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[Intervention Review]

Organisation of health services for preventing and treating pressure ulcers

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ABSTRACT

Background

Pressure ulcers, which are a localised injury to the skin, or underlying tissue, or both, occur when people are unable to reposition themselves to relieve pressure on bony prominences. Pressure ulcers are often difficult to heal, painful, expensive to manage and have a negative impact on quality of life. While individual patient safety and quality care stem largely from direct healthcare practitioner-patient interactions, each practitioner-patient wound-care contact may be constrained or enhanced by healthcare organisation of services. Research is needed to demonstrate clearly the effect of different provider-orientated approaches to pressure ulcer prevention and treatment.

Objectives

To assess the effects of different provider-orientated interventions targeted at the organisation of health services, on the prevention and treatment of pressure ulcers.

Search methods

In April 2018 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched three clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

Randomised controlled trials (RCTs), cluster-RCTs, non-RCTs, controlled before-and-after studies and interrupted time series, which enrolled people at risk of, or people with existing pressure ulcers, were eligible for inclusion in the review.

Data collection and analysis

Two review authors independently performed study selection, risk of bias assessment, data extraction and GRADE assessment of the certainty of evidence.

Main results

The search yielded a total of 3172 citations and, following screening and application of the inclusion and exclusion criteria, we deemed four studies eligible for inclusion. These studies reported the primary outcome of pressure ulcer incidence or pressure ulcer healing, or both.

One controlled before-and-after study explored the impact of transmural care (a care model that provided activities to support patients and their family/partners and activities to promote continuity of care), among 62 participants with spinal cord injury. It is unclear whether transmural care leads to a difference in pressure ulcer incidence compared with usual care (risk ratio (RR) 0.93, 95% confidence interval (CI) 0.53 to 1.64; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

One RCT explored the impact of hospital-in-the-home care, among 100 older adults. It is unclear whether hospital-in-the-home care leads to a difference in pressure ulcer incidence risk compared with hospital admission (RR 0.32, 95% CI 0.03 to 2.98; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

A third study (cluster-randomised stepped-wedge trial), explored the impact of being cared for by enhanced multidisciplinary teams (EMDT), among 161 long-term-care residents. The analyses of the primary outcome used measurements of 201 pressure ulcers from 119 residents. It is unclear if EMDT reduces the pressure ulcer incidence rate compared with usual care (hazard ratio (HR) 1.12, 95% CI 0.74 to 1.68; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear whether there is a difference in the number of wounds healed (RR 1.69, 95% CI 1.00 to 2.87; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear whether there is a difference in the reduction in surface area, with and without EMDT, (healing rate 1.006; 95% CI 0.99 to 1.03; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear if EMDT leads to a difference in time to complete healing (HR 1.48, 95% CI 0.79 to 2.78, very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

The final study (quasi-experimental cluster trial), explored the impact of multidisciplinary wound care among 176 nursing home residents. It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care, or usual care (RR 1.18, 95% CI 0.98 to 1.42; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear if this type of care leads to a difference in time to complete healing compared with usual care (HR 1.73, 95% CI 1.20 to 2.50; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision).

In all studies the certainty of the evidence is very low due to high risk of bias and imprecision. We downgraded the evidence due to study limitations, which included selection and attrition bias, and sample size. Secondary outcomes, such as adverse events were not reported in all studies. Where they were reported it was unclear if there was a difference as the certainty of evidence was very low.

Authors' conclusions

Evidence for the impact of organisation of health services for preventing and treating pressure ulcers remains unclear. Overall, GRADE assessments of the evidence resulted in judgements of very low-certainty evidence. The studies were at high risk of bias, and outcome measures were imprecise due to wide confidence intervals and small sample sizes, meaning that additional research is required to confirm these results. The secondary outcomes reported varied across the studies and some were not reported. We judged the evidence from those that were reported (including adverse events), to be of very low certainty.

PLAIN LANGUAGE SUMMARY

Organisation of health services for preventing and treating pressure ulcers

What is the aim of this review?

The aim of this review was to find out whether the way in which health services are organised can affect prevention and treatment of pressure ulcers. Cochrane researchers collected and analysed all relevant studies to answer this question and found four relevant studies.

Key messages

We cannot be certain whether transmural care (a way of providing care that delivers activities to support patients and their family/partners, and activities to promote continuity of care), hospital-in-the-home care, care provided by a team of different disciplines or care that is usually provided, make any difference to whether people develop pressure ulcers, how fast existing ulcers heal, or whether people with ulcers are admitted or readmitted to hospital.

What was studied in the review?

Pressure ulcers, sometimes known as bedsores or pressure sores, are injuries that develop as a result of continued pressure on bony parts of the body such as the hips, heels or lower back. It is thought that the way health services are organised can influence the development of pressure ulcers among people at risk, and may also influence the healing of these wounds.

Care can be delivered to people with pressure ulcers in various ways. We wanted to find out whether different types of care delivery affected the number of people developing pressure ulcers and how fast existing ulcers healed.

What are the main results of the review?

We found four studies dating from 1999 to 2014, that compared alternative types of care delivery to the way care is usually provided. The mean number of participants in the studies was 140, and the ages of participants ranged from 36.5 years to 83 years. In the studies 198 participants were men and 301 were women. All studies were funded by government agencies. Two studies focused on prevention of pressure ulcers, one on prevention and treatment, and one on treatment only.

It is unclear whether any alternative type of care delivery is better than care that is usually provided at reducing risk of pressure ulcers, or improving pressure ulcer healing. It is also unclear whether the way healthcare services are organised improves quality of life, patient and staff satisfaction, reduces hospital admissions, emergency room visits, or death at 28 days. This is because we are very uncertain about the evidence in all studies.

This Plain language summary is up to date as of 18 April 2018.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Transmural care versus usual follow-up care for preventing pressure ulcers

Transmural care versus usual follow-up care for preventing pressure ulcers

Patient or population: people with spinal cord injury receiving rehabilitation treatment for the first time

Settings: spinal cord injury services

Intervention: transmural care versus usual follow-up care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual follow-up care	Transmural care				
Pressure ulcer incidence rate	Study population		RR 0.93 (0.53 to 1.64)	62 (1 study)	⊕⊕⊕⊕ Very low^a	It is unclear whether there is a difference in the risk of developing a pressure ulcer between transmural care or usual care, as the certainty of the evidence is very low.
Follow-up 12 months	452 per 1000	419 per 1000 (239 to 741)				
		Difference: 33 fewer per 1000 (213 fewer to 258 more)				
Adverse events: readmission to clinical rehabilitation	Study population		RR 2.00 (0.19 to 20.93)	62 (1 study)	⊕⊕⊕⊕ Very low^b	It is unclear whether there is a difference in the probability of readmission between transmural care or usual care, as the certainty of the evidence is very low.
Follow-up 12 months	32 per 1000	65 per 1000 (6 to 675)				
		Difference: 33 fewer per 1000 (26 fewer to 613 more)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

As per the ROBINS-I tool (details in [Appendix 4](#)):

^aDowngraded twice for study limitations, the study was at high risk of selection, and attrition bias and unclear risk of detection bias. Downgraded twice for imprecision, the sample size and event rate were small, and the 95% CI spanned a 47% reduction in risk to a 64% increase in risk.

^bDowngraded twice for study limitations as the study was a non-randomised experimental study, and at high risk of selection, detection and attrition bias. Downgraded twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 81% reduction in risk to a 193% increase in risk.

Summary of findings 2. Hospital-in-the-home versus hospital admission for preventing pressure ulcers

Hospital-in-the-home versus hospital admission for preventing pressure ulcers

Patient or population: people requiring admission to hospital

Settings: tertiary hospital

Intervention: hospital-in-the-home versus hospital admission

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Hospital admission	Hospital-in-the-home				
Pressure ulcer incidence rate Follow-up: 28 days	Study population		RR 0.32 (0.03 to 2.98)	100 (1 study)	⊕⊕⊕⊕ Very low^a	It is unclear whether there is a difference in the probability of pressure ulcer development between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low.
	61 per 1000	20 per 1000 (2 to 182) Difference: 40 fewer per 1000 (59 fewer to 121 more)				
Adverse events: death Follow-up: 28 days	Study population		RR 0.72 (0.17 to 3.06)	100 (1 study)	⊕⊕⊕⊕ Very low^b	It is unclear whether there is a difference in the risk of death at 28 days between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low.
	82 per 1000	59 per 1000 (14 to 250) Difference: 23 fewer per 1000 (68 fewer to 168 more)				

Adverse events: hospital readmission; follow-up 28 days Follow-up: 28 days	Study population		RR 0.58 (0.15 to 2.28)	100 (1 study)	⊕⊕⊕⊕ Very low^c	It is unclear whether there is a difference in the risk of hospital readmission between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low.
	102 per 1000	59 per 1000 (15 to 233)				
		Difference: 43 fewer per 1000 (87 fewer to 131 more)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned a 97% reduction in risk to a 198% increase in risk.

^bDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 83% reduction in risk to a 206% increase in risk.

^cDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 85% reduction in risk to a 128% increase in risk.

Summary of findings 3. Enhanced multidisciplinary team (EMDT) versus usual care for preventing and treating pressure ulcers

Enhanced multidisciplinary team (EMDT) versus usual care for preventing and treating pressure ulcers

Patient or population: people with pressure ulcers residing in long-term-care facilities

Settings: long-term-care facilities

Intervention: EMDT versus usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual Care	EMDT				

Pressure ulcer incidence rate	Not estimated	HR 1.12 (0.74 to 1.68)	161 (1 study)	⊕⊕⊕⊕ Very low^a	It is unclear whether there is a difference in incident rate between EMDT and usual care, as the certainty of the evidence is very low.
Number of pressure ulcers healed Follow-up 14 months	Study population 250 per 1000 422 per 1000 (250 to 717) Difference 170 more healed per 1000 (0 more healed to 467 less healed)	RR 1.69 (1.00 to 2.87)	161 (1 study)	⊕⊕⊕⊕ Very low^b	It is unclear whether there is a difference number of wounds healed between EMDT and usual care, as the certainty of the evidence is very low.
Reduction in pressure ulcer surface area	Not estimated	healing rate 1.006 (0.99-1.03)	161 (1 study)	⊕⊕⊕⊕ Very low^c	It is unclear whether there is a difference in the average healing rate between EMDT and usual care, as the certainty of the evidence is very low.
Time to complete healing Follow-up 12 months	Not estimated	HR 1.48 (0.79 to 2.78)	161 (1 study)	⊕⊕⊕⊕ Very low^d	It is unclear whether there is a difference in time to healing between EMDT and usual care, as the certainty of the evidence is very low.
Adverse events: hospital admission	Not estimated	Mean hospitalisation rate estimated to be 1.2 (0.62 to 2.36) times larger during the EMDT follow-up period than during the usual-care follow-up period.	161 (1 study)	⊕⊕⊕⊕ Very low^e	It is unclear whether there is a difference in hospital admission rate between EMDT and usual care, as the certainty of the evidence is very low.
Adverse events: ED visits	Not estimated	The mean ED visit rate estimated to be 1.3 (0.58 to 2.90) times larger during the EMDT follow-up period than during the usual-care follow-up period.	161 (1 study)	⊕⊕⊕⊕ Very low^f	It is unclear whether there is a difference in ED visits between EMDT and usual care, as the certainty of the evidence is very low.

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ED:** emergency department; **EMDT:** enhanced multidisciplinary team; **HR:** hazard ratio; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^bDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI spanned a 0% reduction in risk to a 187% increase in risk and the study authors did not undertake any analysis for the potential effects of clustering.

^cDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^dDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI spanned a 21% reduction in risk to a 178% increase in risk and the study authors did not undertake any analysis for the potential effects of clustering.

^eDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^fDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size was small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

Summary of findings 4. Multidisciplinary wound care versus usual care for treating pressure ulcers

Multidisciplinary wound care versus usual care for treating pressure ulcers

Patient or population: people who were resident in nursing homes

Settings: high-care nursing homes

Intervention: multidisciplinary wound care versus usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual care	Multidisciplinary wound care				
Number of pressure ulcers healed;	Study population		RR 1.18 (0.98 to 1.42)	176 (1 study)	⊕⊕⊕⊕ Very low ^a	It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care, or usual care, as the certainty of the evidence is very low.
	525 per 1000	617 per 1000 (512 to 712)				

follow-up 20 weeks Follow-up: 20 weeks		Difference: 92 more healed per 1000 (13 more healed to 187 fewer)				
Time to complete healing	Not estimated		HR 1.73 (1.20 to 2.50)	176 (1 study)	⊕⊕⊕⊕ Very low^b	It is unclear whether there is a difference in time to complete healing between multidisciplinary care or usual care, as the certainty of the evidence is very low.
Adverse events	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **HR:** hazard ratio; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded twice due to study limitations: study was at high risk of selection bias, and attrition bias, unclear risk of performance and detection bias there is a unit of analysis error and the study authors did not seem to correctly account for clustering in its analysis. Downgraded twice for imprecision due to the 95% CI spanning a reduction in risk of 2% to an increased risk of 42%. Additionally the 95% CI may have been narrower due to clustering of data not having been accounted for.

^bDowngraded twice due to study limitations: study was at high risk of selection bias, and attrition bias, unclear risk of performance and detection bias. Downgraded twice for imprecision due a wide 95% CI, additionally the 95% CI may have been narrower due to clustering of data not having been accounted for.

BACKGROUND

Description of the condition

A pressure ulcer is defined as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear" (NPUAP 2014). Common pressure ulcer sites are the elbow, heel, hip, shoulder, back, and back of the head. Other terms used to refer to pressure ulcers are decubitus ulcers (bedsores) or pressure sores. Pressure ulcers are often diagnosed by appearance and staged: non-blanchable erythema (persistent redness of the skin) is stage 1; an abrasion, blister, or shallow crater indicating partial loss of skin thickness is stage 2; a deep skin crater, indicating deeper skin loss, is stage 3; and a loss of tissue, skin, and muscle and/or bone is stage 4 (Shea 1975). Under the International NPUAP-EPUAP pressure ulcer classification system (Dealey 2009), two further stages were added to this scheme: unstageable, depth unknown, and suspected deep-tissue injury, depth unknown). Stage 1 or 2 pressure ulcers are the most common (Baumgarten 2006; Whittington 2000).

Pressure ulcers often occur in people who have activity or mobility problems or decreased sensation (neuropathy) and are thereby exposed to prolonged periods of sustained pressure and shear forces (Gefen 2008). Pressure is defined as the amount of force acting on a unit of area and can occur as a result of sitting without a change of position (O'Callaghan 2007). Shear forces occur in soft tissue when these tissues are stretched, for example if someone slides or is moved across a bed as part of nursing care such as cleansing, etc. When this happens, the bony structures move but the skin remains stationary (Sanders 2005). As a result of such pressure and shear forces, the blood supply of oxygen and nutrients to the skin and underlying tissues is impaired (Demidova-Rice 2012). Susceptibility to shear and pressure is exacerbated in people with decreased arterial or venous blood supply and poor nutrition (Demidova-Rice 2012; Pinchcofsky-Devin 1986). Some older people, people with a spinal cord injury, and those who are sedated following trauma or surgery are inclined to have problems with activity and mobility, and therefore commonly display the highest risk for pressure ulcer development (Moore 2014a). Nonetheless, any person of any age can potentially develop a pressure ulcer if they are exposed to the factors that cause sustained unrelieved pressure and shear (McLane 2004).

