC: 80, P = 0.47	Mean total cost per patient for implantation and follow-up <sup>4</sup>  TM:\$374,73; UC:265,44;

**Table 12. Summary of results - Patients after cardiac event/surgery/procedure including implantation/replacement of cardiac medical device** (Continued)

	cause (CV) and unscheduled visits to the electrophysiology clinic for device-related issues at 12 months: TM:32% ; UC:34%, P = 0.77	% CV-related ED visits at 12 months:  TM: 7%; UC: 5%, P = 0.74  % Unscheduled visits to the electrophysiology clinic (for a device-related issue) at 12 months:  TM: 7%; UC: 7%, P = 0.98	EuroQoL score:  at 12 months:  TM: 85; UC: 100, P = 0.29	Mean Diff.: \$109,29
<b>CROSSLEY 2011</b>	No numerical results provided. Authors report no differences in mortality between groups.	CV-related hospitalisations at 15 months, Annualised rate per patient:: TM: 0.47; UC: 0.50, = 0.524  CV-related ED visits at 15 months; Annualised rate per patient: TM:0.24; UC: 0.21, P = 0.325  CV-related Unscheduled visits at 15 months, Annualised rate per patient: TM:2.24; UC:1.95, P = 0.099  <i>Clinic visits at 15 months:</i>  TM: 3.9; UC: 6.2  Note: routine clinic visits replaced with TM visits in intervention group.  <i>Mean LoS per hospitalisation at 15 months:</i> TM: 3.3; UC: 4.0, P = 0.002	Median time from clinical event to clinical decision:  TM: 4.6 days; UC:22 days, P < 0.001	Mean cost per CV-related hospitalisation (\$)⁴:  TM: \$8,114; UC: \$9,822,;  Mean diff.: \$1,793 (95% CI \$1,644 to \$1,940),S
<b>HALIMI 2008</b>	At least one treatment-related Major adverse event: TM:17 (9.2%), UC:26 (13.3%), P = 0.21  Absolute RR⁵:4.1; 95% CI 2.2-10.4, P = 0.98  Proportion of adverse events:  TM:20.1% (n=37); UC:19.05 (n=37)  Absolute RR:1.1; 95% CI 6.9-9.1; P = 0.78	Mean length of stay, days:  TM: 3.2 (SD 3.2), n=184; UC: 4.8 (SD 3.7), n=195, P < 0.001  Note: index stay after implantation	QOL (SF -36) at one month after implantation:  Mean overall scores :  TM:64+19, n=107; UC: 67+19, n=110, Results statistically non-significant (P values not provided)  Mean medical reaction time to a clinical decision-Major event:  TM:3.0±3.5, (n=4); UC:6.6±10.0 days (n=5),	Mean cost per patient for duration of trial (GBP)⁶ TM: 7125 (1543), n=178; UC: 7414(1659), n=187, P = 0.08

**Table 12. Summary of results - Patients after cardiac event/surgery/procedure including implantation/replacement of cardiac medical device** (Continued)

Mean medical re-  
action time to a  
clinical decision-  
Non-major event:

TM:8.2±8.7 (n=8);  
UC:17.5±11.6 (n=4)

1 ED: Emergency Department

2 CV: Cardio Vascular

3 EuroQoL thermometer=European Quality of Life Scale

4 After taking into account hypothetical ICD programming at clinic, travel time and costs, and costs for being absent from work, the difference between groups was no longer significant..

5 Absolute RR: Absolute Relative Risk

6 Cost of care was calculated in both study groups by review of the billing documents for private medical institutions and by compilation of customary reimbursement costs for the public medical centres. The cost calculations were based on (i) the institutional and patient care charges listed in the 2005 and 2006 'Groupe Homogène de Séjour dans le secteur public et privé' publication, (ii) the billable items included on the 'list of products and medical acts' (costs of tele cardiology excluded), (iii) the medical and para-medical fees listed in the 'Classification Commune des Actes Médicaux', (iv) the laboratory costs (from the private sector billing contract), and (v) the transportation costs (<http://www.ameli.fr>). Expenses related to the Biotronik service centre were provided by the manufacturer.

**Table 13. Summary of results - Hypertension and Stroke**

Author Year	Blood pressure  SBP, DBP and arte- rial pressure	Systolic and Diastolic day- time, night time and 24 hours  Ambulatory Blood Pressure  Monitoring	No of patients who achieved normal day- time ABPM/ Target BP	QOL	Costs
<b>ARTINIAN 2007</b>	Mean office SBP at 12 months::  TM:145.0 (21.0), n=167; UC:148.1 (22.3), n=169, P = 0.04  Mean office DBP at 12 months:  TM:83.8 (12.1); UC:83.5 (13.6), P = 0.12				
<b>MADSEN 2008</b>		Daytime ABPM at 6 months:  Systolic:  TM: 141.1 (11.5), n=113; UC: 142.7 (13.3) Change : Mean diff. (95% CI): -2.3 (-6.1 to 1.5), P = 0.225  Diastolic:  TM: 85.0 (7.1); UC: 85.1 (8.2)	Achieved nor- mal daytime  ABPM at 6 months:  TM:32/113 (28%); UC: 46/123 (37%), P = 0.139	Mean SF-36 domain scores at 12 months <sup>2</sup> :  Physical functioning: TM: 88.2 (14.0); UC: 84.2 (19.2), P = 0.078  Role physical: TM: 80.0 (36.4); UC: 77.3 (36.2), P = 0.584	

**Table 13. Summary of results - Hypertension and Stroke** (Continued)

Change: Mean diff. (95% CI): -0.8 (-3.1 to 1.4), P = 0.452		Achieved target BP at 6 months <sup>1</sup> :	Bodily pain: TM: 85.3 (20.2); UC: 78.3 (26.4), P = 0.026
Nighttime ABPM at 6 months:			
Systolic:		TM:68/113 (60%); UC: 47/123 (38%), P < 0.001	General health: TM: 77.1 (15.4); UC: 73.5 (17.4), P = 0.112
TM: 122.6 (14.4); UC: 125.2 (16.0)			Vitality: TM: 68.8 (17.6); UC: 67.8 (21.8), P = 0.727
Change: Mean diff. (95% CI): -1.0 (-5.0 to 3.0), P = 0.623		<b>Note:</b> Target BP was set to different levels in the intervention and control groups, with higher accepted BP levels in the control group.	Social functioning: TM: 89.5 (18.4); UC: 91.6 (17.8), P = 0.385
Diastolic:			Role emotional: TM: 83.8 (32.4); UC: 84.5 (27.8), P = 0.871
TM:71.8 (7.9); UC:72.6 (8.5)			Mental health: TM: 79.3 (16.4); UC: 81.5 (15.7), P = 0.313
Change: Mean diff. (95% CI): -0.7 (-2.9 to 1.6), P = 0.554			TM: n=105; UC: n=118
<hr/>			
<b>PARATI 2009</b>		Percent of patients with day-time arterial BP normalisation <sup>3</sup> at 24 weeks: TM:62%, n=216; UC: 50% , n=113, P < 0.05	QOL (Quality Of Life Assessment in Hypertensive Patients questionnaire <sup>4</sup> ):  End of study:UC: 38.3(5.4 ); TM: 38.4(4.6)  End of study – base-line difference: UC: 0.1(3.9); TM: 0.7(4.3), P = 0.273  End of study – base-line difference (%): UC: 0.5(10.4); TM: 2.6(12.7), P = 0.090  Healthcare costs <sup>5</sup> :  Cost of examinations  (Euros, mean ± SD): TM: 5.83±12.76, n=187; UC: 7.31±21.30, n=111, P = 0.451  Overall cost of patient management  at 24 weeks:  TM: 123.41±36.49; UC: 125.26±60.61, P = 0.742
<hr/>			
<b>ROGERS 2004</b>	Mean change in arterial BP at 8 weeks:	Mean change in systolic ABPM at 8 weeks:	
	Mean diff (95% CI):4.1 mmHg (0.91 to 7.38), P = 0.013	Mean diff. (95% CI): 4.8 mmHg (0.10 to 9.37), P = 0.047	
		Mean change in diastolic ABPM at 8 weeks:	

**Table 13. Summary of results - Hypertension and Stroke** (Continued)

Mean diff. (95% CI): 4.1  
mmHg (0.93 to 7.13), P =  
0.012

N=60 patients in each group

Author Year	Physical performance	Spasticity
<b>Patients recovering after stroke</b>		
<b>PIRON 2009</b>	<p>Fugl-Meyer upper extremity sub-score<sup>6</sup> (measure of physical performance):</p> <p>At the end of intervention:</p> <p>TM: 53.6 (7.7); UC:49.5 (4.8), Diff. +4.1, P value not provided;</p> <p>30 days after the end of intervention: TM: 53.1 (7.3), n=18; UC:48.8 (5.1), n=18; Diff: +4.3, P = not provided</p> <p>ABILHAND score (measure of functional activity)<sup>7</sup></p>	<p>Ashworth score (measure of spasticity)<sup>8</sup></p> <p>At the end of intervention:</p> <p>TM:1.7 (2.0); UC:1.0 (0.8), Diff. +0.7, P value not provided;</p> <p>30 days after the end of the intervention :TM: 2.0 (2.0), n=18; UC:1.1 (0.9), n=18; Diff.: +0.9, p- value not provided</p>

1 In the TM group, target home BP was defined as last average home BP <135/85 mmHg and 125/75 mmHg for non-diabetics and diabetics, respectively. Target office BP was defined as last office BP <140/90 mmHg and 130/80 mmHg for non-diabetics and diabetics, respectively.

2 Domain scores range from 0 to 100 with lower scores indicating lower health-related quality of life. No overall scores provided.

3 ABP normalization, defined as a daytime average systolic blood pressure (SBP) less than 130 mmHg and diastolic blood pressure (DBP) less than 80 mmHg.

4 Quality Of Life Assessment in Hypertensive Patients questionnaire

5 Healthcare costs were computed by considering the number of unscheduled additional visits, the number and type of examinations prescribed, and the number and type

of drugs prescribed during follow-up. Also, the costs of renting of the TeleBPCare service for the duration of the study were considered.

6 Fugl-Meyer upper extremity sub-score is a measure of physical performance; scores from 0-66; a higher score is better.

7 No numerical data reported.

8 Ashworth scale- scores from 0-4 ; a lower score is better.

**Table 14. Summary of results - Diabetes studies**

Author Year	Metabolic markers	Blood pressure  Body weight	QoL (general and disease specific)	Healthcare resource use  Costs	Disease management  and	No hypo-glycaemic events (%) No hyper-gly-
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**Table 14. Summary of results - Diabetes studies** (Continued)

			Psychoso- cial func- tioning	caemic events (%) No of symptom free pa- tients (%)
<b>Tyoe 1 diabetes</b>				
<b>AHRING 1992</b>	% HbA1c <sup>1</sup>  BL:TM: 0.106 (0.028) (0.070-0.208), n=22  UC:0.112; 0.018 (0.082-0.142), n=20  6 weeks:  TM:0.094; 0.012 (0.070-0.115);  UC:0.105; 0.019 (0.080-0.140)  12 weeks:  TM: 0.092; 0.011 (0.080-0.110);  UC: 0.102; 0.012 (0.074-0.110)  Random blood glucose:  BL:TM:8.6 (2.1), n=22; UC:8.9 (3.7), n=20  6 weeks:  TM:7.5 (2.2); UC: 9.5(3.0);  12 weeks: TM:7.7 (2.5); UC:8.0 (2.8)  No between group comparisons.	Total body weight (kg)  BL:TM: 78.8 (16.3), n=22; UC:76.5 (15.8), n=20  6 weeks:  TM:78.5 (16.7); UC: 76.8 (15.6);  12 weeks:  TM:78.6 (16.7); UC:77.0 (15.3)		Total no hypo-gly- caemic  events (%) at 12 weeks:  TM: 112 (mean 5.6 ± 6.3/patient) UC: 99  (mean 5.5 ± 3.4/patien- t);NS
<b>BIERMANN 2000</b>	% HbA1c  BL: TM: 8.3 (2.3), n=30; UC: 8.0 (2.1), n=18  4 months: TM: 6.9 (1.3), n=27; UC:7.0 (1.0), n=16  8 months: TM:7.1 (0.7), n=11; UC: 6.8 (1.1), n=10		Mean con- sultation (patient) time:  at 4 months:  TM: 554 min (range 220 to 1056 min);  UC: 656 (range 255 to 1745);  at 8 months:  TM: 974 min (range 399 to 1762);	No hy- po-gly- caemic  events (%) at 8 months:  Graphical data only.



**Table 14. Summary of results - Diabetes studies** (Continued)

UC:959  
(range 374  
to 3105)

Mean  
physician  
time expen-  
diture:

at 4 months  
(min): TM:  
50;UC:43;

at 8  
months:  
TM:43; UC:  
34

Cost per  
patient  
and year  
(including  
leasing mo-  
dem,tele-  
phone  
consulta-  
tions,da-  
ta trans-  
fer, trav-  
el costs,  
cost for not  
working)<sup>2</sup>:  
TM:389.0  
Euro UC:  
1037.0;  
Diff.-648  
Euro

<b>CHARPEN- TIER 2011</b>	<p>Mean HbA1c(%) at 6 months:</p> <p>TM: 8.41 (1.04), n=59; UC:9.10 (1.16), n=60, P &lt; 0.05 (adjusted for baseline HbA1c and age)</p> <p>Mean change in HbA1c % from base- line: 0.91 (0.60 to 1.21), P &lt; 0.001.</p> <p>Proportion of participants reaching the target of HbA1c &lt;7.5% at 6 months: TM:17% (n = 10); UC:1.6% (n = 1), P = 0.007</p>	<p>DQoL<sup>3</sup> at 6 months (Note: sat- isfaction di- mension only):</p> <p>TM:71.1 ± 15.0; UC:69.5 ± 15.9,  P = 0.1595</p>	<p>Hospital visits and telephone consulta- tions at 6 months: No difference between groups.</p> <p>No numeri- cal data re- ported.</p>	<p>Health Sta- tus (as- sessed with the DHP<sup>4</sup>)</p> <p>at 6 months:</p> <p><i>Disinhibited eating</i> :</p> <p>TM:36.8 (19.2); UC:37.1 (22.8), NS</p> <p><i>Psychoso- cial dis- tress</i>:</p> <p>TM:34.8 (10.4); UC:37.3 (9.3), NS</p>	<p>No of hypo- glycaemic episodes: No dif- ference between groups.</p> <p>The aver- age dura- tion of time spent con- sulting (min) :</p> <p>TM: 72 (30 )min : UC:70 (31) min (mean number of tele consul- tations:</p>
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**Table 14. Summary of results - Diabetes studies** (Continued)

			<i>Barriers to activity:</i>  TM:16.7 (13.1); UC:21.9 (13.6), NS  8.7 (4.9);mean duration for one tele consultation: 7.4(3 min).NS  Time spent travelling to hospital and waiting time: TM: 0 min; UC:274 (178)
<b>CHASE 2003</b>	Mean HbA1c (%) at 6 months:  TM: 8.6 ± 1.7%, n=30; UC:8.6 ±1.2 , n=33, P = 0.96	Mean total costs per patient over a 6 months period (US \$): TM: \$163.00; UC (Clinic visit):\$246 (235–310); P < 0.001.  Time spent per clinic visit was 95 min (range 60–128).If additional costs (average \$59) such as mileage, parking, meals, hotel stays, and babysitting were included, the average cost of a clinic visit increased to \$305 (245–810). <sup>5</sup>  No of school days missed for the 3-month clin-	Episodes of mild diabetic ketonuria (one participant in each group), NS  Mild-to-moderate hypoglycaemia (times/week) TM: 1.5 ; UC: 1.4, P = 0.71. There were no episodes of severe hypoglycaemia in either group

**Table 14. Summary of results - Diabetes studies** (Continued)

			ic visit: 0.4 days per patient (UC only)
			No on parents work days missed for the 3 months vis- it: 0.5 days of work per parent (UC only)
<b>IZQUIERDO 2009</b>	HbA1c values increased from base- line to 6 months for students in the UC group and decreased in the TM cohort ( $P < 0.02$ ).No numerical results are pre- sented in text or tables.	No numer- ical result data pre- sented in text or ta- bles  (Improve- ments in several sub scales of the PDQOL tool <sup>6</sup> in TM group.)	ED <sup>7</sup> visits/ urgent care encoun- ters at 3 months: TM:63; UC:59;  at 6 months: TM:25; UC:49;at 9 months: TM:27; UC:47;  at 12 months: TM:10; UC: 35 Urgent telephone calls at 3 months: TM: 14; UC: 20;  at 6 months: TM:2; UC: 14;at 9 months: TM:6; UC: 27;  at 12 months: TM:2; UC: 23 No of treatments received, No of eye examina- tions at 3 months:

**Table 14. Summary of results - Diabetes studies** (Continued)

TM:50; UC:  
52;

at 6 month-  
s:TM:20;  
UC: 48;

at 9  
months:  
TM:23; UC:  
43,

at 12  
months:  
TM: 9; UC:  
30.

No be-  
tween  
group com-  
parisons.

