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Intensive case management for severe mental illness (Review)

Dieterich M, Irving CB, Bergman H, Khokhar MA, Park B, Marshall M

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[Intervention Review]

Intensive case management for severe mental illness

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ABSTRACT

Background

Intensive Case Management (ICM) is a community-based package of care aiming to provide long-term care for severely mentally ill people who do not require immediate admission. Intensive Case Management evolved from two original community models of care, Assertive Community Treatment (ACT) and Case Management (CM), where ICM emphasises the importance of small caseload (fewer than 20) and high-intensity input.

Objectives

To assess the effects of ICM as a means of caring for severely mentally ill people in the community in comparison with non-ICM (caseload greater than 20) and with standard community care. We did not distinguish between models of ICM. In addition, to assess whether the effect of ICM on hospitalisation (mean number of days per month in hospital) is influenced by the intervention's fidelity to the ACT model and by the rate of hospital use in the setting where the trial was conducted (baseline level of hospital use).

Search methods

We searched the Cochrane Schizophrenia Group's Trials Register (last update search 10 April 2015).

Selection criteria

All relevant randomised clinical trials focusing on people with severe mental illness, aged 18 to 65 years and treated in the community care setting, where ICM is compared to non-ICM or standard care.

Data collection and analysis

At least two review authors independently selected trials, assessed quality, and extracted data. For binary outcomes, we calculated risk ratio (RR) and its 95% confidence interval (CI), on an intention-to-treat basis. For continuous data, we estimated mean difference (MD) between groups and its 95% CI. We employed a random-effects model for analyses.

We performed a random-effects meta-regression analysis to examine the association of the intervention's fidelity to the ACT model and the rate of hospital use in the setting where the trial was conducted with the treatment effect. We assessed overall quality for clinically important outcomes using the GRADE approach and investigated possible risk of bias within included trials.

Main results

The 2016 update included two more studies (n = 196) and more publications with additional data for four already included studies. The updated review therefore includes 7524 participants from 40 randomised controlled trials (RCTs). We found data relevant to two

comparisons: ICM versus standard care, and ICM versus non-ICM. The majority of studies had a high risk of selective reporting. No studies provided data for relapse or important improvement in mental state.

1. ICM versus standard care

When ICM was compared with standard care for the outcome service use, ICM slightly reduced the number of days in hospital per month ($n = 3595$, 24 RCTs, MD -0.86 , 95% CI -1.37 to -0.34 , *low-quality evidence*). Similarly, for the outcome global state, ICM reduced the number of people leaving the trial early ($n = 1798$, 13 RCTs, RR 0.68 , 95% CI 0.58 to 0.79 , *low-quality evidence*). For the outcome adverse events, the evidence showed that ICM may make little or no difference in reducing death by suicide ($n = 1456$, 9 RCTs, RR 0.68 , 95% CI 0.31 to 1.51 , *low-quality evidence*). In addition, for the outcome social functioning, there was uncertainty about the effect of ICM on unemployment due to very low-quality evidence ($n = 1129$, 4 RCTs, RR 0.70 , 95% CI 0.49 to 1.0 , *very low-quality evidence*).

2. ICM versus non-ICM

When ICM was compared with non-ICM for the outcome service use, there was moderate-quality evidence that ICM probably makes little or no difference in the average number of days in hospital per month ($n = 2220$, 21 RCTs, MD -0.08 , 95% CI -0.37 to 0.21 , *moderate-quality evidence*) or in the average number of admissions ($n = 678$, 1 RCT, MD -0.18 , 95% CI -0.41 to 0.05 , *moderate-quality evidence*) compared to non-ICM. Similarly, the results showed that ICM may reduce the number of participants leaving the intervention early ($n = 1970$, 7 RCTs, RR 0.70 , 95% CI 0.52 to 0.95 , *low-quality evidence*) and that ICM may make little or no difference in reducing death by suicide ($n = 1152$, 3 RCTs, RR 0.88 , 95% CI 0.27 to 2.84 , *low-quality evidence*). Finally, for the outcome social functioning, there was uncertainty about the effect of ICM on unemployment as compared to non-ICM ($n = 73$, 1 RCT, RR 1.46 , 95% CI 0.45 to 4.74 , *very low-quality evidence*).

3. Fidelity to ACT

Within the meta-regression we found that i.) the more ICM is adherent to the ACT model, the better it is at decreasing time in hospital ('organisation fidelity' variable coefficient -0.36 , 95% CI -0.66 to -0.07); and ii.) the higher the baseline hospital use in the population, the better ICM is at decreasing time in hospital ('baseline hospital use' variable coefficient -0.20 , 95% CI -0.32 to -0.10). Combining both these variables within the model, 'organisation fidelity' is no longer significant, but the 'baseline hospital use' result still significantly influences time in hospital (regression coefficient -0.18 , 95% CI -0.29 to -0.07 , $P = 0.0027$).

Authors' conclusions

Based on very low- to moderate-quality evidence, ICM is effective in ameliorating many outcomes relevant to people with severe mental illness. Compared to standard care, ICM may reduce hospitalisation and increase retention in care. It also globally improved social functioning, although ICM's effect on mental state and quality of life remains unclear. Intensive Case Management is at least valuable to people with severe mental illnesses in the subgroup of those with a high level of hospitalisation (about four days per month in past two years). Intensive Case Management models with high fidelity to the original team organisation of ACT model were more effective at reducing time in hospital.

However, it is unclear what overall gain ICM provides on top of a less formal non-ICM approach.

We do not think that more trials comparing current ICM with standard care or non-ICM are justified, however we currently know of no review comparing non-ICM with standard care, and this should be undertaken.

PLAIN LANGUAGE SUMMARY

Intensive case management for people with severe mental illness

Background

Severe mental illnesses are defined by diagnosis, degree of disability and the presence of some abnormal behaviour. Including schizophrenia and psychosis, severe mood problems, and personality disorder, severe mental illness can cause considerable distress over a long period of time to both the person affected and his or her family and friends.

Until the 1970s, it was common for those suffering from these disorders to remain in an institution for most of their lives, but in most of the countries of the world, they are now managed in the community with one of several different types of intervention. Intensive Case Management (ICM) is one such intervention. It consists of management of the mental health problem and the rehabilitation and social support needs of the person concerned, over an indefinite period of time, by a team of people who have a fairly small group of clients (fewer than 20). Twenty-four-hour help is offered and clients are seen in a non-clinical setting.

Aims of the review

To find and present good-quality evidence concerning the effectiveness of ICM compared with non-ICM (where people receive the same package of care, but the professionals have caseloads of more than 20 people) and standard care (where people are seen as outpatients, but their support needs are less clearly defined) for people with severe mental illness.

Searching for evidence

We carried out electronic searches for randomised controlled trials comparing ICM with non-ICM or standard care in 2009, 2012, and 2015.

Results

We included 40 trials involving 7524 people. The trials took place in Australia, Canada, China, Europe, and the USA. When ICM was compared to standard care, those in the ICM group were more likely to stay with the service, have improved general functioning, get a job, not be homeless, and have shorter stays in hospital (especially when they had had very long stays in hospital previously). When ICM was compared to non-ICM, the only clear difference was that those in the ICM group were more likely to be kept in care.

Conclusions

None of the evidence for the main outcomes of interest was high quality; at best the evidence was of moderate quality. In addition, the healthcare and social support systems of the countries where the studies took place were quite different, so it was difficult to make valid overall conclusions. Furthermore, we were unable to use much of the data on quality of life and patient and carer satisfaction because the trials used many different scales to measure these outcomes, some of which were not validated. The development of an overall scale and its validation would be very beneficial in producing services that people favour.

(Plain language summary initially prepared for this review by Janey Antoniou of RETHINK, UK (rethink.org))

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Intensive Case Management versus standard care for severe mental illness

Intensive Case Management versus standard care for severe mental illness

Patient or population: people with severe mental illness

Settings: community

Intervention: Intensive Case Management versus standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Intensive Case Management versus standard care				
Service use: 1. Average number of days in hospital per month - by about 24 months	-	The mean service use: 1. average number of days in hospital per month - by about 24 months in the intervention groups was 0.86 lower (1.37 lower to 0.34 lower)	-	3595 (24 studies)	⊕⊕⊕⊕ low 1,2	
Adverse event: 1b. Death - suicide - by long term	20 per 1000	13 per 1000 (6 to 30)	RR 0.68 (0.31 to 1.51)	1456 (9 studies)	⊕⊕⊕⊕ low 1,4	
Global state: 1. Relapse - by long term	-	-	-	-	-	No data available
Global state: 1. Leaving the study early - by long term	331 per 1000	225 per 1000 (192 to 262)	RR 0.68 (0.58 to 0.79)	1798 (13 studies)	⊕⊕⊕⊕ low 1,3	
Social functioning: 2. Employment status (various measurements) - by long term - not employed at the end of the trial	766 per 1000	536 per 1000 (375 to 766)	RR 0.7 (0.49 to 1)	1129 (4 studies)	⊕⊕⊕⊕ very low 1,5	
Mental state: not improved to an important extent - by long term	-	-	-	-	-	No data available

*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 assumed 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 quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹Downgraded one step for risk of bias: randomisation not well described; problematic to blind.

²Downgraded one step for inconsistency: substantial heterogeneity ($I^2 = 74\%$).

³Downgraded one step for selective reporting bias: only 13 studies reported fully on the flow of participants through the study.

⁴Downgraded one step for imprecision: the 95% CI includes both appreciable benefit and appreciable harm.

⁵Downgraded two steps for inconsistency: considerable heterogeneity ($I^2 = 94\%$).

Summary of findings 2. Intensive Case Management versus non-Intensive Case Management for severe mental illness

Intensive Case Management versus non-Intensive Case Management for severe mental illness

Patient or population: people with severe mental illness

Settings: community

Intervention: Intensive Case Management versus non-Intensive Case Management

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Intensive Case Management versus non-Intensive Case Management				
Service use: 1. Average number of days in hospital per month - by about 24 months	-	The mean service use: 1. average number of days in hospital per month - by about 24 months in the intervention groups was 0.08 lower (0.37 lower to 0.21 higher)	-	2220 (21 studies)	⊕⊕⊕⊖ moderate ¹	
Service use: 3b. Average number of admissions (skewed data - sample size ≥ 200) - by long term	-	The mean service use: 3b. average number of admissions (skewed data - sample size ≥ 200) - by long term in the intervention groups was 0.18 lower (0.41 lower to 0.05 higher)	-	678 (1 studies)	⊕⊕⊕⊖ moderate ¹

Adverse event: 1b. Death - suicide - by long term	12 per 1000	11 per 1000 (3 to 35)	RR 0.88 (0.27 to 2.84)	1152 (3 studies)	⊕⊕○○ low 1,3	
Global state: 1. Relapse - by long term	-	-	-	-	-	No data available
Global state: 1. Leaving the study early - by long term	159 per 1000	111 per 1000 (83 to 151)	RR 0.7 (0.52 to 0.95)	1970 (7 studies)	⊕⊕○○ low 1,2	
Social functioning 2. Employment status - by medium term - spent > 1 day employed	111 per 1000	162 per 1000 (50 to 527)	RR 1.46 (0.45 to 4.74)	73 (1 study)	⊕○○○ very low 1,4	
Mental state: not improved to an important extent - by long term	-	-	-	-	-	No data available

*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 assumed 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 quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹Downgraded one step for risk of bias: randomisation not well described; problematic to blind.

²Downgraded one step for selective reporting bias: only 7 studies reported fully on the flow of participants through the study.

³Downgraded one step for imprecision: the 95% CI includes both appreciable benefit and appreciable harm.

⁴Downgraded two steps for imprecision: the 95% CI includes both appreciable benefit and appreciable harm, and only 73 participants were included.

BACKGROUND

Description of the condition

Worldwide, more than 25% of people develop one or more mental or behavioural disorders during their lifetime (WHO 2001). Schizophrenia is one illness that heavily contributes to the numbers of people considered severely mentally ill. The lifetime prevalence of schizophrenia is 0.58% in the adult population (Warner 1995). It is currently 26th on the list of diseases ranked according to contribution to overall burden in term of disability-adjusted life years (DALYs). Its ranking is projected to rise to 20th by the year 2020, with more than 17 million DALYs lost (accounting for 1.25% of overall burden) (Murray 1996). However, other psychiatric/psychological conditions can also profoundly affect a person's functioning. Many people with other types of non-organic psychotic illness, or even non-psychotic disorders such as personality disorder, can be considered to be severely mentally ill.

There has been lack of consensus over the definition of 'severe mental illness', but the most common dimensions used to identify this group are i.) diagnosis, ii.) disability, iii.) duration, and iv.) abnormal behaviour. However, there is little consistency between dimensions and thresholds used in different settings (Slade 1997). The definition of severe mental illness with the widest consensus is that of the National Institute of Mental Health (NIMH) (Schinnar 1990). Their definition is based on three criteria: i.) diagnosis of non-organic psychosis or personality disorder; ii.) duration characterised as involving 'prolonged illness' and 'long term treatment' and operationalised as a two-year or longer history of mental illness or treatment; and iii.) disability, which includes dangerous or disturbing social behaviour, moderate impairment in work and non-work activities, and mild impairment in basic needs (National Institute of Mental Health 1987).

A survey conducted in Europe to calculate prevalence rates of severe mental illness according to the NIMH definition put the total population-based annual prevalence at approximately 2 per 1000 (Ruggeri 2000).