Pressure ulcers are relatively common wounds that can be complex to manage and heal. Prevalence estimates vary according to the population being assessed, the data collection methods used and decisions about whether or not stage 1 pressure ulcers should be included (since there is no active wound at this stage, but patients are 'at risk' and have early tissue damage). A large survey of hospital patients undertaken in several European countries returned a pressure ulcer prevalence (stage 2 and above) of 10.5% (Vanderwee 2007). In 2009, a USA estimate for pressure ulcer prevalence (stage 2 and above), across acute-care, long-term care, and rehabilitation settings in the USA was 9.0%, with prevalence highest in long-term acute-care settings (29.3%), (VanGilder 2009). In England, pressure ulcer data are collected across community and acute settings (although data collection is not yet universal), as part of the National Health Service (NHS) Safety Thermometer initiative (Power 2012). According to National Safety Thermometer data, an estimated that 5% to 6% of patients across these settings had a pressure ulcer in January 2014 (Durkin 2014). Other indicators of

national pressure ulcer data are being considered as part of the NHS Outcomes Framework 2014/15 (DH 2013).

Among surgical patients, pressure ulcer prevalence rates of 8.5% and 33% have been reported (Karadag 2006; Versluisen 1986), and incidence rates of between 14.1% and 54.8% (Aronovitch 2007; Lindgren 2005; Schoonhoven 2002). The majority of these ulcers occur on the heel and the sacrum, and are mainly stage 1 and 2 pressure ulcer damage. Furthermore, it has been suggested that 23% of all nosocomial pressure ulcers develop in the operating department (Aronovitch 2007). According to Bliss 1999, up to a quarter of hospital-acquired pressure sores that develop originate in the operating theatre. A systematic review by Chen 2012, conducted more than 10 years later, suggests that this incidence has increased, and recommends appropriate monitoring and treatment to lower this incidence. Likewise, Jackson 2011 and Tschannen 2012 emphasise the importance of using a valid and reliable risk assessment tool in the prevention of hospital-acquired pressure ulcers.

We note that all the prevalence figures quoted above are for at-risk populations currently receiving medical care. The point prevalence (the proportion of the population that has a condition at a specific point in time), of pressure ulceration in the total adult population was recently estimated using a cross-sectional survey undertaken in Leeds, UK. Of the total adult population of 751,485, the point prevalence of pressure ulceration per 1000 was 0.31 (Hall 2014). UK pressure ulcer prevalence estimates for community settings have reported rates of 0.77 per 1000 adults in an urban area (Stevenson 2013).

Pressure ulcers are a significant healthcare problem, affecting people of all ages, cared for across the variety of healthcare delivery settings (Moore 2013a). Pressure ulcers have an impact on patients and their families, are associated with severe pain in around 43% to 91% of those affected (Briggs 2013; McGinnis 2014; Spilsbury 2007), and increased mortality (Jaul 2015). In addition, people with pressure ulcers report reduced quality of life (Essex 2009), reduced engagement in social activities (Lala 2014), changed body image, and loss of control (Langemo 2000). It has been estimated that pressure ulcer treatment costs account for about 4% of public healthcare expenditure in the UK, with nursing time accounting for 41% of these costs (Bennett 2004). Costs increase with pressure ulcer stage (Bennett 2004; Dealey 2012). It is thought that many pressure ulcers are preventable (Black 2011). Thus, it is important from both patient and service provider perspectives to prevent pressure ulcers where possible, and to treat ulcers effectively when they appear in order to prevent deterioration.

Description of the intervention

This review is based on the premise that patient outcomes are influenced by the ways in which care services are organised and delivered. The organisation of care services is a complex and multidimensional concept that includes culture, leadership, and how human, physical, and financial resources are deployed. Cochrane Effective Practice and Organisation of Care (EPoC), defines four main subtypes of organisational interventions (EPoC 2015):

- provider-orientated interventions (e.g. changes to professional roles, multidisciplinary teams, integration of services, and inter-professional communication);

- patient-orientated interventions (e.g. changes with regards to patient involvement in healthcare governance and mechanisms by which patient feedback is integrated into care delivery);
- structural interventions (e.g. changes in organisational structure, facilities, resources, records, ownership, or nature of services);
- regulatory interventions (e.g. changes to healthcare delivery or costs by legislation or regulation).

This review focuses on the first item in the above list, provider-orientated interventions, which we define here as interventions that change how professionals organise or deliver care to people, or both. As noted by the EPOC taxonomy, such interventions may include various elements related to service delivery such as: changes to professional roles; altered composition of multiprofessional teams; integration of services; and changes to the way that inter-professional communication occurs. Whilst there is no universally agreed way to organise care for pressure ulcer prevention and treatment, there are examples of provider-orientated interventions through introduction of specialist staff roles and multiprofessional care pathways (Asimus 2011; Ramos 1997).

How the intervention might work

There is some evidence that provider-orientated organisational factors such as nursing skill mix (e.g. the number and role of specialist nurses), and inter-professional collaboration can improve patient outcomes (Butler 2011; Zwarenstein 2009). More specifically, it has been suggested that the composition and skill mix of healthcare teams (Armour-Burton 2013; Castle 2011), level of integration of services, and methods of inter-professional communication (Suntken 1996), could positively or negatively affect pressure ulcer outcomes. Given the large number of professional stakeholders often involved in the care of people with, or at risk of pressure ulcers, there are many areas where interventions could be aimed. Dellefield 2014 reported that nurses felt that pressure ulcer care was influenced by nursing homes' risk assessment and teamwork processes and their organisation's general commitment to patient care. Social ecological theory suggests that wider social systems influence an individual's actions and decisions (Bronfenbrenner 1979; McLeroy 1988). Thus, while individual patient safety and quality care stem largely from direct healthcare practitioner-patient interactions, each practitioner-patient wound-care contact, for example, may be constrained or enhanced by healthcare organisation (that is delivery, structure, or management), of services (Paine 2006).

Why it is important to do this review

A position document suggested that involving multidisciplinary teams in pressure ulcer prevention and treatment may have a positive impact on wound healing and amputation rates (Moore 2014b). Further research is needed to demonstrate clearly the effect of the team approach to wound healing, particularly in relation to clinical outcomes. This review considered whether different healthcare provider-orientated interventions influence the prevention and treatment of pressure injury. This review question was one of the top 12 uncertainties generated from a James Lind Alliance Priority Setting Partnership on pressure ulcers; a consultation exercise involving patients, carers and clinicians (James Lind Alliance 2012).

There is some systematic review evidence that organisational factors may influence health care (Gilbody 2003; Laver 2014; Miani 2014; Weaver 2013); such evidence is more tentative for large-scale hospital or system-wide organisational changes (Clay-Williams 2014). Cochrane Reviews have evaluated the impact of a variety of organisational interventions on a generic range of patient outcomes. These interventions include: hospital nurse staffing models (Butler 2011), out-of-hospital staffing models (Hodgkinson 2011), clinical pathways (Rotter 2010), nurse-led intermediate care inpatient units (Griffiths 2007), professional collaboration (Zwarenstein 2009), and shared care (Smith 2007).

We identified one, non-Cochrane systematic review on organisational-level interventions to prevent pressure sores (Soban 2011). Based on evidence from 39, mostly before-and-after studies published between 1990 and 2009, this review concluded that quality improvement initiatives, often with an educational component, reduced the occurrence of pressure ulcers. Other Cochrane Reviews have investigated patient-practitioner-level interventions that might prevent pressure ulcers through use of risk assessment tools, dressings or topical agents, support services, repositioning, or nutrition (Gillespie 2014; Langer 2014; McInnes 2011; Moore 2013b; Moore 2014a). Cochrane Reviews of patient-practitioner treatments of phototherapy, hydrogel dressings, nutrition, support surfaces, and repositioning for pressure ulcers also exist (Chen 2014; Dumville 2015; Langer 2014; McGinnis 2014; Moore 2015). However, we identified no up-to-date, systematically reviewed evidence about the effect of provider-orientated healthcare organisational interventions, for example, changes to professional roles, multidisciplinary teams, integration of services, and inter-professional communication, on the prevention and treatment of pressure ulcers.

This Cochrane Review followed the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We hope that this information is useful for healthcare managers and policymakers in deciding about care structure and systems that prevent patient harm and promote service user well-being.

OBJECTIVES

To assess the effects of different provider-orientated interventions targeted at the organisation of health services, on the prevention and treatment of pressure ulcers.

METHODS

Criteria for considering studies for this review

Types of studies

We followed EPOC 2013 guidance. Due to the nature of the intervention and difficulties associated with randomising individual participants to different service configurations, we planned to include a range of different study designs in this review, all of which have a control group and at least one intervention group: RCTs and appropriately analysed (or re-analysable) cluster-RCTs; non-RCTs; controlled before-and-after studies, with at least two intervention and two control sites; and interrupted time series studies, with at least three data collection points before and after the intervention on the same respondents, were eligible for inclusion in the review.

Types of participants

Studies involving people of any age, in any care setting (hospitals, nursing homes, residential care, rehabilitation centres), who were at risk of developing a pressure ulcer, as identified through either a structured or unstructured risk assessment, or by clinical judgement alone, or who had an existing pressure ulcer (of any stage), were eligible for inclusion.

Types of interventions

The types of interventions that we considered in this review were drawn from EPOC Group taxonomy. They broadly investigate where there is a change in who delivers health care, how care is organised, or where care is delivered (EPOC 2015).

- Revision of professional roles (also known as professional substitution or boundary encroachment): includes the shifting of roles among health professionals, for example, a healthcare assistant without a formal nursing qualification taking an increased role, or the taking on of roles that one would not normally take in their profession.
- Clinical multidisciplinary teams: the creation of a new team of health professionals of different disciplines or adding new members to the team who work together to care for patients.
- Formal integration of services (also known as seamless care): bringing together of services across sectors or teams or the organisation of services to bring all services together at one time.
- Skill mix changes: changes in numbers, types (multidisciplinary), or qualifications of staff.
- Continuity of care: one or many episodes of care for inpatients or outpatients such as the arrangements made for patient follow-up or case management, or both (including co-ordination of assessment, treatment, and arrangement for referrals).
- Communication and case discussion between distant health professionals, for example, telephone links or telemedicine, where there is a television/video link between specialist and remote nurse practitioners.

Types of outcome measures

As this review was concerned with both the prevention and treatment of pressure ulcers, we separated the primary outcome into one outcome for prevention and one outcome for treatment.

We list primary and secondary outcomes below. If a study was apparently eligible (i.e. correct study design, population, and intervention/comparator), but did not report a listed outcome, we contacted the study authors, where possible, to determine whether they measured but did not report an outcome of interest.

We report outcome measures at the latest time point available for a study (assumed to be length of follow-up if not specified), and the time point specified in the methods as being of primary interest (if this was different from latest time point available). We planned to categorise outcomes as follows:

- short-term: under a week to eight weeks;
- medium-term: over eight weeks to 26 weeks;
- long-term: over 26 weeks.

Primary outcomes

Prevention studies

The primary outcome was pressure ulcer incidence, measured in one of the two following ways.

- Incidence rate: number of new cases of pressure ulcers during the specified study period divided by the time each participant was observed, totaled for all participants.
- Incidence proportion or risk: number of participants who developed at least one pressure ulcer during the specified study period divided by the size of population (CDC 2012).

Treatment studies

The primary outcome for treatment studies was complete healing, but study authors may have measured and reported it in several ways, therefore, we planned to include studies that reported any of the following:

- a measure of pressure ulcer healing, such as absolute or percentage change in pressure ulcer area or volume over time;
- proportion of individuals with pressure ulcers healed at the completion of the study period;
- time to complete wound healing (using methods of survival analysis and expressing the intervention effect as a hazard ratio (HR)).

Secondary outcomes

All studies

- Mean or median participant health-related quality of life/health status, measured using a standardised generic questionnaire, such as EQ-5D, SF-36, SF-12 or SF-6. We did not plan to include ad hoc measures of quality of life that were not validated and would not have been common to multiple studies.
- Patient satisfaction
- Staff satisfaction
- Adverse events

Search methods for identification of studies

Electronic searches

We searched the following electronic databases to identify reports of relevant clinical trials:

- Cochrane Wounds Specialised Register (searched 11 April 2018);
- Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library 2018, Issue 3) (searched 11 April 2018);
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 11 April 2018);
- Ovid Embase (1974 to 11 April 2018);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature; 1937 to 11 April 2018).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus can be found in [Appendix 1](#). We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision), (Lefebvre 2011). We combined the Embase search with the Ovid Embase RCT filter

terms developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2017). We also added additional filter terms to the searches, using controlled vocabularies and free-text strings, in order to identify the other study designs that we planned to include in the review (see [Types of studies](#)). There were no restrictions with respect to language, date of publication, or study setting.

We also searched the following clinical trials registries for ongoing studies:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- WHO International Clinical Trials Registry (ICTRP; apps.who.int/trialsearch/Default.aspx);
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu).

Searching other resources

We searched reference lists of all included studies and other relevant publications, such as systematic reviews and guidelines. We contacted experts in the field and the authors of relevant publications to identify any completed or ongoing studies. We also performed manual searches of conference proceedings and other grey literature sources to identify authors and papers related primarily to wound care teams for the prevention or treatment, or both, of pressure ulcers.

Data collection and analysis

We carried out data collection and analysis according to methods stated in the published protocol (Joyce 2016), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Selection of studies

Two review authors independently assessed the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we obtained full-text copies of all studies considered to be potentially relevant. Two review authors independently checked the full papers for eligibility; we resolved any disagreements by discussion and, where required, with the input of a third review author. Where the eligibility of a study was unclear, we contacted study authors. We recorded all reasons for exclusion of studies for which we had obtained full-text copies. We completed a PRISMA flowchart to summarise this process (Liberati 2009).

Data extraction and management

Two review authors (PJ and ZM), independently extracted data from eligible studies using a data extraction sheet developed for this purpose. Specifically, we extracted the following information:

- author, title, source;
- date of study, country of origin;
- study design;
- care setting;
- inclusion and exclusion criteria;
- methods of allocation and level of allocation (i.e. participant or organisation level);
- number of participants allocated to each study treatment;

- intervention details (specifically team composition and focus of the intervention), concurrent intervention(s);
- primary and secondary outcomes (with definitions);
- length of follow-up;
- loss to follow-up;
- outcome data for primary and secondary outcomes (by group);
- funding source.

We resolved any differences in opinion by discussion. If data were missing from reports, we contacted study authors in order to obtain the missing information. In order to extract the maximal amount of information, we included multiple reports of the same study, ensuring that data were not duplicated. One review author (PJ), entered data into Review Manager 5 software (Review Manager 2014), with a second review author (ZM) verifying accuracy.

Assessment of risk of bias in included studies

Two review authors independently assessed the randomised studies using the Cochrane tool for assessing risk of bias, which addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other issues (Appendix 2; Higgins 2017). For studies using cluster randomisation, we assessed the risk of bias using the following domains: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised studies (Appendix 3; Higgins 2011b). The third review author checked the 'Risk of bias' assessment.

We have presented the 'Risk of bias' assessment using two 'Risk of bias' summary figures: one providing a summary of bias for each item across all studies, and the second providing a cross-tabulation of each study for all 'Risk of bias' items.

To assess bias with regard to non-randomised results, we used the ROBINS-I tool (Appendix 4; Sterne 2016). This tool assesses seven domains for non-randomised studies: bias due to confounding; bias in the selection of participants into the study; bias in the classification of interventions; bias due to deviations from intended interventions; bias due to missing data; bias in measurement of outcomes; and bias in selection of the reported results. Each domain can be considered at low risk of bias; moderate risk of bias; serious risk of bias; critical risk of bias; or recorded as there being no information on which to make a decision.

Measures of treatment effect

For dichotomous outcomes (e.g. proportion of participants with a pressure ulcer), we calculated the risk ratio (RR) with 95% confidence intervals (CI). The risk ratio is the ratio of the risk of an event in the two groups. An RR of 1 means there is no difference in risk between the two groups; an RR of less than 1 means the event is less likely to occur in the experimental group than in the control group; and an RR of greater than 1 means the event is more likely to occur in the experimental group than in the control group (Deeks 2017).