<b>JANSA 2006</b>	% HbA1c	Quality of life (as- sessed with the DQOL- Spanish version; lower score is better)	Total fol- low-up costs: TM without technical problems: 347 Euro; TM with technical problems: 421 Euro; UC:696 Eu- ro <sup>8</sup>	Self-man- agement -3 measures combined:  Knowledge test DKQ <sup>9</sup> scores	More than 3 episodes of mild hypogly- caemia/week
	BL:TM: 8.4 (1.2), n=19; UC:8.9 (1.3), n=17				Onset: TM: 75%, n=19; UC: 79%, n=17
	6 months:	Satisfaction		Onset: TM: 27±4;	
	TM:7.5 (1.4); UC: 7.7 (0.9)			UC:26±4	at 6 months: TM:10%; UC:12%
	12 months: TM:7.6 (0.9); UC:7.6 (0.7)	BL: TM: 37 (9), n=19; UC: 28 (7), n=16		6 months: TM:29±3; UC:29±4	at 12 months: TM: 6%; UC:15%, P value not re- ported for between group com- parisons.
		at 6 months: TM:33 (6); UC: 27 (5)		12 months: TM:30±; UC:29±3	
		at 12 months: TM:33 (6); UC: 27 (5)		No of gly- caemic controls > 3 /day	
		Impact:		(%) of pa- tients	
		BL: TM:44 (6);UC:43 (7)		Onset: TM:40; UC:25	
		at 6 months:		6 months: TM:82; UC: 88	
		TM: 41 (7);UC:38 (6);		12 months: TM:80; UC: 92	
		at 12 months:			

**Table 14. Summary of results - Diabetes studies** *(Continued)*

TM:42 (7);UC: 38 (6)	Total daily
Social worry:	insulin doses 6 and 12 months (compared to baseline doses): TG $0.8 \pm 0.2$ ,
BL: TM:14 (2);UC:13 (3);	$0.8 \pm 0.2$
at 6 months:	and $0.8 \pm 0.3$ IU/kg/day; CG $0.8 \pm 0.2$ ,
TM: 14 (3);UC:12 (5)	$0.8 \pm 0.2$
at 12 months:	and $0.8 \pm 0.2$ IU/kg/day, NS.
TM:14 (3);UC:12 (5)	X5 (b-glucose testing frequency, medication changes in logbooks and meter downloads.)
Diabetes worry:	
BL: TM: 8 (10; UC: 8 (2)	
at 6 months:	
TM:8 (2); UC:7.1	
at 12 months:	
TM:8 (2); UC:7 (1)	
SF-12	
BL: TM: 37 (4); UC:37 (3)	
at 6 months:	
TM: 37 (3); UC: 37 (4)	
at 12 months:	
36 (2); UC: 37 (2)	
Non-significant findings.	

**Table 14. Summary of results - Diabetes studies** (Continued)

<b>MCCAR-RIER 2005</b>	<p>Mean (SD) HbA1c at BL: TM: 7.99 (1.1); UC: 8.05 (1.3)</p> <p>Mean (SD) HbA1c at 12 months: TM:7.62 (1.4); UC:8.16 (1.5)</p> <p>Mean (SD) change in score: TM: 0.37 (1.3); UC: 0.11 (1.4),Mean change score: 0.48 1.22 to 0.27; P = 0.160</p> <p>Note:HbA1c values were identified with pre established selection rules that utilized two distinct time windows. We identified the first test result in the EMR in the 13th through 18th study month. If there was no result available in this window, we used the last result appearing in the EMR during the 10th through 12th month of the study. The median follow-up value included in the data set was collected 13 months after enrolment (SD±2.00). Participants without any eligible follow-up values in the EMR were contacted by phone, and one eligible A1C test performed outside of the DCC was subsequently included in the study data set.</p>	<p>Self-efficacy (assessed with DES-scale<sup>10</sup>)</p> <p>Mean (SD) baseline DES score: TM: 4.00 (0.60); UC:4.08 (0.59)</p> <p>Mean (SD) DES score at 12 months: TM:4.14 (0.60); UC: 3.92 (0.63)</p> <p>Mean (SD) change in score TM: 0.14 (0.62); UC: 0.16 (0.62) 0.30 0.01 to 0.59, P = 0.044</p>
<b>MARRERO 1995</b>	<p>% HbA1c BL:TM: 9.4 (1.9), n=52; UC:9.9 (1.5), n=54</p> <p>6 months: TM:9.6 (1.9); UC:9.7 (1.5)</p> <p>at 12 months:TM: 10.0 (1.6); UC: 10.3 (1.8)</p>	<p>No numerical results. No numerical results.</p>
<b>WOJCICKI 2000</b>	<p>% HbA1c (mean of measurements taken during the course of the study): TM: 6.8 (0.9), n=15; UC:6.7 (0.9), n=15, P = 0.72</p> <p>Mean Blood glucose (mg/dL): TM:132 (13), n=15; UC:137 (18), n=15, P = 0.46</p>	<p>Hypoglycaemic events (% of all blood glucose data)</p> <p>TM: 3.19 (1.95); UC: 3.31 (2.66), P = 0.90</p> <p>Hyperglycaemic events (% of all blood glucose data)</p>

**Table 14. Summary of results - Diabetes studies** (Continued)

TM: 10.8  
(5.2);  
UC:12.7  
(10.4), P =  
0.54

Type 2 diabetes			
<b>KIM 2007</b>	% HbA1c		
	BL:TM:8.09 (1.72), n=25;UC: 7.59 (1.09), n=26;		
	at 3 months:		
	TM: 6.94 (1.04); UC:7.66 (0.91)		
	At 6 months:		
	TM: 7.04 (1.39); UC: 7.70 (0.90)		
	Fasting plasma glucose (mg/dL)		
	BL:TM: 151.5 (25.7);UC: 142.2 (24.1);		
	at 3 months:TM:143.5 (33.9);		
	UC:147.6 (41.6):		
	At 6 months:TM:145.7 (39.7)		
	UC: 149.5 (39.3)		
	2 HPMG (mg/dL:BL:		
	TM:256.2 (80.5);UC:231.8 (78.2);		
	at 3 months:		
	TM: 171.1 (78.2);UC:246.5 (75.3)		
	At 6 months:		
	TM:192.6 (55.2)UC:218.0 (82.0)		
<b>KWON 2004</b>	Change from BL:		
	HbA1c: TM: 0.54, n=51; UC: 0.33, n=50, P < 0.05		
	Fasting BG: TM: 7.29; UC: 9.34, NS		
	Total Cholesterol: TM:3.33; UC: 7.30, NS		
	Triglycerider: TM:19.5; UC: 13.5, NS		
	HDL: TM: 2.91; UC: 2.70, P < 0.05		
	LDL: TM: 1.93; UC:1.88, NS		
<b>RALSTON 2009</b>	% HbA1c at between 9 and 15 months follow-up: TM:7.3, n=42; UC:8.1, n=41, Difference: -0.8, P < 0.01 (Note: no measure of dispersion provided.	Blood pressure: Note: No data provided for	No of out-patient visits at 12 months:

**Table 14. Summary of results - Diabetes studies** (Continued)

	Total cholesterol: No data provided for the two groups separately: Total cholesterol (7.6 mg/dl; P = 0.38), NS	the two groups separately.	TM: 10.2 (10.1), n=42;
	<b>Note:</b> Follow-up data were collected at between 9 and 15 months follow-up. The collection of baseline measures of outcomes varied from 12 months before randomisation to the day before randomisation.	Mean changes in SBP (0.9 mmHg; P = 0.84), DBP (0.1 mmHg; P = 0.96), NS	UC: 8.2 (9.1), n=41, P = 0.36
			Mean no of inpatients days over 12 months : TM: 0.5 (2.0), n=42; UC: 0.4 (1.2), n=41, P = 0.31
<b>RO-DRIGUEZ-IDIGORAS 2009*</b>	% HbA1c	SBP mmHG	
	BL:	BL:	
	TM: 7.62 (7.37; 7.87); UC: 7.44 (7.24; 7.65);	TM: 137.25;	
		UC: 137.6;	
	at 6 months: TM: 7.21 (7.01; 7.40);	at 12 months:	
	UC: 7.30 (7.09; 7.51);	TM: 132.69;	
	at 12 months:	UC: 133.6.	
	TM: 7.40 (7.17, 7.62);		
	UC: 7.35 (7.14, 7.56)	DBP mmHg	
		BL:	
	The proportion of patients with HbA1c >8%	TM: 77.71; UC: 76.68;	
	TM: from 35% to 22.5% (P < 0.001). UC: from 28% to 23.6% (P < 0.324).	at 12 months:	
		TM: 75.64;	
	No between group comparisons.	UC: 75.68	
<b>RO-DRIGUEZ-IDIGORAS 2009*</b>	LDL, <b>Note:</b> the unit is mmol/L	No measure of dispersion. No between group comparisons.	
	BL: TM: 3.21; UC: 3.32		
	At 12 months: TM: 3.07 ;	BMI <sup>11</sup> (kg/m <sup>2</sup> )	
	UC: 3.12. No differences between groups.	BL: TM: 30.88 to 30.66 kg/m <sup>2</sup>	
	Total Cholesterol; <b>Note:</b> the unit is mmol/L	at 12 months (P < 0.047). (no data for control group follow-up)	
	BL: TM: 5.14		
	At 12 months:		
	TM: 4.98 No control data available in paper, but authors state no differences between groups		
	Mean blood glucose		



**Table 14. Summary of results - Diabetes studies** (Continued)

BL:TM: 9.01;UC: 8.93

At 12 months:

TM:7.69;UC: 8.31

No between groups comparison.

<b>STONE 2010</b>	LDL(mg/dL)	SBP, mmHG
	BL:TM:9.6 (1.6);UC:9.4 (1.4)	BL:
	At 3 months:	TM:144.8 (21.7)
	TM:7.9 (1.2);UC:8.7 (1.2)	UC:142.3 (18.0), P = 0.46
	At 6 months:	At 3 months:
	TM:7.9 (1.2); UC:8.6 (1.3)	TM:135.9 (23.3)
	HDL(mg/dL)	UC:137.1 (21.4), P = 0.74
	BL:TM:38.4 (13.5);UC:38.4 (13.0)	
	At 3 months:	At 6 months:
	TM:35.0 (10.7);UC:36.2 (11.0)	TM:132.0 (24.3)
	At 6 months:	UC:133.0 (19.0), P = 0.79
	TM:35.1 (11.3);UC:26.4 (13.6)	
	Total Cholesterol	DBP, mmHg
	No control data available in paper, but authors state no differences between groups BL:	BL:
	TM:177.3 (54.2);UC:175.6 (43.5)	TM:79.9 (13.3)
	At 3 months:	UC:80.5 (10.1), 0.78
	TM:149.8 (37.2);UC:160.8 (37.5)	At 3 months:
	At 6 months:	TM:78.4 (12.0)
	TM:148.2 (40.2);UC:159.1 (37.2)	UC:76.6 (12.9), P = 0.55
	TriGlycerides (mg/dl)	At 6 months:
	BL:	TM:72.4 (14.6)
	TM:191.3 (133.3);UC:194.1 (160.4)	UC:75.9 (13.2), P = 0.13
	At 3 months:	Total body weight (lbs)
	TM:149.9 (114.1);UC:170.0 (133.6)	BL:
	At 6 months:	TM:226.6 (45.4)
	TM:152.4 (99.7); UC:170.7 (115.9)	UC:223.5 (44.9)
		At 3 months:
		TM:225.5 (44.5)

**Table 14. Summary of results - Diabetes studies** (Continued)

		UC:222.0 (49.6)
		At 6 months:
		TM:229.5 (47.6)
		UC:223.9 (48.6)
<b>WHITLOCK 2000*</b>	% HbA1c	Total body weight (lbs)
	BL:TM:9.5 (8.1-12.6), n=15;UC:9.5 (8.1-11.9), n=13;	BL:
	at 3 months: TM: 8.2 (5.7-10.2);UC: 8.6 (7.1-11.9)	TM: 214.3 (110-386), n=15; UC:220.6 (148-371), n=13;
		at 3 months: TM:206.7 (106-379);
		UC: 223 (153-375).
		Unclear what measure of dispersion is given.
<b>Type 1 and Type 2 diabetes</b>		
<b>BOAZ 2009</b>	LDL (mg/dL)	Total body weight (kg):
	BL:TM: 8.4±1.4,n=17	BL: TM: 78 (11);
	UC: 9.3±1.6, n=18	UC: 77 (12)
	At 6 months:	at 6 months:
	TM: 8.5±1.7	TM:79 (11)
	UC: 9.6±1.9	UC:77 (12)
	HDL (mg/dL)	
	BL:TM: 47±16	
	UC: 51±18	
	At 6 months:	
	TM: 49±18;UC: 50±12	
	Total Cholesterol (mg/dL)	
	BL:TM: 208±51;UC: 187±44	
	At 6 months:	
	TM: 177±34;UC: 175±37	
	Tri-Glycerides (mg/dl)	

**Table 14. Summary of results - Diabetes studies** (Continued)

BL:TM: 194±133;

UC: 198±107

At 6 months:

TM: 182±116

UC: 165±99

Fasting blood glucose (ml/dl)

BL:TM: 186±82;

UC: 197±93

At 6 months:

TM: 171±77

UC: 214±65

<b>BOND 2007</b>	% HbA1c at 6 months: TM:6.4 (1.2); UC:7.05 (0.99), P = 0.01	Blood pressure (mmHg) at 6 months: SBP:TM: 128 (13.2), n=31; UC: 131 (10.2), n=31, P < 0.01;	QOL (assessed with the PAID scale <sup>12</sup> score) at 6 months: TM: 2.0 (0.67); UC:2.2 (0.99), P < 0.05; Diff. score adjusted: TM:-0.28 (0.93); UC:0.02 (0.10)	Depression (assessed with the CES-D scale <sup>13</sup> ) at 6 months: TM:9.8 (7.9); UC:12.1 (8.5), Diff. score adjusted: TM: -0.23 (0.79); UC: -0.77 (0.83), P < 0.05;
	HDL ( ), at 6 months: TM: 50 (15); UC: 42(15.7)  Total cholesterol ( ) at 6 months:: TM:165 (38), n=31; UC:172 (37), n=31, P < 0.05	DBP: TM: 70 (7.0), UC: 73 (7.2), P = 0.15  Weight, lbs. at 6 months: TM: 196 (35), n=31; UC:207 (42), n=31, P < 0.001		Social support (assessed with the DSS Scale <sup>14</sup> ) at 6 months: TM: 6.0 (0.70); UC: 5.5 (0.85), Diff.scores adjusted: TM:0.65 (0.12); UC:0.00 (0.13), P < 0.001:  Self-efficacy (assessed with the DES scale ) at 6 months: TM:2.0

**Table 14. Summary of results - Diabetes studies** (Continued)

		(0.35); UC:2.2. (0.45); Diff score ad- justed: TM:0.65 (0.12); UC:0.08 (0.13), P < 0.001
<b>DAVIS 2010*</b>	LDL(mg/dL)	SBP mmHg
	BL:TM: 9.4(0.3), n=85;	BL:TM:130.8 (3.6);
	UC:8.8 (0.3), n=80	UC:134.6 (3.4)
	6 months:	6 months:
	TM:8.3 (0.3); UC:8.6 (0.3)	TM:133.0 (3.6)
	12 months: TM:8.3 (0.3); UC: 8.6 (0.3)	UC:137.8 (3.6)
		12 months:
		TM:127.6 (4.0)
		UC:130.9 (3.8)
		DBP mm Hg
		BL:TM:72.7 (2.1);
		UC:73.0 (2.0)
		At 6 months:
		TM:72.3 (2.1)
		UC:75.4 (2.0)
		At 12 months:
		TM:70.2 (2.2)
		UC:71.1 (2.2)
		BMI (kg/m2)
		BL:
		TM:36.0 (1.4)
		UC:34.5 (1.4)
		At 6 months:
		TM:35.7 (1.4)
		UC:34.7 (1.4)
		At 12 months
		TM:35.8 (1.4)

**Table 14. Summary of results - Diabetes studies** (Continued)  
UC:34.3 (1.4)

IZQUIERDO 2003	% HbA1c	No difference in	
	BL:	blood pressure or BMI between groups.	
	TM: 8.7 (2.1);		
	UC:8.6 (1.6)	No numerical data or P values reported	
	At 3 months:		
	TM:7.8 (2.2);		
	UC:7.6 (1.3)		
	LDL	Note :measure in mmol/L	
	BL:TM:2.84 (0.98)		
	UC: 2.93 (0.74)		
	at 3 months.		
	TM:2.55 (0.97)		
	UC:2.67 (0.97)		
No difference between groups for HDL cholesterol, total cholesterol, triglyc- erides.			
No numerical data or P values report- ed.			
MCMAHON 2005	Change in HbA1c from BL to 12 months	Blood pressure (results report- ed for only a subgroup of pa- tients)	Severe hypogly- caemia TM: 46 events in 13 par- ticipants [median: 3 per partici- pant]; UC: 33 events in 11 partici- pants [me- dian: 2 per participan- t]).NS
	TM: -1.6 ± 1.4%; UC: -1.2 ± 1.4%, P < 0.05		
	Change in LDL cholesterol from BL to 12 months:TM:-6 ± 12 mg/dl; UC:: -5 ± 11 mg/dl, NS		
	Change in HDL cholesterol from BL to 12 months: TM:3 ± 6 mg/dl; P < 0.05 vs. baseline; UC:1 ± 6 mg/dl		
	Change in Triglycerides from BL to 12 months:TM:-38 ± 99 mg/dl; P < 0.01 vs. baseline:UC:-2 ± 60 mg/dl. No be- tween group comparisons provided.		
SHEA 2006 (and SHEA 2009)	Mean adjusted HbA1c (SE)	Mean adjusted SBP	Mean annu- al Medicare payments (SE) per participant: TM: \$9669 (\$443); UC: \$9040 (\$386) (P > 0.05).
	BL: 7.43 (0.05), n=829; UC: 7.20 (0.05), n=701	(SE)	
	1 year: TM: 7.08 (0.05), n=681; UC: 7.20 (0.05), n=701	BL: TM: 140.34 (0.73), n=842;	
	2 year: TM: 7.06 (0.05), n=618; UC: 7.17 (0.05), n=633	UC:141.85 (0.74), n=815	