Description of the intervention

Since the 1960s, there has been an almost worldwide trend towards the closure of institutions for the mentally ill. Coupled with these closures, many government policies have focused on reducing the number of hospital beds for people with severe mental illness in favour of providing care in a variety of non-hospital settings - outpatient clinics, day centres, or community mental health centres. These changes were consistent with the increasing shift from hospital-based care in favour of a more community-focused approach (Malone 2007).

Assertive Community Treatment and Case Management (Table 1) are community-based packages of care developed in the early 1970s. They were initially conceived to co-ordinate the care of severely mentally ill people discharged from closing mental hospitals. However, they were soon more widely applied as a means of caring for severely mentally ill people who did not require immediate admission (Thompson 1990).

Core features of Assertive Community Treatment (ACT) were clearly stated since the first paradigm-shifting study of Stein and Test (Stein 1980), and successively critical ingredients of ACT have

operationally defined by developing fidelity scale (McGrew 1994; McGrew 1995).

Case Management was not likewise defined; brokerage case management was rapidly abandoned in favour of Clinical Case Management (Holloway 1995), and more sophisticated, but poorly defined models were developed. In these models case managers have clinical training, provide at least some clinical services, and operate with low caseloads (Rubin 1992; Solomon 1992).

Assertive Community Treatment and Case Management do share common goals such as maintaining contact, reducing hospitalisation (and hence cost), and improving outcome. However, there are, at least in theory and with respect to the original models, important structural distinctions between them. Nonetheless, across time through clinical practice the two interventions have evolved and tended to converge into a package of care known as Intensive Case Management, which contains elements from the two original models (Burns 2008; Scott 1995). In both clinical trials and clinical practice, what is currently called 'Case Management' is thus likely to contain some elements of ACT practice. These models can be called 'Clinical Case Management', 'Intensive Case Management', and 'Strengths Case Management' (Solomon 1992). However, 'Intensive Case Management' is a broader term often used interchangeably with Assertive Community Treatment but distinguished from it on the grounds that it often lacks one or more ACT programme elements (Burns 2001). Intensive Case Management (ICM) emphasises the importance of small caseload (usually considerably fewer than 20) and high-intensity input. Intensive case managers are usually clinicians who act as therapist in addition to their case management duties (Marshall 2008).

Until a few years ago, the approaches to care within community mental health teams differed. These approaches (evolved over the last 30 years) fell into two main categories: i.) services with well-delimited aims, such as crisis resolution and home treatments teams, vocational rehabilitation, and early intervention service; and ii.) services aimed at meeting a wide range of patient needs, such as ACT and Case Management (CM) (merging in the Intensive Case Management model) (Ruggeri 2008).

In the last decade such a distinction has no longer been so relevant. Intensive Case Management partly lost its purity and closeness to the original models (ACT and CM), where many services are offering a less intensive but more flexible and responsive form of assertive outreach (Drukker 2008), investing on the 'critical ingredients' of ICM research helped to identify (Burns 2007) (Killaspy 2012). Many emerging practices are developed within ICM framework, where their aim is to address specific target populations and outcome domains (Bond 2015). Specifically, many specialised models of intervention within community mental health teams are based on adaptation of key principles of ICM, where they are addressing specific population subgroups (difficult to engage in traditional settings, high-risk and revolving door, with comorbidity) (Brewer 2015). Among these, there are packages of care for homeless populations with severe mental illness (Coldwell 2007); populations with severe mental illness and substance abuse (Pettersen 2014), substance abuse, Kirk 2013 or alcohol dependence only (Gilbert 2012), and early intervention in first-episode psychosis (Brewer 2015). The recent proliferation of models inspired by ICM that focus on a special issue was permitted by the structure and flexibility of the original ACT model, but

exploring this emerging area goes beyond the objectives of this review.

How the intervention might work

The theory behind care in the community is that it enables people to live as independently as possible within their own homes or 'homely settings' out of hospital, because unnecessary hospital care is wasteful, untherapeutic, and stigmatising. It was hoped that living in the community would increase opportunities for people with severe mental illness to achieve their full potential as autonomous members of society (Department of Health 1990). Community care policies are also aimed at promoting choice and independence for people experiencing mental health difficulties.

Intensive Case Management is an intervention at the level of local service organisation. It is a way of organising teams, rather than a specific treatment model (Johnson 2008). Intensive Case Management should provide a mental health service that is a reliable, systematic, flexible, and co-ordinated care method, addressed to answer the unique combination of health and social care needs of people with severe mental illness. It represents a long-term intensive approach to the patient in the community (Killaspy 2008), providing a comprehensive range of treatment, rehabilitation, and support services (Scott 1995); in the last decade ICM has absorbed the recovery principle of promoting emancipation, through policies encouraging graduation (Finnerty 2015). Intensive Case Management aims to help people with severe mental illness acquire material resources (such as food, shelter, clothing, and medical care) and to improve their psychosocial functioning; to provide sufficient support to keep the patient involved in community life and to encourage growth towards greater autonomy; to develop coping skills to meet the demands of community life; and to ensure continuity of care among treatment agencies (Stein 1980). Key purposes of ICM are to improve outcome, reduce hospitalisation, and prevent loss of contact with services.

A cornerstone in the research field was a study by Burns and colleagues exploring the mechanism for ICM to be effective (Burns 2007). It suggested that the success of ICM depends on its fidelity to the ACT model (i.e. if a team approach is properly implemented) and on the setting (i.e. it would work better where there is a high baseline level of bed use).

Why it is important to do this review

With the evolution of the original intervention models, there was a need to update and merge two previous relevant Cochrane reviews (Marshall 2000a; Marshall 2000b), and to take into account the findings of work by the same authoring team (Burns 2007). During the last 15 years, not only have intervention models been modified, merged, and become more difficult to distinguish in practice, but also research has been more widespread, with new studies evaluating these approaches outside of the USA.

Since early 2000, ICM has been a very implemented and widespread intervention in the community care setting, with many nations in Europe, North America, and Australia, investing great efforts and resources in its promotion and dissemination (in England Care Programme Approach promoting ACT team (Department of Health 1999)).

Since then, research providing long-term follow-up outcomes and data on the impact of ACT teams on inpatient service use in

specific national settings has been published with emerging data casting doubt on the opportunity of such an initial enthusiastic approach, especially in England, one of the nations where there had been stronger investments in it (Glover 2006). This topic is therefore still under an international debate (Burns 2009; Burns 2010; Burns 2012; Killaspy 2012; Rosen 2013). Almost in the same years (since the mid-2000s), ICM landed in Asia, where the idea of comprehensive community programmes is gradually catching on, and wide implementation of both programs has inspired programmes highly faithful to ICM (Low 2013; Nishio 2014).

The effects of the currently implemented packages of care in different settings should be fully understood across a range of outcomes.

OBJECTIVES

To assess the effects of ICM as a means of caring for severely mentally ill people in the community in comparison with non-ICM (caseload greater than 20) and with standard community care. We did not distinguish between models of ICM. In addition, to assess whether the effect of ICM on hospitalisation (mean number of days per month in hospital) is influenced by the intervention's fidelity to the ACT model and by the rate of hospital use in the setting where the trial was conducted (baseline level of hospital use).

METHODS

Criteria for considering studies for this review

Types of studies

We considered all relevant randomised controlled trials, and economic evaluations conducted alongside included randomised controlled trials. We excluded quasi-randomised studies, such as those allocating by alternate days of the week. Where trials were described in some way as to suggest or imply that the study was randomised and where the demographic details of each group's participants were similar, we included these trials and undertook a Sensitivity analysis.

Types of participants

We required the majority of participants to be:

1. within the age range of 18 to 65 years;
2. suffering from severe mental illness, preferably as defined by National Institute of Mental Health 1987, or in the absence of this, from illness such as schizophrenia, schizophrenia-like disorders, bipolar disorder, depression with psychotic features or/and personality disorder; and
3. not acutely ill.

We did not consider substance abuse to be a severe mental disorder in its own right, however studies were eligible if they dealt with people with both diagnoses, that is those with severe mental illness plus substance abuse. Dementia and mental retardation are not considered to be severe mental disorders, hence we excluded studies focusing on these populations. We considered only participants treated in the community care setting.

Types of interventions

We considered only interventions and management packages not focused primarily on alternatives to acute hospital admission.

1. Intensive Case Management

We defined Intensive Case Management as where the majority of people received:

- a. a package of care shaped on the:
 - Assertive Community Treatment model, being based on the Treatment in Community Living, Assertive Community Treatment (Stein 1980);
 - Assertive Outreach model (Witheridge 1982; Witheridge 1991) (i.e. multidisciplinary team-based approach, practising 'assertive outreach', offering 24-hour emergency cover, providing care themselves) (McGrew 1995); or
 - Case Management model (Intagliata 1982), however described as such in the trial report.
- b. with a caseload up to and including 20 people.

2. Non-Intensive Case Management

We defined non-Intensive Case Management as where the majority of people received:

- a. a package of care shaped on the:
 - Assertive Community Treatment model, being based on the Treatment in Community Living, Assertive Community Treatment (Stein 1980);
 - Assertive Outreach model (Witheridge 1982; Witheridge 1991) (i.e. multidisciplinary team-based approach, practising 'assertive outreach', offering 24-hour emergency cover, providing care themselves) (McGrew 1995); or
 - Case Management model (Intagliata 1982), however described as such in the trial report.
- b. with a caseload over 20 people.

3. Standard care

We defined standard care as where the majority of people received a community or outpatient model of care not specifically shaped on either the model of Assertive Community Treatment and Case Management, and not working within a designated named package or approach to care. If data were available on the standard care caseload, we undertook a final sensitivity analysis testing how prone the primary outcomes were to change when trials comparing Intensive Case Management with standard community care only (caseload greater than 20) were included.

Types of outcome measures

We grouped outcomes by time into short term (up to and including 6 months), medium term (7 months to up to and including 12 months), and long term (over 12 months). Where available, 24 months was the preferred follow-up point for calculating mean days per months in hospital. If more than one follow-up point within the same period was available, we reported the latest one. During this period, participants remained allocated in their trial arm.

We grouped outcomes assessed after active intervention was stopped or after participants could choose to which arm they were transferred, by time into short-term follow-up (up to and including one year), medium-term follow-up (from one to five years), and

long-term follow-up (over five years). We calculated follow-up length as time since intervention stopped.

To simplify distinguishing between outcomes assessed during and after the active intervention, we entered ones explicitly reporting follow-up (FUP) length.

Primary outcomes

1. Service use

- 1.1 Hospitalisation: mean number of days per month in hospital
- 1.2 Not remaining in contact with psychiatric services

Secondary outcomes

1. Service use

- 1.1 Admitted to hospital
- 1.2 Hospital admission rate
- 1.3 Use of services outside of mental health provision (i.e. emergency services)

2. Adverse effects

- 2.1 Death - all causes and suicide

3. Global state

- 3.1 Leaving the study early (lost to follow-up)
- 3.2 Relapse (as defined in trial)
- 3.3 Not improved to a clinically meaningful extent (as defined in trial)
- 3.4 Not improved
- 3.5 Average endpoint score
- 3.6 Average change score
- 3.7 Compliance with medication
- 3.8 Average endpoint score
- 3.9 Average change score

4. Social functioning

- 4.1 Contact with legal system (i.e. police contacts, arrests, imprisonments)
- 4.2 Employment status (number unemployed at end of study)
- 4.3 Accommodation status (number homeless or not living independently during or at the end of the study, mean days homeless and mean days in stable accommodation per month in study)
- 4.4 Alcohol use
- 4.5 Illicit drug use
- 4.6 Average endpoint score
- 4.7 Average change score

5. Mental state

- 5.1 General symptoms
 - 5.1.1 Not improved to a clinically meaningful extent (as defined in trial)
 - 5.1.2 Not improved
 - 5.1.3 Average endpoint score
 - 5.1.4 Average change score
- 5.2 Specific symptoms
 - 5.2.1 Positive symptoms (delusions, hallucinations, disordered thinking)
 - 5.2.1.1 Not improved to a clinically meaningful extent (as defined in trial)

- 5.2.1.2 Not improved
- 5.2.1.3 Average endpoint score
- 5.2.1.4 Average change score

5.2.2 Negative symptoms (poor volition, poor self care, blunted affect)

- 5.2.2.1 Not improved to a clinically meaningful extent (as defined in trial)
- 5.2.2.2 Not improved
- 5.2.2.3 Average endpoint score
- 5.2.2.4 Average change score

5.2.3 Mood depression

- 5.2.3.1 Not improved to a clinically meaningful extent (as defined in trial)
- 5.2.3.2 Not improved
- 5.2.3.3 Average endpoint score
- 5.2.3.4 Average change score

6. Behaviour

- 6.1 General behaviour
- 6.2 Not improved to a clinically meaningful extent (as defined in trial)
- 6.3 Not improved
- 6.4 Average endpoint score
- 6.5 Average change score
- 6.6 Specific behaviours (i.e. self harm; injury to others or property)

7. Quality of life

- 7.1 Not improved to a clinically meaningful extent (as defined in trial)
- 7.2 Not improved
- 7.3 Average endpoint score
- 7.4 Average change score

8. Satisfaction

- 8.1 Participant satisfaction
 - 8.1.1 Not improved to a clinically meaningful extent (as defined in trial)
 - 8.1.2 Not improved
 - 8.1.3 Average endpoint score
 - 8.1.4 Average change score
- 8.2 Carer satisfaction
 - 8.2.1 Not improved to a clinically meaningful extent (as defined in trial)
 - 8.2.2 Not improved
 - 8.2.3 Average endpoint score
 - 8.2.4 Average change score

9. Costs

- 9.1 Direct costs of psychiatric hospital care
- 9.2 Direct healthcare costs (including all medical and psychiatric care and the costs of case management, but excluding accommodation other than hospital care)
- 9.3 Direct costs of all care (including costs of accommodation and subtracting benefits, such as earnings, where these are known)

Summary of findings

We used the GRADE approach to interpret findings, [Schünemann 2008](#), and GRADEpro, [GRADEpro](#), to import data from Review

Manager5, [Review Manager](#), to create 'Summary of findings' tables. These tables provide outcome-specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes we rated as important to patient care and decision making. We selected the following main outcomes for inclusion in the 'Summary of findings' table.