For continuously distributed outcome data (e.g. pain), if all studies used the same assessment scale, we planned to use the mean difference (MD) with 95% CIs. If studies used different assessment scales, we planned to use the standardised mean difference (SMD) with 95% CI. The MD is a standard statistic that measures the absolute difference between the mean value in two groups in a

clinical study. It estimates the amount by which the experimental intervention changes the outcome on average compared with the control. Interpretation of the results is the same as with RR except the point of no effect is 0 rather than 1 (Deeks 2017). The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study. An SMD of 0 means that in a clinical study the intervention and the control have equivalent effects (Deeks 2017). As we did not find any continuously distributed outcome data that lent themselves to this type of analysis, we were unable to use this approach.

We reported time-to-event data (e.g. time to complete wound healing), as hazard ratios (HR), where possible, in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). The HR is the chance of an event occurring in the treatment arm divided by the chance of the event occurring in the control arm, or vice versa, of a study (Deeks 2017). We planned to present incidence rate data meta-analysis as a rate ratio, which compares the rate of events in the two groups by dividing one by the other (Deeks 2017), and would have analysed the data using the generic inverse-variance method in Review Manager 5 (Review Manager 2014).

If we suspected skewness, and if scale data had finite upper and lower limits, we planned to use the easy 'rule of thumb' calculation to test for skewness, that is, if the standard deviation, when doubled, was greater than the mean, it is unlikely that the mean is the centre of the distribution (Altman 1996), and we planned not to enter the data into any meta-analysis. If we found relevant data that were skewed, we planned to present the data in 'Other data' tables. As we did not find these types of data, we were unable to use this approach to the analysis.

Unit of analysis issues

We anticipated unit of analysis issues occurring in cluster studies when allocation occurred at the level of the organisation or the team and data were collected from individual participants. Where a cluster study had been conducted and correctly analysed, we planned to use the generic inverse-variance method in Review Manager 5 to meta-analyse effect estimates and their standard errors (Deeks 2017; Review Manager 2014).

We planned to record where a cluster-randomised study had been conducted but incorrectly analysed as part of the 'Risk of bias' assessment. If possible, we planned to approximate the correct analyses based on *Cochrane Handbook for Systematic Reviews of Interventions* guidance (Higgins 2011b), using information on:

- the number of clusters (or groups), randomised to each intervention group or the average (mean), size of each cluster;
- the outcome data, ignoring the cluster design, for the total number of participants (e.g. number or proportion of participants with events, or means and standard deviations); and
- an estimate of the intraclass (or intraclass) correlation coefficient.

Where we could not analyse the study data, we extracted and presented, but did not further analyse and did not include, outcome data in any otherwise relevant meta-analysis.

Dealing with missing data

It is often the case that data are missing from studies. Excluding participants after allocation from the analysis, or ignoring those participants who are lost to follow-up, compromises findings from all study designs, potentially introducing bias. Where data that we thought should be included in the analyses were missing, we contacted the relevant study authors to enquire whether these data were available.

Where data for 'proportion of pressure ulcers healed' remained missing, we planned to assume that if participants were not included in an analysis, their pressure ulcer did not heal (that is they would be considered in the denominator but not the numerator). As we did not find missing data, we did not need to adopt this approach to the analysis.

In a time-to-healing analysis using survival analysis methods, dropouts should be accounted for as censored data, so we planned to take no action regarding missing data. As we did not find these types of data, we did not need to adopt this approach to the analysis.

For continuous variables and all secondary outcomes, we planned to present the data available from the study reports/study authors and not impute missing data. Where possible, we planned to calculate missing measures of variance if not reported using the total number at the start of the study. Where these measures of variation were not available, we planned to exclude the study from any relevant meta-analyses we might conduct. As we did not find these types of data, we did not need to adopt this approach to the analysis.

Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multifaceted process. Firstly, we planned to consider clinical and methodological heterogeneity, that is the degree to which the included studies varied in terms of participants, interventions, outcomes, and characteristics such as length of follow-up. We planned to supplement this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity assessed using the χ^2 test (we planned to consider a significance level of P less than 0.10 to indicate statistically significant heterogeneity), in conjunction with the I^2 statistic (Higgins 2003). The I^2 statistic examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (Higgins 2003). Very broadly, we planned to consider that I^2 statistic values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of 75% or more may indicate very high heterogeneity (Deeks 2017). Where there was evidence of high heterogeneity, we planned to explore this further; see [Data synthesis](#) section. As we did not undertake meta-analysis, we did not use this approach to the analysis.

Assessment of reporting biases

We assessed reporting bias using guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2017). If enough studies had been available for a meaningful assessment of publication bias, we planned to construct a funnel plot of primary outcomes to test for asymmetry. We also planned to consider selective reporting, that is, reporting some outcomes and not others, in our assessment of reporting bias.

Data synthesis

We planned to combine details of included studies in a narrative review according to the comparison between intervention and comparator, the population, and the time point of the outcome measurement. We also planned to consider clinical and methodological heterogeneity and would have undertaken pooling only when studies appeared appropriately similar in terms of intervention type, study design, duration of treatment, and outcome assessment, and when we could have clearly interpreted data. We planned to present RCTs and non-randomised studies separately. As we did not combine data, we did not use this approach to the analysis.

We were unable to pre-specify the amount of clinical, methodological and statistical heterogeneity in included studies but it might have been extensive. Thus, we anticipated using a random-effects approach for meta-analysis. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We would only have used a fixed-effect approach when we assessed clinical and methodological heterogeneity to be minimal, and the assumption that a single underlying treatment effect was being estimated held. We would have used the Chi² test and I² statistic to quantify heterogeneity but would not have used these results to guide our choice of model for meta-analysis. We would have exercised caution when meta-analysed data were at risk of small-study effects, because a random-effects model may be unsuitable. In this case, or where there were other reasons to question the selection of a fixed-effect or random-effects model, we would have assessed the impact of the approach using sensitivity analyses to compare results from alternate models. (Thompson 1999).

We would have presented data using forest plots where possible. For dichotomous outcomes, we have presented the summary estimate as a RR with 95% CI. Where continuous outcomes had been measured in the same way across studies, we planned to present a pooled MD with 95% CI; we planned to pool SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we planned to plot (and, if appropriate, pool), estimates of HRs and 95% CIs as presented in the study reports using the generic inverse variance method in Review Manager 5 (Review Manager 2014). Where studies analysed time to healing as a continuous measure, but it was not clear if all wounds had healed, we planned to document use of the outcome in the study but not to summarise or use the data in any meta-analysis. As we did not undertake meta-analysis, we did not use this approach to the analysis.

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity existed between studies for the primary outcomes, we planned to explore reasons for heterogeneity. We envisaged that the number of studies meeting our inclusion criteria would have been low. Consequently, in order to avoid type 1 errors we planned to conduct a minimal number of subgroup analyses, including the following:

- the setting in which service delivery took place: hospital, community nursing home, or the participant's home.

Sensitivity analysis

We planned to perform a sensitivity analysis by including only those studies assessed as having a low risk of selection bias (i.e. both low risk for sequence generation and allocation concealment). We also planned to explore the effect of unpublished studies and cluster studies, where the analysis was not at the same level as the allocation (i.e. allocation by cluster and analysis by participant).

'Summary of findings' tables and assessment of the certainty of the evidence using the GRADE approach

We have presented the main results of the review in 'Summary of findings' tables, using [GRADEpro GDT 2015](#). These tables present key information concerning the certainty of the evidence, the magnitude of the effects of the interventions examined, and the sum of available data for the main outcomes (Schünemann 2011a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE approach, which defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The certainty of a body of evidence involves consideration of 5 factors: within-study risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Schünemann 2011b).

When undertaking a GRADE assessment, we downgraded only when studies were classed as high risk of bias for one or more domains and there was unclear risk of bias. In assessing the precision of effect estimates, we also followed GRADE guidance (GRADE 2013); we assessed the size of confidence intervals, downgrading twice for imprecision where there were few events, wide CIs or if clustering effects were not considered during analysis.

Where relevant, we have presented 2 sets of outcomes in the 'Summary of findings' tables, firstly prevention outcomes and secondly treatment outcomes.

For prevention studies we have presented the following outcomes:

- pressure ulcer incidence;
- adverse events.

For treatment studies we have presented the following outcomes:

- pressure ulcer healing;
- adverse events.

We did not pool data, so we conducted the GRADE assessment for each comparison and have presented this narratively within the results section with associated 'Summary of findings' tables.

RESULTS

Description of studies

Results of the search

The search yielded a total of 3172 citations. Two review authors examined the abstracts of all papers independently to assess for potential relevance. After excluding duplicates, we screened 3114 records. We excluded 3082 records which included six further duplicates. We obtained the full texts of 31 articles and were unable to get the full text of one article, which is still awaiting classification.

We excluded a further 27 studies; reasons for their exclusion are shown in [Figure 1](#) and are detailed in the [Characteristics of excluded studies](#) table. PJ contacted 15 study authors and experts in the

field, and no further studies were found. We did not identify any additional studies through the searches of the clinical trials registries.

Figure 1. Study flow diagram

Figure 1. (Continued)

included in
quantitative
synthesis

Included studies

We included four studies, with a total of 499 participants, in the review: one controlled before-and-after study ([Bloemen-Vrencken 2007](#)), one randomised, parallel RCT ([Caplan 1999](#)), one cluster-randomised stepped wedge study ([Stern 2014](#)) and one quasi-experimental cluster study ([Vu 2007](#)). See the [Characteristics of included studies](#) table. Two studies ([Bloemen-Vrencken 2007](#); [Caplan 1999](#)), related to the prevention of pressure ulcers, one related to prevention and treatment ([Stern 2014](#)), and one related to treatment only ([Vu 2007](#)).

Participants

The studies included the following participants: people with spinal cord injuries, attending rehabilitation centres ([Bloemen-Vrencken 2007](#)), people with a variety of acute medical conditions, attending a tertiary referral hospital affiliated with a university ([Caplan 1999](#)) and people in long-term care ([Stern 2014](#); [Vu 2007](#)).

[Bloemen-Vrencken 2007](#) was conducted in the Netherlands (n=62); [Caplan 1999](#) (n=100), and [Vu 2007](#) (n=176), were conducted in Australia; and [Stern 2014](#) (n=161), was conducted in Canada.

The mean age of participants in [Bloemen-Vrencken 2007](#) was 36.5 years, whereas, in [Caplan 1999](#), the mean age of participants was 76 years. The mean age of the participants in [Stern 2014](#) and [Vu 2007](#) was 82 years and 83 years respectively.

Interventions and comparisons

In [Bloemen-Vrencken 2007](#), the intervention was transmural care. The core component of the transmural care consisted of a transmural nurse, who liaised between former patients living in the community, primary care professionals and the rehabilitation team. The transmural care model provided activities to support patients and their family/partners and activities to promote continuity of care. The comparator was usual follow-up in the rehabilitation centre.

In [Caplan 1999](#), the intervention was a hospital-in-the-home service. This involved the delivery of treatment in the home by a hospital community outreach team, to the individual, based on their presenting diagnosis in the hospital. The comparison was to admission to hospital.

The intervention in [Stern 2014](#) was an enhanced multidisciplinary team (EMDT). They consisted of advanced practice nurses (APNs), who provided outreach to long-term-care facilities, and were linked to a hospital-based expert wound care team. The intervention was

implemented in two phases at each long-term-care facility. Phase 1 was three months in length and focused on training of long-term-care staff. Phase 2 was 1 to 11 months in length, and involved primarily remote support of the facilities' wound care, led by the APNs via email and telephone. The comparison was to wound care within long-term-care facilities, typically provided by the usual care staff, who may or may not have had expertise in wound care.

In [Vu 2007](#) the intervention was a multidisciplinary team of pharmacists and nurses. Training was provided to the team in the intervention arm in both how to use the study protocol and documentation procedures for data collection purposes. The comparator was usual care from nurses.

Outcomes

Three studies reported the primary outcome of pressure ulcer incidence ([Bloemen-Vrencken 2007](#); [Caplan 1999](#); [Stern 2014](#)), and two studies reported the primary outcome pressure ulcer healing ([Stern 2014](#); [Vu 2007](#)). One study reported the secondary outcome, quality of life ([Stern 2014](#)). Two studies reported staff/participant satisfaction ([Bloemen-Vrencken 2007](#); [Caplan 1999](#)). Three studies reported adverse events ([Bloemen-Vrencken 2007](#); [Caplan 1999](#); [Stern 2014](#)).

Excluded studies

We excluded 13 studies because they had a non-eligible study design ([Abadi 2017](#); [Alvarez 1993](#); [Anderson 2009](#); [Brosolo 1989](#); [Charrier 2008](#); [Elliott 2008](#); [Ellis 2006](#); [Futtrup 2013](#); [Kapoor 2008](#); [Liu 2016](#); [Hart 2011](#); [O'Leary 2011](#); [Rodney 2015](#)), and one because it was a description of a programme rather than a study ([Bensmail 2012](#)). We evaluated 11 studies as having non-eligible interventions ([Al Awamleh 2012](#); [Anonymous 1994](#); [Arora 2017](#); [Berlowitz 2007](#); [Chaboyer 2016](#); [Houser 2012](#); [Jones 1993](#); [Rantz 2012](#); [Van Gaal 2011](#); [Warshawsky 2013](#); [Yap 2013](#)), and two included a non-eligible patient population ([Biji 2014](#); [Zarchi 2015](#)).

One study is awaiting classification [Onyebueke 2017](#). We have contacted the study author for more information on the study. See the [Characteristics of excluded studies](#) table and [Figure 1](#).

Risk of bias in included studies

We assessed [Caplan 1999](#), [Stern 2014](#) and [Vu 2007](#) using the Cochrane 'Risk of bias' tool and we used the Cochrane ROBINS-I tool ([Reeves 2011](#)), to assess [Bloemen-Vrencken 2007](#), as it was non-randomised. All included studies were at high risk of bias. See [Figure 2](#) for the summary of the risk of bias and [Figure 3](#) for the graph of the risk of bias of the included studies.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies, except for [Bloemen-Vrencken 2007](#), which was a non-randomised controlled trial, and not assessed using these criteria.

Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study, except for [Bloemen-Vrencken 2007](#), which was an non-randomised controlled trial, and not assessed using these criteria.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bloemen-Vrencken 2007							
Caplan 1999	+	?	-	+	+	?	-
Stern 2014	+	+	-	+	-	+	-
Vu 2007	-	-	-	?	-	?	-

Allocation

Random sequence generation

[Vu 2007](#) was at high risk for this domain. Within each geographic domain of the sample, investigators approached nursing homes by telephone to participate. They assigned the first nursing home to accept the invitation to take part in the study to the intervention arm and the second, with similar resident numbers, from the same region, to the control arm. We classed [Caplan 1999](#) and [Stern 2014](#)

as being at low risk of bias, with the allocation sequence achieved using computer-generated random numbers.

Allocation concealment

[Vu 2007](#) did not describe a method for achieving allocation concealment and we classed this study at high risk of bias based on the assessment that it was a quasi-randomised study. [Stern 2014](#) used a researcher external to the study team to generate random allocation and we classed it at low risk of bias. [Caplan 1999](#) used

sealed envelopes, but it was not clear whether these had sequential numerical coding or were opaque. We judged this study to be at unclear risk of bias for allocation concealment.

Blinding

We judged [Vu 2007](#) as being at high risk of performance bias, as blinding of staff and participants would not have been possible. We classed [Caplan 1999](#) and [Stern 2014](#) as high risk of performance bias as the staff and participants knew which group they were allocated to.

We judged two studies at low risk of detection bias. [Caplan 1999](#) used independent reviewers to assess the study outcomes and [Stern 2014](#) used an assessor blinded to facility allocation. Blinding was not mentioned in [Vu 2007](#), and therefore we judged it as at unclear risk of detection bias.