**Table 14. Summary of results - Diabetes studies** (Continued)

3 year: TM: 7.10 (0.05), n=466; UC: 7.21 (0.05), n=531	1 year: TM: 139.43 (0.68), n=698
4 year: TM: 7.13 (0.05), n=436; UC: 7.29 (0.05), n=494	UC: 141.51 (0.68), n=714
5 year: TM: 7.09 (0.06), n=355; UC: 7.38 (0.06), n=372	2 year: TM: 138.53 (0.67), n=620; UC: 141.17 (0.66), n=636
LDL (mg/dL)	
Mean adjusted (SE)	3 year: TM: 137.63 (0.70), n=468; UC: 140.83 (0.69), n=535
BL: TM: 106.64 (1.22); UC: 108.11 (1.21)	
1 year: TM: 97.84 (1.11); UC: 105.49 (1.10)	4 year: TM: 136.73 (0.77), n=437; UC: 140.49 (0.76), n=493
2 year: TM: 94.29 (1.12); UC: 102.86 (1.06)	5 year: TM: 135.83 (0.87), n=362; UC: 140.19 (0.86), n=373
3 year: TM: 92.68 (1.08); UC: 100.23 (1.11)	Mean adjusted DBP (SE)
4 year: TM: 91.77 (1.17); UC: 97.60 (1.23)	BL: TM: 69.88 (0.33), n=842; UC: 70.35 (0.34), n=815
5 year: TM: 91.13 (1.43); UC: 94.97 (1.40)	1 year: TM: 69.04 (0.31), n=698; UC: 69.94 (0.32), n=714
	2 year: TM: 68.19 (0.30), n=620; UC: 69.53 (0.31), n=636
	3 year: TM: 67.35 (0.32), n=468; UC: 69.12 (0.32), n=535
	4 year: TM: 66.5 (0.35), n=437; UC: 68.7 (0.35), n=493

**Table 14. Summary of results - Diabetes studies** (Continued)

5 year:  
TM:65.66  
(0.40), n=362;  
UC:68.29 (0.40),  
n=373

1 HbA1c: Glycaeted haemoglobin

2 The boundary conditions and assumptions are based on 1999 costs for the German telecom and public transportation system. Presumptions: Eu: 0.23 for a data transfer of 2 min duration; Eu 1.60 for a telephone call of 15 min duration; costs for not working 2h30min×Eu 25=Eu 62.5 per consultation; travel expenses for 50 min=Eu 23.0; costs for modem leasing=Eu 16.0 per month. Twenty data transfers per year, two personal visits of tele care patients per year; ten telephone consultations per year. Conventional care: one personal visit per month on average.

3 DQOL: Diabetes Quality of Life questionnaire

4 DHP: Diabetes Health Profile

5 Data are \$ and \$ (range). \*The total cost of the modem (\$101.95) with use for 6 months was amortized over 3 years; †the time of entering data by the patients was estimated based on the number of entries received (22/patient 3 min/day 66 min/180 days).

6 PDQOL: Paediatric Quality of Life questionnaire

7 ED: Emergency Department

8 The patient and family costs included: a) cost per each type of telemetric or hospital appointment (length and expenses, transport, GlucoBeep device); b) total cost per type of follow-up; c) daily activities that the patients were unable to perform because of the appointment. The medical team costs: a) time and expenses spent on both types of appointments; b) total cost per type of follow-up.

9 DKQ: Diabetes Knowledge Questionnaire

10 DES-scale: Dissociative Experiences Scale (DES) is a psychological self-assessment questionnaire that measures dissociative symptoms. It contains twenty-eight questions and returns an overall score as well as four sub-scale results

11 BMI: Body Mass Index (kg/m<sup>2</sup>)

12 Problem Areas in Diabetes (PAID) scale (13), the Diabetes Quality of Life (DQOL) scale (14), and one measure of cognitive appraisal, the Appraisal of Diabetes Scale (ADS) (15). Participants also completed the Diabetes Treatment Satisfaction Questionnaire (DTSQ), which has been specifically designed to measure satisfaction with diabetes treatment regimens in people with diabetes. Izquierdo 2003 also reported on nutritional goal attainment.

13 CES-D scale: Center for Epidemiologic Studies Depression scale: Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

14 DSS scale: Diabetes Social Support scale-check

Note: The target HbA1c for people with diabetes is 6.5% (48 mmol/mol), the target for people with diabetes at higher risk of hypoglycaemia is 7.5% (59 mmol/mol) (source: <http://www.diabetes.co.uk/what-is-hba1c.html>)

The LDL target level for most people is lower than 130 mg/dL (or below 3.3 mmol/L), and for people at risk of heart disease lower than 100 mg/dL (or below 2.6 mmol/L).

The HDL level should optimally be higher than 60 mg/dL (or >1.6 mmol/L), and the triglyceride level lower than 150 mg/dL (below 1.7 mmol/L).

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD**

Author Year	Response to treatment/ Disease control	Adherence	Healthcare re- source use	QoL	Adverse ef- fects	Costs
<b>Asthma</b>						
<b>CHAN 2007</b>	<i>Disease control measures:</i>  PEF values <sup>1</sup> , mean±SD, % of personal best:  Virtual group: 91.6±27.2; Of- fice-based group: 100±17.6, NS  Symptom-free days (of days in diary), mean±SD, %  Virtual group: 61.1±29.6; Of- fice-based group: 51.7±37.6, NS	<i>Diagnostic adherence measures:</i>  Total no. of asthma diary entries:  Virtual group: 6,835;	Total no of un- scheduled asth- ma-related visits at 12 months:  Virtual group: 44 Office-based group: 47, NS  Total No. of ED asthma visits:	PAQoL <sup>5</sup> scores at BL: Virtual group: 6.0±1.1  Office-based group: 5.7±1.2  at 12 month:  Virtual group: 6.1±0.7 ;		

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

Knowledge test score at 12 months, mean±SD, %	Office based group: 4,498, NS	Virtual group: 4; Office-based group: 2	Office-based group: 5.8±0.9, NS
Virtual group: 90.4±7.5; Office-based group: 89.5±8.3,,NS	Asthma diary adherence, % : Virtual group: 35.4; Office-based group:20.8, P < 0.01	Total no of asthma hospitalisations Virtual group: 1; Office-based group: 1	Also no difference for the caregiver QoL score between groups.
Knowledge test score change from baseline, mean±SD, %			
Virtual group +10.0±10.2 ; Office-based group: +9.27.5, P < 0.01	Virtual group only:	Total no. of -receptor agonist refills: Virtual group: 309; Office-based group: 323, NS	
Satisfaction survey, mean±SD, % Virtual group :4.0±1.0 ; Office-based group: 4.8±0.2,NS	Total No. of peak flow video evaluations :792	Total no. of steroid bursts: Virtual group: 133; Office-based group: 129, NS	
Final FVC <sup>2</sup> , mean±SD, % predicted at 12 months:	Peak flow video submission adherence,% :25.9		
Virtual group :102.6±18.1 ; Office-based group: 99.5±16.1,NS	Peak flow technique score, mean ±SD, %: Virtual group: 87.2±3.8; Office-based group: 86.6±3.0, NS		
Final FEV <sub>1</sub> <sup>3</sup> , mean±SD, % predicted: Virtual group 97.4±19.2; Office-based group: 92.7±18.1,NS	Therapeutic adherence measures:		
Final FEF <sub>25-75</sub> <sup>4</sup> , mean±SD, % predicted	Total No. of controller inhalers re-filled:		
Virtual group: 90.7±31.4 ; Office-based group: 84.2±33.0,NS	Virtual group: 636; Office-based group:771, NS		
	Virtual group only:		
	Total No. of inhaler videos sent : 996		
	e-check (inhaler video submission)		



**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

		adherence, %: 33.1	
<b>JAN 2007</b>	<i>PEF values</i>	<i>DPI and MDI 6plus spacer technique score (%)</i>	PAQOL score at 12 weeks:
	<i>Mean ± SD</i>		TM: 6.5±0.5;
	<i>at 12 weeks:</i>		UC:4.3±1.3, P < 0.05
	<i>Morning:</i>	BL:	
	TM:241.9±81.4, n=82	TM 82.1, n=88; UC:	
	UC:223.1±55.5, N=71, P = 0.017	80.3 , n=76	
	<i>Night:</i>	At 12 weeks	
	TM:255.6±86.7, N=82	TM:96.5, n=82	
	UC:232.5±55.3, n=71, P = 0.010	UC: 93.4, n=71, NS	
	ACT Test <sup>7</sup>		
	<i>No of well controlled (ACT &gt; 25):</i>	Adherence to inhaled corticosteroids	
	BL:	(ICS, controller) (%)	
	TM: 52 (59.1); UC:40 (52.6)		
	<i>at 12 weeks:</i>	BL:	
	TM:62 (70.4);UC: 42 (55.3)	TM:83.5, n=88;	
	<i>No of not controlled (ACT&lt;20)</i>	UC:82.3, n=76	
	BL:		
	TM:18 (20.4); UC: 12 (15.8)		
	<i>12 weeks:</i>	At 12 weeks:	
	TM : 8 (9.1); UC:10 (13.2)	TM:63.2, n=82	
	Significant differences between	UC:43.1, n=71	
	groups (P value not provided).	(P < 0.05,	
	<i>Symptom scores at 12 weeks,</i>		
	<i>change from BL Mean ± SD</i>	Note: the significant difference is not due to increased adherence in the TM group, but to a greater decrease in adherence in the	
	<i>Daytime:</i>		
	TM:-0.08±0.33, N=88		
	UC: 0.01±0.18, N=76, P = 0.009		
	<i>Night-time:</i>		
	TM: -0.08±0.33, N=88		
	UC: 0.00±0.20, N=76, P = 0.028,		

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

		control group at 12 weeks)			
<b>RAS-MUSSEN 2005</b>	FEV <sub>1</sub> . Change from BL	Take ICS <sup>8</sup> at follow-up:	Acute unsched-uled visits:	AQOL scores at follow-up	Dysphonia:
	Mean (SE)	Internet:			Internet:
	Internet:0.187 mL (SE 0.04), n=100;	91%, n=85	Internet: 3.7%; GP group: 1.3%, P < 0.05	Total % improving:	17%; GP group: 9%, P = 0.002
	GP:0.004 mL (SEM 0.03), n=100	GP:29%, n=80	ED visits: Internet:2; GP group:1	Internet: 33; GP group: 19	Candidiasis:
	At 6 months	Daily recommended ICS dose (µg) received:	Hospitalisations over 6 months:	Total % deteriorating:	Internet:
	Internet vs GP: OR:4.86, P < 0.001),			Internet: 8:GP group:16	18%; GP group:4 %, P < 0.001
	Airway responsiveness Internet vs GP: OR: 3.06, P = 0.02	Internet: 866 (0-1600);	Internet:0; GP group: 0	Improvement in AQOL: Internet vs GP: OR: 2.10, P =0 .04	over 6 months
	Airway responsiveness	GP group: 0 (0-1200)	No of asthma medications		No significant between groups differences
	Only ORs for improved scores reported, no raw-data.	Good compliance (use of medication always or almost always at 6 months; Internet:	BL: Internet:44; GP group:53		in respect to tachycardia and tremor
		87%; GP:54%	At 6 months follow-up Internet:TM:0; GP group:26%		(data not shown)
		(Internet vs. GP, P < .001).			
<b>VAN DER MEER 2010</b>	Proportion of symptom free patients at 12 months,mean (change from BL (95% CI)::	Use of Internet-based monitoring tool: Optional daily lung function	Healthcare provider contacts for asthma, average number per patient:	Asthma QoL at 12 months, mean (change from BL (95% CI):	Exacerbations did not differ between groups.
	TM:63.1 (18.2 (10.8 to 25.6)	scores, average days per patient:107.8			
	UC:51.8 (-7.3 (0.0 to 14.6); Adjusted absolute diff: 10.9% (95% CI, 0.05% to 21.3 %)		Physician visits: TM:1.11; UC: 1.86 ; Diff. (95% CI):0.74 (1.55 to 0.06), P = 0.071	TM:6.29 (0.56 (0.43 to 0.68), n=101	
	Asthma control (ACQ scores) at 12 months, mean (change from BL (95% CI)::	Asthma control; Questionnaire monitoring, average weeks per patients: 34.8	Telephone contacts: TM: 2.39; UC: 2.35; Diff. (96% CI) 0.04 (0.75 to 0.84), P = 0.91	UC: 5.97 (0.18 (0.05 to 0.31), n=99; Adjusted mean diff: 0.38 (95%CI, 0.20 to 0.56), NS	
	TM: 1.04 (-0.06 (-0.18 to 0.05)		Online contacts with asthma nurse: 5.93 (intervention group only)		
	UC:0.59 (-0.54 (-0.65 to -0.42); Adjusted mean diff: -0.47 95% CI -0.64 to -0.30)				
	Medication changes, average no per patient:	Online contacts with asthma nurse: 5.93			
	Step up treatment:TM:0.90, n=91; UC:0.39, n=92, Mean				

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

diff:0.51 (95% CI,0.30 to 0.72), P < 0.001

Step-down treatment: TM:0.75 ; UC:0.44; Mean diff: 0.31 (0.09 to 0.53); P = 0.006

Self-reported medication adherence: TM:6.32; UC:6.37; Mean Dif: -0.05 (-0.59 to 0.49), P = 0.86

Inhaler technique: TM:4.63 ; UC:4.49; Mean diff: 0.15 (-0.05 to 0.34), P = 0.143

Asthma knowledge: TM:9.21; UC:9.10, Mean diff; 0.11 (-0.44 to 0.66), P = 0.70

Daily inhaled dose corticosteroids (picogram) at 12 months, mean (95% CI): TM:470 (-48 (-115 to 20); UC:506.9 (-58 to 76); Mean diff: 57 picogram (95%CI, -38 to 152 picogram), NS

**Note:**87 intervention participants attended (86%) the first educational session, and 70 intervention participants attended (69%) received the second session delivered by nurses

WILLEMS 2008	Summary of results - Respiratory conditions: Asthma and COPD			
	PEF and FEV <sub>1</sub> results not reported.	Cumulated over 1 year	PAQOL at 12 months:	Mean total cost per patient over one year for total group: Adult mean (SD): TM:2.973 (2.650); UC:1.948 (1.777); Children mean (SD): TM:1,206 (601); UC:597 (863).Higher total cost in TM.
	Self-reported Asthma symptoms, mean/patient:	No hospitalisations: TM: 0; UC: 0	Symptoms: TM: 5.73 (1.9); UC:5.48 (1.18), P = 0.396	
	Coughing (morning):TM:0.23 (0.38); UC:0.41 (0.49), P = 0.245; (evening): TM:0.41 (0.61); UC:0.48 (0.54), P = 0.154;	No ED visits: TM: 0; UC: 4	Activity limitation: TM: 5.13 (1.17); UC: 5.21 (1.32), P = 0.640	
	Production of sputum (morning): TM:0.18 (0.31); UC:0.27 (0.44),P = 0.191 (evening): TM:0.25 (0.400; UC: 0.34 (0.46),P = 0.166	No patients consumed primary care: TM: 28 ; UC:22	Emotional function: TM:6.39 (0.76); UC:6.28 (0.81), P = 0.245	
	Shortness of breath (morning): TM:0.27 (0.45); UC:0.40 (0.48), P = 0.081 (evening):TM:0.35 (0.55); UC:0.57 (0.65), P = 0.252	No patients consumed secondary care; TM:19; UC:19	No differences between groups.	The intervention costs the society 31.035 Euro/ QUALY <sup>9</sup> gained with regard to adults and with regard to children 59.071 Euro/QUALY gained.
		No difference between groups for the total scores.	No summary scores were presented for EQ-5D and SF-36 results.	
		Relative amount of patients who consumed medical care or who used medications only graphically presented.		