1. Service use: average number of days in hospital per month by about 24 months
2. Service use: average number of admissions (skewed data - sample size ≥ 200) by long term (> 12 months)
3. Adverse event: death - suicide by long term (> 12 months)
4. Global state: relapse
5. Global state: leaving the study early by long term (> 12 months)
6. Social functioning: employment status - spent less than 1 day employed - by medium term (6 to 12 months)
7. Mental state: not improved to an important extent

Search methods for identification of studies

Electronic searches

1. *Cochrane Schizophrenia Group's Trials Register*

On 10 April 2015, the Information Specialist searched the Register using the following search strategy:

(*ca?e manag* OR *cpa* OR *community treat* OR *community team* OR *community cent* OR *community care* OR *madison model* OR *outreach* OR *hostel* OR *aftercare* OR *residential* OR *housing* OR *transitional* OR *post?hospital* OR *partial hospitali?ation* OR *foster* OR *guardianship* OR *daily living program* OR *crisis interven* OR *early interven* OR *ambulatory* OR *community liv* OR *social support* OR *patient care team* OR *community mental health* OR *patient participation* OR *drop? in* OR *day hospital* OR *day care* OR *day treat* OR *day cent* OR *day unit* OR *intensive care* OR *intensive interven* OR *intensive treat* OR *intensive therap* OR *intensive manag* OR *intensive model* OR *intensive program* OR *intensive team* OR *intensive service* OR *mobile care* OR *mobile interven* OR *mobile treat* OR *mobile therap* OR *mobile manag* OR *mobile model* OR *mobile program* OR *mobile team* OR *mobile service* OR *community interven* OR *community therap* OR *community manag* OR *community model* OR *community program* OR *community service* OR *community base* OR *home care* OR *home interven* OR *home treat* OR *home therap* OR *home manag* OR *home model* OR *home program* OR *home team* OR *home service* OR *home base* OR *broker* OR *care program*) in Title, Abstract, and Index Terms of REFERENCE OR (*ca?e manag* OR *community* OR *outreach* OR *hostel* OR *aftercare* OR *residential* OR *hous* OR *transitional* OR *foster* OR *crisis interven* OR *early interven* OR *ambul* OR *social support* OR *drop-in* OR *day* OR *(intensive)* OR *(home)* OR *care program*) in Intervention of STUDY

The Cochrane Schizophrenia Group's Register of Trials is compiled by systematic searches of major resources (including MEDLINE, Embase, AMED, BIOSIS, CINAHL, PsycINFO, PubMed, and registries of clinical trials) and their monthly updates, handsearches, grey literature, and conference proceedings (see [Group Module](#)). There

is no language, date, document type, or publication status limitations for inclusion of records into the register.

For search methods of previous versions of this review, please see [Appendix 1](#).

Searching other resources

References

Should an included or excluded study suggest that another study was relevant, we identified the reference and acquired the full text.

Personal contact

We contacted authors of trials for additional data where required. We did not systematically contact all authors for additional papers.

Data collection and analysis

Methods used for this version are presented below; previous methods are presented in [Appendix 2](#).

Selection of studies

Two review authors (HB, MK) inspected results of the update search and identified potentially relevant reports. Disagreements were resolved by discussion, or where there was still doubt, we acquired the full article for further inspection. We obtained the full articles of relevant reports for reassessment and inspected them carefully to decide on inclusion or exclusion (see [Criteria for considering studies for this review](#)). Review authors were not blinded to the names of the authors, institutions, or journal of publication. Where difficulties or disputes arose, we discussed; if we were unable to decide, we added these studies to those awaiting assessment and contacted the authors of the papers for clarification.

Data extraction and management

1. Extraction

1.1 Data extraction for criteria and outcomes

Three review authors (MD, HB, MK) independently extracted data from the included studies and compared results of the data extraction. We would have discussed any disagreements, documented our decisions, and contacted the authors of studies for clarification where necessary. Whenever possible, we would have extracted data presented only in graphs and figures and included the data if two review authors independently reached the same result. In order to obtain any missing information or for clarification, we attempted to contact authors through an open-ended request. Where possible, we would have extracted data relevant to each component centre of multicentre studies separately.

1.2 Additional data extraction

1.2.1 Fidelity

We rated fidelity of the ICM intervention to ACT on the 'team membership' and 'team structure and organisation' subscales of the Index of Fidelity to Assertive Community Treatment (IFACT) ([McGrew 1994](#)). This index was derived from a survey of 20 clinical experts in ACT and validated in a survey of 18 programmes.

a. The 'team membership' subscale comprises four items:

- ratio of patients to staff;

- total size of team;
- extent of psychiatric input;
- extent of nursing input to the team.

b. The 'structure and organisation' subscale comprises seven items, whether the team is:

- the primary source of care for its patients;
- situated away from the hospital;
- meets daily;
- shares responsibility for caseloads;
- is available 24 hours a day;
- has a team leader who is also a case manager;
- offers unlimited time for its services.

We chose IFACT because the subscales are brief and can be completed from published or unpublished text. For each item on the index, a score of 1 indicates high fidelity to the model. Score ranges from 0 to 11, where the maximum score available on the 'team membership' subscale is 4 and on the 'structure and organisation' subscale is 7, with higher scores indicating higher fidelity to the model.

We obtained fidelity data from published and unpublished trial reports, direct contact with trialists, and data previously obtained directly from trialists reported by previous reviews ([Burns 2001](#); [Burns 2007](#); [Catty 2002](#)). Two raters (MD and CBI) independently combined these data into a single fidelity score. Multicentre trials of ICM often struggle to implement a uniform approach, with centres operating at differing degrees of fidelity. Where possible, we rated each component centre separately.

1.2.2 Baseline hospital use

We extracted data relating to the average number of days per month in hospital for all participants in the two years before the study began. We obtained this data from published and unpublished trial reports and from direct contact with trialists.

1.2.3 Service use: hospitalisation

We obtained the primary outcome mean number of days per month in hospital for the included studies from published and unpublished trial reports, direct contact with trialists, and data previously obtained directly from trialists reported by a previous review ([Burns 2007](#)).

2. Management

2.1 Forms

Two review authors (HB, MK) extracted data onto simple, standard forms.

2.2 Data from multicentre trials

For the original version, where possible review authors MD and CBI verified independently calculated centre data against original trial reports.

2.3 Scale-derived data

We included continuous data from rating scales only if:

- a. the psychometric properties of the measuring instrument had been described in a peer-reviewed journal ([Marshall 2000](#));

- b. the measuring instrument was not written or modified by one of the trialists for that particular trial; and
- c. the measuring instrument was either i.) a self report or ii.) completed by an independent rater or relative.

2.3 Endpoint versus change data

Both endpoint and change data have advantages. Change data can remove a component of between-person variability from the analysis. On the other hand, calculation of change needs two assessments (baseline and endpoint), which can be difficult in unstable and difficult-to-measure conditions such as schizophrenia. We decided to primarily use endpoint data, and only use change data if the former were not available. When relevant, we combined endpoint and change data in the analysis, as we aimed to use mean differences rather than standardised mean differences throughout (Higgins 2011).

2.4 Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we applied the following standards to relevant continuous data before inclusion.

We entered all relevant data from studies of more than 200 participants in the analysis irrespective of the following rules, because skewed data pose less of a problem in large studies. We also entered all relevant change data, as when continuous data are presented on a scale that includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not.

For endpoint data from studies of fewer than 200 participants, we used the following methods.

- a. If a scale started from the finite number zero, we subtracted the lowest possible value from the mean, and divided this by the standard deviation (SD). If this value is lower than 1, it strongly suggests a skew, and we excluded these data. If this ratio is higher than 1 but below 2, there is suggestion of skew. We entered these data to test whether their inclusion or exclusion changed the results substantially. Finally, if the ratio was larger than 2, we included these data, because skew is less likely (Altman 1996; Higgins 2011).
- b. If a scale starts from a positive value (such as the Positive and Negative Syndrome Scale (PANSS), which can have values from 30 to 210) (Kay 1986), we modified the calculation described above to take the scale starting point into account. In these cases skew is present if $2 \text{ SD} > (S - S_{\min})$, where S is the mean score and ' $S_{\min}$ ' is the minimum score.

Exception to above rules - mean number of days in hospital

We implemented one exception to the above rules in order to present more data, recognising that this is a post hoc decision,

but also that the rules with regards to management of skewed data and how robust skewed data are within meta-analysis are unclear (Higgins 2011). Where mean number of days in hospital data were skewed, and they were provided by studies of fewer than 200 participants, we entered those data into a subgroup of the overall analysis. We also presented the overall effect from all data pooled.

2.5 Common measure

To facilitate comparison between trials, we converted variables that can be reported in different metrics, such as days in hospital (mean days per year, per week, or per month) to a common metric (e.g. mean days per month).

2.6. Conversion of continuous to binary

Where possible, we attempted to convert outcome measures to dichotomous data. This can be done by identifying cutoff points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It was generally assumed that if there had been a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS), in Overall 1962, or the PANSS (Kay 1986), this could be considered to be a clinically significant response (Leucht 2005a; Leucht 2005b). If data based on these thresholds were not available, we used the primary cutoff presented by the original authors.

2.7. Direction of graphs

Where possible, we entered data in such a way that the area to the left of the line of no effect indicated a favourable outcome for ICM.

Assessment of risk of bias in included studies

For this version of the review, two review authors (HB, MK) assessed risk of bias of all new included studies using the tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

This set of criteria is based on evidence of associations between overestimate of effect and high risk of bias of the article such as sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting.

If the raters had disagreed, we planned to make the final rating by consensus. Where inadequate details of randomisation and other characteristics of trials were provided, we contacted the authors of the studies to obtain further information. We would have reported non-concurrence in quality assessment, and if disputes had arisen as to which category a trial was to be allocated, again, we would have resolved this by discussion.

We noted the level of risk of bias in Risk of bias in included studies, Summary of findings for the main comparison, Summary of findings 2, and Figure 1.

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection 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
Aberg-Wistedt-Sweden 1995	?	?	?	-	?	?	-	+
Audini-UK 1994	?	?	?	-	?	+	+	+
Bjorkman-Sweden 2002	+	?	?	-	?	?	+	+
Bond-Chicago1 1990	?	?	?	-	-	-	-	+
Bond-Indiana1 (A)								
Bond-Indiana1 (B)								
Bond-Indiana1 (C)								
Bond-Indiana1 1988	?	?	?	?	?	?	-	+
Bush-Georgia 1990	?	?	?	-	?	+	-	+
Chandler-California1 (A)								
Chandler-California1 (B)								
Chandler-California1 1991	?	?	?	-	?	?	-	+
Chan-Hong Kong 2000	?	?	?	?	?	?	-	+
Curtis-New York 1992	?	?	?	-	?	?	+	+
Cusack-North Carolina	+	?	?	?	+	+	+	+
Drake-NHamp (A)								
Drake-NHamp (B)								
Drake-NHamp (C)								
Drake-NHamp (D)								
Drake-NHamp (E)								

Figure 1. (Continued)

Drake-NHamp (E)								
Drake-NHamp (F)								
Drake-NHamp (G)								
Drake-NHamp 1998	?	?	?	?	?	?	+	+
Essock-Connecticut1 1995	?	?	?	?	?	+	-	+
Essock-Connecticut2 2006	+	?	?	?	?	?	-	+
Ford-UK 1995	+	?	?	-	?	-	+	+
Hampton-Illinois (A)								
Hampton-Illinois (B)								
Hampton-Illinois 1992	?	?	?	?	?	?	-	?
Harrison-Read-UK 2000	+	?	?	?	-	?	+	+
Herinckx-Oregon 1996	?	?	?	-	?	?	-	+
Holloway-UK 1996	?	?	?	-	?	+	+	+
Jerrell-SCarolina1 1991	?	?	?	?	?	?	-	+
Johnston-Australia 1998	?	?	?	?	?	+	+	+
Lehman-Maryland1 1994	?	?	?	-	?	?	-	+
Macias-Utah 1994	?	?	?	?	?	?	?	+
Marshall-UK 1995	+	?	?	-	?	?	+	+
McDonel-Indiana (A)								
McDonel-Indiana (B)								
McDonel-Indiana 1997	?	?	?	?	?	?	-	+
Morse-Missouri1 1992	?	?	?	-	?	?	-	+
Morse-Missouri3 2005	?	?	?	-	?	?	+	+
Muijen-UK2 1994	?	?	?	-	?	?	-	+
Muller-Clemm-Canada 1996	?	?	?	-	?	?	-	+
Okpaku-Tennessee 1997	?	?	?	?	-	?	-	+
OPUS-Denmark 1999	+	+	?	-	?	+	-	+
Pique-California 1999	+	?	?	-	?	?	-	+
Quinlivan-California 1995	?	?	?	?	+	?	+	+
REACT-UK 2002	+	+	?	?	-	+	+	+
Rosenheck-USA 1993	+	?	?	-	?	?	-	+

Figure 1. (Continued)

Rosenheck-USA 1993	+	?	?	-	?	?	-	+
Rosenheck-USA-GMS								
Rosenheck-USA-GMS (A)								
Rosenheck-USA-GMS (B)								
Rosenheck-USA-GMS (D)								
Rosenheck-USA-GMS (F)								
Rosenheck-USA-GMS (I)								
Rosenheck-USA-NP								
Rosenheck-USA-NP (C)								
Rosenheck-USA-NP (E)								
Rosenheck-USA-NP (G)								
Rosenheck-USA-NP (H)								
Salkever-SCarolina 1999	?	?	?	?	?	?	-	+
Shern-USA1 2000	?	?	-	-	-	?	-	+
Solomon-Pennsylvania 1994	?	?	?	-	?	?	-	+
Sytema-Netherlands 1999	+	+	?	-	?	+	+	+
Test-Wisconsin 1985	?	?	?	-	?	?	-	+
UK700-UK (A)								
UK700-UK (B)								
UK700-UK (C)								
UK700-UK (D)								
UK700-UK 1999	?	+	?	?	?	+	?	+

Measures of treatment effect

1. Binary data

For binary outcomes, we calculated a standard estimation of the random-effects risk ratio (RR) and its 95% confidence interval. It has been shown that RR is more intuitive than odds ratios (OR), and that clinicians tend to interpret ORs as RR (Boissel 1999; Deeks 2000). Within the 'Summary of findings' table, we aimed to calculate the lowest control risk applied to all data. We assumed the same for the highest-risk groups. We used the 'Summary of findings' table to calculate absolute risk reduction for primary outcomes.