Incomplete outcome data

It is not known how many people were excluded from the [Bloemen-Vrencken 2007](#) study on the basis of incomplete outcome data and if this differed between the groups. [Caplan 1999](#) reported no losses to follow-up. We judged the study to be at low risk of bias for this domain. We judged outcome data reporting to be incomplete for [Stern 2014](#) and [Vu 2007](#). In the [Stern 2014](#) study the loss to follow-up was N = 11 (control) and N = 23 (intervention period). Outcomes reported in the [Vu 2007](#) study were per wound, and some wounds were lost to follow-up. We judged these studies to be at high risk of bias for this domain.

Selective reporting

[Stern 2014](#) had a registered protocol and reported outcomes as per the protocol, and we judged it to be at low risk of selective reporting bias. We judged [Caplan 1999](#) and [Vu 2007](#) to be at unclear risk of selective reporting bias as their study protocols were not registered and thus we could not verify if they had reported all their planned outcomes.

Other potential sources of bias

We judged [Caplan 1999](#), [Stern 2014](#) and [Vu 2007](#) to be at high risk of other bias. In [Caplan 1999](#), there was a difference in the length of time spent in the emergency department, and in hospital length of stay between the study groups. The follow-up differed for each facility in [Stern 2014](#) and the baseline characteristics were not similar across the groups. In [Vu 2007](#), there were differences in baseline characteristics for nutrition and history of pressure ulcers. There were also differences in wound characteristics at baseline.

Risk of bias (ROBINS-I Tool)

As [Bloemen-Vrencken 2007](#) was a non-randomised study we assessed it for risk of bias using the ROBINS-I tool.

See [Table 1](#)

Bias due to confounding

While the groups were comparable at baseline, we judged [Bloemen-Vrencken 2007](#) as being at serious risk of bias because it had not controlled for at least one important domain.

Bias in selection of participants into the study

Participants were not randomised. Matching between the experimental and control groups was not done until the 12-month point so as to include those for whom follow-up data was available. For this reason we judged the [Bloemen-Vrencken 2007](#) study to be at unclear risk of bias for this domain.

Bias in classification of interventions

As [Bloemen-Vrencken 2007](#) determined some aspects of assignment retrospectively, we judged the study as at moderate risk of bias for this domain.

Bias due to deviations from intended interventions

We judged [Bloemen-Vrencken 2007](#) as being at moderate risk of bias for this domain, as deviation from the protocol was apparent but it was unclear if this deviation was sufficient to have an effect.

Bias due to missing data

We judged [Bloemen-Vrencken 2007](#) as being at moderate risk of bias for this domain because it was not clear how many people were excluded from the study on the basis of incomplete outcome data and if this differed between the groups.

Bias in measurement of outcomes

In this domain, we judged [Bloemen-Vrencken 2007](#) as low risk of bias because the prevalence of pressure ulcers was unlikely to be influenced by knowledge of the intervention.

Bias in selection of the reported result

As there was no subgroup analysis (other than a retrospective analysis of participants for whom data were available), we judged [Bloemen-Vrencken 2007](#) as low risk of bias for this domain.

Overall bias

We judged [Bloemen-Vrencken 2007](#) as being at a critical risk of bias overall due to a critical risk of bias in one domain.

Effects of interventions

See: [Summary of findings for the main comparison](#) Transmural care versus usual follow-up care for preventing pressure ulcers; [Summary of findings 2](#) Hospital-in-the-home versus hospital admission for preventing pressure ulcers; [Summary of findings 3](#) Enhanced multidisciplinary team (EMDT) versus usual care for preventing and treating pressure ulcers; [Summary of findings 4](#) Multidisciplinary wound care versus usual care for treating pressure ulcers

One study assessed the effect of transmural care versus the usual follow-up care, a second study assessed the effect of hospital-in-the-home versus hospital admission, a third study assessed EMDTs versus usual care, and a fourth study assessed multidisciplinary wound care versus usual care. For all outcomes, the level of evidence is of very low certainty due to downgrading for serious study limitations and imprecision.

Comparison 1: transmural care versus usual follow-up care (1 study; 62 participants)

One study ([Bloemen-Vrencken 2007](#)), assessed the effect of transmural care versus usual follow-up care on the development of a new pressure ulcer.

Primary outcome

Incidence proportion or risk: number of new cases of pressure ulcers during specified study period divided by the size of population

It is unclear whether there is a difference in the risk of developing a pressure ulcer between transmural care or usual care (RR 0.93, 95% CI 0.53 to 1.64; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Analysis 1.1](#) and [Summary of findings for the main comparison](#).

Secondary outcomes

Health-related quality of life

Not measured

Participant satisfaction

It was not clear in the included study how many people reported the outcomes, as the study authors reported these as a range of numbers. In the transmural care group, between 27 and 29 participants gave their opinion on the quality of follow-up care; in the usual follow-up-care group, between 20 and 23 participants gave their opinion. The study authors reported results individually for each of the 15 items on the questionnaire, however, they did not provide an overall result, but rather reported narratively that there was no difference between the study groups in the perceived quality of follow-up care experienced (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Staff satisfaction

Not measured

Adverse events

Adverse incident: hospital readmission

It is unclear whether there is a difference in the probability of hospital readmission between transmural care or usual care (RR 2.00, 95% CI 0.19 to 20.93; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Analysis 1.2](#) and [Summary of findings for the main comparison](#).

Comparison 2: hospital-in-the-home versus hospital admission (1 study; 100 participants)

One study ([Caplan 1999](#)), assessed the effect of hospital-in-the-home care versus hospital admission on the development of a new pressure ulcer. Follow-up was for 28 days.

Primary outcome

Incidence proportion or risk: number of new cases of pressure ulcers during specified study period divided by the size of population

It is unclear whether there is a difference in the probability of pressure ulcer development between hospital-in-the-home, or hospital admission (RR 0.32, 95% CI 0.03 to 2.98; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision) see [Analysis 2.1](#) and [Summary of findings 2](#). In the hospital-in-the-home group, 2% (1 of 51), participants developed a pressure ulcer, whereas, 6% (3 of 49), in the hospital-admission group developed a pressure ulcer.

Secondary outcomes

Health-related quality of life

Not measured

Satisfaction

After discharge, the study investigators sent a satisfaction survey to participants, carers and general practitioners (GPs). They asked participants, "How would you rate your treatment overall?", with answers on a four-point scale: excellent (1), good (2), fair (3) and poor (4). Lower scores indicated higher satisfaction. They asked the participants' GPs how satisfied they were with the participants' care, and scored responses in a similar way to the participants' responses, with lower scores indicating higher satisfaction.

Patient satisfaction

It is unclear whether there is a difference in participant satisfaction scores between the study groups (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). Mean satisfaction scores for the participants were: 1.1 (95% CI 1.0 to 1.2; hospital-in-the-home group), and 2.0 (95% CI 1.7 to 2.6; hospital-admission group). We have not re-analysed these data, the results presented are from the study authors' analysis.

Staff satisfaction

It is unclear whether there is a difference in staff satisfaction scores between the study groups (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). Mean satisfaction scores for the participants' GPs (number not specified) were: 1.7 (95% CI 1.4 to 2.0; hospital-in-the-home group), and 1.8 (95% CI 1.4 to 2.2; hospital-admission group). We have not re-analysed these data, the results presented are from the study authors' analysis.

Adverse events

Death at 28 days

It is unclear whether there is a difference in the risk of death at 28 days between hospital-in-the-home, or hospital admission, because the evidence is of very low certainty (evidence downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 2](#). In the hospital-in-the-home group, 6% (3 of 51), died, whereas, 8% (4 of 49), died in the hospital-admission group (RR 0.72, 95% CI 0.17 to 3.06; [Analysis 2.2](#)).

Readmission to hospital

It is unclear whether there is a difference in the risk of hospital readmission between hospital-in-the-home, or hospital admission, (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 2](#). In the hospital-in-the-home group, 6% (3 of 51), were readmitted, whereas, 10% (5 of 49), in the hospital-admission group were readmitted (RR 0.58, 95% CI 0.15 to 2.28; [Analysis 2.3](#)).

Comparison 3: enhanced multidisciplinary teams (EMDTs) versus usual care (1 study; 161 participants)

The study by [Stern 2014](#) investigated the effect of an EMDT via telemedicine, who provided outreach to long-term-care facilities,

versus usual care in these facilities. The study focused on prevention and treatment of pressure ulcers.

Primary outcome

Pressure ulcer incidence rate

The pressure ulcer incidence rate in the EMDT follow-up period was HR 1.12 (95% CI 0.74 to 1.68), times larger than the incident rate of the usual-care follow-up period (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). We have not re-analysed these data, the results presented are from the study authors' analysis

Number of pressure ulcers healed

It is unclear whether there is a difference in the number of pressure ulcers healed between EMDT care, or usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). In the EMDT period 42% (30 of 71), participants had healed pressure ulcers, whereas, in the control period, 25% (14 of 56) participants had healed pressure ulcers (RR 1.69, 95% CI 1.00 to 2.87; [Analysis 3.1](#)).

Reduction in pressure ulcer surface area

The analyses of the primary outcome used measurements of 201 pressure ulcers from 119 long-term-care facility residents. It is unclear whether there is a difference in the incidence of reduction in pressure ulcer surface areas, with and without EMDT, (healing rate 1.006; 95% CI 0.99 to 1.03; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Time to complete healing

It is uncertain whether there is a difference in time to healing between EMDT compared with usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). Hazard ratios (HR) for time to healing were 1.48 (95% CI 0.79 to 2.78). We have not re-analysed these data, the results presented are from the study authors' analysis.

Secondary outcomes

Health-related quality of life

[Stern 2014](#) measured quality of life using the EQ5D. The mean utilities were 0.03 (95% CI -0.03 to 0.09), units lower during the intervention period than during the control period. We have not re-analysed these data, the results presented are from the study authors' analysis. It is unclear whether there is a difference in quality of life between EMDT care, or usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Patient or staff satisfaction

Not measured

Adverse events

Hospitalisation

The study authors estimated the mean hospitalisation rate to be 1.2 (95% CI 0.62 to 2.36), times larger during the EMDT follow-up period than during the usual-care follow-up period (very low-certainty

evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). We have not re-analysed these data, the results presented are from the study authors' analysis.

Emergency department visits

The study authors estimated the mean emergency department visit rate to be 1.3 (95% CI 0.58 to 2.90), times larger during the EMDT follow-up period than during the usual-care follow-up period. We have not re-analysed these data, the results presented are from the study authors' analysis. The evidence is of very low certainty (downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#).

Comparison 4: multidisciplinary wound care versus usual care (1 study; 176 participants)

[Vu 2007](#) evaluated the impact of multidisciplinary wound care in nursing homes versus usual care on treatment of pressure ulcers.

Primary outcome

Number of pressure ulcers healed

While the study authors' planned outcome measure for treatment studies was 'proportion of individuals with pressure ulcers healed at the completion of the study period', this study reports on the percentage of pressure ulcers healed (i.e. a unit of analysis error, in addition to not accounting for clustering). It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care or usual care (RR 1.18, 95% CI 0.98 to 1.42; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision), see [Analysis 4.1](#) and [Summary of findings 4](#).

Time to complete healing

This study randomised individuals but analysed data at the ulcer level not the patient level, thus results for this outcome are also impacted by unit of analysis issues. It is unclear whether there is a difference in time to complete healing between multidisciplinary care or usual care, as the certainty of the evidence is very low (HR 1.73, 95% CI 1.20 to 2.50; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 4](#).

Secondary outcomes

None reported

DISCUSSION

Summary of main results

The search yielded a total of 3172 citations and, following screening and application of the inclusion and exclusion criteria, four studies were eligible for inclusion. The studies reported the primary outcome of pressure ulcer incidence or pressure ulcer healing, or both. The studies included four different interventions, namely, transmur care, hospital-in-the-home, EMDT care and multidisciplinary wound care. The studies compared these interventions with usual care, which, in the case of the hospital-in-the-home study, involved hospital admission. Participants included people with spinal cord injuries, people with a variety of acute medical conditions, and people in long-term care.

- It is unclear whether transmurial care leads to a difference in pressure ulcer incidence rate, participant satisfaction and adverse events compared with usual care because the certainty of the evidence is very low.
- It is unclear whether hospital-in-the-home leads to a difference in pressure ulcer incidence rate, participant satisfaction, staff satisfaction and adverse events compared with hospital admission because the certainty of the evidence is very low.
- It is unclear whether EMDTs lead to a difference in time to complete healing, reduction in pressure ulcer surface area, number of wounds healed, pressure ulcer incidence rate, quality of life and adverse events compared with usual care because the certainty of the evidence is very low.
- It is unclear whether multidisciplinary wound care leads to a difference in time to complete healing and number of wounds healed compared with usual care because the certainty of the evidence is very low.

While reviewing the organisation of health services it is important to consider national differences in healthcare systems. One could suggest that what works in one country around organisation of health services may work in another country. However, the healthcare services are very much bounded by the societal, policy and economic factors of the country in which the study takes place. Even though, for example, studies can show that transmurial care in the Netherlands prevents pressure ulcers, it may not be possible to apply this model to another country, due to variations in organising health care from country to country. This is a huge challenge for the future as we try to find a good model of care or recommendation for organisation of service for prevention and effective treatment of pressure ulcers. Overall, the uncertainty in the evidence arises because GRADE assessments of the evidence resulted predominantly in judgements of very low certainty. The studies were at high risk of bias, and outcome measures were imprecise due to wide confidence intervals and small sample sizes. Thus, more research is warranted, as it is likely that further studies that address some of the problems identified with the certainty of evidence will alter the effect estimate.

Overall completeness and applicability of evidence

Given the importance of pressure ulcer management for health service budgets, there remains a gap in the evidence base. Four studies evaluated different types of organisation of health services for treating and preventing pressure ulcers; one RCT, one pragmatic cluster-randomised trial, one controlled before-and-after study, and one quasi-randomised pragmatic-cluster trial. The participants included in these studies, older people and people with spinal cord injuries, are representative of those most at risk of pressure ulcer development, however, there are other at-risk groups who were not included, for example, those with mobility problems from other causes, such as neurological problems, stroke or multiple sclerosis. The studies did not report data for all outcomes. Furthermore, the studies generally had small sample sizes, so were underpowered to detect a difference between the study groups, should such a difference have existed. Thus, the evidence to date is incomplete pertaining to the organisation of health services for the prevention and treatment of pressure ulcers.

Quality of the evidence

Limitations in study design and implementation

We assessed risk of bias according to six domains for three studies: sequence generation; allocation concealment; blinding; incomplete follow-up, selective outcome reporting, and other potential biases (Caplan 1999; Stern 2014; Vu 2007). We used the ROBINS-I tool to assess Bloemen-Vrencken 2007. This tool assesses seven domains for non-randomised studies: bias due to confounding; bias in the selection of participants into the study; bias in the classification of interventions; bias due to deviations from intended interventions; bias due to missing data; bias in measurement of outcomes; and bias in selection of the reported results. Each domain can be considered at low risk of bias; moderate risk of bias; serious risk of bias; critical risk of bias; or recorded as there being no information on which to make a decision. The methodological quality of the four studies was poor, with limitations in a number of these domains (Figure 3).

Indirectness of evidence

We did not downgrade the evidence for indirectness.

Imprecision of results

For the individual analysis of results, the confidence intervals are wide. This indicates a high level of uncertainty around the effect size. Further research is, therefore, very likely to have an important impact on the confidence of the estimate of the effect of the organisation of health services on the prevention and treatment of pressure ulcers. Although altogether the four studies reported each of the outcomes proposed in the methods section, the certainty of the evidence would have been enhanced had each individual study reported all of the outcomes. Due to the absence of sufficient data we were unable to carry out a meta-analysis.

Publication bias

We feel confident that our comprehensive electronic searches identified all existing, published RCTs addressing the review question. It is theoretically possible, though unlikely, that we did not manage to locate some potentially eligible studies that have been published. There is always the risk that there are unpublished studies available that we have not been able to locate. In line with Cochrane policy, we will update this review again in future, and will include any further studies identified that meet the inclusion criteria at that stage.