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

			Subtotal healthcare costs (in 2002 Eu- ros): Adult mean (SD): TM: 2.228 (1,582), n=26; UC:1,720 (1,742),n=27;
			Children mean (SD): TM:1,193 (582), n=29; UC:588 (850), n=27
			Subtotal patient and family costs: Adult mean (SD): TM:2.361 (1.673); UC:1.787 (1.794); Children mean (SD): TM:1.200 (591); UC: 592 (855)
			Subtotal produc- tivity loss- es: Adult mean (SD): TM:612 (1.390); UC:161 (352); Chil- dren mean (SD): TM:6 (20); UC:6 (18)
<b>Chronic Obstructive Pulmonary Disease (COPD)</b>			
<b>KOFF 2009</b>	<i>Pre-study:</i>	SGRQ <sup>10</sup> score (disease spe- cific)	Pre-study healthcare costs (US \$): <sup>11</sup>
	<i>ED visits:</i>		
	TM:0.7±0.23 ; UC: 0.9±0.23, P = 0.79	BL:TM: 54.7±14.9, n=19; UC: 51.5±14.3, n=19, P = 0.50, NS	TM: 7273±10483 UC: 9248±18897, P = 0.69
	<i>Hospitalisations</i>		
	TM: 0.55±0.21 UC: 0.6±0.21, P = 0.97		

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

	<p><i>Hospital LOS days :</i> TM:3.2±7.0</p> <p>UC: 2.8±5.6, P = 0.82</p> <p><i>Study period (difference between during study period and during pre-study period):</i></p> <p>COPD ED visits, n (%)</p> <p>TM: 1 (5.3); UC: 3 (15.8)</p> <p>COPD hospitalisations:</p> <p>TM: 1 (5.3) ; UC: 3 (15.8)</p> <p>Total ED visits per group: TM:-2.25; UC: -1.25</p> <p>Total hospitalisations per group : TM:-1.75; UC: 0)</p>	<p>At 3 months (Difference in score at 3 months):</p> <p>TM: -10.3 (-17.4– -3.1)</p> <p>UC: -0.6 (-6.5– 5.3), P = 0.018</p> <p>Post-study (difference between costs during study period and during pre-study period):</p> <p>TM: -1401 (-6566– 3764)</p> <p>UC: 1709 (-4349– 7768), P = 0.21</p>
<b>LEWIS 2010</b>	<p>Median (IQR) ED<sup>12</sup> attendances for COPD:</p> <p>TM: 0 (0, 08); UC:0 (0, 1.0)</p> <p>Days in hospital:</p> <p>TM: 0 (0,0); UC: 0 (0, 1.5)</p> <p>Primary care contacts (Chest):</p> <p>TM: 2 (1, 3.8); UC: 4 (2, 6)</p> <p>Primary care contacts (non-chest):</p> <p>TM: 1 (0, 2); UC:1 (1, 3)</p> <p>CDMT phone calls:</p> <p>TM: 5 (0, 16.5); UC: 2 (0, 10.5)</p> <p>CDMT home visits:</p> <p>TM:1.5 (0,4); UC: 0 (0, 3)</p>	

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

<b>NGUYEN 2008</b>	<i>Dyspnoea with ADL scores</i>	<i>HRQOL<sup>13</sup> CRQ (disease spe- cific)</i>
	BL:	
	TM: 18.8 (6.2), n=19; UC: 15.9 (5.4), n=20	<i>Total score:</i> BL: TM: 93.5 (15.7); UC:85.8 (18.9)
	at 3 months:	
	TM: 22.3 (4.6); UC:19.2 (5.8)	at 3 months:
	at 6 months:	TM: 102.1 (15.6); UC: 92.7 (22.5)
	TM: 21.3 (6.0); UC: 19.9 (6.2), P =0.51	
	<i>Endurance exercise (total min/ week)</i>	at 6 months:
	BL: TM: 89 (102), n=19; UC: 77 (113), n=20	TM: 99.9 (16.8); UC:94.5 (22.6),
	at 3 months: TM: 173(130); UC: 141 (100)	No differ- ence between groups.
	at 6 months: 121 (81); UC: 128 (11), NS	<i>SF-36<sup>14</sup>(gen- eral):</i>
	<i>Strengthening exercise (total min/week)</i>	Physical com- posite
	BL: TM: 11 (29); UC: 21 (46)	Score (0-100), mean ±SD:
	at 3 months: TM: 53 (70); UC:56 (66)	BL: TM: 32.8±8.5; UC:37.3±7.0
	at 6 months: TM:34 (37); UC: 53 (59)- NOTE: P value not provid- ed, but looks like patients in UC group do more strength train- ing.	At 3 months: TM:35.3±11.0;UC:41.0±7.9
	Exercise performance:	(At 6 months: TM:35.2±10.6; UC:39.9±7.6)
	6 min walk test (min)	
	BL: TM: 436 (92); UC: 406 (150)	Mental com- posite score (0-100), mean ±SD:
	at 3 months:	
	TM:450 (91); UC: 386 (157)	BL: TM:51.8±9.9; UC:49.7±10.1
	at 6 months:	At 3 months: TM:52.2±11.7; UC:52.8±9.6
	TM:456 (91); UC:394 (165), P val- ue not provided	(at 6 months: TM:53.5±11.6; UC:51.3 ±10.0
	No significant difference in physical functioning or self-effi- cacy between groups.	

**Table 15. Summary of results - Respiratory conditions: Asthma and COPD** (Continued)

No differences  
between  
groups

- 1 PEF:Peak expiratory flow  
2 FVC indicates forced vital capacity  
3 FEV<sub>1</sub> forced expiratory volume in 1 second  
4 FEF<sub>25-75</sub> forced expiratory flow in mid expiratory phase  
5 PAQOL: Peadiatric Asthma Quality of Life questionnaire  
6 DPI and MDI plus spacer technique  
7 ACT: Asthma Control Test  
8 ICS:Inhaled Cortico Steroids  
9 QALY: The quality-adjusted life year or quality-adjusted life-year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.  
10 SGRQ score (disease specific): St. George's Respiratory Questionnaire (SGRQ).Scores range from 0 to 100, with higher scores indicating more limitations  
11 Costs included visits to clinics and the ED room, hospitalisations, radiology services and other diagnostic tests, and blood tests.  
12 ED: Emergency Department  
13 HRQOL /CRQ: Health-Related Quality of Life/  
14 SF-36: Short form 36 questionnaire

**Table 16. Summary of results - Mental health and substance abuse problems**

Author Year	Response to treatment	Acceptability	QoL	Costs
		Adherence	Self-esteem	
		Satisfaction		
Depression				
CHONG 2012	Severity of depression (assessed with the PHQ-9 <sup>1</sup> ) at 3 months: TM: 8,4 (5.5); UC: 9.9 (6.5), at 6 months: TM: 4.7 (5.1), UC:6.8 (6.0). No difference between groups.	<p>Proportion of completed mental health visits: TM: 0,7 (0.3), n=80; UC:0,7 (0.3), n=87, NS</p> <p>Antidepressant use: TM: 56 , n=80; UC: 40, n=87, Higher use in TM.</p> <p>Satisfaction (by the Visit Specific Satisfaction Questionnaire).</p> <p>at 3 months:TM: 35.6 (1.5); UC:35.0 (1.9); at 6 months: TM:35.8 (1.2); UC:35.6 (1.2)</p> <p>(TM versus UC): F (1,97) = 6.9, P &lt; 0.01. Time (baseline, 3 and 6 months): F (2,194) = 46.6, P &lt; 0.001. Time · Assignment: F (2,194) = 10.8, P &lt; 0.05.</p>		

**Table 16. Summary of results - Mental health and substance abuse problems** (Continued)

		By the Working Alliance Inventory Short Form.24 Assignment (TM versus UC): $F(1,94) = 31.6$ , $P < 0.01$ . Time: $F(2,188) = 87.4$ , $P < 0.001$ . Time · Assignment: $F(2,188) = 2.1$ , not significant. eBy Chi squared test: $\chi^2(1,152) = 3.8$ , $P > 0.05$ .	
<b>RUSKIN 2004</b>	<p><i>Hamilton depression scale<sup>2</sup>:</i></p> <p>(i) <i>Depressive symptoms</i></p> <p>Improved over the treatment period (time main effect: <math>F=49.0</math>, <math>df=3</math>, <math>117</math>, <math>P &lt; 0.001</math>),</p> <p>Improvement did not differ between groups (time-by-treatment interaction: <math>F=0.4</math>, <math>df=3</math>, <math>117</math>, NS.).</p> <p>No raw data provided.</p> <p>(ii) <i>Proportion of patients with &gt; 50% improvement in depression scores</i>: TM:49%; UC: 43% (<math>\chi^2=0.4</math>, <math>df=1</math>, NS).</p> <p>(iii) <i>Remission (as indicated by a final 17-item Hamilton depression scale score of 7 or less)</i>: TM: 39%; UC: 35% in the in-person group (<math>\chi^2=0.2</math>, <math>df=1</math>, NS).</p> <p>Beck Depression Inventory, state anxiety scale, GAF, CGI, and Short-Form Health Survey were similar to those obtained with the Hamilton depression scale. No differences between groups. No raw data provided.</p>	<p><i>Dropout rate:</i></p> <p>TM: 16 (27%) ; UC:18 (30%) dropped out of the study (<math>\chi^2=0.4</math>, <math>df=1</math>, NS.).</p> <p><i>Appointments kept:</i></p> <p>Both groups kept appointments for an average of 6.5 visits during the study period (<math>t=0.2</math>, <math>df=117</math>, NS)</p> <p><i>Medication adherence:</i></p> <p>No difference in the percentage of adherent patients between groups (<math>\chi^2=0.2</math>, <math>df=1</math>, NS.).</p> <p>No raw data provided.</p>	<p>The estimated marginal costs to the institution:</p> <p>TM session:\$86.16 ;</p> <p>UC session:\$63.25</p> <p>(<math>t=3.2</math>, <math>P &lt; 0.001</math>)<sup>3</sup>.</p>
<b>Mental disorders (mixed conditions)</b>			
<b>DE LAS QUEVAS 2006</b>	<p><i>Severity of illness (assessed with the CGI-S instrument<sup>4</sup>)</i></p> <p>Mean score: % 24 weeks</p> <p>CGI-Severity <math>\leq 2</math></p> <p>TM: 67.2%, <math>n=66</math>; UC: 62.5%, <math>n=64</math>, <math>P = 0.751</math></p> <p><i>Improvement measured by the CGI-I<sup>5</sup> score:</i></p> <p>CGI-Imp <math>\leq 2</math></p> <p>TM: 80.0; UC: 75.7, <math>P = 0.959</math></p>		
<b>Substance abuse</b>			



**Table 16. Summary of results - Mental health and substance abuse problems** (Continued)

<b>KING 2009</b>	<p><i>Drug use during 6 weeks study (%)</i>:</p> <p>TM:37, n=20; UC:42, n=17, NS (P value not provided)</p> <p><i>Counselling adherence</i> <sup>6</sup>(%):</p> <p>TM:89, n=20; UC: 74,n=17, P = 0.07</p> <p><i>Step completion</i><sup>7</sup>(%):</p> <p>TM:40; UC:71, NS (P value not provided)</p>	<p>Patient Satisfaction questionnaire:No numerical data or P values provided.</p> <p>(graphical data only).</p> <p>No difference between groups.</p>		
<b>Eating disorders</b>				
<b>MITCHELL 2008</b>	<p><i>Abstinence rates, no (%)</i><sup>8</sup></p>	.	<p><i>QOL (assessed with the SF-36 11instrument):</i></p>	<p><i>The total cost per recovered (abstinent) patient</i> <sup>13</sup></p>
<b>(CROW 2009)</b>	<p><i>Objective binge eating:</i></p> <p>BL:TM: 17 (27.4), n=62 ;UC: 10 (15.2) , n=66</p> <p>End of treatment:</p> <p>TM: 31 (50.0), n=41; UC: 33 (50.0), n=39,</p> <p><i>Purging (vomiting, laxative abuse and diuretic abuse):</i></p> <p>BL:TM: 4 (6.5) ; UC: 6 (9.1)</p> <p>End of treatment:</p> <p>TM: 19 (30.6); UC: 24 (36.4),</p> <p><i>Combined objective binge eating and purging:</i></p> <p>BL:TM: 2 (3.2) ; UC 1 (1.5 )</p> <p>End of treatment:</p> <p>TM: 17 (27.4); UC: 19 (28.8),</p> <p>No differences between groups for any of the abstinence outcomes.</p> <p><i>OBE episodes</i><sup>9</sup>, mean (SD)</p> <p>BL: TM: 19.1 (24.7); UC: 21.9 (27.3);</p> <p>At end of treatment:</p> <p>TM: 6.2 (12.3); UC: 3.7 (11.2);</p> <p>At 3 months:</p> <p>TM: 6.5 (12.3) ;UC:5.1 (11.5)</p> <p><i>Purging episodes, mean (SD)</i></p> <p>BL:TM: 36.8 (34.7); UC: 35.6 (34.1)</p> <p>At end of treatment:</p>	<p><i>Physical component scores:</i></p> <p>BL:TM: 53.4 (9.1); UC: 54.6 (8.0 )</p> <p>End of treatment:</p> <p>TM: 54.1 (7.9); UC: 56.2 (5.7)</p> <p><i>Mental component:</i></p> <p>BL:TM: 35.4 (14.2) ;UC: 34.2 (12.7)</p> <p>End of treatment:</p> <p>TM: 42.9 (12.6); UC: 45.5 (11.9)</p> <p>No differences between groups.</p> <p><i>Self-esteem (assessed with the Rosenberg self-esteem scale</i><sup>12</sup>):</p> <p>BL:TM: 3.6 (1.9) ;UC: 3.6 (2.0)</p> <p>End of treatment:</p> <p>TM: 2.2( 2.0); UC: 2.0 (1.9)</p> <p>No differences between groups</p>	<p>:TM: \$7300.40; UC: \$9324.68</p>	

**Table 16. Summary of results - Mental health and substance abuse problems** (Continued)

TM:11.1 (19.0); UC:5.6 (12.5)

At 3 months:

TM: 10.7(17.9); UC:8.7 (16.5)

*EDE<sup>10</sup> sub scales:*

*Restraint:*

BL: TM: 3.4 (1.4); UC: 3.5 (1.2 )

End of treatment:

TM: 1.7 (1.5);

UC: 1.5 (1.5),

*Eating concerns:*

BL:TM: 1.7( 1.3 ), UC: 2.1 (1.4 )

End of treatment:

TM: 0.8 (1.0);

UC: 0.7 (1.0),

*Shape concerns:*

BL:TM: 3.5 (1.4); UC: 3.8 (1.3 )

End of treatment:

TM: 2.3 (1.5);

UC: 2.3 (1.5),

*Weight concerns:*

BL: TM: 3.4 (1.3 ) ;UC: 3.5 (1.3)

End of treatment:

TM: 1.9 (1.3);

UC: 2.1 (1.6),

No differences between groups.

*Hamilton depression scale:*

BL:TM: 14.5 (9.0) ;UC: 15.7 (9.2)

End of treatment:

TM: 8.7 (9.4); UC: 7.0 (7.4),

Greater decrease in depression score in the usual care group as compared to the TM group.

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**Post traumatic stress disorder (PTSD)**


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**MORLAND 2010**

Novaco Anger Scale <sup>14</sup> total score:

BL: TM: 109.3 (16.1), n=57; UC: 109.8 (14.0), n=55

No significant differences in attrition, treatment adherence

**Table 16. Summary of results - Mental health and substance abuse problems** (Continued)

Post treatment: TM: 94.2 (19.1); UC:99.2 (17.1) and satisfaction between groups.

at 3 months: TM:96.4 (18.4); UC:105.2 (19.2)

at 6 months: TM:97.7 (20.2); UC:101.0 (22.5)

PTSD checklist Military version (PTSD symptom reduction):

BL: TM: 64.5 (11.6), n=57; UC:65.8 (10.8), n=55

Post treatment:59.2 (15.0); UC: 57.4 (16.0)

No significant differences between groups.

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**Cognitive impairment and dementia**


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<b>POON 2005</b>	<p><i>CMMSE-scores</i><sup>15</sup>(cognitive status):</p> <p>BL: TM: 18.73 (2.15), n=11; UC:18.27 (2.41), n=11</p> <p>at 6 weeks: TM: 21.91 (2.95); UC: 22.09 (3.53)</p> <p>C-RBMT<sup>16</sup>memory)</p> <p>BL: TM: 5.64 (2.29); UC: 7.45 (2.16)</p> <p>at 6 weeks: TM: 8.81 (3.12); UC: 10.36 (2.73)</p> <p>HDS scores<sup>17</sup> (dementia grade)</p> <p>BL: TM: 154.82 (24.99); UC:156.09 (17.1)</p> <p>at 6 weeks: TM: 169.27 (26.06); UC: 170.64 (15.95)</p> <p>Overall, the two groups did not differ significantly in neuropsychological outcomes.</p>	<p>The compliance rate of both groups was 95%.</p>
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- 1 PHQ-9: The PHQ-9 is the depression module, which scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day).
- 2 Hamilton Depression scale: The original 1960 version contains 17 items to be rated (HRSD-17), but four other questions are not added to the total score and are used to provide additional clinical information. Each item on the questionnaire is scored on a 3 or 5 point scale, depending on the item, and the total score is compared to the corresponding descriptor.
- 3 When the cost of psychiatrist travel time was factored in and the time-distance effect was modelled, the cost of remote treatment was equal to that of in-person treatment if the psychiatrist had to travel 22 miles from the medical centre to the clinic and was less if the psychiatrist had to travel more than 22 miles to the clinic.
- 4 CGI-S: Clinical Global Impressions Score: CGI Severity of Illness score  $\leq 2$  (1 = normal, not at all ill; 2 = borderline, mentally ill)
- 5 CGI Global Improvement score  $\leq 2$  (1 = very much improved; 2 = much improved).
- 6 Counselling adherence includes group session and standard individual session (%)
- 7 Step completion (%): At least 2 consecutive weeks of abstinence and 100% attendance to return to less-intensive care.
- 8 Abstinence rates: Note: Last observation carried forward in results above (i.e. BL data) Almost half of the participants were lost to follow-up at 3 and 12 months after the intervention- and therefore only the results directly after treatment reported here.
- 9 OBE episodes: Objective Binge Eating episodes
- 10 EDE:: Eating Disorder Examination (Fairburn & Cooper, 1993). The EDE is an investigator-administered interview used to determine DSM-IV eating disorder diagnosis and assess current eating disorder symptoms. The EDE provides frequency measures of binge eating and compensatory behaviours, which were used as the primary measures of treatment outcome. The EDE also contains four sub scales (Dietary Restraint, Eating Concerns, Shape Concerns and Weight Concerns) associated with core psychopathology of eating disorders.
- 11 SF-36: the SF-36 is a measure of health status. The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability.