2. Continuous data

For continuous outcomes, we estimated the mean difference between groups. We preferred not to calculate effect size measures (standardised mean difference). However, if in future versions of

this review scales of very considerable similarity are used, we will presume there is a small difference in measurement and will calculate effect size and transform the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice), but analysis and pooling of clustered data pose problems. Firstly, authors often fail to account for intraclass correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992), whereby P values are spuriously low, confidence intervals unduly narrow, and statistical significance overestimated. This causes type I errors (Bland 1997; Gulliford 1999).

Where clustering is not accounted for in primary studies, we would present data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. If we find such studies in subsequent versions of this review, we will attempt to contact first authors of studies to obtain intraclass correlation coefficients for their clustered data and to adjust for this by using accepted methods (Gulliford 1999). Where clustering has been incorporated into the analysis of primary studies, we would present these data as if from a non-cluster randomised study, but adjust for the clustering effect.

We have sought statistical advice and have been advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intraclass correlation coefficient (ICC) [Design effect = $1 + (m - 1) \times \text{ICC}$] (Donner 2002). If the ICC is not reported, we would assume it to be 0.1 (Ukoumunne 1999).

If cluster studies have been appropriately analysed taking into account intraclass correlation coefficients, and relevant data documented in the report, synthesis with other studies would be possible using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect, which occurs if an effect (e.g. pharmacological, physiological, or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence, on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason, cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we only used data from the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, we presented the additional treatment arms in comparisons if relevant. Where the additional treatment arms were not relevant, we did not reproduce these data.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up data loses credibility (Xia 2009). For any particular outcome, should more than 50% of data be unaccounted for, we did not reproduce these data or use them within analyses. If, however, more than 50% of participants in one arm of a study were lost, but the total loss was less than 50%, we marked such data with (*) to indicate that such a result may well be prone to bias.

2. Binary

Where attrition for a binary outcome was between 0 and 50%, and where these data were not clearly described, we presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis). We assumed all those leaving the study early to have the same rates of negative outcome as those who completed, with the exception of the outcome of death. We undertook a [Sensitivity analysis](#) testing how prone the primary outcomes were to change when we compared data from only those who completed the study with intention-to-treat data using the assumption outlined above.

Where number of deaths was more than 10% of the sample overall, we applied the above statement but did not impute attrition due to death.

3. Continuous

3.1 Attrition

Where attrition for a continuous outcome was between 0 and 50%, and data from only those who completed the study were reported, we reproduced these.

3.2 Standard deviations

3.2.1 General

Where there were missing measures of variance for continuous data, but exact standard errors or confidence intervals for group means, or either 'P' or 't' values for differences in means, we calculated standard deviation value according to the method described in Section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If standard deviations were not reported and could not be calculated from the available data, we asked authors to supply the data. In the absence of data from authors, we used the mean standard deviation from other studies.

3.2.2 Standard deviation mean number of days per month in hospital

For the primary outcome mean number of days per month in hospital, if standard deviations were not reported and could not be calculated from available data, we asked the authors for additional information. In the absence of data from authors, we imputed the missing standard deviations using a regression analysis of SD against mean from those trials that provided both. We documented in what studies we imputed SDs according to the above technique in [Table 2](#).

3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results. Therefore, where LOCF data had been used in the trial, if less than 50% of the data had been assumed, we reproduced these data and indicated that they were the product of LOCF assumptions.

3.4 Incomplete data for meta-regression

We anticipated that in some cases not all IFACT score variables would be available. If we could not calculate IFACT score from the available data, we imputed it by multiple imputation using the Multiple Imputation with Diagnostics (mi) library in R (R 2008). As explained above, we only made these assumptions if we were able to directly rate over 50% of the data. We documented in what studies we calculated IFACT score according to the above technique in [Table 3](#).

We anticipated that in some cases not all baseline hospital use data would be available. We imputed missing data as for the IFACT scores. As explained above, we only made these assumptions if we were able to directly rate over 50% of the data. We documented for which studies we calculated baseline hospital use data according to the above technique ([Table 3](#)).

We undertook a [Sensitivity analysis](#) testing how prone the results from meta-regression were to change when we compared data

from only those who completed the studies with the imputed data using the assumption outlined above.

Assessment of heterogeneity

1. Clinical heterogeneity

We considered all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We simply inspected all studies for clearly outlying situations or people that we had not predicted would arise. When such situations or participant groups arose, we discussed these fully.

In addition, we specified two potential sources of heterogeneity a priori (fidelity and baseline level of hospital use) ([Data extraction and management](#)). We extracted these data as described above.

2. Methodological heterogeneity

We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods that we had not predicted would arise. If such methodological outliers arose, we discussed these fully.

3. Statistical heterogeneity

3.1 Visual inspection

We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I^2 statistic

We investigated heterogeneity between studies by considering the I^2 statistic alongside the χ^2 P value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance ([Higgins 2003](#)). The importance of the observed value of I^2 depends on i.) magnitude and direction of effects, and ii.) strength of evidence for heterogeneity (e.g. P value from χ^2 test, or a confidence interval for I^2). We interpreted an I^2 estimate greater than or equal to 50% accompanied by a statistically significant χ^2 statistic, as evidence of substantial levels of heterogeneity (Section 9.5.2; [Higgins 2011](#)). When we found substantial levels of heterogeneity in the primary outcome, we explored reasons for the heterogeneity ([Subgroup analysis and investigation of heterogeneity](#)).

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results ([Egger 1997](#)). These are described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We did not use funnel plots for outcomes where there were 10 or fewer studies, or where all studies were of similar size. In other cases, where funnel plots were possible, we sought statistical advice in their interpretation.

Data synthesis

Where possible, we employed a random-effects model for analyses. We understand that there is no closed argument for preference for use of fixed-effect or random-effects models. The random-effects method incorporates an assumption that different studies

are estimating different, yet related, intervention effects. According to our hypothesis of an existing variation across studies, to be explored further in the meta-regression analysis, despite being cautious that random-effects methods do put added weight onto the smaller of the studies, we favoured using random-effects model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We anticipated conducting two subgroup analyses. For the first version of the protocol for this review, we did not anticipate any subgroup analyses. On further consideration, we now realise that analysis at separate time periods could be thought of as subgroups. The second subgroup is within the primary outcome and relates to skewed and non-skewed data. We introduced this late into the protocol, and it could be considered post hoc. However, we are also aware that our original rule for management of these data could be considered overly cautious and result in some important data not being presented ([Higgins 2011](#)).

2. Investigation of heterogeneity

2.1 Anticipated heterogeneity - outcome of mean days per month in hospital

Investigation of heterogeneity formed part of the secondary objectives of the review. We hypothesised that the effect of ICM on one of our primary outcomes (mean number of days per month in hospital) differs according to fidelity of intervention to the ACT model and the baseline level of hospital use.

We examined the association of the IFACT score and the baseline number of days in hospital with the treatment effect by performing random-effects meta-regression analysis in R ([R 2008](#)). The script we used to perform meta-regression analyses is reported in [Appendix 3](#). We also carried out meta-regression using both variables within the same model. In addition, we examined the relationship between the treatment effect and the two variables using a thin plate spline. If possible, we aimed to enter data from multicentre studies in the meta-regression disaggregated into the component centre with outcome and fidelity data for each.

Meta-regression was performed only if at least 10 studies per comparison were available ([Higgins 2011](#)). We also tested comparison type as an additional regressor in the model.

2.2 Unanticipated heterogeneity - other outcomes

2.2.1 For outcomes other than the second primary outcome (not remaining in contact with psychiatric services)

We reported if inconsistency was high and undertook no exploration.

2.2.2 For outcome 'not remaining in contact with psychiatric services'

We reported if inconsistency was high. First we investigated whether data had been entered correctly. Second, if data was correct, we visually inspected the graph and successively removed studies outside of the company of the rest to see if homogeneity was restored. Should this occur with no more than 10% of the data being excluded, we presented the data. If not, these data were not pooled.

Should unanticipated clinical or methodological heterogeneity have been obvious, we simply stated hypotheses regarding these for future reviews or versions of this review. We did not anticipate undertaking analyses relating to these.

Sensitivity analysis

1. Implication of randomisation

We aimed to include trials in a sensitivity analysis if they were described in some way as to imply randomisation. For the primary outcomes, we included these studies, and if there was no substantive difference when the implied randomised studies were added to those with a better description of randomisation, then we employed all data from these studies.

2. Standard-care caseload

If data were available, we undertook a sensitivity analysis testing how prone the primary outcomes were to change when trials comparing ICM to standard community care caseload less than or equal to 20 were compared with trials comparing ICM to standard community care caseload greater than 20. If there was a substantial difference, we reported the results and discussed them but continued to pool the data.

3. Assumptions for lost binary data

Where we needed to make assumptions regarding participants lost to follow-up (see [Dealing with missing data](#)), we compared the findings of the primary outcomes when we used our assumption compared with completer data only. If there was a substantial difference, we reported the results and discussed them but continued to employ our assumption.

4. Assumptions for incomplete data for meta-regression

Where we needed to make assumptions regarding missing SDs data in studies entering meta-regression (see [Dealing with missing data](#)), we compared the findings of the meta-regression on our primary outcome when we used our assumption compared with data taken from only those who completed the studies. We tested how prone results from meta-regression were to change when we compared data from those who completed with imputed data using the assumption outlined above. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

RESULTS

Description of studies

Results of the search

We have presented the results of the latest update search below; for previous results, please see [Appendix 4](#).

The April 2015 update search of Cochrane Schizophrenia Group's Register of Trials yielded 299 references. We selected 87 for further inspection. One hundred and twenty-seven references (corresponding to 96 studies with 31 companion papers) were available from the 'awaiting classification' section of the previous version of the review and were all selected for further inspection. We excluded a total of 85 studies from the review. Only two

trials met the inclusion criteria and were included ([Chan-Hong Kong 2000](#); [Cusack-North Carolina](#)). There were 26 new companion papers to previously included studies such as [Morse-Missouri 2005](#), [OPUS-Denmark 1999](#), [REACT-UK 2002](#), and [UK700-UK 1999](#).

We have entered 20 trials in the 'awaiting classification' section and have sought further information. We added five new studies to the ongoing studies.

Problematic trials

There were two problematic trials worth special mention.

[Jerrell-SCarolina 1991](#) was a three-arm trial, with two of the arms qualifying as Intensive Case Management (Programme Assertive Community Treatment and Intensive Broker Case Management) and one a control (standard care). As results were reported separately for each arm, it was not possible to present continuous data from two ICM arms pooled together. One option was to treat each arm as a separate 'site', effectively treating the study as two trials, but with the same control group. A second option was to include only one of the experimental arms. Although aware of excluding potentially useful data on an arbitrary basis, we decided to include only one of the arms compared to standard care, per the second option. The main reason for this was to avoid a unit of analysis error, which would have occurred in the first option. We undertook a sensitivity analysis testing how prone results were to change when this trial was not included in meta-analysis.