Potential biases in the review process

We followed clearly described procedures to prevent potential bias in the review process. This included a careful literature search, and the methods that we used were transparent and reproducible. It is possible that studies published in journals that were outside our search strategy may have been missed.

Agreements and disagreements with other studies or reviews

There are no other reviews relating to the organisation of health services for preventing and treating pressure ulcers. Therefore, we cannot say if the outcomes of this review agree or disagree with other studies or reviews.

AUTHORS' CONCLUSIONS

Implications for practice

Pressure ulcers are common and costly, with a negative impact on the individual and on the health service as a whole. It is thought that the way in which the delivery of health care is organised, be this in the home, or in a hospital setting, can influence the development of pressure ulcers among people at risk, and also influence the healing of these wounds.

The overall certainty of the evidence is very low, as the findings of the studies included in this review were inconsistent, there was one non-RCT, the studies had wide confidence intervals around the effect size and were at high risk of bias, meaning that additional research is required to confirm these results. Therefore, there is insufficient evidence from independently funded clinical studies to support or refute the use of different types of organisation of healthcare delivery, for the prevention of pressure ulcers. The organisation of health care is very much culturally and socially bounded and this demands special attention while the results of analysis are summarised and discussed.

Implications for research

The evidence base for the organisation of health services for preventing and treating pressure ulcers is very limited. Further, high-quality, RCTs are needed to provide the evidence to underpin

these treatment and preventative practices. Further studies are justified, based on the incidence of pressure ulcers and the high costs associated with pressure ulcer prevention and management. Future studies should be large enough to show meaningful differences to assist healthcare managers to make decisions about the most effective methods of care delivery. The interventions could include teams that include new professional roles or new teams where new disciplines work together.

Selection should include people of any age, in any care setting (hospitals, nursing homes, residential care, rehabilitation centres), who are at risk of developing a pressure ulcer (as identified through either a structured or unstructured risk assessment, or by clinical judgement alone), or who have an existing pressure ulcer (of any stage).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bloemen-Vrencken 2007

Methods	<p>Study design: controlled before-and-after study</p> <p>Study grouping: parallel</p> <p>Ethics and informed consent: not reported</p> <p>Follow-up period: 12 months</p> <p>Sample size estimate: no, but inclusion of 60 experimental and 60 control was expected</p> <p>ITT analysis: no; met criteria: 149; number analysed: 115</p> <p>Funding: the study was supported by: ZonMw, the Netherlands Organisation for Health Research and Development, ZonMw, Rehabilitation programme, grant numbers. 01432030 & 14350003; and the healthcare insurance companies Agis and CZ.</p>
Participants	<p>Country: Netherlands</p> <p>Setting: spinal cord Injury</p> <p>Number: 62 (intervention group 31 participants); (control group: 31 participants)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 18–65 years of age • Spinal cord injury, both tetraplegia and para-plegia • American Spinal Injury Association(ASIA) impairment scale A–D, 15 in some way wheelchair dependent • The injury itself is stable (no progressive disease) • Receiving rehabilitation treatment for the first time (no re-admissions) <p>Exclusion criteria</p> <ul style="list-style-type: none"> • None stated <p>Pre-treatment: (reported for N = 31 intervention and N = 31 matched controls)</p> <ul style="list-style-type: none"> • Age, mean, years (SD); intervention: 37.8 (13.8); control: 36.1 (13.6) • Men (N): intervention: 24; control: 24 • Complete tetraplegia (C1–C5) (N): intervention: 2; control: 2 • Incomplete tetraplegia (C1–C5) (N): intervention: 1; control: 2 • Complete tetraplegia (C6–T1) (N): intervention: 5; control: 5 • Incomplete tetraplegia (C6–T1) (N): intervention: 5; control: 4 • Complete paraplegia (N): intervention: 15; control: 15 • Incomplete paraplegia (N): intervention: 3; control: 3 • Cause of injury (N): traumatic: intervention: 27; control: 26; non-traumatic (N): intervention: 4; control: 5

Bloemen-Vrencken 2007 (Continued)

- Average clinical rehabilitation, days (SD): intervention: 270.7 (123.6); control: 294.1 (168.2)

Interventions	<p>Intervention characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> • In addition to the usual follow-up care by the rehabilitation doctor at the rehabilitation centre, the participants in the intervention group had access to transmural care for at least 1 year after discharge • The core component of the transmural care consisted of a transmural nurse as liaison between people with spinal cord injury living in the community, primary care professionals and the rehabilitation centre • The transmural nurse was a member of the clinical rehabilitation team (also worked as a nurse at the spinal cord unit) and was engaged for 8 h/week to perform 4 main tasks: <ul style="list-style-type: none"> * to support people with spinal cord injury and their partner/family with their health problems, within the scope of the nursing discipline * to support primary care professionals with the specific care of people with spinal cord injury * to promote continuity of care between primary care professionals and the rehabilitation team * to give feedback and initiate improvements in care for the rehabilitation team, based on the experiences with participants <p>Control</p> <ul style="list-style-type: none"> • The participants in the usual follow-up-care group were able to make use of periodic outpatient visits to the rehabilitation doctor at their rehabilitation centre • During these visits a comprehensive assessment of functioning (i.e. physical, psychological, social and communicative functioning, and functioning regarding ADL) was performed and, if necessary, interventions were applied or other forms of support given.
Outcomes	<p>Primary outcome</p> <p><i>PU incidence:</i></p> <ul style="list-style-type: none"> • outcome type: dichotomous outcome • reporting: fully reported • unit of measure: numbers • direction: lower is better • data value: endpoint <p>Secondary outcomes</p> <p><i>Participant satisfaction:</i></p> <ul style="list-style-type: none"> • outcome type: continuous outcome • reporting: fully reported • unit of measure: numbers • direction: higher is better • data value: endpoint <p><i>Adverse events: readmission to clinical rehabilitation due to PUs:</i></p> <ul style="list-style-type: none"> • outcome type: dichotomous outcome • reporting: fully reported • unit of measure: numbers • direction: lower is better • data value: endpoint
Identification	<p>Sponsorship source: the study was supported by ZonMw, the Netherlands Organisation for Health Research and Development, ZonMw, Rehabilitation programme, grant numbers. 01432030& 14350003; and the health care insurance companies Agis and CZ</p>

Bloemen-Vrencken 2007 (Continued)

Country: Netherlands

Setting: spinal cord rehabilitation centres

Comments: none

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Notes

See [Table 1](#) for 'Risk of bias' assessment for this study

Caplan 1999

Methods

Study design: RCT

Study grouping: parallel group

Ethics and informed consent: not reported

Follow-up period: 28 days

Sample size estimate: yes, the study had a power of 80% and an alpha of ≤ 0.05 , to detect a 20% difference in the occurrence of complications

ITT analysis: yes; **number randomised** 100: **number analysed:** 100

Funding: the study was supported by a grant from the Commonwealth Department of Health and Family Services - Hospital Access (National Projects) Programme

Participants

Country: Australia

Setting: tertiary hospital

Number: 100 (intervention group 51 participants; control group: 49 participants)

Inclusion criteria

- Patients > 65 years
- Including those living in nursing homes
- Accepted younger patients if they had been assessed as requiring admission by the relevant medical or surgical team

Exclusion criteria

- Evidence of shock (systolic blood pressure, 100 mmHg)
- Required oxygen (PaO₂, 60 mmHg)
- Judged too unwell by the study team
- Had no available care
- Lived outside the local area
- Their home was unsuitable for home treatment (lack of running water, electricity or an inside toilet, concerns about safety, or dangerous pets)

Pretreatment

- Age: median (range): intervention: 73 (17-111); control: 79 (22-97)
- male/female: intervention: 21/30; control: 24/25

Caplan 1999 (Continued)

- Barthel index (max 20) (range): intervention: 15.2 (13.3-17.1); control: 14.8 (12.8-16.8)
- Instrumental ADL (max 12) (range): intervention: 6.8 (5.5-8.1); control: 6.2 (4.7-7.7)
- Mental status questionnaire (max 10) (range): intervention: 7.1 (6.1-8.1); control: 6.9 (5.8-8.0)

Interventions

Intervention characteristics

HIH service

- HIH participants were treated according to the presenting diagnosis by the hospital community outreach team. The range of treatments included administration of parenteral antibiotics and other medications and blood transfusions

Control group

- Admitted to hospital and treated according to the usual standards of the hospital

Outcomes

Primary outcome

PU incidence rate:

- **outcome type:** dichotomous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Secondary outcomes

Participants' carers and GPs' satisfaction:

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** higher is better
- **data value:** endpoint

Adverse events: deaths

- **outcome type:** dichotomous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Adverse events: unplanned readmission:

- **outcome type:** dichotomous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Identification

Sponsorship source: supported by a grant from the Commonwealth Department of Health and Family Services - Hospital Access (National projects) Programme

Country: Australia

Setting: a tertiary referral hospital affiliated with the University of New South Wales

Comments: none

Caplan 1999 (Continued)

Author's name: Caplan GA

Institution: Prince of Wales Hospital, Sydney

Email: g.caplan@unsw.edu.au

Address: Post Acute Care Services, Prince of Wales Hospital, Sydney, NSW

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "allocation sequence was achieved using computer-generated random numbers"
Allocation concealment (selection bias)	Unclear risk	Used sealed envelopes, but the nature of these envelopes in terms of sequential numerical coding, or opaqueness, was not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Staff and participants knew who was in the HIH group as they were cared for either at home or in the hospital
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Independent reviewers assessed outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up
Selective reporting (reporting bias)	Unclear risk	Protocol for the study not registered, therefore, unclear if all outcomes were reported
Other bias	High risk	There was a difference in the length of time spent in the ED, with those in the control group spending longer than those in the experimental group ($P < 0.003$). In addition, those in the intervention group had a longer mean length of stay in hospital at baseline (10.1 days; 95% CI 7.7 to 12.5) compared with the control group (7.4 days; 95% CI 10.1 to 14.3)

Stern 2014

Methods

Study design: pragmatic, cluster-randomised trial

Study grouping: stepped wedge

Ethics and informed consent: ethics not reported but consent obtained from facility leader

Follow-up period: 14 months

Sample size estimate: yes

ITT analysis: yes; **number randomised** 181; **number analysed:** 161

Funding: the study was funded by the Canadian Patient Safety Institute, the Central Community Care Access Center, and the Ministry of Health and Long Term Care

Stern 2014 (Continued)

Participants

Country: Canada

Setting: LTC

Number: 161 (intervention group 94 participants; control group: 67 participants)

Inclusion criteria

- Facilities:
 - * had a minimum of 100 beds
 - * were within 100 km from the hospital housing the expert wound team
 - * had a PU prevalence > the provincial average (5.5%, based on data collected from LTC facilities in Ontario by the Canadian Institute of Health Research in 2009)
 - * the facility administrator provided consent
- Participants:
 - * the study population was residents with $\geq$ Stage 2 PUs
 - * residing in eligible LTC facilities situated within 2 geographic regions

Exclusion criteria

- Stage 1 and deep tissue injury PUs

Pretreatment

- Age: mean (SD): intervention: 81 (12); control: 83 (12)
- Sex (female): N (%): intervention: 43 (64.2); control: 65 (69.1)
- Incontinence (urine): N (%): intervention: 66 (98.5%); control: 91 (96.8%)
- Incontinence (stool): intervention: 58 (86.6); control 79 (84.0)
- Bedbound N (%): intervention: 49 (81.7); control: 71 (87.7)
- Mental status (not alert/not oriented): N (%): intervention: 52 (77.6); control: 78 (83.0)
- Nutritional supplement: N (%): intervention: 55 (82.1); control: 80 (85.1)
- Tube feed N (%): intervention: 5 (7.5); control: 7 (7.4)
- BMI: mean (SD): intervention: 25 (8); control: 24 (6)

Interventions

Intervention characteristics
Intervention

- The EMDT consisted of APNs who provided outreach to LTC facilities, and were linked to a hospital based expert wound care team
- They visited LTC facilities to educate staff on the prevention and treatment of PUs, consulting with a hospital-based expert wound care team via email, telephone, or video link following a referral rubric
- The intervention was implemented in 2 phases at each LTC facility
- Phase 1 was 3 months in length at each facility and focused on training of LTC staff
- Phase 2 (1-11 months in length), involved primarily remote support of the facility wound care lead by the APNs via email and telephone
- This process was repeated every 2 weeks for all PUs until healed, or until the end of the study period, whichever came first.

Control

- Wound care within LTC facilities was typically provided by registered nurses, registered practical nurses, personal support workers, and nutritionists, who may or may not have had expertise in wound care
- Access to other disciplines (e.g. enterostomal therapists, physiotherapists, occupational therapists) was available, typically on a reactive basis

Outcomes

Primary outcome
PU incidence rate:

Stern 2014 (Continued)

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Number of wounds healed:

- **outcome type:** dichotomous outcome
- **reporting:** fully reported
- **unit of measure:** probability of healing, expressed as a percentage
- **direction:** higher is better
- **data value:** endpoint

Reduction in PU surface area

- **outcome type:** dichotomous outcome
- **reporting:** fully reported
- **unit of measure:** pixels, converted to cm²
- **direction:** lower is better
- **data value:** endpoint

Time to complete healing (in days):

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** random-effects model - changes in slope
- **direction:** values < 1 indicate benefit
- **data value:** endpoint

Secondary outcomes:

Health-related quality of life

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Adverse events: hospitalisation:

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

ED visits:

- **outcome type:** continuous outcome
- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Identification

Sponsorship source: the study was funded by the Canadian Patient Safety Institute, the Central Community Care Access Center, and the Ministry of Health and Long Term Care.

Stern 2014 (Continued)

Country: Canada

Setting: LTC facilities in Canada

Comments: none

Author's name: Stern A

Institution: ELLICSR, University Health Network

Email: anita.stern@rmp.uhn.ca

Address: 200 Elizabeth Street, Munk Building, BCS021, Toronto, Ontario M5G 2C4, Canada

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "LTC facilities were randomised to start date of the intervention by a researcher external to the study team, using a computer generated random number sequence"
Allocation concealment (selection bias)	Low risk	Quote: "computer generated random number sequence"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "blinding of facility staff or residents was not possible due to the nature of the intervention"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The primary outcome was assessed using standard photographs by an assessor blinded to facility allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up N = 11 (control); N = 23 (intervention period)
Selective reporting (reporting bias)	Low risk	Protocol for the study was registered and outcomes were reported
Other bias	High risk	The follow-up differed for each facility. The baseline characteristics were not similar across the groups

Vu 2007

Methods

Study design: quasi-experimental cluster trial

Study grouping: parallel groups

Ethics and informed consent: yes

Follow-up period: 20 weeks

Sample size estimate: yes

ITT analysis: yes; **number randomised:** 176 residents located in 44 homes; **number analysed:** 176 residents located in 44 homes

Vu 2007 (Continued)

Funding: this project was funded by the Australian Government Department of Health and Ageing under the Third Community Pharmacy Agreement Research and Development Grants Programme that is managed by the Pharmacy Guild of Australia (Community Pharmacy Agreement Research and Development Grant No. 5002553/99)

Participants

Country: Australia

Setting: high-care nursing homes

Number: 176 residents located in 44 homes (intervention group 21 homes and 94 participants; control group: 23 homes and 82 participants)

Inclusion criteria

- Residents with leg or pressure wounds who could provide informed consent

Exclusion criteria

- Residents with infected wounds or diabetes
- Those undergoing long-term corticosteroid therapy chemotherapy or treatment with immunosuppressants

Pretreatment

- Mean (SD) age (years): intervention 83.0 (9.1); control: 83.7 (8.9) 0.635
- Mean (SD) days in nursing home: intervention: 681.5 (877.2); control: 731.7 (973.0) 0.749
- Women: intervention: 60 (63.8%); control: 64 (78.0%) 0.039
- Underweight: intervention: 46 (48.9%); control: 17 (20.7%) 0.000
- History of previous leg or PUs: yes: intervention 40 (42.6%); control: 49 (62.0%) 0.011; no: intervention: 54 (57.4%); control: 30 (38.0%)
- Ability to describe pain or discomfort: yes: intervention: 62 (66.0%); control: 57 (69.5%) 0.615; no: intervention: 32 (34.0%); control: 25 (30.5%)
- Urinary incontinence: significant: intervention: 38 (40.4%); control: 25 (30.5%)
- Faecal incontinence: significant: intervention: 32 (34.0%); control: 18 (21.9%)

Interventions

Intervention characteristics

Intervention

- Multidisciplinary team of pharmacists and nurses
- Study staff developed a standard treatment protocol for use in the intervention arm based on the colour, depth and exudate method for assessing wounds and their academic and clinical experience
- Before the study commenced, training was provided to nurses and pharmacists in the intervention arm in both how to use the protocol and documentation procedures for data collection purposes

Control

- Residents in the control arm received usual care from nurses

Outcomes

Primary outcome

Number of wounds healed:

- outcome type:** dichotomous outcome
- reporting:** fully reported
- unit of measure:** numbers
- direction:** higher is better
- data value:** endpoint

Time to complete healing:

- outcome type:** continuous outcome

Vu 2007 (Continued)

- **reporting:** fully reported
- **unit of measure:** numbers
- **direction:** lower is better
- **data value:** endpoint

Identification

Sponsorship source: funded by the Australian Government Department of Health and Ageing under the Third Community Pharmacy Agreement Research and Development Grants Program that is managed by the Pharmacy Guild of Australia.