12 Rosenberg's self-esteem scale: is a 9 item scale. The scale ranges from 0-30. Scores between 15 and 25 are within normal range; scores below 15 suggest low self-esteem.

13 Costs data extracted from Crow 2009

14 Novaco Anger Scale: lower scores is better

15 *Cantonese version of Mini-Mental State Examination/Mental state (cognitive status)*. The mini-mental state examination (MMSE) or Folstein test is a brief 30-point questionnaire test that is used to screen for cognitive impairment. Any score greater than or equal to 25 points (out of 30) indicates a normal cognition. Below this, scores can indicate severe ( $\leq 9$  points), moderate (10-20 points) or mild (21-24 points) cognitive impairment.[9] The raw score may also need to be corrected for educational attainment and age

16 *Cantonese version of Rivermead Behavioural Memory test/ Memory*:

17 Hierarchic Dementia Scale- assesses the grade of dementia:

**Table 17. Summary of results - Co-morbidities**

Author Year	Mortality	Cognitive status and functional level	Healthcare resource use and Discharge to a higher level of care	Quality of Life and Satisfaction	Costs
<b>FINKELSTEIN 2006</b>	TM (Video+ Video and monitoring+UC):20.6% (7/34); UC:26.3% (5/19),  P = 0.74 <sup>1</sup>	Morbidity <sup>2</sup> , Omaha Assessment Tool, showed no differences between groups. <sup>1</sup>	Discharge to a higher level of care: at 6 months:  Video+monitoring+UC: 15%, n=20; UC: 42% , n=19; P = 0.055 <sup>3</sup>	Satisfaction assessed with  a non-validated tool.  Results not reported here.	Average cost per visit 4:  Virtual visits +monitoring: \$33.11  Face-to-face visits/UC: \$48.27
<b>HOPP 2006</b>			Mean no of hospital admissions:  TM:0.67 (1.03), n=18; UC:1.26 (2.00), n=19, P = 0.61  Total inpatient bed days of care: TM: 2.83 (4.12); UC: 7.11 (12.86), P = 0.41  Total no of outpatients visits: TM:29.06 (30.1); UC:38.89 (28.88), P = 0.10  No of primary care visits:  TM:3.39 (3.85); UC:3.89 (5.03), P = 0.43  No of specialist care visits:  TM: 2.06 (2.49); UC:2.47 (2.61), P = 0.41  ED visits:  TM:1.00 (1.33); UC: 2.11 (2.89), P = 0.83	QOL (assessed with the SF- 36 <sup>5</sup> tool)  Physical component summary score, mean change (95% CI):  TM: 1.56 (-3.53 to 6.64), n=18; UC:0.64 (-3.83 to 5.11), n=19, P = 0.77  Mental component summary score, mean change (95% CI):  TM:4.05 (-0.40 to 8.51); UC: -4.11 (-12.13 to 3.9)  P = 0.04  <i>General Home care satisfaction scale score</i> <sup>6</sup> (95% CI):  TM:-1.00 (-2.37 to 0.38); UC:-1.56 (-3.93 to 0.82), P = 0.64	
<b>NOEL 2004</b>		OARS Multidimensional Functional Assessment 7:	<i>Bed days stayed</i> :  BL: TM:12.19 (11.95); UC: 13.82(10.27)	Self-Rated Health Status (from OARS):	Average healthcare costs per participant

**Table 17. Summary of results - Co-morbidities** (Continued)

Cognitive status:	During 6 months (when receiving the intervention)	BL: TM:81.32 (13.07); UC:84.86 (15.33),	at 6 months pre study:
BL: TM: 19.31 (1.7); UC:19.42 (1.51), P = 0.751	TM: 1.88 (3.33), n=47; UC:5.11 (10.54), n=57, P = 0.085	at 3 months: TM: 81.34 (13.71); UC: 82.25 (15.83);P = 0.755	TM: \$ 8278,, n=15
at 3 months	<i>Total clinic visits (scheduled):</i>	at 6 months: TM:82.47 (12.89); UC:85.14 (16.28), P = 0.383	UC: \$ 12386, n=57
TM: 19.62 (1.06); UC: 19.46 (0.169), P = 0.578	BL: TM:14.51 (10.49); UC:16.33 (14.60)	at 9 months: TM: 84.40 (13.23), n=15; UC:82.11 (13.34), n=27, P = 0.596	Average healthcare costs per participant
at 6 months	During 6 months:TM: 14.83 (11.28), n=47; UC: 14.96 (15.09), n=57, P = 0.958	Patient satisfaction with care (from OARS):	at 6 months post study:
TM: 19.70(1.06); UC:19.68 (0.69), P = 0.921	<i>Urgent visits (ED visits and unscheduled visits):</i>	BL: TM:103.55 (17.54)	TM: \$ 4849;n=47
at 9 months: TM: 19.80 (0.414), n=15; UC:19.56 (0.892), n=27, P = 0.234	BL: 7.27 (5.12); UC: 5.59 (4.69)	UC: 98.70 (16.63),	UC:\$ 5832, n=57
Functional level:	During 6 months:TM: 5.39 (5.50); UC: 5.69 (6.01), P = 0.798	at 3 months: TM: 110.8 (18.32); UC:98.98 (17.24);P = 0.001	Healthcare costs decreased by 58% for the TM group and by 47% for the control group in the 6 months intervention period as compared with the 6 months preceding the intervention..
BL: TM: 37.02 (9.25); UC:40.19 (4.47), P = 0.035	BL: TM: 2.53 (5.90); UC:1.82 (5.19)	at 6 months: TM: 106.38 (20.99); UC: 97.14 (18.22), P = 0.020	
at 3 months: TM: 37.17 (9.15); UC:39.88 (5.38), P = 0.780	During 6 months: TM: 2.00 (4.60); UC: 1.81 (5.66), P = 0.848	at 9 months: TM:109.13 (23.21), n=15; UC:98.11 (16.58), n=27	
at 6 months: TM:37.91 (9.22); UC:40.19 (5.81), P = 0.146			
at 9 months: TM: 38.67 (5.63), n=15; UC:40.96 (4.83), n=27, P = 0.195			

1 No results data for the separate intervention groups provided.

2 Morbidity, as evaluated by changes in the knowledge, behaviour and status scales of the Omaha Assessment Tool.

3 Note: 15 patients dropped out but unclear from which group

4 The estimated cost of an actual visit was based on the average mileage and travel time to each patient's home, the average time of the visit itself, the Internal Revenue Service approved mileage reimbursement, the average nurse total hourly compensation (salary and fringe benefits) for travel and visit, and administrative overhead. The estimated cost of virtual visits included visit time, nursing personnel compensation, amortized equipment costs, technical support costs and administrative overhead.

5 SF-36:the SF-36 is a measure of health status. The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability.

6 General Home Care Satisfaction scale:unknown scale

7 OARS Multidimensional Functional Assessment. Higher score is better. Note: 12 months results are not reported here due to less than 10 remaining participants in the TM group

**Table 18. Summary of results - Conditions requiring a specialist consultation**

Author Year	Clinical outcome	Time for consul- tation  Consultation fail- ure rate  Correct treat- ment decisions	Healthcare resource use / Follow-up ap- pointments	Quality of life (QOL) Self-management be- haviour  Satisfaction	Mortality, Adverse events	Costs
<b>Dermatological conditions (n=3)</b>						
<b>BERGMO 2009</b>	<p>SCORAD<sup>1</sup> severity score:</p> <p>BL: TM: 21.6; UC: 21.6</p> <p>at 12 months: TM:18.3, n=50 ;UC: 21.0, n=48, P = 0.55</p> <p>No mea- sure of dis- persion provided.</p> <p><b>Note:</b> Two out of five parents (circa 10/26 parents) used the web-based consulta- tions on at least one occasion during the 12 months interven- tion period.</p>		No between group dif- ferences in self-report- ed healthcare visits.No results data for the sep- arate groups provided.	No difference be- tween groups in the mean number of skin care treatments per week.No results data for the separate groups provided.		No dif- ferences between groups in family costs. No results da- ta for the separate groups pro- vided.
<b>OAKLEY 2000</b>		<p>Patient time <sup>2</sup> (minutes) involved in index consulta- tion:</p> <p>TM: 51 (22 to 130), n= 109; UC:259 (127-440), n=94</p>	<p>No of patients needing a further consultation (after index consulta- tion):</p> <p>TM: 26 (25%), n=109; UC: 24 (26%), n=94</p>			
<b>WOOTTON 2000  (LOANE 2000)</b>		<p>Patient time in- volved in index consultation, Mean ±SD, (95% CI):</p>	<p>Mean no of addition- al visits to primary and secondary care at 12 months:</p>			The net so- cietal cost <sup>4</sup> of the ini- tial consul-

**Table 18. Summary of results - Conditions requiring a specialist consultation** (Continued)

TM: 52.2 ±32.2, (43.9 to 60.5); UC: 83.0 ±50.3, (72.4 to 93.6)	TM: 1.63 (SD 0.78), 95% CI 1.43 to 1.83, range 1-4), n=102	tation per patient:
Travel distance (km): TM: 10.3 (9.1), n=58; UC:26.0 (23.2), n=101	UC: 2.12 (SD 1.93), 95% CI 1.62 to 2.62, range 1-10), n=102	TM: £132.10
	At least one subsequent hospital appointment (%):TM: 46%; UC: 45%; data from 96 of 103 patients extracted from Loane 2000 <sup>3</sup> with longer follow-up).	UC: £48.73
	A further hospital appointment recommended by physician:	
	TM:47 (46%) patients;	
	UC:46 (45%) patients	

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**Acute injuries and conditions (patients visiting the ED department, n=1; and patients with suspected stroke presenting at the spoke, n=1)**


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<b>MEYER 2008</b>	Functional outcomes at 90 days (assessed with the Barthel Index <sup>5</sup> ; 95-100): TM:45 (43%), n=111; UC:56 (54%), n=111; OR 0.6;95% CI 0.4 to 1.1; P = 0.1268	Correct treatment decisions made: TM:108 [98%]; UC:91 [82%]; OR:10.9 , 95% CI 2.7 to 44.6; P = 0.0009	Rates of intracerebral haemorrhage (after treatment with thrombolytics) at 90 days: TM:7%; UC:8%; OR 0.8; 95% CI 0.1-6.3; P = 0.10
	Functional outcomes at 90 days (as assessed with the modified Rankin scale <sup>6</sup> ): TM: 36 (34%), n=111; UC:45 (47%), n=111; OR 0.6; 95%CI 0.3-1.1; P = 0.0898	Overall rate of intravenous thrombolytic use: TM:31 [28%]; UC:25 [23%], OR 1.3, 95% CI 0.7 to 2.5, P = 0.43	Mortality rate at 90 days:TM: UC: OR 1.6; 95%CI 0.8-3.4; P = 0.2690
		Incomplete data:TM: 3%; UC, 12%; OR:0.2, 95% CI 0.1 to 0.3), P < 0.001	

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**Table 18. Summary of results - Conditions requiring a specialist consultation** (Continued)

<b>WONG 2006</b>	Clinical outcomes (GOS score <sup>7</sup> ) at 6 months:  TM (video): 127, n=235;  UC: 81, n=236,:P = 0.960	Consultation process time in hours (SD):TM (Video): 1.30 (2.5); UC:0.70 (0.9), P = 0.003  Consultation failure rate:  TM (Video):30.1  UC:9; P < 0.001	Total Mor-tality:  at 6 months:  TM (video): 79; UC:81,  P = 0.923	
<b>Non-acute conditions (patients visiting the GP clinic, n=2)</b>				
<b>HARRISON 1999</b>	Median time (hours) taken to visit the surgery: TM:0.5; UC:2.5  No measure of dispersion,P value  or CI provided.	General QOL (assessed with the SF-12 <sup>8</sup> ) at 3 months:  Mean scores for physical component:TM:37.7; n=41/62; UC:33.7; n=30/70  Mean scores for mental component:TM: 36.8; UC:34.9, no P value/ CI provided, but stated not to differ between groups.  Patient satisfaction.  Results only graphically presented and no statistical tests performed.		
<b>WAL-LACE 2004 (JACKLIN 2003)</b>	Professionals time spent for index visit was estimated through observation by non participants of a small sample of consultations selected opportunistically, because of the logistical problems of scheduling observations and the substantial research time involved.  Data not reported here.	Follow-up appointments up to 8 weeks:  TM: 502 (52%), n=971/1051; UC:400 (41%), n=968/1043  OR 1.52 95% CI 1.27 to 1.82, P < 0.0001  No of tests and investigations:  At 6 months after index visit: TM: 3.22 (4.48), n=1033; UC: 4.01 (5.25),n=1025,  OR -0.79  (95% CI -1.21 to -0.37) P = 0.0002  No of outpatients visits: TM: 1.32 (1.57); UC:1.28	QOL (assessed with the SF 12 for adults)  Physical component summary score:  TM: 43.1 (12.0), n=648; UC: 42.7 (12.2), n=700;  Difference:0.34 95% CI -0.96 to 1.64, P = 0.61  Mental component summary score:  TM:47.5 (11.8), n=648; UC:48.1 (11.9);Difference:  -0.51 95% CI -1.78 to 0.76, P = 0.43  QOL (assessed with the Child Health Question-	<i>Total NHS<sup>12</sup> costs (£) (imputed):</i>  TM: 723.29 (832.04); UC: 632.49 (1199.68), Adjusted Diff. (95% CI):93.87 (7.34 to 180.40)  <i>Attributable NHS costs (imputed):</i>  TM: 392.65 (388.88); UC: 292.98 (407.15); Adjusted Diff.: 102.58



**Table 18. Summary of results - Conditions requiring a specialist consultation** (Continued)

(1.59); Difference:0.04 (-0.10 to 0.18), P = 0.57	naire <sup>9</sup> for the 170 pa- tients younger than 16 years):	(68.87 to 136.29)
No of contacts with GP: TM: 3.47 (3.65); UC:3.27 (3.39); Difference:0.20 (-0.11 to0.50), P = 0.21	Mental health score:  BL: TM:82.3 (16.5), n=57; UC: 78.2 (19.0), n=49	Total pa- tient costs (imputed):  TM:3.69 (16.89); UC: 11.38 (33.85), Adjusted Diff.: -7.65 (-10.30 to -5.01)
No of accident and emergency visits: TM:0.06 (0.30); UC:0.06 (0.28); Difference:0.002 (-0.02 to 0.03), P = 0.85	at 6 months:  TM: 84.1 (16.9), n=46; UC: 85.0 (13.7), n=46; Diff.: -0.91 (-7.28 to 5.47), P = 0.78	
No of inpatient stays: TM:0.11 (0.36); UC:0.13 (0.39); Difference:-0.02 (-0.06 to 0.01), P = 0.15	Physical health score:  BL: TM: 88.7 (1.0), n=56; UC: 85.3 (23.4), n=49	
No of days surgery and inpatient procedures: TM: 0.11 (0.36); UC: 0.12 (0.38); Difference:-0.01 (-0.04 to 0.02), P = 0.52	at 6 months:  TM:89.1 (23.0), n=46; UC:94.9 (14.3), n=46; Diff.: -5.80 (-13.44 to 1.65),P = 0.14	
	<i>Patient satisfaction</i> <sup>10</sup>	
	TM:3.97 (0.99), n=767; UC:3.64 (1.06), n=817,	
	TM: 3.97 (0.99), n=767; UC:3.64 (1.06), n=817; Difference: 0.33 95% CI 0.23 to 0.43 P < 0.001	
	<i>Patient Independence</i> (assessed with the PEI	
	<sup>11</sup> : TM: 2.5 (3.2), n=752; UC: 2.4 (3.1), n=805; Difference 0.07 95% CI -0.24 to 0.38, P = 0.67	

1 SCORAD (Scoring Atopic Dermatitis): is a clinical tool for assessing the area of the affected skin, the severity of the eczematous skin and subjective symptoms such as itching and sleep disturbance. In the objective SCORAD (range 0–83), the patient reported symptoms are omitted so it reflects the physician's (subjective) assessment only. Lower scores are better.

2 Total patient time (min) involved in attending initial appointment (including waiting, consultation and travel).

3 Loane MA, Bloomer SE, Corbett R, Eedy DJ, Hicks N, Lotery HE. A randomised controlled trial to assess the clinical effectiveness of both real time and store-and-forward tele dermatology compared with traditional care. *Journal of Telemedicine and Telecare* 2000;6 (Suppl 1):S1:1 -S1:3.

4 The hourly rate of a consultant dermatologist including overhead costs was estimated to be £150.00 and the hourly rate of a general practitioner £114.00 (MedEconomics). The average cost of consultant time was £39.25 for a tele dermatology consultation and £34.75 for a conventional consultation. The average cost of general practitioner time at a tele dermatology consultation was £29.83.