[Curtis-New York 1992](#) was a trial comparing ICM with standard care presenting two main difficulties. The first was regarding ICM caseload size. The study reported caseload ratio as 1:35 (above the 1:20 ratio defining an ICM intervention). As we derived estimation of caseload size by dividing the number of intervention participants by the number of whole-time equivalent clinical staff in the team (not just those formally classified as 'case managers'), we found that the actual staff:participant ratio was about 1:17. We therefore found this trial eligible for inclusion in the review. The second issue was regarding the peculiar way this trial provided the ICM intervention. Both experimental and control interventions were community-oriented and fit fully into the review's inclusion criteria, but the ICM team was located in hospital. While undesirable, the team office being based in hospital is not unusual. In any case, the case management was provided in the community. We therefore confirmed inclusion of the study, not wanting to penalise it because it reported details that were not available for all trials. However, we found a discrepancy in the data the study provided on service use outcomes (average number of days in hospital per month, admitted to hospital). [Curtis-New York 1992](#) was an outlier, being the only study clearly favouring standard care over ICM. We undertook a sensitivity analysis testing how prone results were to change when this trial was not included in the meta-analysis. Neither results for the primary outcome 'average number of days per month in hospital' nor for the outcome 'admitted to hospital' changed significantly when this study was dropped, but it did significantly affect the level of heterogeneity. We could just advance the hypothesis that the reason for heterogeneity could be the unusual way the intervention was provided in this trial ([Table 4](#)).

For a summary of the trial selection from the 2015 search, please see [Figure 2](#).

Figure 2. Study flow diagram 2015 update

Included studies

See: [Characteristics of included studies](#).

The previous updates of two reviews included 176 reports describing 38 studies. This review now includes these 38 separate trials with an additional two studies including data on 196 participants ([Chan-Hong Kong 2000](#); [Cusack-North Carolina](#)). These 40 trials provide data on 7524 randomised people. Twenty-four of these studies had already been included in two original reviews (as included or awaiting assessment), with 14 more derived from the 2008 search and two more derived from the 2015 search. Twenty-eight trials provided data for the ICM versus standard care comparison, 11 for the ICM versus non-ICM comparison, and only one for both comparisons. Both of the two newly included studies provided data for the ICM versus standard care comparison. Please note that it was possible to report data for several separate centres of seven multicentre trials ([Bond-Indiana1 1988](#) (3); [Chandler-California1 1991](#) (2); [Drake-NHamp 1998](#) (7); [Hampton-Illinois 1992](#) (2); [McDonel-Indiana 1997](#) (2); [Rosenheck-USA 1993](#) (9); and [UK700-UK 1999](#) (4)). Several of these centres are reported separately in the [Characteristics of included studies](#) table.

1. Study length

Only one study fell into the short-term category, with a maximum length of six months ([Bond-Indiana1 1988](#)); nine studies reported medium-term data, with only one study reporting data by seven months, [Okpaku-Tennessee 1997](#), and the remaining eight studies reporting data by 12 months ([Bond-Chicago1 1990](#); [Bush-Georgia 1990](#); [Hampton-Illinois 1992](#); [Johnston-Australia 1998](#); [Lehman-Maryland1 1994](#); [Morse-Missouri1 1992](#); [Solomon-Pennsylvania 1994](#); [Sytema-Netherlands 1999](#)). The remaining 29 studies all fell into the long-term category, with a maximum length of four years ([Test-Wisconsin 1985](#)), and an average length of 23.5 months.

One study reported data only on short-term follow-up (five months of active intervention followed by six months' follow-up) ([Chan-Hong Kong 2000](#)), not reporting data assessed during the intervention. Newly retrieved companion papers provided data from medium- and long-term follow-up for two studies already included in the previous version of this review. Those two studies were [OPUS-Denmark 1999](#), now reporting data at three and eight years after active intervention was discontinued (i.e. 5 and 10 years after randomisation), and [REACT-UK 2002](#), now reporting data at 18

months and 8.5 years after participants could choose to which arm they were allocated (i.e. 3 and 10 years after randomisation). During the follow-up period, all participants in [OPUS-Denmark 1999](#) received the control intervention, where participants in [REACT-UK 2002](#) could remain in the originally allocated intervention or be transferred to the control one.

2. Design

All included studies were randomised with a parallel longitudinal design. Twelve were multicentre trials, but only seven of these provided data for single centres (see above).

3. Participants

We included a total of 7524 participants from 40 trials. Most trials included from the previous review were conducted in Australia, Canada, and the USA. Specifically, most of the trials included from the previous two reviews were conducted in the USA (16 trials; 3474 participants), and only five were European (345 participants). In the first update of 2010, we added 1964 participants from seven trials conducted in Europe, and 1545 participants from 10 studies conducted in Australia, Canada, and the USA. In the current version of the review, we added 62 participants from one trial conducted in China ([Chan-Hong Kong 2000](#)), and 134 participants from one trial conducted in the USA ([Cusack-North Carolina](#)).

The review now provides data on 27 trials, including 5153 participants, conducted in Australia, Canada, and the USA; 12 trials, including 2309 participants, conducted in Europe; and one trial, including 62 participants, conducted in China.

Twenty studies included participants with severe mental illness. None of these studies provided operationalised definitions addressing dimensions of diagnosis, duration, and disability. However, 14 provided criteria for either the diagnosis, impairment, or level of service use. The remaining six studies provided no criteria for defining serious mental illness. Diagnoses of 'severe mental illness' varied across studies, from schizophrenic disorder alone to wider diagnostic groups including schizophrenic, affective, and personality disorder.

Of the remaining 20 studies, 18 involved participants with various diagnoses, but the great majority had some psychotic disorder, and most trials reported criteria for service use or impairment, or both. Two studies included participants with a high level of impairment or service use due to psychiatric illness, but provided no diagnostic criteria for inclusion ([Harrison-Read-UK 2000](#); [Okpaku-Tennessee 1997](#)).

Most trials (23) involved participants that had been diagnosed using operationalised criteria (DSM, ICD, OPCRIT, RDC, SADS, see [Characteristics of included studies](#) footnotes), whilst 17 (10 in the group including participants with serious mental illness and six in the group including participants with various diagnoses) did not report using any diagnostic tool, but only stated type of illness or level of impairment. Only [OPUS-Denmark 1999](#) included participants with a first episode of psychotic illness.

Four studies included a total of 742 dually diagnosed participants ([Drake-NHamp 1998](#); [Essock-Connecticut2 2006](#); [Morse-Missouri3 2005](#); [Muller-Clemm-Canada 1996](#)), and eight studies included a total of 1337 homeless participants.

Information on mean age was available from 32 trials (6473 participants). The average age was about 38 years old. Only [Macias-Utah 1994](#) did not report information on participant age.

4. Settings

As stated in the inclusion criteria, all of the included studies took place in a community setting, provided both by private and public mental health services. No study was carried out in a low-income country, as the included studies were conducted in Australia, Canada, the USA, Europe, and China.

5. Interventions

Twenty-nine trials were included in the comparison ICM versus standard care, and 12 in the ICM versus non-ICM comparison. [Quinlivan-California 1995](#) was a three-arm trial (ICM, non-ICM, and standard care) and provided data for both comparisons. We considered [REACT-UK 2002](#) to be an ICM versus non-ICM comparison due to our assumption that standard care could be considered to be Care Programme Approach, even if not clearly reported by trial authors. The Care Programme Approach was introduced in England in the mid-1990s and become standard care thereafter; it is a combination of non-Intensive Case Management and care from a Community Mental Health Team ([Department of Health 1999](#)), hence to be considered as non-ICM according to the definitions in this review.

5.1 Intensive Case Management

On average, the ICM included in this review was well defined. The majority of experimental interventions were explicitly modelled on the ACT model, being based on the Treatment in Community Living model of [Stein 1980](#). Only a few studies based ICM on the Case Management model. The experimental intervention was provided either by an already existing team or ICM services newly established for the trial. [Cusack-North Carolina](#) was the only trial that included ICM as forensic adaptation of ACT compared with standard care.

5.2 Non-Intensive Case Management

There were no discernable differences between the practice of non-ICM and ICM except for the intensity of contact. The degree of training and skill of the staff was similar in the ICM and non-ICM teams. In some studies, non-ICM was itself an experimental intervention, but it mostly represented the average standard care, as what in this review we call 'standard care' has increasingly shifted towards non-ICM across decades. Mental health systems increasingly included elements from ICM, melding them with community mental health service. English mental health policy is one example, where the Care Programme Approach was introduced in the UK in the mid-1990s and become standard care thereafter. It is a combination of non-ICM and care from a Community Mental Health Team, hence to be considered as non-ICM, according to the definitions in this review. Therefore the [REACT-UK 2002](#) study was considered in the ICM versus non-ICM comparison due to our assumption that standard care could be considered as Care Programme Approach, even if not clearly reported by trial authors.

5.3 Standard care

On average, the definition of standard care was blurred, as this intervention was modelled on a generalist model. Its core was being provided by a community mental health service, but its features were variable across trials run in different countries at

different time periods. Presence of further specialised services, such as rehabilitation or psychotherapist services, were variable within standard care services. In a few studies, both ICM and standard care incorporated services for substance abuse treatment and homelessness care.

6. Outcome measures

6.1 Overall

The outcomes for which we could obtain usable data were: service use, adverse effects, global state, social functioning, mental state - general and specific symptoms, behaviour, quality of life, satisfaction, and costs.

Many trials used different scales in assessing treatment effects in various outcomes (global state, social functioning, mental state - general and specific symptoms, behaviour, quality of life, and satisfaction). As most of the scales were used by only one study in each comparison group, it was not possible to enter these data in a unique analysis. Even where studies used the same scale, they often applied different rating scores. Therefore, again, data could not be entered together in the analysis. Some studies failed to clearly report the rating score they used for a pre-stated scale. We noted this in the 'Risk of bias' tables (see 'Outcomes' in [Characteristics of included studies](#) table). No studies assessed improvement by measuring it on scales. We did not calculate effect size measures (standardised mean difference, see [Measures of treatment effect](#)).

6.2 Outcome scales

Only details of the scales that provided usable data are shown below. Reasons for exclusions of data are provided under 'Outcomes' in [Characteristics of included studies](#) table.

6.2.1. Global Assessment Scale (GAS) ([Endicott 1976](#)): in [Audini-UK 1994](#), [Muijen-UK2 1994](#), [Rosenheck-USA 1993](#)

This is an observer-rated scale for evaluating the overall functioning of a person during a specified time period on a continuum from psychological or psychiatric sickness to health. The score ranges from 0 to 100, where a higher score indicates a better outcome. A modified version of the GAS was included in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) as the Global Assessment of Functioning Scale (GAF) ([APA 1987](#)): in [Bjorkman-Sweden 2002](#). Outcomes from the two scales are reported together as GAF, as these two scales are very similar, and they report results on the same score range.

6.2.2 Health of the Nation Outcome Scale (HoNOS) ([Stein 1999](#); [Wing 1998](#)): in [Harrison-Read-UK 2000](#), [REACT-UK 2002](#)

This scale provides a systematic summary of behaviours and functioning, measuring mental health and social/behavioural functioning. It consists of four areas (behaviour, impairment, symptoms, and social), each assessed through 12 items on a five-point scale (0 to 4). Ratings are from 0 to 48; high score means severe dysfunction.

6.2.3 Rating of Medication Influence (ROMI) ([Weiden 1994](#)): in [Harrison-Read-UK 2000](#), [REACT-UK 2002](#)

This 20-item scale measures the influence of factor on medication adherence. Each item is rated according to the degree of influence on medication-taking behaviour: none (1), mild (2), and strong (3).

It has two subscales: patient-reported compliance (items 1 to 7) and patient-reported non-compliance (items 8 to 20). A high score on the compliance subscale indicates high compliance; a high score on the non-compliance subscale indicates high non-compliance. Results from the two studies are presented on a different range score ([Harrison-Read-UK 2000](#) range score of 1 to 3; [REACT-UK 2002](#) range score not clearly reported).

6.2.4 Disability Assessment Schedule (DAS) ([WHO 2001a](#)): in [Holloway-UK 1996](#)

The World Health Organization's Psychiatric Disability Assessment Schedule (DAS) is a measure of functioning and disability. It contains 36 items with six domains of functioning, including: understanding and communicating, getting around, self care, getting along with others, household and work activities, and participation in society. Higher scores indicate a worse outcome.

6.2.5 Interview Schedule for Social Interaction - abbreviated version (ISSI) ([Henderson 1980](#); [Unden 1989](#)): in [Bjorkman-Sweden 2002](#)

The ISSI scale is a self report scale consisting of 30 items that measures social integration and attachment. The maximum score is 30 points; higher scores indicate better social integration and attachment.

6.2.6 Life Skills Profile (LSP) ([Parker 1992](#); [Rosen 1989](#)): in [REACT-UK 2002](#)

The Life Skills Profile is a clinician-rated questionnaire developed in Australia primarily for use with people with psychotic illnesses. Thirty-nine items and five subscales assess the general domain of disability over the last three months. The five subscales measure self care, non-turbulence, social contact, communication, and responsibility. Each of the 39 items on the scale range from 'not at all disabled' to 'extremely disabled'.

6.2.7 REHAB Scale (REHAB) ([Baker 1983](#)): in [Marshall-UK 1995](#)

The REHAB Scale is an observer-rated measure of social functioning, covering social activity, self care, speech disturbance, and community skills. It rates the frequency of items of embarrassing or disruptive behaviour, such as violence, self harm, shouting and swearing, and sexual offensiveness (deviant behaviour - REHAB DB); and lack of general skills (general behaviour - REHAB GB). The scale ranges from 0 to 144, with higher scores indicating poorer functioning.

6.2.8 Role Functioning Scale (RFS) ([Green 1987](#)): in [Jerrell-SCarolina2 1994](#)

This is a self report scale whereby the total of four subscales measures global role functioning. Higher scores indicate better functioning.