Country: Australia

Setting: nursing homes in Melbourne, Australia

Comments: none

Authors name: Vu, T

Institution: Centre for Health Economics, Monash University

Email: vu@buseco.monash.edu.au

Address: Clayton, Victoria, Australia

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Non-random component in the sequence generation process: quote: "The first nursing home to accept our invitation was assigned to the intervention arm, and the second with similar resident numbers from the same region allocated to the control arm"
Allocation concealment (selection bias)	High risk	Alternation or rotation employed: quote: "The first nursing home to accept our invitation was assigned to the intervention arm, and the second with similar resident numbers from the same region allocated to the control arm"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not mentioned in the paper, however, blinding not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned in the paper
Incomplete outcome data (attrition bias) All outcomes	High risk	Outcomes reported per wound, and some wounds lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Protocol for the study not registered, therefore, unclear if all outcomes were reported
Other bias	High risk	Difference in baseline characteristics for nutrition and history of previous PU. Differences in wound characteristics at baseline. In the intervention arm, the wounds are bigger, producing more exudate and are more painful. No analysis for the effect of clustering undertaken by the study authors.

ADL: activities of daily living; **APN:** advanced practice nurse; **BMI:** body mass index; **ED:** emergency department; **EMDT:** enhanced multidisciplinary team; **HIH:** hospital-in-the-home; **ITT:** intention-to-treat; **LTC:** long-term care; **PU:** pressure ulcer; **RCT:** randomised controlled trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abadi 2017	Non-eligible study design
Al Awamleh 2012	Non-eligible intervention
Alvarez 1993	Non-eligible study design
Anderson 2009	Non-eligible study design
Anonymous 1994	Non-eligible intervention
Arora 2017	Non-eligible intervention
Bensmail 2012	It is a description of a programme, not an original study
Berlowitz 2007	Non-eligible intervention
Biji 2014	Non-eligible patient population
Brosolo 1989	Non-eligible study design
Chaboyer 2016	Non-eligible intervention
Charrier 2008	Non-eligible study design
Elliott 2008	Non-eligible study design
Ellis 2006	Non-eligible study design
Futtrup 2013	Non-eligible study design
Hart 2011	Non-eligible study design
Houser 2012	Non-eligible intervention
Jones 1993	Non-eligible intervention
Kapoor 2008	Non-eligible study design
Liu 2016	Non-eligible study design
O'Leary 2011	Non-eligible study design
Rantz 2012	Non-eligible intervention
Rodney 2015	Non-eligible study design
Van Gaal 2011	Non-eligible intervention
Warshawsky 2013	Non-eligible intervention

Study	Reason for exclusion
Yap 2013	Non-eligible intervention
Zarchi 2015	Wrong study population

Characteristics of studies awaiting assessment [ordered by study ID]

Onyebueke 2017

Methods	Non-RCT
Participants	Veterans with chronic spinal cord injury admitted for urinary tract infection, pressure ulcer/os-teomyelitis or pneumonia
Interventions	Hospital-in-the-home (HIH) consisting of: daily registered nurse visits and daily physician oversight with follow-up visits as needed
Outcomes	Health: readmission and mortality rates; cost care: cost per bed-day; patient satisfaction: survey
Notes	Unclear about sample. Unable to source full text as yet, trying to contact study author

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Transmural care versus usual follow-up care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence; follow-up 12 months	1	62	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.53, 1.64]
2 Adverse event: readmission to clinical re-habilitation; follow-up 12 months	1	62	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.19, 20.93]

Analysis 1.1. Comparison 1 Transmural care versus usual follow-up care, Outcome 1 Pressure ulcer incidence; follow-up 12 months.

Analysis 1.2. Comparison 1 Transmural care versus usual follow-up care, Outcome 2 Adverse event: readmission to clinical rehabilitation; follow-up 12 months.

Comparison 2. Hospital-in-the-home versus hospital admission

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Adverse event: death; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Adverse event: hospital readmission; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 2.1. Comparison 2 Hospital-in-the-home versus hospital admission, Outcome 1 Pressure ulcer incidence; follow-up 28 days.

Analysis 2.2. Comparison 2 Hospital-in-the-home versus hospital admission, Outcome 2 Adverse event: death; follow-up 28 days.

Analysis 2.3. Comparison 2 Hospital-in-the-home versus hospital admission, Outcome 3 Adverse event: hospital readmission; follow-up 28 days.

Study or subgroup	Hospital in the home n/N	Hospital admission n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Caplan 1999	3/51	5/49		0.58[0.15,2.28]

Comparison 3. Enhanced multidisciplinary team versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers healed; follow-up 14 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 3.1. Comparison 3 Enhanced multidisciplinary team versus usual care, Outcome 1 Pressure ulcers healed; follow-up 14 months.

Study or subgroup	Enhanced MDT n/N	Usual Care n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Stern 2014	30/71	14/56		1.69[1.28,2.27]

Comparison 4. Multidisciplinary wound care versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers healed; follow-up 20 weeks	1	342	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.98, 1.42]

Analysis 4.1. Comparison 4 Multidisciplinary wound care versus usual care, Outcome 1 Pressure ulcers healed; follow-up 20 weeks.

Study or subgroup	MDT wound care n/N	Usual care n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Vu 2007	111/180	85/162		100%	1.18[0.98,1.42]
Total (95% CI)	180	162		100%	1.18[0.98,1.42]
Total events: 111 (MDT wound care), 85 (Usual care)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.7(P=0.09)					

ADDITIONAL TABLES

Table 1. ROBINS-I 'Risk of bias' table

Bloe- men-Vrenck- en 2007	Bias due to confound- ing	Bias in selection of participants into the study	Bias in classifi- cation of inter- ventions	Bias due to deviations from intended interven- tions	Bias due to missing da- ta	Bias in measure- ment of outcomes	Bias in selection of the reported result	Overall bias
	Serious risk ^a	Critical risk ^b	Moderate risk ^c	Moderate risk ^d	Moderate risk ^e	Low risk ^f	Low risk ^g	Critical ^h

^aAt least one known important domain was not appropriately controlled for.

^bParticipants were not randomised. Matching between the experimental and control groups was not done until the 12-month point so as to include those for whom follow-up data was available. For this reason we judged the bias of the study to be unclear.

^cSome aspects of assignment were determined retrospectively.

^dDeviation from protocol apparent but unclear if deviation sufficient to have an effect.

^eIt is not known how many people were excluded from the study on the basis of incomplete outcome data and if this differed between the groups.

^fPrevalence of pressure ulcers unlikely to be influenced by knowledge of intervention.

^gSome multiple domain reporting, but no differences noted; no subgroup analysis (other than retrospective of participants for whom data were available).

^hWe judged the study as 'critical' risk of bias overall due to critical risk of bias in one domain.

APPENDICES

Appendix 1. Search strategies

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Pressure Ulcer] explode all trees

#2 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw (Word variations have been searched)

#3 (decubitus next (ulcer* or sore*)):ti,ab,kw (Word variations have been searched)

#4 ((bed next sore*) or bedsore*):ti,ab,kw (Word variations have been searched)

#5 {or #1-#4}

#6 MeSH descriptor: [Role] explode all trees

#7 MeSH descriptor: [Physician's Practice Patterns] explode all trees

#8 MeSH descriptor: [Nurse's Practice Patterns] explode all trees

#9 ((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) near/4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*)):ti,ab,kw (Word variations have been searched)

#10 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or prosthetist? or profession*) near/4 (role? or skill? or duty or duties or task* or responsibilit* or charg* or reprofil*)):ti,ab,kw (Word variations have been searched)

#11 {or #6-#10}

#12 MeSH descriptor: [Patient Care Team] explode all trees

#13 MeSH descriptor: [Interprofessional Relations] explode all trees

#14 (interdisciplinar* or multidisciplinar* or interprofessional* or multi?profession*):ti,ab,kw (Word variations have been searched)

#15 {or #12-#14}

#16 MeSH descriptor: [Patient Care Management] explode all trees

#17 MeSH descriptor: [Continuity of Patient Care] explode all trees

#18 MeSH descriptor: [Health Planning] explode all trees

#19 MeSH descriptor: [Delivery of Health Care] explode all trees

#20 pathway*:ti,ab,kw (Word variations have been searched)

#21 ((integrat* or comprehensive or "patient centered" or "patient-centered" or "patient centred" or "patient-centred" or continu* or transmural*) near/4 (care or system?)):ti,ab,kw

#22 ((case or care) near/4 (co?ordination or management or meeting* or discussion* or consultat* or refer*)):ti,ab,kw

#23 ((skill or team or staff* or grade) near/4 (mix or substitut* or re-profil*)):ti,ab,kw

#24 (staff* near/4 level*):ti,ab,kw

#25 telemedicine or telehealth or telecommunic* or teleconsult*:ti,ab,kw

#26 ((refer* or consult*) near/4 (special* or expert*))

#27 {or #16-#26}

#28 MeSH descriptor: [Personal Satisfaction] explode all trees

#29 MeSH descriptor: [Reinforcement (Psychology)] explode all trees

#30 MeSH descriptor: [Motivation] explode all trees

#31 MeSH descriptor: [Reward] explode all trees

#32 MeSH descriptor: [Reimbursement, Incentive] explode all trees

#33 {or #28-#32}

#34 MeSH descriptor: [Health Personnel] explode all trees

#35 {and #33-#34}

#36 MeSH descriptor: [Job Satisfaction] explode all trees

#37 MeSH descriptor: [Workplace] explode all trees

#38 {or #35-#37}

#39 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) near/4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)):ti,ab,kw (Word variations have been searched)

#40 organi?ational:ti,ab,kw (Word variations have been searched)

#41 {or #39-#40}

#42 {or #11, #15, #27, #35, #38, #41}

#43 {and #5, #42} in Trials

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

2 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER

3 (decubitus next (ulcer* or sore*)) AND INREGISTER

4 ((bed next sore*) or bed sore*) AND INREGISTER

5 #1 OR #2 OR #3 OR #4

6 MESH DESCRIPTOR Role EXPLODE ALL AND INREGISTER

7 MESH DESCRIPTOR Practice Patterns, Physicians' EXPLODE ALL AND INREGISTER

8 MESH DESCRIPTOR Practice Patterns, Nurses' EXPLODE ALL AND INREGISTER

9 ((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) NEAR4 (role* or boundar* or pattern* or professional* or practice* or responsibilit*)) AND INREGISTER

10 ((nurse* or physician* or practitioner* or pharmacist* or therapist* or assistant* or doctor* or podiatrist* or orthotist* or prosthetist* or profession*) NEAR4 (role* or skill* or duty or duties or task* or responsibilit* or charg* or reprofil*)) AND INREGISTER

11 #10 OR #9 OR #8 OR #7 OR #6

12 MESH DESCRIPTOR Patient Care Team EXPLODE ALL AND INREGISTER

13 MESH DESCRIPTOR Interprofessional Relations EXPLODE ALL AND INREGISTER

14 (interdisciplinar* or multidisciplinar* or interprofessional* or multi-profession* OR multiprofession*) AND INREGISTER

15 #12 OR #13 OR #14

16 MESH DESCRIPTOR Patient Care Management EXPLODE ALL AND INREGISTER

17 MESH DESCRIPTOR Continuity of Patient Care EXPLODE ALL AND INREGISTER

18 MESH DESCRIPTOR Health Planning EXPLODE ALL AND INREGISTER

19 MESH DESCRIPTOR Delivery of Health Care EXPLODE ALL AND INREGISTER

20 pathway* AND INREGISTER

21 ((integrat* or comprehensive or "patient centered" or "patient centred" or "patient-centered" OR "patient-centred" or continu* or transmural) NEAR4 (care or system* or service* or deliv*)) AND INREGISTER

22 ((case or care) NEAR4 (co-ordination or coordination or management or meeting* or discussion* or consultat* or refer*)) AND INREGISTER

23 ((skill or team or staff* or grade) NEAR4 (mix or substitut* or re-profil*)) AND INREGISTER

24 (staff* NEAR4 level*) AND INREGISTER

25 (telemedicine or telehealth or telecommunic* or teleconsult*) AND INREGISTER

26 ((refer* or consult*) NEAR4 (special* or expert*)) AND INREGISTER

27 #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26

28 MESH DESCRIPTOR Personal Satisfaction EXPLODE ALL AND INREGISTER

29 MESH DESCRIPTOR Reinforcement (Psychology) EXPLODE ALL AND INREGISTER

30 MESH DESCRIPTOR Motivation EXPLODE ALL AND INREGISTER

31 MESH DESCRIPTOR Reward EXPLODE ALL AND INREGISTER

32 MESH DESCRIPTOR Reimbursement, Incentive EXPLODE ALL AND INREGISTER

33 MESH DESCRIPTOR Job Satisfaction EXPLODE ALL AND INREGISTER

34 MESH DESCRIPTOR Workplace EXPLODE ALL AND INREGISTER

35 #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34

36 MESH DESCRIPTOR Health Personnel EXPLODE ALL AND INREGISTER

37 #35 AND #36

38 ((nurse* or physician* or practitioner* or pharmacist* or therapist* or assistant* or doctor* or podiatrist* or orthotist* or prosthetist* or profession*) NEAR4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)) AND INREGISTER

39 organisational OR organizational AND INREGISTER

40 #38 OR #39

41 #40 OR #37 OR #27 OR #15 OR #11

42 #5 AND #41

Ovid MEDLINE

1 exp Pressure Ulcer/

2 (pressure adj (ulcer* or sore* or injur*)).tw.

3 (decubitus adj (ulcer* or sore*)).tw.

4 (bedsore* or bed sore*).tw.

5 or/1-4

6 exp Role/

7 exp Physicians's Practice Patterns/

8 exp Nurse's Practice Patterns/

9 ((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) adj4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*)).ti,ab.

10 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) adj4 (role? or skill? or duty or duties or task* or responsibilit* or charg* or reprofil*)).ti,ab.

11 or/6-10

12 exp Patient Care Team/

13 exp Interprofessional Relations/

14 (interdisciplinar* or multidisciplinar* or interprofessional* or multi?profession*).ti,ab.

15 or/12-14

16 exp Patient Care Management/

17 exp Continuity of Patient Care/

18 exp Health Planning/

19 exp Delivery of Health Care/

20 pathway*.ti,ab.