5 Barthel Index: The Barthel scale or Barthel ADL index is a scale used to measure performance in activities of daily living (ADL). A higher rating is associated with a greater likelihood of being able to live at home with a degree of independence following discharge from hospital.

6 Rankin scale: The modified Rankin Scale (mRS) is a commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability. The scale runs from 0–6, running from perfect health without symptoms to death.

7 GOS score: Glasgow Outcome Score: A favourable outcome was defined as good recovery to moderate disability (GOS 4–5)

8 SF-12: shorter version of the SF-36 instrument: scores 0 to 100, a higher score indicates better health

9 Child Health Questionnaire (CHQ): 14 unique physical and psychosocial concepts. The child self-reported version of the CHQ consists of 87 items (CHQ-CF87) and was developed for completion by children from ages 10 and older.

10 Overall satisfaction, scored from 1= poor, 2=fair, 3=good, 4=very good, 5=excellent.

11 PEI (Patient Enablement Index): the scores are calculated from six questionnaire items: Higher scores indicate improved enablement.

12 NHS: National Health Services

**Table 19. Summary of results - Gastrointestinal conditions**

Author Year	Response to treatment/ Clinical Dis- ease Activity	Quality of Life	Medication adherence	Healthcare Resource use	Hospital Anxiety and Depression	Other out- comes
<b>CHAMBERS 2006</b>		<p>QOL (assessed with the SF36):</p> <p>Physical Component Summary at 6 months:</p> <p>TM: 29.9;</p> <p>UC: 32.7, P = 0.66</p> <p>Mental Component Summary at 6 months:</p> <p>TM: 45.5; UC: 46.7, P = 0.83</p> <p>EQ5D scores</p> <p>No difference between groups.</p> <p>No numerical data or P values provided.</p> <p><b>Note:</b> Initially 15 patients in each group, however unclear no of patients remaining in the study at 6 months. At 12 months less than half (14/30) pa- tients remained but unclear how these patients were divided be- tween groups.</p>		<p>No data provided on outpa- tients re at- tendances and hospi- tal re-ad- missions at 6 months.</p>	<p>Hospital anxiety and Depression scores</p> <p><i>Hospital anxiety</i> mean (SD):</p> <p><i>At BL (2 days):</i> TM: 7.6 (4.7) ; UC: 6.6 (3.1)</p> <p><i>at 6 months:</i></p> <p>TM: 7.3 (4.9); UC: 6.8 (4.4), NS, P val- ues not provided.</p> <p><i>Hospital Depres- sion</i> mean (SD)</p> <p><i>At BL (2 days):</i> TM: 6.7 (3.7);</p> <p>UC: 5.9 (3.3)</p> <p><i>at 6 months:</i></p> <p>TM: 6.4 (4.6);</p> <p>UC: 6.5 (4.1), NS, P values not provid- ed.</p>	<p>No of cen- tral lines re- quired: no data pro- vided at 6 months.</p>
<b>CROSS 2012</b>	<p><i>Clinical Dis- ease activity at BL:</i></p> <p>TM: 127± 42.3, n=25; UC: 115.1±21.5, n=22, P = 0.24</p> <p><i>At 12 months:</i></p> <p>TM: 122.0±39.3; UC:</p>	<p><i>Disease specific Quality of life at BL:</i></p> <p>TM: 171.6±30, n=25; UC: 190.8±24.2, n=22, P = 0.02</p> <p><i>At 12 months:</i></p> <p>TM: 178.1±32.1; UC: 187.3±32.2, NS, P value not provided</p>	<p><i>Medication Adherence at BL:</i></p> <p>TM: 40%, n=25; UC: 45%, n=22, P = 0.71</p> <p><i>At 12 months:</i></p> <p>TM: 44%; UC: 68%, P = 0.10</p>			

**Table 19. Summary of results - Gastrointestinal conditions** (Continued)

113.6±28.0, P  
= 0.41

**Note:** n=8 TM  
and n=4 UC  
patients with-  
drew from the  
study.

1 Seo Index Score- lower score better i.e. less disease activity.

2 IBD questionnaire - score from 32 to 224- higher score indicate better disease specific quality of life

3 Morisky Medication Adherence Score- score 0-4 with higher score indicating better medication adherence

**Table 20. Summary of results - Urological conditions**

Author Year	Treatment re- sponse	Morbidity	Length of stay	Satisfaction
<b>Post-operative care after minor urological procedure</b>				
<b>ELLISON 2004</b>				<p>Patient satisfaction only graphically reported.</p> <p>Only one of seven questionnaire items</p> <p>showed greater satisfaction with care</p> <p>in the tele-rounding group as compared</p> <p>to controls (i.e. physician availability).</p>
<b>ELLISON 2007</b>		<p>Overall complications<sup>1</sup>, no of events:</p> <p>TM: 18 (16.7), n=108<sup>2</sup>;</p> <p>UC: 18 (15.9), n=112, P = 0.88</p> <p>Note: 26 and 28 patients missing in respective group at follow-up.</p> <p><i>Minor complications:</i></p> <p>TM:14 (13.0)</p> <p>UC:16 (14.3), P = 0.39</p> <p><i>Major complications, no events:</i></p> <p>TM: 4 (3.7); UC: 2 (1.8), P = 0.82</p> <p>Morbidity rates overall:</p> <p>TM: 13%; UC:16%, P = 0.64</p>	<p>LOS, mean days:</p> <p>TM:2.8, n=134;</p> <p>UC:2.8, n=136; P = 0.94.</p>	<p>Patient satisfaction with post-operative care (data only graphically reported)</p> <p>No difference between groups.</p>
<b>Urinary incontinence</b>				

**Table 20. Summary of results - Urological conditions** (Continued)

<b>HUI 2006</b>	Number of incontinence episodes/day:at 8 weeks: TM: 0.2 (0.2); UC:0.1 (0.5), P = 0.39  Note: 5 patients from TM  group dropped out and none from the control group
-----------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1 Overall complications (during hospital stay)- including major complications=an event that required transfer to a monitored setting; and minor complications=events that delayed discharge more than 24 hours beyond the expected length of stay

2 Participant numbers calculated using percentages and numbers given in table 2. 112 is maybe 111 or 113, it depends on the values used to calculate it (18/0.159; 2/0.018; 16/0.143).

**Table 21. Summary of results - Non-acute neurological conditions**

Author Year	Response to treatment/ Clinical outcome	Adverse events	Healthcare resource use
<b>DALLOLLIO 2008<sup>1</sup></b>	Functional status FIM score <sup>2</sup> <i>Bologna-Italy</i> Mean discharge total FIM score (95% CI) at BL TM: 83.90±23.09 (75.28–92.52), n=30; UC: 92.83±26.02 (82.93–102.72),n=29, P = 0.17  Mean increase in total FIM score at 6 months : TM: 7.69±6.88 (5.07–10.31), n=29; UC: 3.38±4.43 (1.69–5.06), n=28;  Mean post intervention diff. 4.31 (1.27–7.35), P < 0.01 <i>Salisbury and Stanmore</i> Mean discharge total FIM score (95% CI)at BL TM: 93.70±24.32 (83.18–104.21), n=25; UC: 81.88±27.45 (70.55–93.21), n=26, P = 0.12  Mean increase in total FIM at 6 months TM: -1.83±6.91 (-5.21–1.60), n=18; UC: -0.14±6.31 (-3.02–2.73), n=21;	Clinical complications <sup>4</sup>  No differences between groups  (P values 0.07 to 0.88).  Note: 18 to 56% of participants lost.	Re-admissions to the spinal cord unit:  TM: 1 (2.0%) UC:4 (7.7), P = 0.18  Note:17.7% and 20% of patients missing from respective group  Re-admissions to other hospitals:  Intervention: 6 (12.0%)  UC:8 (15.1%), P = 0.65  Note: 19.4% and 18.5 % participants missing from respective group

**Table 21. Summary of results - Non-acute neurological conditions** (Continued)

Mean post intervention diff: -1.69 (-5.98–2.60),

P = 0.43

Disability<sup>3</sup>

SCIM II score

Bologna:

Mean discharge SCIM score (95% CI) at BL

TM: 50.76±16.51 (44.60–56.93);

UC: 54.48±19.46 (47.08–61.88), P = 0.43

Mean increase at 6 months

TM: 3.38±4.66 (1.61–5.15);

UC: 3.38±4.69 (1.59–5.16);

Mean diff.: 0 (2.46–2.46), P = 1.0

Salisbury and Stanmore

Mean discharge SCIM (95% CI) at BL

TM: 52.17±21.67 (42.80–61.55);

UC: 40.68±22.63 (31.34–50.02); P = 0.08

Mean increase in SCIM at 6 months

TM: -2.06±9.06 (-6.56–2.45);

UC: 0.10±7.39 (-3.27–3.46);;

Mean diff.: -2.15 (-7.49–3.18), P = 0.42

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**HERMENS 2007**

Arm/hand function:

All patients groups:

ARA score<sup>5</sup>

BL (T1): TM: 46.0 (13.5), n=50;

UC: 47.2 (10.9), n=23

At one month:

TM: 46.1 (14.2), n=46;

UC: 50.2 (8.2), n=22, P value not provided

MS participants only:

Mean diff. (T1=BL/before intervention, TM: n=21;

UC: n=11; T2=at one month after start of intervention,

TM; n=18, UC: n=11): 1.26 (90% CI -1.90 to 4.42)

NHPT score<sup>6</sup>

BL: TM: 65.5 (39.4), n=45;

**Table 21. Summary of results - Non-acute neurological conditions** (Continued)

UC: 60.5 (27.9), n=23

At one month:TM:71.7 (44.2), n=44;

UC: 63.4 (31.2), n=22, P value not provided

MS participants only<sup>7</sup>:

Mean diff. (T1=BL/before intervention, TM:n=18;

UC:n=11; T2=at one month after start of intervention):

TM:n=16, UC:n=11): 7.24 (90% CI -6.55 to 23.25),

**Note:**The exercise compliance varied; the average

days exercising with the system was 24 days (SD = 9, range 7-39 days).

Also the amount of time and the number of exercises varied from person

to person (range number of exercises a day: 2-24 per exercise). No

information was provided on average days exercising or no of exercises for

the control group.

1 Results from Brussels not reported here as fewer than 10 participants in one arm.

2 The Functional Independence Measure (FIM scale) is a widely used standardized functional outcome measure consisting of 13 motor and 5 cognitive items rated on an ordinal scale. It has a minimum score of 18 which indicates complete dependence up to a maximum of 126 indicating total functional independence.

3 The Spinal Cord Independency Measure (SCIM II) is a disability scale to assess the ability of the individual patient with a spinal cord lesion to perform daily tasks. SCIM II covers 18 tasks, all activities of daily living, grouped into 4 areas: Self-Care (scored 0–20), Respiration and Sphincter Management (0–40), Mobility in Room and Toilet (0–10), and Mobility Indoors and Outdoors (0–30). The total score ranges between 0 and 100. Patients are evaluated by observation.

4 The complications monitored during the first 6 months post-discharge included skin ulcers (pressure ulcers), urinary tract infections, problems associated with the use of urinary catheters, pulmonary infections, fever, pain, autonomic dysreflexia, and deep vein thrombosis.

5 The Action Research Arm (ARA) test: is an observational test consisting of 19 items focusing on grasping objects of different shapes and sizes, and gross movements in the vertical and horizontal planes (score range: 0 to 57; higher is better?). Only the difference between time-point T1 (end of one month UC=BL) and T2 (end of month with TM treatment) were used for the comparison.

6 The Nine Hole Peg Test (NHPT): is a test which measures manual dexterity (and reaching and grasping). The total time needed to move the 9 pegs with the affected arm was used as outcome parameter. When the patient was unable to move all nine pegs, the total time of 180 seconds was used. Only the difference between time-point T1 (end of one month UC=BL) and T2 (end of month with TM treatment) were used for the comparison.

7 There were fewer than 10 participants in one or both arms of the stroke and TBI groups, why no results for these groups separately are presented in this table.

**Table 22. Summary of results - Other conditions**

Author Year	Morbidity/ Adverse events	Depression, State and trait anxiety Satisfaction	Healthcare resource use/ LoS/ Transfer to a higher level of care/ Costs
<b>Cancer patients receiving outpatients chemotherapy</b>			

**Table 22. Summary of results - Other conditions** (Continued)

KEARNEY 2009	<p>Chemotherapy-related morbidity (6 items).Proportion of patients with symptoms, OR<sup>1</sup> (95% CI<sup>2</sup>):</p> <p>Vomiting: TM:20.3, n=56; UC:21.9, n=56;</p> <p>OR: 1.23 (0.57 to 2.68), P = 0.60</p> <p>Nausea: TM: 53.9; UC:61.1;</p> <p>OR:1.55 (0.77 to 3.12), P = 0.22</p> <p>Diarrohoea:TM: 33.0; UC:30.2;</p> <p>OR: 0.97 (0.51 to 1.82), P = 0.91</p> <p>Hand-foot syndrome:TM: 24.0;UC:12.2;</p> <p>OR:0.39 (0.17 to 0.92), P = 0.031</p> <p>Sore mouth and throat: TM:53.3;UC:42.1;</p> <p>OR. 0.78 (0.41 to 1.48), P = 0.44</p> <p>Fatigue:TM:67.3; UC:81.3;</p> <p>OR 2.29 (1.04 to 5.05), P = 0.040</p> <p>Note: only 29 (51.7%) of participants remained in each group at follow-up.</p>	
Transplant recipients after discharge from hospital		
LEIMIG 2008 * companion study to Thompson 2009	<p>Morbidity:</p> <p>at 6 months:</p> <p>Infections (no events):TM: 32, n=53;</p> <p>UC: 31, n=53 ,</p> <p>Rejections (no events): TM:2;</p> <p>UC 3,</p> <p>Hospitalisations:TM:10;</p> <p>UC: 10,</p>	
THOMPSON 2009	<p>CES-D™ scores<sup>3</sup></p> <p>Change from BL to 6 months:</p> <p>TM: 12.4 ± 10.6, n=70;</p> <p>UC: 9.7 ± 7.6, n=68, P = NS,</p> <p>P value not provided</p> <p>Change from 6 to 12 months:</p> <p>TM: 9.4 ± 8.0, n=70;</p> <p>UC: 11.5 ± 7.3, n=68, P = NS,</p>	<p>Number of visits per patient</p> <p>at 6 month</p> <p>TM:2.97 ± 2.00;</p> <p>UC: 2.79 ± 2.04, P = 0.6744</p> <p>at 12 month</p> <p>TM:1.24 ± 1.14;</p> <p>UC: 1.08 ± 1.22, P = 0.2985</p>

**Table 22. Summary of results - Other conditions** (Continued)

P value not provided

High risk infants requiring specialist neonatal care		
GRAY 2000	Family Satisfaction survey:	Mean LoS $\pm$ SD (days)
	Mean problem scores ( $\pm$ SE):	TM: 68.5 $\pm$ 28.3, n=26;
	results graphically presented	UC: 70.6 $\pm$ 35.6, n=30;
	and numerical results only provided	P $\geq$ 0.05
	for (2/8) items showing a significant difference	Proportion of infants back-transported
	between groups (see below)	to a higher level of care
	Problems with quality of care::	at the time of discharge:
	TM: 3%; UC:13%, P < 0.05	TM:0%;UC:20 %, P < 0.05
	Problems with the physical environment and	
MC CROSSAN 2012	visitation policies:TM:13%; UC:50%, P < 0.05	
		Total NHS episodes at 10 weeks:
		TM: 7.7 (SD 3.2), n=35; UC:12.9 (SD 7.2), n=24, P < 0.001
		Total healthcare costs per patients at 10 weeks:
		TM:822,32 (449.32 to 1399,04); UC: 3581,91 (1615,04 to 6254,98) <sup>4</sup>

1 OR: Odds Ratio

2 CI: Confidence Interval

3 Center for Epidemiologic Studies–Depression (CES-D™) survey. The survey consists of 20 questions assessing the patient's emotional state during the previous week. Using a Likert-type scale, response options include 0 (rarely or none of the time) to 3 (most or all of the time), and total scores range from 0 to 60. A score of 16 or higher suggests a depressive state and requires additional evaluation.<sup>10,17</sup> The CES-D identifies symptoms in six areas: depressed mood, guilt/worthlessness, helplessness/hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance.

4 95% non-parametric CI based on 1000 bootstrap replications.