6.2.9 Social Adjustment Scale (SAS) ([Weissman 1971](#); [Weissman 1974](#)): in [Audini-UK 1994](#), [Muijen-UK2 1994](#)

Measures social functioning in a number of life domains (work, social, extended family, marital, parental, family unit, and economic adequacy). Score ranges from 1 to 7, with higher score indicating poorer outcome.

6.2.10 *Social Adjustment Scale-II (SAS-II)* (Schooler 1979): in Jerrell-SCarolina1 1991

Revised version of the Social Adjustment Scale (see above), used to assess social adjustment. Self reported scale similar to SAS, but adapted for schizophrenia; it comprises 24 items covering seven areas including social, family, and work functioning. The scoring system of the two versions appears to differ, perhaps because this was an adapted version. Higher score indicates better outcome.

6.2.11 *Social Functioning Questionnaire (SFQ)* (Tyrer 1990; Tyrer 2005): in Harrison-Read-UK 2000

An eight-item self report scale (score range is 0 to 24). It provides a quick assessment of perceived social function. Higher score indicates poorer social functioning.

6.2.12 *Strauss-Carpenter Outcome Scale* (Strauss 1972; Strauss 1974): in Bjorkman-Sweden 2002

The Strauss-Carpenter Outcome Scale assesses a 21 items exploring frequency of social contacts, employment duration, symptomatology, and duration of rehospitalisation. The scaling of each item extends from 0 (maximal negative) to 4 (maximal positive). The scoring range of the scale extends from 0 (maximal negative) to 84 (maximal positive).

6.2.13 *Alcohol Use Scale (AUS)* (Drake 1996; Mueser 1995): in Drake-NHamp 1998

A five-point scale based on clinicians' ratings of the severity of the disorder, ranging from 1 (abstinence) to 5 (severe dependence).

6.2.14 *Dartmouth Assessment of Lifestyle Interview (DALI)* (Rosenberg 1998): in Sytema-Netherlands 1999

An 18-item, interviewer-administered scale addressing the detection of substance use disorder in people with severe mental illness. DALI focuses on alcohol, cannabis, and cocaine use disorders. DALI-alcohol: scores range from -4 to +6, higher scores indicate higher risk of alcohol abuse. DALI-drugs: scores range from -4 to +4, higher scores indicate higher risk of drug abuse. As scale ranges from negative to positive value, skew is difficult to detect. We therefore entered data from this scale in Additional tables rather than into an analysis.

6.2.15 *Substance Abuse Treatment Scale (SATS)* (Drake 1996; McHugo 1995): in Drake-NHamp 1998

An eight-point scale indicating progression toward recovery, ranging from 1 (early stages of engagement) to 8 (relapse prevention). Higher scores indicate greater progression.

6.2.16 *Timeline Followback (TLFB)* (Sobell 1980): in Drake-NHamp 1998

Scale administered by an interviewer to assess days of alcohol and drug use over the previous six months. Outcome reported as binary data.

6.2.17 *Brief Psychiatric Rating Scale (BPRS)* (Overall 1962): in Audini-UK 1994, Drake-NHamp 1998, Muijen-UK2 1994, REACT-UK 2002, Sytema-Netherlands 1999 (BPRS 24-item - Velligan 2005); in Chan-Hong Kong 2000, Ford-UK 1995, Rosenheck-USA 1993 (BPRS 18-item)

The BPRS measures positive symptoms, general psychopathology, and affective symptoms. The original scale has 16 items, but a revised 18-item scale is commonly used. Symptoms are reported in several ways (i.e. on a scale of 0 to 6 or 1 to 7), but it is most common for each item to be rated on a seven-point scale (1 = not present to 7 = extremely severe). The 18-item scale can range from 18 to 126 or from 0 to 108 (as in Ford-UK 1995 and Rosenheck-USA 1993). A further version is a 24-item scale ranging from 24 to 168. For all of the scales, higher scores indicate more severe symptoms.

6.2.18 *Brief Symptom Inventory (BSI)* (Derogatis 1983): in Rosenheck-USA 1993

A brief rating scale used by an independent rater to assess the severity of psychiatric symptoms. Scores range from 0 to 4, with higher scores indicating more symptoms.

6.2.19 *Comprehensive Psychopathological Rating Scale (CPRS)* (Asberg 1978): in Holloway-UK 1996, UK700-UK 1999

This is an interview rating scale covering a wide range of psychiatric symptoms; it can be used in total or as subscales. CPRS consists of 65 items that cover the range of psychopathology over the preceding week (40 symptom items are rated by the participant, and 25 observed items are rated by the rater during the interview). Each item is rated on a 0 to 3 scale ranging from 'not present' to 'extremely severe', with higher scores indicating more severe symptoms.

6.2.20 *Colorado Symptom Index (CSI)* (Shern 1994): in Lehman-Maryland1 1994, Shern-USA1 2000

A brief rating scale used by an independent rater to assess the severity of a range of psychiatric symptoms. A lower score indicates more symptoms.

6.2.21 *Krawiecka Scale (KS) alias Manchester Scale* (Krawiecka 1977): in Harrison-Read-UK 2000

This scale rates severity of psychiatric symptoms. It consists of eight categories of symptoms assessed on a five-point scale, which are depression, anxiety, hallucinations, delusions, flattened and incongruous effect, psychomotor retardation, incoherence and irrelevance of speech, and poverty of speech. A score of 0 or 1 denotes an absence of pathology, while ratings of 2, 3, or 4 denote the presence of the target symptoms in increasing severity. Rating is from 0 to 36. Higher scores indicate a worse outcome.

6.2.22 *Present State Examination (PSE)* (Wing 1974): in Audini-UK 1994, Muijen-UK2 1994

This is a clinician-rated scale measuring mental status. The scale rates and combines 140 symptom items to give various syndrome and subsyndrome scores. A short version covering the first 40 'neurotic' symptoms has been used in several population surveys. Score ranges from 1 to 120. Higher scores indicate greater clinical impairment.

6.2.23 *Symptom Checklist-90 (SCL-90)* (Hopkins Symptoms Checklist) (Derogatis 1974): in Bjorkman-Sweden 2002

This is a self report clinical rating scale of psychiatric symptomatology comprised of 90 symptom-related questions. Out of 90 items, 83 items represent nine subscales: somatisation (12

items), obsessive-compulsive (10 items), interpersonal sensitivity (9 items), depression (3 items), anxiety (10 items), anger-hostility (6 items), phobic anxiety (7 items), paranoid ideation (6 items), and psychoticism (10 items). Seven additional items include disturbances in appetite and sleep. The SCL-90 also utilises three global distress indices: Global Severity Index (GSI), Positive Symptom Distress Index (PSDI), and Positive Symptom Total (PST). The participant assesses the degree of severity of each symptom. Items are rated on a five-point Likert scale, ranging from 'not at all distressing' (0) to 'extremely distressing' (4), with higher scores indicating greater symptomatology.

6.2.24 Beck Depression Inventory (BDI) (Beck 1979): in [Holloway-UK 1996](#)

A 21-item self rating scale for depression. Each item comprises 4 statements (rated from 0 to 4) describing increasing severity of the abnormality concerned. The person completing the scale is required to read each group of statements and identify the one that best describes the way they have felt over the preceding week. Score ranges from 0 to 84, with higher score indicating more severe symptoms.

6.2.25 Hospital Anxiety and Depression Scale (HADS) (Zigmond 1983): [Harrison-Read-UK 2000](#)

This scale is a questionnaire composed of statements relevant to either generalised anxiety or depression referring to the past week. Seven items in the questionnaire reflect anxiety, and seven reflect depression. The participant answers each item on a four-point (0 to 3) response category; the possible scores range from 0 to 21 for anxiety and 0 to 21 for depression. Higher score indicates a worse outcome.

6.2.26 Scale for the Assessment of Negative Symptoms (SANS) (Andreasen 1982; Andreasen 1989): in [Holloway-UK 1996](#), [UK700-UK 1999](#)

This scale assesses five symptom complexes to obtain clinical ratings of negative symptoms in people with schizophrenia over the preceding week. They are: affective blunting, alogia (impoverished speech), avolition/apathy, anhedonia/asociality, and disturbance of attention. The final symptom complex seems to have less obvious relevance to negative symptoms than the other four complexes. Assessments are conducted on a six-point scale (from 0 indicating 'not at all' to 5 indicating 'severe'). Higher scores indicate a worse outcome.

6.2.27 Scale for the Assessment of Positive Symptoms (SAPS) (Andreasen 1984): in [OPUS-Denmark 1999](#)

The SAPS measures positive symptoms in schizophrenia. It is intended to serve as a complementary instrument to the Scale for the Assessment of Negative Symptoms (SANS). SAPS is split into four domains: hallucinations, delusions, bizarre behavior, and positive formal thought disorder. Within each domain, separate symptoms are rated from 0 (absent) to 5 (severe). Higher scores indicate a worse outcome.

6.2.28 Social Behaviour Schedule (SBS) (Wykes 1986): in [Holloway-UK 1996](#)

The SBS is a 21-item scale designed to assess a range of areas of functioning in people with long-term mental illness. The scale

covers areas such as social behaviour and communication, self care, and inappropriate behaviour. The respondent's behaviour on each item during the previous month is scored by a person familiar with him or her. Each item is rated on a five-point Likert scale (from 0 to 4), with higher scores indicating greater deficits.

6.2.29 Lancashire Quality of Life Profile (LQoLP) (Oliver 1996; Oliver 1997): in [Bjorkman-Sweden 2002](#), [Holloway-UK 1996](#), [UK700-UK 1999](#)

A structured self report interview with 105 items, combining objective and subjective measures in the following nine life domains (range of values 1 to 7): living situation, social relationships, work and education, legal status and safety, religion, family relations, leisure activities, finances, and health. The LQoLP also measures the following additional areas: positive and negative affect (with the Bradburn Affect-Balance Scale), self esteem, global well-being (Cantril's Ladder and Happiness Scale), perceived quality of life, and the quality of life of the patient independent of the patient's own opinion (with the Quality of Life Uniscale). The measures from LQoLP used in [Bjorkman-Sweden 2002](#) were: overall quality of life (which is the mean of subjective quality of life in nine life domains) and global well-being. Higher score indicates better subjective quality of life/satisfaction.

6.2.30 Manchester Short Assessment of Quality of Life (MANSA) (Priebe 1999): [REACT-UK 2002](#), [Sytema-Netherlands 1999](#)

A 16-item scale composed of 4 objective and 12 subjective questions. The 12 subjective items are rated on a 7-point scale (from 'couldn't be worse' to 'couldn't be better', scored from 1 to 7, range 12 to 84) assessing satisfaction with life 'in general', and in a range of domains such as vocational, financial, friendships, leisure, personal safety, physical health, and mental health. Four objective items, answered yes or no, assess the existence of a close friend, contacts with friends per week, accusation of a crime, and victimisation of physical violence. Higher score indicates better quality of life. In [REACT-UK 2002](#) and [Sytema-Netherlands 1999](#), score is reported as a mean ranging from 1 to 7.

6.2.31 Lehman's Quality of Life Interview (QOLI) (Lehman 1988): in [Drake-NHamp 1998](#), [Lehman-Maryland1 1994](#), [Shern-USA1 2000](#); (Lehman 1993) in [Ford-UK 1995](#); (Lehman 1983) in [Marshall-UK 1995](#)

The QOLI contains 153 items that measure global life satisfaction as well as objective and subjective quality of life, in eight life domains (living situation, daily activities and functioning, family relations, social relations, finances, work and school, legal and safety issues, and health). The QOLI is rated on a seven-point scale, with higher scores indicating better quality of life. Subjective assessment of general life satisfaction ranges from 1 to 7 (terrible to delighted). [Ford-UK 1995](#) reported objective quality of life, and [Marshall-UK 1995](#) reported subjective quality of life.

6.2.32 Camberwell Assessment of Need interview (CAN) (Phelan 1993): in [Bjorkman-Sweden 2002](#), [Harrison-Read-UK 2000](#), [UK700-UK 1999](#)

The Camberwell Assessment of Need assesses the health and social needs of people with mental health problems. It measures 22 areas to yield numbers of met and unmet needs as rated by the participant. Possible scores range from 0 to 22, with a higher score indicating poorer level of met needs.

6.2.33 *Camberwell Assessment of Need Short Appraisal Schedule (CANSAS)* (Phelan 1995; Slade 1999): in REACT-UK 2002, Sytema-Netherlands 1999

This is an abbreviated form of the above CAN.

6.2.34 *Client Satisfaction Questionnaire (CSQ)* (Larsen 1979): in Audini-UK 1994, Muijen-UK2 1994, OPUS-Denmark 1999, Sytema-Netherlands 1999

The CQS is a self report instrument designed to measure patient's global satisfaction with services. Items are concerned with quality of services received, how well services met the client's needs, and general satisfaction. The CSQ is substantially correlated with treatment attrition, number of therapy sessions attended, and change in client-reported symptoms. It consists of eight items that are scored on four-point Likert scales (1 to 4). Total score ranges from 8 to 32. Higher scores indicate greater satisfaction.

6.2.35 *Client Satisfaction Questionnaire (CSQ) - modified version* (Gerber 1999; Larsen 1979): in REACT-UK 2002

This survey has 35 questions covering the location of services, services clients expect, delays in obtaining services, client's input into treatment, information received about drug treatment, satisfaction with treatment, access to clinical files, satisfaction with the therapist, family involvement in treatment, the treatment process, and overall satisfaction. Possible responses to most items range from 1 (most negative) to 7 (most positive). A rating of zero on certain items enables the respondent to indicate that the question was not relevant to his or her situation. Six items within the questionnaire, also on a seven-point scale, form a general satisfaction questionnaire. Higher score indicates greater satisfaction.