21 ((integrat* or comprehensive or "patient centered" or "patient-centered" or "patient-centred" or "patient centred" or continu* or seamless or re?organis* or co?ordinat* or transmural?) adj4 (care or system? or service? or deliv*)).ti,ab.

22 ((case or care) adj4 (co?ordination or management or meeting* or discussion* or consultat* or refer*)).ti,ab.

23 ((skill or team or staff* or grade) adj4 (mix or substitut* or re-profil*)).ti,ab.

24 (staff* adj4 level*).ti,ab.

25 (telemedicine or telehealth or telecommunic* or teleconsult*).ti,ab.

26 ((refer* or consult*) adj4 (special* or expert*)).ti,ab.

27 or/16-26

28 Personal Satisfaction/

29 exp "Reinforcement (Psychology)"/

30 exp Motivation/

31 exp Reward/

32 "Reimbursement, Incentive"/

33 or/28-32

34 exp Health Personnel/

35 33 and 34

36 Job Satisfaction/

37 Workplace/

38 or/35-37

39 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) adj4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)).ti,ab.

40 organi?ational.ti,ab.

41 og.fs.

42 11 or 15 or 27 or 38 or 39 or 40 or 41

43 5 and 42

44 randomized controlled trial.pt.

45 controlled clinical trial.pt.

46 randomi?ed.ab.

47 placebo.ab.

48 clinical trials as topic.sh.

49 randomly.ab.

50 trial.ti.

51 non-randomized controlled trials as topic/

52 interrupted time series analysis/

53 controlled before-after studies/

54 ((before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or time series or time point? or repeated measur*).ti,ab.

55 or/44-54

56 exp animals/ not humans.sh.

57 55 not 56

58 43 and 57

Ovid Embase

1 exp decubitus/

2 (pressure adj (ulcer* or sore* or injur*)).tw.

3 (decubitus adj (ulcer* or sore*)).tw.

4 (bedsore* or bed sore*).tw.

5 or/1-4

6 role playing/

7 clinical practice/

8 exp nursing practice/

9 ((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) adj4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*)).ti,ab.

10 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or prosthetist? or profession*) adj4 (role? or skill? or duty or duties or task* or responsibilit* or charg* or reprofil*)).ti,ab.

11 or/6-10

12 interdisciplinary communication/

13 team building/ or team nursing/

14 (interdisciplinar* or multidisciplinar* or interprofessional* or multi?profession*).ti,ab.

15 or/12-14

- 16 exp *patient care/
- 17 exp *health care planning/
- 18 exp *patient care planning/
- 19 exp *program development/
- 20 exp *health care management/
- 21 exp *health care delivery/
- 22 pathway*.ti,ab.
- 23 ((integrat* or comprehensive or "patient centered" or "patient-centered" or "patient centred" or "patient-centred" or continu* or seamless or re?organis? or co?ordinat* or transmural*) adj4 (care or system? or service? or deliv*)).ti,ab.
- 24 ((case or care) adj4 (co?ordination or management or meeting* or discussion* or consultat* or refer*)).ti,ab.
- 25 ((skill or team or staff* or grade) adj4 (mix or substitut* or re-profil*)).ti,ab.
- 26 (staff* adj4 level*).ti,ab.
- 27 exp telehealth/
- 28 (telemedicine or telehealth or telecommunic* or teleconsult*).ti,ab.
- 29 ((refer* or consult*) adj4 (special* or expert*)).ti,ab.
- 30 or/16-29
- 31 exp satisfaction/
- 32 reinforcement/
- 33 reward/
- 34 motivation/
- 35 reimbursement/
- 36 or/31-35
- 37 exp health care personnel/
- 38 36 and 37
- 39 ((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) adj4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)).ti,ab.
- 40 organi?ational.ti,ab.
- 41 11 or 15 or 30 or 38 or 39 or 40
- 42 5 and 41
- 43 Randomized controlled trials/
- 44 Single-Blind Method/
- 45 Double-Blind Method/
- 46 Crossover Procedure/
- 47 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.
- 48 (doubl* adj blind*).ti,ab.
- 49 (singl* adj blind*).ti,ab.

50 controlled clinical trial/

51 quasi experimental study/

52 pretest posttest control group design/

53 time series analysis/

54 ((before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or time series or time point? or repeated measur*).ti,ab.

55 or/43-54

56 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/

57 human/ or human cell/

58 and/56-57

59 56 not 58

60 55 not 59

61 42 and 60

EBSCO CINAHL Plus

S63 S45 AND S62

S62 S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61

S61 TI (before N5 after or pre N5 post or ((pretest or "pre test") and (posttest or "post test"))) or quasiexperiment* or quasi W0 experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or "time series" or time W0 point* or repeated W0 measur*) OR AB (before N5 after or pre N5 post or ((pretest or "pre test") and (posttest or "post test"))) or quasiexperiment* or quasi W0 experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or "time series" or time W0 point* or repeated W0 measure)

S60 (MH "Pretest-Posttest Design+")

S59 (MH "Controlled Before-After Studies")

S58 (MH "Interrupted Time Series Analysis")

S57 TI allocat* random* or AB allocat* random*

S56 MH "Quantitative Studies"

S55 TI placebo* or AB placebo*

S54 MH "Placebos"

S53 TI random* allocat* or AB random* allocat*

S52 MH "Random Assignment"

S51 TI randomi?ed control* trial* or AB randomi?ed control* trial*

S50 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)

S49 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)

S48 TI clinic* N1 trial* or AB clinic* N1 trial*

S47 PT Clinical trial

S46 MH "Clinical Trials+"

S45 S5 AND S44

S44 S10 OR S17 OR S29 OR S37 OR S42 OR S43

Organisation of health services for preventing and treating pressure ulcers (Review)

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S43 TI organi?ational OR AB organi?ational

S42 S38 OR S39 OR S40 OR S41

S41 TI (((nurse? or physician? or practitioner? or pharmacist? or therapist? or or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) N4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*))) OR AB (((nurse? or physician? or practitioner? or pharmacist? or therapist? or or assistant? or doctor? or podiatrist? or orthotist? or Prosthetist? or profession*) N4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)))

S40 (MH "Job Satisfaction+")

S39 (MH "Employee Incentive Programs")

S38 (MH "Physician Incentive Plans")

S37 S35 AND S36

S36 (MH "Health Personnel+")

S35 S30 OR S31 OR S32 OR S33 OR S34

S34 (MH "Personal Satisfaction+")

S33 (MH "Reward")

S32 (MH "Reinforcement (Psychology)")

S31 (MH "Motivation")

S30 (MH "Reimbursement, Incentive")

S29 S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28

S28 TI (((refer* or consult*) N4 (special* or expert*))) OR AB (((refer* or consult*) N4 (special* or expert*)))

S27 (MH "Telehealth+")

S26 TI ((telemedicine or telehealth or telecommunic* or teleconsult*)) OR AB ((telemedicine or telehealth or telecommunic* or teleconsult*))

S25 TI (staff* N4 level*) OR AB (staff* N4 level*)

S24 TI ((skill or team or staff* or grade) N4 (mix OR substitut* or re-profil*)) OR AB ((skill or team or staff* or grade) N4 (mix OR substitut* or re-profil*))

S23 TI (((case or care) N4 (coordination or co-ordination or management or meeting* or discussion* or consultat* or refer*))) OR AB (((case or care) N4 (coordination or co-ordination or management or meeting* or discussion* or consultat* or refer*)))

S22 TI (((integrat* or comprehensive or "patient centered" or "patient-centered" or "patient centred" or "patient-centred" or continu* or seamless or re-organis* or reorganis* OR coordinat* OR co-ordinat* OR transmural*) N4 (care or system? or service? or deliv*))) OR AB (((integrat* or comprehensive or "patient centered" or "patient-centered" or "patient centred" or "patient-centred" or continu* or seamless or re-organis* or reorganis* OR coordinat* OR co-ordinat* or transmural*) N4 (care or system? or service? or deliv*)))

S21 TI pathway* OR AB pathway*

S20 (MH "Patient Care+")

S19 (MH "Health Care Delivery+")

S18 (MH "Health and Welfare Planning+")

S17 S11 OR S12 OR S13 OR S14 OR S15 OR S16

S16 TI (interdisciplinary* or multidisciplinary* or interprofessional OR multi-profession* OR multiprofession*) OR AB (interdisciplinary* or multidisciplinary* or interprofessional OR multi-profession* OR multiprofession*)

S15 (MH "Interprofessional Relations")

S14 (MH "Multidisciplinary Care Team")

S13 (MH "Team Nursing")

S12 (MH "Team Building")

S11 (MH "Teamwork")

S10 S6 OR S7 OR S8 OR S9

S9 TI (((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or prosthetist? or profession*) N4 (role? or skill? or duty or duties or task* or responsibilit* or charg* or reprofil*))) OR AB (((nurse? or physician? or practitioner? or pharmacist? or therapist? or assistant? or doctor? or podiatrist? or orthotist? or prosthetist? or profession*) N4 (role? or skill? or duty or duties or task* or responsibilit* or charg* or reprofil*)))

S8 TI (((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) N4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*))) OR AB (((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) N4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*)))

S7 (MH "Practice Patterns")

S6 (MH "Role")

S5 S1 OR S2 OR S3 OR S4

S4 TI decubitus OR AB decubitus

S3 TI ((bed sore* or bedsore*)) OR AB ((bed sore* or bedsore*))

S2 TI ((pressure ulcer* or pressure sore* or pressure injur*)) OR AB ((pressure ulcer* or pressure sore* or pressure injur*))

S1 (MH "Pressure Ulcer+")

Appendix 2. 'Risk of bias' criteria: individually randomised controlled trials

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process provided to permit a judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: use of an open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. envelopes were unsealed, non-opaque, or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information provided to permit a judgement of low or high risk of bias. This is usually the case if the method of concealment is not described, or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?**Low risk of bias**

Any one of the following:

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following:

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Either of the following:

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?**Low risk of bias**

Any one of the following:

- No missing outcome data.
- Reasons for missing outcome data are unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data are balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is not enough to have a clinically relevant impact on the observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following:

- Reason for missing outcome data are likely to be related to the true outcome, with either an imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk is enough to induce clinically relevant bias in the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is enough to induce a clinically relevant bias in the observed effect size.
- 'As-treated' analysis done with a substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either of the following:

- Insufficient reporting of attrition/exclusions to permit a judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Either of the following:

- The study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following:

- Not all of the study's prespecified primary outcomes have been reported.
- One or more primary outcomes is/are reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified.
- One or more reported primary outcomes was/were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review is/are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information provided to permit a judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 3. 'Risk of bias' criteria: cluster-controlled trials

In cluster-randomised trials, particular biases to consider include recruitment bias; baseline imbalance; loss of clusters; incorrect analysis; and comparability with individually randomised trials.

- Recruitment bias can occur when individuals are recruited to the trial after the clusters have been randomly assigned, as knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.
- Cluster randomised trials often randomly assigned all clusters at once, so lack of concealment of an allocation sequence should not usually be an issue. However, because small numbers of clusters are randomly assigned, there is a possibility of chance baseline imbalance between randomly assigned groups, in terms of the clusters or the individuals. Although not a form of bias as such, the risk of baseline differences can be reduced by using stratified or pair-matched randomisation of clusters. Reporting of the baseline comparability of clusters, or statistical adjustment for baseline characteristics, can help reduce concern about the effects of baseline imbalance.

- Occasionally, complete clusters are lost from a trial and have to be omitted from the analysis. Just as for missing outcome data in individually randomised trials, this may lead to bias. In addition, missing outcomes for individuals within clusters may lead to risk of bias in cluster randomised trials.
- Many cluster randomised trials are analysed by incorrect statistical methods, without taking the clustering into account. Such analyses create a 'unit of analysis error' and produce overly precise results (the standard error of the estimated intervention effect is too small) and P values that are too small. They do not lead to biased estimates of effect. However, if they remain uncorrected, they will receive too much weight in a meta-analysis.
- In a meta-analysis including both cluster and individually randomised trials, or including cluster randomised trials with different types of clusters, possible differences between the intervention effects estimated need to be considered. For example, in a vaccine trial of infectious diseases, a vaccine applied to all individuals in a community would be expected to be more effective than vaccine applied to only half of the people. Another example is provided by a Cochrane Review of hip protectors ([Hahn 2005](#)). The cluster trials showed a large positive effect, whereas individually randomised trials did not show clear benefit. One possibility is that there was a 'herd effect' in the cluster randomised trials (which were often performed in nursing homes, where compliance with using the protectors may have been enhanced). In general, such 'contamination' would lead to underestimates of effect. Thus, if an intervention effect is still demonstrated despite contamination in those trials that were not cluster randomised, a confident conclusion about the presence of an effect can be drawn. However, the size of the effect is likely to be underestimated. Contamination and 'herd effects' may be different for different types of clusters.

Appendix 4. ROBINS-I 'Risk of bias' table (transmural care versus usual care for preventing and treating pressure ulcers)

Bloemen-Vrencken 2007	
Study design	Controlled before-and-after study
Participants	62 people with spinal cord injuries
Experimental intervention	<p>In addition to the usual follow-up care by the rehabilitation doctor at the rehabilitation centre, the participants in the intervention group had access to transmural care for at least one year after discharge. The core component of the transmural care consists of a transmural nurse as liaison between people with spinal cord injury living in the community, primary care professionals and the rehabilitation centre. The transmural nurse is a member of the clinical rehabilitation team (also works as a nurse at the spinal cord unit) and is engaged for 8 hours per week to perform 4 main tasks:</p> <ol style="list-style-type: none"> to support people with spinal cord injury and their partner/family with their health problems, which come within the scope of the nursing discipline to support primary care professionals with the specific care of people with spinal cord injury to promote continuity of care between primary care professionals and the rehabilitation team to give feedback and initiate improvements in care for the rehabilitation team, based on the experiences with patients.
Comparator	The participants in the usual follow-up-care group were able to make use of periodic outpatient visits to the rehabilitation doctor at their rehabilitation centre. During these visits a comprehensive assessment of functioning (i.e. physical, psychological, social and communicative functioning, and functioning regarding activities of daily living) was performed and, if necessary, interventions were applied or other forms of support given.

Is your aim for this study...?

No	to assess the effect of <i>assignment to</i> intervention
----	---

(Continued)

Yes to assess the effect of *starting and adhering to* intervention

Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the 'Summary of findings' table). Specify whether this is a proposed benefit or harm of intervention.

Pressure ulcer prevalence

Specify the numerical result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR (risk ratio) = 1.52 (95% CI (confidence interval) 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph), that uniquely defines the result being assessed.

RR 0.93 (0.53 to 1.64) ('Summary of findings' table 1)

Confounding domains relevant to the setting of this particular study, or which the study authors identified as important

Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
Pre-intervention Bias due to confounding	Baseline characteristics (comparable among groups)	Yes	Yes	N/A
Pre-intervention Bias in selection of participants into the study	How the participants were allocated to the study groups	No	No information	Favour experimental
At intervention Bias in classification of interventions	Performance bias (non-blinded)	No	No information	Favour experimental
Post-intervention Bias due to deviations from intended interventions	Performance bias (transmural care was incompletely implemented)	No	Yes	Favour comparator
Post-intervention Bias due to missing data	Attrition bias (loss to follow-up of 8 participants in the inter-	No	Yes	Favour experimental

(Continued)

vention group and 26 participants in the control group)

Post-intervention	Detection bias	No	No information	Favour experimental
Bias in measurement of outcomes				
Post-intervention	Reporting bias	No	No information (protocol for the trial not registered)	Favour experimental
Bias in selection of the reported result				

Abbreviations used in risk of bias assessment:

Y = yes

PY = probably yes

PN = probably no

N = no

NI = no information

'Risk of bias' assessment

Signalling questions	Description	Response options
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study?	<p>Quote: "Matching patients on level and motor completeness of the spinal cord injury, gender and age"</p> <p>Quote: "Participants were recruited from the Dutch research programme 'Physical strain, work capacity, and mechanisms of restoration of mobility in the rehabilitation of people with spinal cord injuries'. This programme consists of 18 research projects conducted in a network of eight rehabilitation centres specialized in the rehabilitation of people with spinal cord injury and five research groups"</p> <p>Quote: "Since pressure sores and bladder problems frequently occur and are important causes for follow-up care models for spinal cord-injured patients re-admission in hospital and rehabilitation centres, the primary outcome measures were as follows: The prevalence of pressure sores and urinary tract infections reported during the first year after discharge. For these complications the patients were asked to indicate whether or not they had faced the problem during the previous 12 months. For pressure sores, additional questions were asked about the type, location and seriousness. The number and duration of re-admissions to hospital and rehabilitation centre due to pressure sores, bladder and bowel problems in the first year after discharge."</p>	NI
If N/PN to 1.1: the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered		

(Continued)

Comment: not clear if there were similar levels of pressure ulcer (or other study outcomes) in 2 groups at baseline. Participants were pre-enrolled in an earlier study, so it is not clear if there were baseline differences in pre-this study treatments of the participants allocated to transmural or usual-care groups- the link in the paper no longer works.