## APPENDICES

### Appendix 1. Full search strategies

#### MEDLINE (OVID)

Search date: 19/06/2013

1 Telemedicine/ or Telepathology/ or Teleradiology/ or Telenursing/ (12270)

Interactive telemedicine: effects on professional practice and health care outcomes (Review)

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2 Remote Consultation/ [Part of Telemedicine Tree, but may use technology other than phones] (3458)

3 (Telephone/ or Cellular Phone/ or Text Messaging/) and (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care).ti,ab. [June 2013] (1797)

4 (teleassist\$ or tele-assist\$ or teleaudiolog\$ or tele-audiolog\$ or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\$ or telecardiolog\$ or teleconsult\$ or tele-consult\$ or telecounselling or tele-counselling teledental or tele-dental or telederm\$ or tele-derm\$ or telediagnos\$ or tele-diagnos\$ or teledialysis or tele-dialysis or teleecho\$ or tele-echo\$ or teleemerg\$ or tele-emerg\$ or telepileps\$ or tele-epileps\$ or telefollow\$ or tele-follow\$ or teleguidance or tele-guidance or telehealth\$ or tele-health\$ or telehome\$ or tele-home\$ or teleICU or tele-ICU or teleintervention\$ or tele-intervention\$ or telemanag\$ or tele-manag\$ or telemedicine or tele-medicine or telemental\$ or tele-mental\$ or telemonitor\$ or tele-monitor\$ or telenurs\$ or tele-nurs\$ or teleoncolo\$ or tele-oncolo\$ or teleophthalm\$ or tele-opthalm\$ or telepalliat\$ or tele-palliat\$ or tele-patholog\$ or tele-patholog\$ or teleprocedu\$ or tele-procedu\$ or telepsych\$ or tele-psych\$ or teleradiol\$ or tele-radiol\$ or telerefer\$ or tele-refer\$ or telerehab\$ or tele-rehab\$ or telesurger\$ or tele-surger\$ or telesurgic\$ or tele-surgic\$ or teletherap\$ or tele-therap\$ or teletreat\$ or tele-treat\$ or teletriage or tele-triage).ti. (7612)

5 (teleassist\$ or tele-assist\$ or teleaudiolog\$ or tele-audiolog\$ or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\$ or telecardiolog\$ or teleconsult\$ or tele-consult\$ or telecounselling or tele-counselling teledental or tele-dental or telederm\$ or tele-derm\$ or telediagnos\$ or tele-diagnos\$ or teledialysis or tele-dialysis or teleecho\$ or tele-echo\$ or teleemerg\$ or tele-emerg\$ or telepileps\$ or tele-epileps\$ or telefollow\$ or tele-follow\$ or teleguidance or tele-guidance or telehealth\$ or tele-health\$ or telehome\$ or tele-home\$ or teleICU or tele-ICU or teleintervention\$ or tele-intervention\$ or telemanag\$ or tele-manag\$ or telemedicine or tele-medicine or telemental\$ or tele-mental\$ or telemonitor\$ or tele-monitor\$ or telenurs\$ or tele-nurs\$ or teleoncolo\$ or tele-oncolo\$ or teleophthalm\$ or tele-opthalm\$ or telepalliat\$ or tele-palliat\$ or tele-patholog\$ or tele-patholog\$ or teleprocedu\$ or tele-procedu\$ or telepsych\$ or tele-psych\$ or teleradiol\$ or tele-radiol\$ or telerefer\$ or tele-refer\$ or telerehab\$ or tele-rehab\$ or telesurger\$ or tele-surger\$ or telesurgic\$ or tele-surgic\$ or teletherap\$ or tele-therap\$ or teletreat\$ or tele-treat\$ or teletriage or tele-triage).ab. (7984)

6 (tele adj (care or counselling or diagnos\$ or health\$ or intervention? or manag\$ or therap\$ or treat\$ or medicine or medical or nursing)).ab. [edited june 2013 removed truncation and doctor, physician, practitioner] (142)

7 ((iphone? or i-phone? or smartphone? or PDA or Personal Digital Assistant? or telephone or telephones or TRANSTELEPHON\$ or phone or phones) and (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care)).ti. [June 2013] (261)

8 ((iphone? or i-phone? or smartphone? or PDA or Personal Digital Assistant? or telephone or telephones or TRANSTELEPHON\$ or phone or phones) adj3 (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care)).ab. [June 2013] (498)

9 (telephone based or phone based or text-messag\$).ti,ab. [2013 Telemed] (1839)

10 or/1-9 [Telemedicine] (21369)

11 Cellular Phone/ (3791)

12 ((cell or mobile) adj (phone or phones or telephone or telephones)).ab. (3316)

13 Telephone/ or Text Messaging/ [telephone moved from telemed set] (9289)

14 exp Telemetry/ or (telecommunications/ not Television/) or videoconferencing/ [June 2013--used in 2010 but notted with tv] (13175)

15 (iphone? or i-phone? or smartphone or text-messag\$).ti,ab. or (telephone or telephones or phone or phones).ti. (8631)

16 (videoconsult\$ or video consultation? or video consulting).ti,ab. [Added June 2013] (75)

17 ((pda adj (device or phone)) or personal digital assistant).ti,ab. [June 2013] (549)

18 or/11-17 [Telephones/telecommunication 2013] (29486)

19 (remote adj2 (consult\$ or diagnos\$ or monitor\$ or treat\$ or therap\$ or care)).ti,ab. (2017)

20 (e-care or ecare or e-consult\$ or econsult\$ or e-diagnos\$ or edagnosis\$ or e-health\$ or ehealth\$ or e-medicine or emedicine or e-nurse? or enurse? or e-nursing or enursing or e-physician? or ephysician? or e-psych\$ or epsych\$ or e-therapy or etherapy or mhEALTH or M-HEALTH).ti,ab. [e-Health] (2426)

21 exp Monitoring, Physiologic/ (125284)

**Interactive telemedicine: effects on professional practice and health care outcomes (Review)**

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- 22 exp Diagnosis/ (6340336)
- 23 exp Self Care/ (38745)
- 24 exp Mass Screening/ (97417)
- 25 Medically Underserved Area/ or Rural Health Services/ (13291)
- 26 (care or health or OUTPATIENT? or OUT-Patient? or patient? or rural or screening or UNDERSERVED or outreach).ti,hw. or ((project? or programme or programmes) adj3 (care or patient care or healthcare or patient? or outpatient? or out-patient? or family practice? or general practitioner? or ambulatory or preventive or preventative or monitor? or monitoring or general practice or family practice or primary care or primary healthcare or primary health care)).ab. (3251250)
- 27 diagnosis.fs. (1926850)
- 28 Patient Education as Topic/ (68479)
- 29 Physician's Role/ or Nurse's Role/ (56049)
- 30 exp Patient Care Management/ (513263)
- 31 or/19-30 [Care/Role] (9238868)
- 32 (randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti. (877728)
- 33 exp animals/ not humans.sh. (3905620)
- 34 32 not 33 [Cochrane RCT Filter 6.4.d Sens/Precision Maximizing] (811245)
- 35 \*Monitoring, Physiologic/ (17355)
- 36 monitoring.hw. (170218)
- 37 exp Monitoring, Ambulatory/ or Blood Glucose Self-Monitoring/ or Self Care/ (46729)
- 38 (self care or self monitor\$ or (ambulatory adj2 monitor\$)).ti,ab. (18630)
- 39 \*Telephone/ or Cellular Phone/ or Text Messaging/ (8047)
- 40 (telephone or telecommunication? or telephones).ti. (5428)
- 41 (iphone or i-phone or iphones or i-phones or smartphone? or smart phone? or (PDA adj3 (mobile or device or phone)) or personal digital assistant? or text-messag\$).ti,ab. (1677)
- 42 (telemedicine or tele-medicine or telehealth or tele-health).ti. and (multidisciplin\$ or multi-disciplin\$ or interdisciplin\$ or inter-disciplin\$ or (care adj2 team) or teambased or team-based).ti,ab. (97)
- 43 ((telephon\$ or transtelephon\$ or telemetric\$) adj3 monitoring).ti,ab. (485)
- 44 (telemetric\$ and (care or home or patient? or monitoring or self or ambulatory or outpatient?)).ti. (119)
- 45 transtelephonic\$.ti. (96)
- 46 remote monitoring.ti. (261)
- 47 (or/35-38) and (or/39-41) [Focussed set 1] (905)
- 48 or/42-46 [Focussed Set 2] (934)
- 49 ((mobile or phone?) adj5 (tumour? or radiation? or migraine or headache? or brain?)).ti,ab. (619)
- 50 electromagnetic fields/ or radio waves/ or microwaves/ (30288)
- 51 radiation induced.hw. (17467)
- 52 ((driver? adj distract\$) or (driving adj2 safety) or impaired driving or traffic accident?).ti,ab,hw. (8012)

53 Automobile Driving/ (13035)

54 ((phone? or telephone? or phoning) adj2 driving).ti,ab. (120)

55 Accidents, Traffic/ (33518)

56 Environmental Exposure/ or exp Environmental Monitoring/ (123626)

57 radiation effects.fs. (181878)

58 or/49-57 [To exclude studies related to cell phone use & side effects] (381821)

59 ((telephone or phone) adj2 (survey or surveys or surveyed or question?aire?)).ti,ab. (9896)

60 questionnaire survey.ti. (1328)

61 or/59-60 [Telephone Survey to exclude] (11216)

62 (rat or rats or cow or cows or chicken? or horse or horses or mice or mouse or bovine or animal?).ti. (1322634)

63 exp animals/ not humans.sh. (3905620)

64 10 not (or/58,61) [Telemedicine Set] (20671)

65 (18 and 31) not 10 not (or/58,61) [Telephones & Care] (14155)

66 (or/47-48) not (or/58,61-63) [Focussed Keyword & MeSH Set do not apply filter] (1484)

67 64 and 34 [Telemedicine & RCT] (2403)

68 65 and 34 [Telephones & Care & RCT] (1178)

69 (66 and 34) not (or/67-68) [Focussed KW & MeSH RCT] (74)

70 66 not (or/67-69) [Focussed KW & MeSH set --used instead of using EPOC Filter; screen all] (1125)

71 (\*telemedicine/ or (telemedicine or tele-medicine).ti.) and (systematic adj2 review).ti. (118)

72 (201008\$ or 201009\$ or 201010\$ or 201011\$ or 201012\$ or 2011\$ or 2012\$ or 2013\$).ep,ed. (3292526)

73 201\$.yr. (3359941)

74 67 and (or/72-73) [RCT Set 1 June 2013] (1142)

75 68 and (or/72-73) [RCT Set 2 June 2013] (400)

76 69 and (or/72-73) [RCT KW June 2013] (26)

77 70 and (or/72-73) [No filter June 2013] (463)

78 (\*telemedicine/ or (telemedicine or tele-medicine).ti.) and (systematic adj2 review).ti. and (or/72-73) [SR Set June 2013] (79)

## EMBASE (OVID)

Search date: 19/06/2013

1 \*telemedicine/ or \*telecardiology/ or \*teleconsultation/ or \*teledermatology/ or \*telemonitoring/ or \*telepathology/ or \*telepsychiatry/ or \*teleradiology/ or \*teleradiotherapy/ or \*telesurgery/ or \*teletherapy/ or \*telehealth/ or \*telemonitoring/ or \*telenursing/ or \*telephone telemetry/ [EMTREE] (11051)

2 \*telemetry/ and (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care).ti,ab. [June 2013] (218)

3 \*Telephone/ and (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care).ti,ab. [June 2013] (593)

4 (teleassist\$ or tele-assist\$ or teleaudiolog\$ or tele-audiolog\$ or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\$ or telecardiolog\$ or teleconsult\$ or tele-consult\$ or telecounselling or tele-counselling teledental or tele-dental or telederm\$ or tele-derm\$ or telediagnos\$ or tele-diagnos\$ or teledialysis or tele-dialysis or teleecho\$ or tele-echo\$ or teleemerg\$ or tele-emerg\$ or telepileps\$ or tele-epileps\$ or telefollow\$ or tele-follow\$ or teleguidance or tele-guidance or telehealth\$ or tele-health\$ or telehome\$ or tele-home\$ or teleICU or tele-ICU or teleintervention\$ or tele-intervention\$ or telemanag\$ or tele-manag\$ or telemedicine or tele-medicine or telemental\$ or tele-mental\$ or telemonitor\$ or tele-monitor\$ or telenurs\$ or tele-nurs\$ or teleoncolo\$ or tele-oncolo\$ or teleophthalm\$ or tele-opthalm\$ or telepalliat\$ or tele-palliat\$ or tele-patholog\$ or tele-patholog\$ or teleprocedu\$ or tele-procedu\$ or telepsych\$ or tele-psych\$ or teleradiol\$ or tele-radiol\$ or telerefer\$ or tele-refer\$ or telerehab\$ or tele-rehab\$ or telesurger\$ or tele-surger\$ or telesurgic\$ or tele-surgic\$ or teletherap\$ or tele-therap\$ or teletreat\$ or tele-treat\$ or teletriage or tele-triage).ti. (8655)

5 (teleassist\$ or tele-assist\$ or teleaudiolog\$ or tele-audiolog\$ or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\$ or telecardiolog\$ or teleconsult\$ or tele-consult\$ or telecounselling or tele-counselling teledental or tele-dental or telederm\$ or tele-derm\$ or telediagnos\$ or tele-diagnos\$ or teledialysis or tele-dialysis or teleecho\$ or tele-echo\$ or teleemerg\$ or tele-emerg\$ or telepileps\$ or tele-epileps\$ or telefollow\$ or tele-follow\$ or teleguidance or tele-guidance or telehealth\$ or tele-health\$ or telehome\$ or tele-home\$ or teleICU or tele-ICU or teleintervention\$ or tele-intervention\$ or telemanag\$ or tele-manag\$ or telemedicine or tele-medicine or telemental\$ or tele-mental\$ or telemonitor\$ or tele-monitor\$ or telenurs\$ or tele-nurs\$ or teleoncolo\$ or tele-oncolo\$ or teleophthalm\$ or tele-opthalm\$ or telepalliat\$ or tele-palliat\$ or tele-patholog\$ or tele-patholog\$ or teleprocedu\$ or tele-procedu\$ or telepsych\$ or tele-psych\$ or teleradiol\$ or tele-radiol\$ or telerefer\$ or tele-refer\$ or telerehab\$ or tele-rehab\$ or telesurger\$ or tele-surger\$ or telesurgic\$ or tele-surgic\$ or teletherap\$ or tele-therap\$ or teletreat\$ or tele-treat\$ or teletriage or tele-triage).ab. (9564)

6 (tele adj (care or counselling or diagnos\$ or health\$ or intervention? or manag\$ or therap\$ or treat\$ or medicine or medical or nursing)).ab. [edited june 2013 removed truncation and doctor, physician, practitioner] (200)

7 ((iphone? or i-phone? or smartphone? or PDA or Personal Digital Assistant? or telephone or telephones or TRANSTELEPHON\$ or phone or phones) and (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care)).ti. [June 2013] (316)

8 ((iphone? or i-phone? or smartphone? or PDA or Personal Digital Assistant? or telephone or telephones or TRANSTELEPHON\$ or phone or phones) adj3 (counselling or diagnose? or diagnosing or ((drug? or prescription? or disease? or outpatient? or inpatient? or patient?) adj3 (care or management or therapy or treat or treating or treatment?)) or (patient? adj2 education) or ((preventive or preventative) adj2 care) or public health or self-care)).ab. [June 2013] (719)

9 (telephone based or phone based or text-messag\$).ti,ab. [2013 Telemed] (2028)

10 or/1-9 [Telemed] (20375)

11 ((mobile or phone?) adj5 (tumour? or radiation? or migraine or headache? or brain?)).ti,ab. (846)

12 ((driver? adj distract\$) or (driving adj2 safety) or impaired driving or traffic accident?).ti,ab,hw. (49383)

13 ((phone? or telephone? or phoning) adj2 driving).ti,ab. (131)

14 \*telephone/ (4948)

15 car driving/ (11128)

16 traffic accident/ (46076)

17 environmental monitoring/ or air monitoring/ or exp radiation monitoring/ (54881)

18 (radiation adj2 (induced or effect?)).ti,ab,hw. (43154)

19 electromagnetic field/ (16723)

20 radiofrequency radiation/ or electromagnetic radiation/ (7635)

21 ((telephone or phone) adj2 (survey or surveys or surveyed or question?aire?)).ti,ab. (11418)

22 questionnaire survey.ti. (1589)

23 or/11-22 [Terms to exclude] (194496)

24 10 not 23 (19085)

25 (random\$ or placebo\$ or double-blind\$).tw. [EM RCT Wong J Med Libr Assoc 94(1) January 2006] (937193)

26 controlled clinical trial/ or controlled study/ or randomized controlled trial/ [EM] (4136645)

27 randomi?ed.ti. or ((random\$ or control) adj3 (group? or cohort? or patient? or hospital\$ or department?)).ab. or (controlled adj2 (study or trial)).ti. (662982)

28 (random sampl\$ or random digit\$ or random effect\$ or random survey or random regression).ti,ab. not randomized controlled trial/ [Per BMJ Clinical Evidence filter] (50814)

29 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) and (human/ or normal human/ or human cell/) (14700412)

30 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) not 29 (5820151)

31 (or/26-27) not (or/28,30) [RCT Filter for EMBASE] (2809972)

32 (24 and 25) not 30 (1882)

33 (20103\$ or 20104\$ or 20105\$ or 2011\$ or 2012\$ or 2013\$).em. or ("2011" or "2012" or "2013").yr. (3052856)

34 32 and 33 (775)

35 (systematic adj3 review).ti. (32577)

36 34 and 35 [SR] (25)

37 34 not 36 [RCT] (750)

**Cochrane Library; CENTRAL, CDSR, DARE, NHS EED, HTA, MTH (WILEY)**

Search date: 20/06/2013

ID Search Hits

#1 MeSH descriptor: [Telemedicine] this term only 764

#2 MeSH descriptor: [Telepathology] this term only 5

#3 MeSH descriptor: [Teleradiology] this term only 21

#4 MeSH descriptor: [Telenursing] this term only 14

#5 MeSH descriptor: [Remote Consultation] this term only 288

#6 MeSH descriptor: [Telephone] this term only 1197

#7 MeSH descriptor: [Cellular Phone] this term only 224

#8 MeSH descriptor: [Text Messaging] this term only 30

#9 (counselling or diagnose or diagnosing or ((drug or prescription or disease or outpatient or inpatient or patient) near/3 (care or management or therapy or "treat" or treating or treatment)) or (patient near/2 education) or ((preventive or preventative) near/2 care) or "public health" or self-care):ti,ab 120832