6.2.36 *Patient's satisfaction with health services* (Tyrer 1979): in UK700-UK 1999

A self reporting questionnaire that rates nine components of satisfaction with services, each on a four-point scale (1 to 4). Scores can range from 9 to 36, with higher values indicating less satisfaction.

6.2.37 *Patient Satisfaction Instrument (PSI)* (Risser 1975): in Chan-Hong Kong 2000

The PSI assesses patient and client satisfaction. It is a 26-item questionnaire designed to measure clients' satisfaction with nursing care in the community setting.

6.2.38 *Specific Level of Functioning Scale (SLOF)* (Schneider 1983): in Chan-Hong Kong 2000

The SLOF assesses clients' behavioural functioning and daily skills. It is a 43-item behavioural rating scale designed for use in clients with chronic mental illness in the community.

6.3 Missing outcomes

No trial reported or rated relapse, mental state: not improved, or carer satisfaction.

Excluded studies

See: [Characteristics of excluded studies](#).

Eighty-one studies were excluded from the previous versions of this review, while a total of 85 studies were excluded from this version.

The earlier update excluded four trials included in the original reviews as the trials did not match the new inclusion criteria. (De Cangas-Canada 1994; Franklin-Texas 1987; Lafave-Canada 1996; Marx-Wisconsin 1973). Morse-Missouri2 1997 was also excluded, as it did not report the number of people randomised to each treatment group.

One further trial (Tyrer-UK 1995), originally included in the Case Management (CM) review, was now excluded because of a methodological issue. Tyrer-UK 1995 is a trial comparing ICM to standard care. The first issue was to clarify the ICM caseload. Thanks to further information provided from the author, we clarified that there were 25 key workers in the service looking after 400 patients on the register, therefore each key worker had a caseload of 1 to 16, or 'high-intensity' case management by this review's definition. The second issue that arose was that the case managers in the treatment group were also workers in the control group. The problem was therefore one of contamination, as requiring someone to carry out close monitoring of one participant in the treatment group could affect their care of a similar participant in the control group in an unpredictable way. We decided to exclude this study on the grounds that we could not be sure that high-intensity case management was really being compared with standard care.

We also excluded three trials that had been awaiting assessment in the original Case Management and Assertive Case Management reviews (see [Other published versions of this review](#)) for varying reasons (Godley-Illinois 1994; Jerrell-California 1989; Mulder-Missouri 1985) (for more details see [Characteristics of excluded studies](#)).

Jerrell-California 1989 was a partially published trial previously classified as 'awaiting further assessment' because we needed information on number of people excluded after randomisation (participants were excluded if they refused to participate after randomisation or if they had not been discharged from hospital within six months of entering the study). As these data have not become available, we have now excluded the trial.

Godley-Illinois 1994 was an unpublished, two-centre trial initially classified as 'awaiting further assessment' because we could not determine if the intervention was ACT or CM. During the current update we classified the intervention as ICM versus standard care. We had to exclude this study because it contained no usable data due to incomplete data reporting, and no further information became available (i.e. there was an apparent error in the reporting of numbers admitted to hospital: in one table admission rates were reported as 31/52 experimental group and 33/45 control group, while in another table admission rates were reported as 31/52 experimental and 25/45 control).

Mulder-Missouri 1985 was a report of data from randomised and non-randomised participants. We excluded this study because these data were not reported separately and, in addition, the intervention did not fit our inclusion criteria (ICM was compared to acute hospital admission).

Overall, we excluded 42 studies because they were not randomised or because randomisation was compromised (Jerrell-California 1989). We had to exclude five studies because participants

required immediate hospital admission ([Fenton-Canada 1978](#); [Hoult-Australia 1981](#); [Muijen-UK1 1992](#); [Mulder-Missouri 1985](#); [Stein-Wisconsin](#)), one study because participants were dually diagnosed with intellectual disability and mental illness ([Martin-UK 2005](#)), and one additional study because the majority of participants were simply homeless and not clearly ill ([Toro-New York 1997](#)). Most trials had to be excluded because of the intervention: 54 because the experimental intervention was not ICM. We had to exclude [Modcrin-Kansas 1988](#) as caseload was not reported in either the experimental or the control group. We excluded 48 trials as the comparison intervention was neither standard care nor non-ICM. We excluded 10 trials as the intervention administered to the experimental group was not only ICM ([Chandler-California2 2006](#); [COAST-UK 2004](#); [Cosden-California 2005](#); [Gold-SCarolina 2006](#); [Grawe-Norway 2005](#); [Lehman-Maryland2 1993](#); [LEO-UK 1994](#); [McHugo-Washington DC 2004](#); [Shern-USA2](#); [Shern-USA3](#)). We excluded 10 trials as they did not present with relevant comparisons. Finally, we excluded two trials, [Godley-Illinois 1994](#) and [Morse-Missouri2 1997](#), because we could extract no usable data from the study report (as previously explained).

Awaiting classification

See: [Characteristics of studies awaiting classification](#).

Five trials described as 'awaiting classification' in the previous review have now been excluded as more data have become available ([Agius-Croatia 2007](#); [Kane-Virginia 2004](#); [Klotz-California 2001](#); [Li-China 2004](#); [NCT00781079](#)); two more have now been excluded based only on the abstract, and so they were not included in the excluded studies section ([Huang-China](#) and [Johnson-UK](#)).

Twenty trials, of which three are in the Chinese language, are awaiting classification, and their authors have been contacted for further clarification.

Ongoing studies

See: [Characteristics of ongoing studies](#).

We are aware of six currently ongoing trials, five more than the ongoing studies in the previous version of this review ([Walsh-Connecticut](#)).

Risk of bias in included studies

For multicentre trials that provided data for individual single centres, we did not assess the risk of bias for each centre. Our judgements regarding the overall risk of bias in individual studies are illustrated in [Figure 1](#).

Allocation

All 40 studies were stated to be randomised, but only 11 provided descriptions of the methods used to generate the sequence. We therefore classified these studies as at low risk of selection bias. The most common method of randomisation was random allocation according to a sequence of random numbers generated by a computer program in one of two sites ([Bjorkman-Sweden 2002](#); [Essock-Connecticut2 2006](#); [Ford-UK 1995](#); [Harrison-Read-UK 2000](#); [OPUS-Denmark 1999](#)), while [Cusack-North Carolina](#) employed randomisation using a random number table, assigned in blocks of two. Three trials used permuted block ([Marshall-UK 1995](#); [REACT-UK 2002](#); [Sytema-Netherlands 1999](#)), one used a table of random

permutation ([Pique-California 1999](#)), and one used coin tossing ([Rosenheck-USA 1993](#)). In one of the two sites of the [OPUS-Denmark 1999](#) trial (Aarhus site), allocation was performed by drawing lots – from among five red and five white lots from a black box. Overall, however, most studies, including [Chan-Hong Kong 2000](#), were classified as at unclear risk of selection bias with an overestimate of positive effect, as no description of the methods used to generate the sequence was provided.

Regarding the allocation concealment, we rated only four studies as low risk of bias as they provided descriptions of the methods used to conceal random allocation ([OPUS-Denmark 1999](#); [REACT-UK 2002](#); [Sytema-Netherlands 1999](#); [UK700-UK 1999](#)). All four studies used centralised allocation carried on by telephone, fax, or mail. We classified the remaining 33 studies as at unclear risk of selection bias with an overestimate of positive effect.

Blinding

We classified blinding with respect to only primary outcomes. Due to intervention characteristics, that is being a model of service organisation, we assumed participants and clinicians implicitly not being blind to treatment assignment. We also assumed that primary outcomes were likely to be influenced by participant and clinician lack of blinding, as the knowledge of treatment allocation could determine both performance and attrition bias at a level that is difficult to predict/quantify. Whereas we did not consider the primary outcomes as interviewer mediated, we assumed that lack of interviewer blinding would produce less detection bias. We therefore classified all studies providing primary outcome data as at unclear risk of performance and attrition bias. This creates further potential for overestimate of positive effects and underestimate of negative ones.

We have reported blinding to secondary outcomes in the 'Risk of bias' table, but we did not account for it in the global rating of the study blinding risk of bias. Again, if the secondary outcome was clinician/participant mediated, we rated it as unclear. If it was interviewer rated, we assessed it according to information provided in the study. We rated only [Shern-USA1 2000](#) as at high risk of bias, as it provided only secondary outcome data and was only interviewer mediated, and it was therefore possible to assess risk of bias for this study with greater confidence. We rated [Chan-Hong Kong 2000](#) as at unclear risk of performance and detection bias, as it did not clearly report any information on blinding.

Incomplete outcome data

Where information was available, we assessed incomplete outcome data separately for primary and secondary outcomes and presented both assessments in [Figure 1](#). However, we only rated risk of bias with respect to primary outcome. Only three trials provided separate information for incomplete primary and secondary outcome data, and so we could assess the risk of bias separately ([Holloway-UK 1996](#); [Johnston-Australia 1998](#); [REACT-UK 2002](#)). We judged nine trials as adequately addressing incomplete outcome data and rated them as at low risk of attrition bias. We so rated four of these studies because there were no missing outcome data ([Bush-Georgia 1990](#); [Holloway-UK 1996](#); [REACT-UK 2002](#); [Sytema-Netherlands 1999](#)); three because they made the number and reason for missing data explicit, and the missing data were balanced across groups ([Audini-UK 1994](#); [Essock-Connecticut1 1995](#); [Johnston-Australia 1998](#)); and two because they undertook

intention-to-treat (ITT) analysis ([OPUS-Denmark 1999](#); [UK700-UK 1999](#)).

In [Cusack-North Carolina](#), all analyses were intention to treat and outcomes were observed regardless of active or continued participation. Although [Chan-Hong Kong 2000](#) reported the analyses as ITT, it was not clearly reported whether any participants left early.

We judged [Bond-Chicago1 1990](#) and [Ford-UK 1995](#) as at high risk of attrition bias because, although clearly reporting number and reasons for missing data, the reasons for missing outcome data were likely to be related to true outcome, with imbalance either in numbers or reasons for missing data across intervention group. However, our protocol compensated for this somewhat (see [Dealing with missing data](#)), and despite the high rating, information from these studies remains included.

We rated the remaining trials as at unclear risk of attrition bias. Either they did not address this issue or presented insufficient information of attrition/exclusions to permit judgement (i.e. no reasons for missing data provided or number randomised not stated. [Jerrell-SCarolina1 1991](#) reported only number of randomised participants completing the study period).

Some specific examples may serve to illustrate the difficulty in rating this issue. [Essock-Connecticut2 2006](#) was not an ITT analysis (seven participants were excluded from the study immediately after randomisation because they were lost to follow-up), but the authors failed to provide information on to what intervention those participants had been allocated and reason for leaving the study early. As this study provided only continuous outcome data, we reproduced completer-only data that were reported. No action was undertaken to deal with other missing data.

[Macias-Utah 1994](#) had three problems. First, the study was not an ITT analysis: seven participants were excluded from the study because they were lost to follow-up. The authors of this study broke with standard practice by failing to provide any data on participants lost to follow-up, in particular data on admissions to hospital. Second, one participant (presumably randomised to the treatment group) was excluded after randomisation, having refused to participate (again, it was unclear whether this person had been admitted to hospital). Third, five further participants were added (randomly) to the treatment and control groups part way through the study, some as late as "late 1990" (final assessments took place in February 1991). No further information has become available since first review publication, which potentially could substantially affect findings.

In [Morse-Missouri1 1992](#), 28 further participants were added (randomly) to the initial randomised sample, to replace participants leaving the study within the first month after entering. As replacement was carried out through randomised assignment, we did not raise any questions on the replacement issue and included the study. We presented data from the final sample, obtained after randomised replacement had occurred.

In [Muller-Clemm-Canada 1996](#), the number randomised was not clearly reported; authors declared that "Clients who withdrew from the study within the first 6 months were replaced by other clients".

Finally, [Sytema-Netherlands 1999](#) randomised 119 participants, but one was excluded because he or she moved to another area directly after randomisation. (We performed ITT analysis on the remaining 118 participants.)

Selective reporting

We rated most of the trials (24) as at high risk of reporting bias, as their data was presented in such a way that we could not consider it to be free of the suggestion of selective outcome reporting (i.e. prespecified outcomes were not reported, or they were reported incompletely so that they could not be entered in the analysis, or outcomes were reported that were not prespecified). We rated 16 studies as at low risk of reporting bias. We assessed two studies as at unclear risk of reporting bias.

Other potential sources of bias

Only [Hampton-Illinois 1992](#) was rated as at unclear risk of other potential sources of bias, as it was unclear whether the study was interrupted early in one of the two centres.

We rated all of the remaining trials as at low risk of other potential sources of bias, as we found no evidence of other bias. Most of these studies were publicly funded. No declaration of interest was made by authors, and we assume there was none to be made. However, many study authors were active pioneers in the development and implementation of the experimental intervention model across the scientific community and the clinical world. This raises the issue of how researcher beliefs could affect the entire process of evaluating an intervention in a randomised clinical trial. Although conscious of this issue, we decided not to make any attempt in rating it as it is very difficult to judge, and erroneous quantification could drive bias into our conclusions.