If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:

1.2. Was the analysis based on splitting participants' follow-up time according to intervention received?

Comment: no discussion if participant allocation changed over time; it is hard to tell if it is likely that participants could have moved between rehabilitation centres.

NI

If N/PN, answer questions relating to baseline confounding (1.4 to 1.6)

If Y/PY, go to question 1.3.

1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?

NI

If N/PN, answer questions relating to baseline confounding (1.4 to 1.6)

If Y/PY, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)

Questions relating to baseline confounding only

1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?

Quote: "Matching patients on level and motor completeness of the spinal cord injury, gender and age" p998

N

Quote: "Differences regarding the outcomes measures in

the intervention and usual follow-up care groups

were tested with the Fisher exact test ($P < 0.05$)."

Comment: no evidence of statistical or matching control for baseline imbalances in pressure ulcer

(Continued)

1.5. **If Y/PY to 1.4:** Were confounding domains that were controlled for measured validly and reliably by the variables available in this study? NA

1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention? **Quote:** "Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available"
Comment: participants without data availability were excluded PY

Questions relating to baseline and time-varying confounding

1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding? **Quote:** "Differences regarding the outcomes measures in the intervention and usual follow-up care groups were tested with the Fisher exact test ($P < 0.05$)."
Comment: no evidence of pre-testing on outcome variables N

1.8. **If Y/PY to 1.7:** Were confounding domains that were controlled for measured validly and reliably by the variables available in this study? NA

'Risk of bias' judgement

Serious: at least one known important domain was not appropriately controlled for

Optional: What is the predicted direction of bias due to confounding? **Uncertain**

Bias in selection of participants into the study

2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **Quote:** "For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available."
If N/PN to 2.1: go to 2.4 **Comment:** participants retrospectively matched on basis of complete data available Y

(Continued)

<p>2.2. If Y/PY to 2.1: Were the post-intervention variables that influenced selection likely to be associated with intervention?</p>	<p>Quote: “The transmural care group consisted of 39 people and the usual follow-up care group consisted of 110 people. Six people died during the 12 months of follow-up, three were excluded from follow-up since they were not dependent on a wheelchair anymore, and four were not able to visit the rehabilitation centre for follow-up measurements due to secondary complications. Non-medical reasons for withdrawal were lack of motivation (n = 14) and address unknown (n = 7). There were 31 participants who received the intervention and who were followed up at 12 months. There were 84 participants with follow-up measurements in the usual follow-up care group. Matching was applied with regard to the level and motor completeness of the injury, gender and age. Twenty-eight participants in the intervention group (90.3%) were matched to participants of the control group within five years of age and same sex and same level and motor completeness of the injury”</p>	<p>PN NA</p>
<p>2.3 If Y/PY to 2.2: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?</p>	<p>Comment: not clear, less likely that that level and motor completeness of injury, gender and age would change after 12 months; intervention does not appear to address functional restoration.</p>	
<p>2.4. Do start of follow-up and start of intervention coincide for most participants?</p>	<p>Quote: “For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available.”</p> <p>Quote: “Since pressure sores and bladder problems frequently occur and are important causes for follow-up care models for spinal cord-injured patients re-admission in hospital and rehabilitation centres, the primary outcome measures were as follows: The prevalence of pressure sores and urinary tract infections reported during the first year after discharge. For these complications the patients were asked to indicate whether or not they had faced the problem during the previous 12 months. For pressure sores, additional questions were asked about the type, location and seriousness. The number and duration of re-admissions to hospital and rehabilitation centre due to pressure sores, bladder and bowel problems in the first year after discharge.”</p>	<p>N</p>
<p>2.5. If Y/PY to 2.2 and 2.3, or N/PN to 2.4: Were adjustment techniques used that are likely to correct for the presence of selection biases?</p>	<p>Quote: “Differences regarding the outcomes measures in the intervention and usual follow-up care groups were tested with the Fisher exact test ($P < 0.05$).”</p> <p>Comment: no adjustment made for possible selection bias</p>	<p>N</p>
<p>'Risk of bias' judgement</p>	<p>Not an RCT, no allocation concealment</p>	<p>Critical: selection into the study occurred after the fact, the authors</p>

(Continued)

didn't use appropriate adjustment, post intervention/retrospective data collection

Optional: what is the predicted direction of bias due to selection of participants into the study?

Unpredictable

Bias in classification of interventions

3.1 Were intervention groups clearly defined?

Quote: "Thirty-one patients who received transmural care in two 'experimental' rehabilitation centres were compared with a matched sample of 31 patients having received 'usual follow-up care' in six other rehabilitation centres."

Y

Quote: "The intervention and usual follow-up care groups differed with respect to the intensity of follow-up care given by the rehabilitation centre after conclusion of clinical rehabilitation"

Comment: yes

3.2 Was the information used to define intervention groups recorded at the start of the intervention?

Quote: "Thirty-one patients who received transmural care in two 'experimental' rehabilitation centres were compared with a matched sample of 31 patients having received 'usual follow-up care' in six other rehabilitation centres."

PY/NI

Comment: possibly yes/not clear this might be a study that was thought about after the fact

3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?

Quote: "Thirty-one patients who received transmural care in two 'experimental' rehabilitation centres were compared with a matched sample of 31 patients having received 'usual follow-up care' in six other rehabilitation centres."

PY/NI

Quote: "For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available."

Comment: no-classification as per treatment centre, but participants with incomplete data were dropped from study; i.e. we can't fully assess this as no baseline pressure ulcer data available for people who were excluded due to missing data.

'Risk of bias' judgement

Moderate: some aspects of assignment were determined retrospectively

(Continued)

Optional: what is the predicted direction of bias due to classification of interventions?

Unpredictable

Bias due to deviations from intended interventions

If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2

4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?

Quote: "Although the transmural nurses spent most of their time on the individual support of patients after discharge, only 15 patients (48%) received the number of contacts indicated in the protocol (6 contacts). The remaining patients had fewer contacts and two patients (6.5%) chose to organize their care autonomously and to contact the transmural nurse on their own initiative. On average there were 4.3 contacts (SD 2.4) per patient in the first year after discharge. In one of the 'experimental' rehabilitation centres the number of contacts (average of 3.4 versus 5.2, SD in both centres 2.2) and the variation in types of contacts were fewer compared with the other 'experimental' rehabilitation centre. The number of interventions per patient were also different in the two 'experimental' rehabilitation centres (average of 1.3 versus 2.3, SD in both centres 1.5)."

NI/PN

Quote: "For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available."

Comment: participants didn't get the full 'dose' of intervention as expected and there is variation between patients' use of the intervention between the intervention rehabilitation centres- unclear if a 1.8 visit difference is clinically significant nor if the overall deviation is different from what would happen in usual practice. Flow diagram dropout similar across groups; nonetheless, it is unclear how many intervention participants did not meet the retrospectively applied inclusion criteria of having data collected at 12 months, i.e. the amount of true deviation is unclear.

4.2. **If Y/PY to 4.1:** Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?

No quote

NI

Comment: no information

(Continued)

If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6

4.3. Were important co-interventions balanced across intervention groups?	Comment: co-interventions not recorded e.g. number of doctor or nurse contacts	NI
4.4. Was the intervention implemented successfully for most participants?	<p>Quote: "Although the transmural nurses spent most of their time on the individual support of patients after discharge, only 15 patients (48%) received the number of contacts indicated in the protocol (6 contacts). The remaining patients had fewer contacts and two patients (6.5%) chose to organize their care autonomously and to contact the transmural nurse on their own initiative. On average there were 4.3 contacts (SD 2.4) per patient in the first year after discharge. In one of the 'experimental' rehabilitation centres the number of contacts (average of 3.4 versus 5.2, SD in both centres 2.2) and the variation in types of contacts were fewer compared with the other 'experimental' rehabilitation centre. The number of interventions per patient were also different in the two 'experimental' rehabilitation centres (average of 1.3 versus 2.3, SD in both centres 1.5)."</p> <p>Comment: most participants did not receive expected full 'dose' of the intervention, reason for this is unclear.</p>	N
4.5. Did study participants adhere to the assigned intervention regimen?	<p>Quote: "and two patients (6.5%) chose to organize their care autonomously and to contact the transmural nurse."</p> <p>Comment: 2 participants did not adhere to way intervention was offered, it is unclear why most participants did not receive intervention planned, i.e. transmural nurse issue e.g. sickness or participant adherence to contact times.</p>	PN/NI
4.6. If N/PN to 4.3, 4.4 or 4.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?	Comment: no weighting etc. analysis undertaken	N
'Risk of bias' judgement		Moderate: based on answers to 4.2, deviation from protocol apparent but unclear if deviation sufficient to have an effect
Optional: what is the predicted direction of bias due to deviations from the intended interventions?		Uncertain

Bias due to missing data

5.1 Were outcome data available for all, or nearly all, participants?	<p>Quote: “For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available.”</p> <p>Comment: participants were selected on basis that follow-up data were available, therefore all data available.</p>	Y
5.2 Were participants excluded due to missing data on intervention status?	<p>No quote</p> <p>Comment: probably no, the participants were selected on the basis they attended specific treatment centres</p>	PN
5.3 Were participants excluded due to missing data on other variables needed for the analysis?	<p>Quote: “For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available.”</p> <p>Comment: unclear how many people were excluded from the study due to incomplete 12-month follow-up data</p>	Y
5.4 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across interventions?	<p>Quote: “For each subject in the experimental group, a subject in the control group was selected who was similar with regard to level and motor completeness of the spinal cord injury, gender and age. Matching between the groups was done at the 12-month point, to include only those for whom 12-month follow-up data were available.”</p> <p>Comment: most people were removed from analysis due to not matching participants, i.e. retrospective matching criteria applied last. However, it is not known if there was a difference between not having complete 12-month data for the control and intervention groups</p>	PY
5.5 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Is there evidence that results were robust to the presence of missing data?	<p>No quote</p> <p>Comment: no information to assess this, i.e. no missing data analysis undertaken</p>	NI
'Risk of bias' judgement		Moderate -it is not known how many people were excluded from the study on the basis of incomplete outcome data and if this differed between the groups.
Optional: What is the predicted direction of		Unpredictable

(Continued)

bias due to missing data?

Bias in measurement of outcomes

6.1 Could the outcome measure have been influenced by knowledge of the intervention received?

Quote: “The prevalence of pressure sores and urinary tract infections reported during the first year after discharge. For these complications the patients were asked to indicate whether or not they had faced the problem during the previous 12 months. For pressure sores, additional questions were asked about the type, location and seriousness.”

PN

Comment: participants who couldn't be blinded to this intervention reported pressure ulcer data, reporting having a pressure ulcer is probably unlikely to have been influenced by knowledge of the intervention

6.2 Were outcome assessors aware of the intervention received by study participants?

Comment: no mention of assessor/data collector blinding

NI

6.3 Were the methods of outcome assessment comparable across intervention groups?

Quote: “The prevalence of pressure sores and urinary tract infections reported during the first year after discharge. For these complications the patients were asked to indicate whether or not they had faced the problem during the previous 12 months. For pressure sores, additional questions were asked about the type, location and seriousness.”

PY

Comment: probably yes, no differences reported

6.4 Were any systematic errors in measurement of the outcome related to intervention received?

Comment: possible as patient-report based, ? if someone with a spinal injury would know/wouldn't know they had a pressure ulcer

NI

'Risk of bias' judgement

Low: prevalence of pressure ulcer unlikely to be influenced by knowledge of intervention

Optional: what is the predicted direction of bias due to measurement of outcomes?

Unpredictable

Bias in selection of the reported result

(Continued)

Is the reported effect estimate likely to be selected, on the basis of the results, from...

7.1. ... multiple outcome <i>measurements</i> within the outcome domain?	Comment: some multiple domain reporting, but no differences noted	N
7.2 ... multiple <i>analyses</i> of the intervention-outcome relationship?	<p>Quote: “There were also no significant effects found in the prevalence of spasms, pain, oedema, respiratory tract infections, autonomic dysreflexia, low blood pressure and increasing weight.”</p> <p>Comment: Outcome measures - pressure sores, urinary tract infection, re-admissions and, views of care in methods section are reported. Outcomes for measures not reported in methods section are also reported. No difference between intervention and matched controls is found</p>	N
7.3 ... different <i>subgroups</i> ?	Comment: no subgroup analysis (other than retrospective of participants for whom data were available)	N
'Risk of bias' judgement		Low
Optional: what is the predicted direction of bias due to selection of the reported result?		Unpredictable

Overall bias

'Risk of bias' judgement	Critical- as one critical reported
Optional: what is the overall predicted direction of bias for this outcome?	Unpredictable

CONTRIBUTIONS OF AUTHORS

Pauline Joyce: conceived, designed and coordinated the review; extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; produced the first draft of the review; contributed to writing or editing the review; wrote to study authors/experts/companies; approved the final review prior to submission and is guarantor of the review.

Zena Moore: conceived and designed the review; extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; produced the first draft of the review; contributed to writing or editing the review and approved the final review prior to submission.

Janice Christie: conceived and designed the review; analysed or interpreted data; undertook and checked quality assessment; contributed to writing or editing the review; advised on the review; performed previous work that was the foundation of the current review and approved the final review prior to submission.

Contributions of editorial base:

Nicky Cullum (Coordinating Editor): edited the protocol; advised on methodology, interpretation and content; approved the final protocol prior to publication.

Gill Norman (Editor): edited the review; advised on methodology, interpretation and content; approved the final review prior to publication.

Gill Rizzello (Managing Editor): coordinated the editorial process; advised on interpretation and content; edited the protocol and the review.

Naomi Shaw and Reetu Child (Information Specialists): designed the search strategy, ran the searches and edited the search methods section.

Ursula Gonthier (Editorial Assistant): edited the Plain language summary and reference sections of the protocol and the review.

DECLARATIONS OF INTEREST

Pauline Joyce: none known.

Zena Moore: has received an honorarium for speaking at professional meetings for Smith & Nephew and Molnlycke. The School of Nursing and Midwifery, RCSI has received a research grant from BSN Medical.

Janice Christie: none known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

To assess bias in regards to non-randomised results, we planned to use ACROBAT-NRSI tool. However, we used the ROBINS-I tool as this is now standard practice for such studies. We have reported on all primary outcomes in the 'Summary of findings' table and added 'time to complete healing' in the 'Summary of findings' table for treatment studies.

INDEX TERMS

Medical Subject Headings (MeSH)

*Health Services Administration; Controlled Before-After Studies; Home Care Services, Hospital-Based; Hospitalization; Incidence; Patient Care Team; Pressure Ulcer [epidemiology] [prevention & control] [*therapy]; Randomized Controlled Trials as Topic; Spinal Cord Injuries [complications]; Wound Healing

MeSH check words

Adult; Aged; Aged, 80 and over; Humans; Middle Aged