#10 (#6 or #7 or #8) and #9 526

#11 (teleassist\* or tele-assist\* or teleaudiolog\* or tele-audiolog\* or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\* or telecardiolog\* or teleconsult\* or tele-consult\* or telecounselling or tele-counselling teledental or tele-dental or telederm\* or tele-derm\* or telediagnos\* or tele-diagnos\* or teledialysis or tele-dialysis or teleecho\* or tele-echo\* or teleemerg\* or tele-emerg\* or teleepileps\* or tele-epileps\* or telefollow\* or tele-follow\* or teleguidance or tele-guidance or telehealth\* or tele-health\* or telehome\* or tele-home\* or teleICU or tele-ICU or teleintervention\* or tele-intervention\* or telemanag\* or tele-manag\* or telemedicine or tele-medicine or telemental\* or tele-mental\* or telemonitor\* or tele-monitor\* or telenurs\* or tele-nurs\* or teleoncolog\* or tele-oncolog\* or teleophthalm\* or tele-opthalm\* or telepalliat\* or tele-palliat\* or tele-patholog\* or tele-patholog\* or teleprocedu\* or tele-procedu\* or telepsych\* or tele-psych\* or teleradiol\* or tele-radiol\* or telerefer\* or tele-refer\* or telerehab\* or tele-rehab\* or telesurger\* or tele-surger\* or telesurgic\* or tele-surgic\* or teletherap\* or tele-therap\* or teletreat\* or tele-treat\* or teletriage or tele-triage):ti 721

#12 (teleassist\* or tele-assist\* or teleaudiolog\* or tele-audiolog\* or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo\* or telecardiolog\* or teleconsult\* or tele-consult\* or telecounselling or tele-counselling teledental or tele-dental or telederm\* or tele-derm\* or telediagnos\* or tele-diagnos\* or teledialysis or tele-dialysis or teleecho\* or tele-echo\* or teleemerg\* or tele-emerg\* or teleepileps\* or tele-epileps\* or telefollow\* or tele-follow\* or teleguidance or tele-guidance or telehealth\* or tele-health\* or telehome\* or tele-home\* or teleICU or tele-ICU or teleintervention\* or tele-intervention\* or telemanag\* or tele-manag\* or telemedicine or tele-medicine or telemental\* or tele-mental\* or telemonitor\* or tele-monitor\* or telenurs\* or tele-nurs\* or teleoncolo\* or tele-oncolo\* or teleophthalm\* or tele-opthalm\* or telepalliat\* or tele-palliat\* or tele-patholog\* or tele-patholog\* or teleprocedu\* or tele-procedu\* or telepsych\* or tele-psych\* or teleradiol\* or tele-radiol\* or telerefer\* or tele-refer\* or telerehab\* or tele-rehab\* or telesurger\* or tele-surger\* or telesurgic\* or tele-surgic\* or teletherap\* or tele-therap\* or teletreat\* or tele-treat\* or teletriage or tele-triage):ab 520

#13 (tele near/2 (care or counselling or diagnos\* or health\* or intervention or manag\* or therap\* or treat\* or medicine or medical or nursing)):ab 21

#14 ((iphone or i-phone or smartphone or PDA or "Personal Digital Assistant" or telephone or telephones or TRANSTELEPHON\* or phone or phones) and (counselling or diagnose or diagnosing or ((drug or prescription or disease or outpatient or inpatient or patient) near/3 (care or management or therapy or treat or treating or treatment)) or (patient near/2 education) or ((preventive or preventative) near/2 care) or "public health" or self-care)):ti 207

#15 ((iphone or i-phone or smartphone or PDA or "Personal Digital Assistant" or telephone or telephones or TRANSTELEPHON\* or phone or phones) near/3 (counselling or diagnose or diagnosing or ((drug or prescription or disease or outpatient or inpatient or patient) near/3 (care or management or therapy or treat or treating or treatment)) or (patient near/2 education) or ((preventive or preventative) near/2 care) or public health or self-care)):ab 474

#16 ("telephone based" or "phone based" or text-messag\*):ti,ab 400

#17 #1 or #2 or #3 or #4 or #5 or #10 or #11 or #12 or #13 or #14 or #15 or #16 from 2010 to 2013 769

#18 ((mobile or phone) near/5 (tumour or radiation or migraine or headache or brain)):ti,ab 16

#19 "radiation induced":kw 96

#20 ((driver near/2 distract\*) or (driving near/2 safety) or "impaired driving" or "traffic accident" or "traffic accidents"):ti,ab,kw 217

#21 ((phone or telephone or phoning) near/2 driving):ti,ab 7

#22 MeSH descriptor: [Electromagnetic Fields] this term only 316

#23 MeSH descriptor: [Radio Waves] this term only 97

#24 MeSH descriptor: [Microwaves] this term only 177

#25 MeSH descriptor: [Automobile Driving] this term only 569

#26 MeSH descriptor: [Accidents, Traffic] this term only 346

#27 MeSH descriptor: [Environmental Exposure] this term only 388

#28 MeSH descriptor: [Environmental Monitoring] explode all trees 189

#29 #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 2108

#30 ((telephone or phone) near/2 (survey or surveys or surveyed or question?aire)):ti,ab 482

#31 questionnaire survey:ti 762

#32 #30 or #31 1197

#33 #17 not (#29 or #32) from 2010 to 2013 758

## CINAHL (Ebsco)

Search date: 20/06/2013

#	Query	Results
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(Continued)

S30	S20 and S29	306
<i>Limiters - Published Date from: 20100801-20130631</i>		
S29	S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28	143,578
S28	TI controlled AND TI ( trial or trials or study or experiment* or intervention )	16,803
S27	AB ( (multicent* n2 design*) or (multicent* n2 study) or (multicent* n2 studies) or (multicent* n2 trial*) ) or AB ( (multi-cent* n2 design*) or (multi-cent* n2 study) or (multi-cent* n2 studies) or (multi-cent* n2 trial*) )	6,232
S26	TI multicentre or multicenter or multi-centre or multi-center	4,167
S25	TI ( cluster N2 trial* or cluster N2 study or cluster N2 group or cluster N2 groups or cluster N2 cohort or cluster N2 design or cluster N2 experiment* ) OR AB ( cluster N2 trial* or cluster N2 study or cluster N2 group or cluster N2 groups or cluster N2 cohort or cluster N2 design or cluster N2 experiment* )	1,560
S24	TI ( control group or control groups OR control* experiment* or control* design or controlled study ) OR AB ( control group OR control groups or control* cohort* or controlled experiment* controlled design or controlled study)	46,759
S23	TI random* or AB random*	102,162
S22	TI ( "clinical study" or "clinical studies" ) or AB ( "clinical study" or "clinical studies" )	6,557
S21	(MM "Clinical Trials+")	7,844
S20	S9 NOT ( S19 or S16 )	8,179
S19	S17 OR S18	3,706
S18	TI questionnaire survey	444
S17	TI ( ((telephone or phone) N2 (survey or surveys or surveyed or question#aire#)) ) OR AB ( ((telephone or phone) N2 (survey or surveys or surveyed or question#aire#)) )	3,265
S16	S10 OR S11 OR S12 OR S13 OR S14 OR S15	22,290
S15	TI ( ((phone# or telephone# or phoning) N2 driving) ) OR AB ( ((phone# or telephone# or phoning) N2 driving) )	36
S14	(MH "Environmental Exposure") OR (MH "Environmental Monitoring+")	9,632
S13	TI ( ((driver# N distract*) or (driving N2 safety) or impaired driving or traffic accident#) ) OR AB ( ((driver# N distract*) or (driving N2 safety) or impaired driving or traffic accident#) ) OR MW ( ((driver# N distract*) or (driving N2 safety) or impaired driving or traffic accident#) )	7,990
S12	MW radiation induced	520
S11	MH electromagnetic fields OR MH radio waves OR MH microwaves OR MH Automobile Driving OR MH Accidents, Traffic	11,952

(Continued)

S10	TI ( ((mobile or phone#) N5 (tumour# or radiation# or migraine or headache# or brain#)) ) OR AB ( ((mobile or phone#) N5 (tumour# or radiation# or migraine or headache# or brain#)) )	90
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8	8,723
S8	AB ( (telephone based or phone based or text-messag*) ) OR TI ( (telephone based or phone based or text-messag*) )	1,110
S7	AB ((iphone# or i-phone# or smartphone# or PDA or Personal Digital Assistant# or telephone or telephones or TRANSTELEPHON* or phone or phones) N3 (counselling or diagnose# or diagnosing or ((drug# or prescription# or disease# or outpatient# or inpatient# or patient#) N3 (care or management or therapy or treat or treating or treatment#)) or (patient# N2 education) or ((pre-ventive or preventative) N2 care) or public health or self-care))	268
S6	TI ((iphone# or i-phone# or smartphone# or PDA or Personal Digital Assistant# or telephone or telephones or TRANSTELEPHON* or phone or phones) and (counselling or diagnose# or diagnosing or ((drug# or prescription# or disease# or outpatient# or inpatient# or patient#) N3 (care or management or therapy or treat or treating or treatment#)) or (patient# N2 education) or ((pre-ventive or preventative) N2 care) or public health or self-care))	148
S5	AB (tele N2 (care or counselling or diagnos* or health* or intervention# or man- ag* or therap* or treat* or medicine or medical or nursing))	58
S4	AB (teleassist* or tele-assist* or teleaudiolog* or tele-audiolog* or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo* or telecardiolog* or teleconsult* or tele-consult* or telecounselling or tele-counselling tele- dental or tele-dental or telederm* or tele-derm* or telediagnos* or tele-diag- nos* or teledialysis or tele-dialysis or teleecho* or tele-echo* or teleemerg* or tele-emerg* or telepileps* or tele-epileps* or telefollow* or tele-follow* or teleguidance or tele-guidance or telehealth* or tele-health* or telehome* or tele-home* or teleICU or tele-ICU or teleintervention* or tele-intervention* or telemanag* or tele-manag* or telemedicine or tele-medicine or telemen- tal* or tele-mental* or telemonitor* or tele-monitor* or telenurs* or tele-nurs* or teleoncolo* or tele-oncolo* or teleophthalm* or tele-opthalm* or telepalli- at* or tele-palliat* or tele-patholog* or tele-patholog* or teleprocedu* or tele- procedu* or telepsych* or tele-psych* or teleradiol* or tele-radiol* or telere- fer* or tele-refer* or telerehab* or tele-rehab* or telesurger* or tele-surger* or telesurgic* or tele-surgic* or teletherap* or tele-therap* or teletreat* or tele- treat* or teletriage or tele-triage)	1,489
S3	TI (teleassist* or tele-assist* or teleaudiolog* or tele-audiolog* or telebased or tele-based or telecancer or tele-cancer or tele-cardiolo* or telecardiolog* or teleconsult* or tele-consult* or telecounselling or tele-counselling tele- dental or tele-dental or telederm* or tele-derm* or telediagnos* or tele-diag- nos* or teledialysis or tele-dialysis or teleecho* or tele-echo* or teleemerg* or tele-emerg* or telepileps* or tele-epileps* or telefollow* or tele-follow* or teleguidance or tele-guidance or telehealth* or tele-health* or telehome* or tele-home* or teleICU or tele-ICU or teleintervention* or tele-intervention* or telemanag* or tele-manag* or telemedicine or tele-medicine or telemen- tal* or tele-mental* or telemonitor* or tele-monitor* or telenurs* or tele-nurs* or teleoncolo* or tele-oncolo* or teleophthalm* or tele-opthalm* or telepalli- at* or tele-palliat* or tele-patholog* or tele-patholog* or teleprocedu* or tele- procedu* or telepsych* or tele-psych* or teleradiol* or tele-radiol* or telere- fer* or tele-refer* or telerehab* or tele-rehab* or telesurger* or tele-surger* or telesurgic* or tele-surgic* or teletherap* or tele-therap* or teletreat* or tele- treat* or teletriage or tele-triage)	2,348



(Continued)

S2	( MH Telephone or Wireless Communications or Text Messaging ) AND ( TI ( (counselling or diagnose# or diagnosing or ((drug# or prescription# or disease# or outpatient# or inpatient# or patient#) N3 (care or management or therapy or treat or treating or treatment#)) or (patient# N2 education) or ((pre-ventive or preventative) N2 care) or public health or self-care) ) OR AB ( (counselling or diagnose# or diagnosing or ((drug# or prescription# or disease# or outpatient# or inpatient# or patient#) N3 (care or management or therapy or treat or treating or treatment#)) or (patient# N2 education) or ((preventive or preventative) N2 care) or public health or self-care) ) )	1,796
S1	MH Telemedicine OR MH Telepathology OR MH Teleradiology OR MH Telenursing OR MH Remote Consultation	4,858

## EPOC Specialised Register, Reference Manager 12

Search date: 21/06/2013

Connector	Field	Parameter	Results
	All Fields	{teleassist*} or {tele-assist*} or {teleaudiolog*} or {tele-audiolog*} or {telebased} or {tele-based} or {telecancer} or {tele-cancer} or {tele-cardiolo*} or {telecardiolog*} or {teleconsult*} or {tele-consult*} or {telecounselling} or {tele-counselling tele-dental} or {tele-dental} or {telederm*} or {tele-derm*} or {tele-diagnos*} or {tele-diagnos*} or {teledialysis} or {tele-dialysis} or {teleecho*} or {tele-echo*} or {teleemerg*} or {tele-emerg*} or {teleepileps*} or {tele-epileps*} or {telefollow*} or {tele-follow*} or {teleguidance} or {tele-guidance} or {telehealth*} or {tele-health*} or {telehome*} or {tele-home*} or {teleICU} or {tele-ICU} or {teleintervention*} or {tele-intervention*} or {telemanag*} or {tele-manag*} or {telemedicine} or {tele-medicine} or {telemental*} or {tele-mental*} or {telemonitor*} or {tele-monitor*} or {telenurs*} or {tele-nurs*} or {teleoncolog*} or {tele-oncolog*} or {teleophthalm*} or {tele-opthalm*} or {telepalliat*} or {tele-palli-at*} or {tele-patholog*} or {tele-patholog*} or {teleprocedu*} or {tele-procedu*} or {telepsych*} or {tele-psych*} or {teleradiol*} or {tele-radiol*} or {telerefer*} or {tele-refer*} or {telerehab*} or {tele-rehab*} or {telesurger*} or {tele-surger*} or {telesurgic*} or {tele-surgic*} or {teletherap*} or {tele-therap*} or {teletreat*} or {tele-treat*} or {teletriage} or {tele-triage}	280
AND	Date Added	{2010} or {2011} or {2012} or {2013}	109

## WHAT'S NEW

Date	Event	Description
2 December 2016	Amended	Minor edit to correct the contribution of Kate Bird in the Acknowledgments section.

## HISTORY

Protocol first published: Issue 4, 1997

Review first published: Issue 2, 2000

Date	Event	Description
19 March 2015	New citation required and conclusions have changed	New author team, changed review title (to correspond with review objectives), updated background, revised study inclusion criteria (only randomised controlled trials included), incorporated new methods to conduct searches, assess risk of bias, and grade the certainty of the evidence. New conclusions made.  This review includes 93 studies.
3 June 2013	New search has been performed	New searches performed; 90 new studies identified.
11 November 2009	Amended	Contact author details updated
9 September 2008	Amended	Converted to new review format.
24 January 2000	New citation required and conclusions have changed	Substantive amendment

## CONTRIBUTIONS OF AUTHORS

GF, AR, MI and SS contributed to sifting and/or data extraction and assessment of risk of bias of included studies; AF, AR and MI provided clinical advice. GF conducted the analysis (checked by SS) and GF and SS drafted the review; all authors read and approved the final version. SS is the Principal Investigator of the NIHR Cochrane Programme grant supporting completion of this review.

## DECLARATIONS OF INTEREST

Authors Gerd Flodgren, Antoine Rachas, Andrew J Farmer, Marco Inzitari, and Sasha Shepperd have declared no competing interests.

## SOURCES OF SUPPORT

### Internal sources

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### External sources

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## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

SS, GF, RC and CU updated and revised the review protocol. The revised protocol was peer reviewed. Revisions included updating the background section and methods, clarifying the scope of the review and revising the inclusion criteria to specify the inclusion of randomised controlled trials (RCTs) only, and which types of interventions to exclude. The search strategies were revised by Michelle Fiander (EPOC Trials Search Co-ordinator (TSC)) to increase sensitivity of telemedicine terminology and to employ up to date methodological filters. The revised protocol was peer reviewed, has not been published, but is available from the EPOC Editorial base ([epoc.cochrane@gmail.com](mailto:epoc.cochrane@gmail.com)). Five new review authors conducted this review update (GF, AR, MI, AF, and SS). Two authors involved in the previous version of the review withdrew from the update (RC, CU).

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## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Communication; \*Outcome and Process Assessment, Health Care; \*Physician-Patient Relations; \*Practice Patterns, Physicians'; Diabetes Mellitus [therapy]; Heart Failure [therapy]; Mental Disorders [therapy]; Monitoring, Physiologic [methods]; Telemedicine [\*methods]; Videoconferencing

### MeSH check words

Humans