Effects of interventions

See: [Summary of findings for the main comparison Intensive Case Management versus standard care for severe mental illness](#); [Summary of findings 2 Intensive Case Management versus non-Intensive Case Management for severe mental illness](#)

We categorised studies into two comparisons: Intensive Case Management versus standard care, and Intensive Case Management versus non-Intensive Case Management. The nine main indices of outcome were:

1. service use;
2. adverse effects;
3. global state;
4. social functioning;
5. mental state;
6. behaviour;
7. quality of life;
8. satisfaction; and
9. direct costs.

We considered each index in turn for each of the two comparisons. We were able to extract numerical data from 40 randomised trials, among which seven multicentre trials provided data for individual single centre.

1. COMPARISON 1: INTENSIVE CASE MANAGEMENT versus STANDARD CARE

(Summary of findings for the main comparison). There were 45 outcomes in this comparison.

1.1 Service use: 1. Average number of days in hospital per month - by about 24 months

Data were available from five studies presenting skewed data from a sample size greater than or equal to 200 participants and from 19 trials reporting skewed data from sample sizes less than 200. We entered these data in separate subgroups, but we also presented the overall data.

1.1.1 Skewed data (sample size ≥ 200)

In the first subgroup analysis (i.e. skewed data from studies with sample size greater than or equal to 200 participants), we found no significant difference in length of hospitalisation per month ($n = 1812$, 5 randomised controlled trials (RCTs), mean difference (MD) -0.46, confidence interval (CI) -0.95 to 0.03), although data suggested a trend favouring ICM ($P = 0.06$). This subgroup had moderate levels of heterogeneity ($\text{Chi}^2 = 6.36$; $df = 4.0$; $P = 0.17$; $I^2 = 37\%$; Analysis 1.1).

1.1.2 Skewed data (sample size < 200)

In the second subgroup analysis (i.e. skewed data from study sample size less than 200 participants), there was a significant

difference between groups, favouring the ICM group in reducing length of hospitalisation ($n = 1783$, 19 RCTs, MD -1.01, 95% CI -1.74 to -0.28), but these data were highly heterogeneous ($\text{Chi}^2 = 79.27$; $df = 18.0$; $P = 0.0$; $I^2 = 77\%$; Analysis 1.1).

1.1.3 Overall data (skewed data: sample size ≥ 200 and sample size < 200)

When synthesising data from the two subgroups, we found that length of hospitalisation was significantly reduced in the ICM group ($n = 3595$, 24 RCTs, MD -0.86, 95% CI -1.37 to -0.34), but the level of heterogeneity was high ($\text{Chi}^2 = 89.43$; $df = 23.0$; $P = 0.0$; $I^2 = 74\%$; Figure 3). We investigated the heterogeneity by checking again for correctness of data and removing one outlier study from the analysis (Curtis-New York 1992), as it was the only study favouring standard care. After excluding Curtis-New York 1992, the level of heterogeneity was still high ($I^2 = 59\%$; $P < 0.0002$). We therefore removed the second-most outlier study from the analysis (Bond-Indiana1 (A), one of three centres from a multicentre study), as this was the most extreme result (favouring ICM). By excluding Bond-Indiana1 (A), data remained significant, favouring ICM ($n = 3245$, 22 RCTs, MD -0.79, 95% CI -1.22 to -0.36). The heterogeneity was reduced to just within our cutoff point ($I^2 = 49\%$; $P = 0.005$). Removing two further outliers (Bond-Indiana1 (C) and Quinlivan-California 1995) reduced heterogeneity still further ($I^2 = 36\%$; $P = 0.05$) as well as the overall estimate, but ICM still seemed to significantly decrease time in hospital ($n = 3143$, 20 RCTs, MD -0.62, 95% CI -1.00 to -0.23, Figure 4).

Figure 3. Forest plot of comparison: 1 Intensive Case Management versus standard care, outcome: 1.1 Service use: 1. Average number of days in hospital per month - at about 24 months.

Figure 4. Service use: 1. Average number of days in hospital per month - at about 24 months - restoring homogeneity - 4 studies removed from analysis.

No substantial reporting biases were highlighted when investigated through visual inspection of funnel plot (Figure 5). Two studies -

Bond-Indiana1 (A) and Quinlivan-California 1995 - seemed most heterogeneous (see above).

Figure 5. Funnel plot of comparison: 1 Intensive Case Management versus standard care, outcome: 1.1 Service use: 1. Average number of days in hospital per month - by about 24 months.

We ran meta-regression on trials providing data for the primary outcome 'average number of days in hospital per month - at about 24 months' (combining data from all ICM studies within Comparison 1 and 2). Within the meta-regression we found that i.) the more ICM is adherent to the organisation model, the better it is at decreasing time in hospital ('organisation fidelity' variable coefficient -0.36, 95% CI -0.66 to -0.07, [Figure 6](#)); and ii.) the higher the baseline hospital use in the population, the better ICM is at decreasing time in hospital ('baseline hospital use' variable coefficient -0.20, 95% CI -0.32 to -0.10, [Figure 7](#)). Combining both

these variables within the model, 'organisation fidelity' is no longer significant (regression coefficient -0.24, 95% CI -0.52 to 0.04, $P = 0.089$), but 'baseline hospital use' result still significantly influences time in hospital, although it seems to lose some of its potency (regression coefficient -0.18, 95% CI -0.29 to -0.07, $P = 0.0027$) ([Figure 8](#)). [Figure 8](#) shows the interaction of the two variables on study outcome graphically through the use of thin plate spline modelling. The plot provides a locally weighted two-dimensional representation of the collinearity between the variables used in the regression.

Figure 6. Meta-regression: Scatterplot of IFACT organisation subscore versus mean days per month in hospital.

Figure 7. Meta-regression: Scatterplot of mean baseline days in hospital versus mean days per month in hospital.

Figure 8. Weighted thin plate spline regression showing combined effect of baseline days in hospital and organisational fidelity score on treatment effect.

1.2 Service use: 1 Number of days in hospital - by follow-up (skewed data, sample size # 200)

We identified one study relevant to this outcome, providing data by medium- and long-term follow-up (FUP) and measuring outcome during the previous year.

1.2.1 By medium-term FUP (3 years) (previous year)

We found one trial to be relevant to this subgroup, with a total of 547 participants. For this subgroup, we did not find evidence of a clear difference between the two treatments (MD 0.1, 95% CI -10.26 to 10.46; [Analysis 1.2](#)).

1.2.2 By long-term FUP (8 years) (previous year)

There was a single trial in this subgroup, with a total of 547 participants. There was no clear difference between ICM and standard care within this subgroup (MD 4.3, 95% CI -4.63 to 13.23; [Analysis 1.2](#)).

1.3 Service use: 2. Not remaining in contact with psychiatric services

We found nine relevant studies (total n = 1633) for this outcome, providing data on different follow-up length. Overall, when pooling studies from different time subgroups, we found a significant advantage to the ICM group, where people were less likely to be lost

to psychiatric services than people in the standard care group (n = 1633, 9 RCTs, risk ratio (RR) 0.43, 95% CI 0.30 to 0.61, [Figure 9](#)).

Heterogeneity was moderately high for this outcome ($\text{Chi}^2 = 15.57$; $\text{df} = 8.0$; $P = 0.05$; $I^2 = 48\%$).

Figure 9. Forest plot of comparison: 1 Intensive Case Management versus standard care, outcome: 1.2 Service use: 2. Not remaining in contact with psychiatric services by short, medium, long term and overall.

As there were fewer than 10 studies for this outcome, we did not use a funnel plot (see [Assessment of reporting biases](#)).

1.3.1 By short term

We included only one short-term study and found no significant difference between treatment groups (n = 95, 1 RCT, RR 0.54, 95% CI 0.28 to 1.05; [Analysis 1.3](#)).

1.3.2 By medium term

Medium-term data available from three studies showed a significant difference between treatment groups, favouring the ICM group, where participants had a lower risk of not remaining in contact with psychiatric services compared with participants in the standard care group (n = 1063, 3 RCTs, RR 0.51, 95% CI 0.36 to 0.71). Heterogeneity was moderately high for this subgroup ($\text{Chi}^2 = 3.02$; $\text{df} = 2.0$; $P = 0.22$; $I^2 = 33\%$; [Analysis 1.3](#)).

1.3.3 By long term

Six long-term studies data confirmed the trend favouring ICM, showing a significant advantage for the ICM group (n = 653, 6 RCTs, RR 0.35, 95% CI 0.18 to 0.68), but data were heterogeneous ($I^2 = 63\%$; $P = 0.02$). [Herinckx-Oregon 1996](#) seemed to be the sole cause of this, and on further consideration post hoc, we think we were in error in including the outcome from this study because it was defined so differently from the other trials. [Herinckx-Oregon 1996](#) did not include refusing to re-interview, moving out, and death - as all the other studies had done - and it was impossible to amend this at this stage. We therefore feel justified in removing this study

altogether from this part of the review outcomes. Once [Herinckx-Oregon 1996](#) was removed, the five remaining trials confirmed the significant advantage for the ICM group (n = 475, 5 RCTs, RR 0.27, 95% CI 0.11 to 0.66), and heterogeneity was restored to a moderate level ($\text{Chi}^2 = 7.19$; $\text{df} = 4.0$; $P = 0.13$; $I^2 = 44\%$; [Analysis 1.3](#)).

1.4 Service use: 3a. Admitted to hospital

We identified 16 studies relevant to this outcome and categorised data into five subgroups (in keeping with our protocol).

1.4.1 By short term

Data were available from two short-term studies and showed no significant differences between treatment groups (n = 244, 2 RCTs, RR 0.61, 95% CI 0.22 to 1.69), but these data were heterogeneous ($\text{Chi}^2 = 5.36$; $\text{df} = 1.0$; $P = 0.02$; $I^2 = 81\%$; [Analysis 1.4](#)).

1.4.2 By medium term

Five studies reported medium-term data, and these favoured the ICM group, which had less admission to hospital across time compared with standard care (n = 1303, 5 RCTs, RR 0.85, 95% CI 0.77 to 0.93; [Analysis 1.4](#)).

1.4.3 By long term

Eleven studies provided long-term data. As with the short-term data, they showed no significant differences between treatment groups (n = 1516, 11 RCTs, RR 0.96, 95% CI 0.74 to 1.23), but data were heterogeneous ($\text{Chi}^2 = 32.88$; $\text{df} = 10.0$; $P = 0.0$; $I^2 = 69\%$; [Analysis 1.4](#)).

1.4.4 By long term- during previous 12 months

Only one study reported data by long term, but referring to the number of admissions across the previous year. We therefore could not enter this data in the long-term data subgroup analysis. This data showed a significant effect favouring the ICM group ($n = 547$, 1 RCT, RR 0.67, 95% CI 0.52 to 0.86), therefore not consistent with long-term data shown above. As these findings were based on data from one study only, we consider them less robust than the findings from the 11 long-term studies [Analysis 1.4](#).

1.4.5 By short term FUP - unplanned admission through emergency department (ED)

We found one trial to be relevant to this subgroup (total $n = 62$). For this subgroup, we did not find evidence of a clear difference between the two treatments (RR 1.0, 95% CI 0.07 to 15.28; [Analysis 1.4](#)).

1.5 Service use: 3b. Average number of admissions per month (skewed data)

Data describing the average number of admissions per month were available from one medium-term and three long-term studies. All of these data were skewed and did not enter the analysis. Data from the medium-term study suggested a trend favouring the ICM group. Data from the long-term studies showed no trend favouring one group over the other. [Audini-UK 1994](#) and [Muller-Clemm-Canada 1996](#) did not report variance measurements. We assumed consistency between studies and used the fully reported variance for [Sytema-Netherlands 1999](#), and employed these data for [Audini-UK 1994](#) and [Muller-Clemm-Canada 1996](#) as well.

1.6 Service use: 4a. Admitted to ER - by long term

The only study identified describing 'number admitted to ER' showed a non-significant difference between the two groups ($n = 178$, 1 RCT, RR 1.13, 95% CI 0.72 to 1.76).

1.7 Service use: 4b. Average number of admissions to ER (skewed data) - by medium term

The two studies describing the average number of admissions to ER reported skewed data. Skewed data were not consistent, as one study did not show any trend in the direction of effect, and the other study showed a trend favouring the ICM group. As in one study the variance measurement was not reported ([Jerrell-SCarolina1 1991](#)), we carried the standard deviation over from the other available study ([Lehman-Maryland1 1994](#)).

1.8 Service use: 5a. Received day hospital care - by short-term FUP

We identified only one study relevant to this outcome (total $n = 62$). There was not a significant difference between ICM and standard care (RR 2.0, 95% CI 0.19 to 20.93; [Analysis 1.8](#)).

1.9 Service use: 5b. Outpatient visits - by short-term FUP (6 months)

We identified only one study relevant to this outcome. There was not a significant difference between ICM and standard care ($n = 62$, 1 RCT, MD 0.29, 95% CI -0.14 to 0.72; [Analysis 1.9](#)).

1.10 Service use: 5c. Outpatient visits - by medium term (skewed data)

One more small study provided data for this outcome ($n = 134$), but as data were skewed and the total sample less than 200, we entered them as 'Other' data. Data showed a trend favouring ICM, where the ICM group received more outpatient visits than the standard care group by medium term ([Analysis 1.10](#)).

1.11 Service use: 5d. Received home visits - by short-term FUP

We found a single study showing a significant difference between ICM and standard care in the mean number of home visits received, favouring the ICM group ($n = 62$, 1 RCT, MD 4.32, 95% CI 3.42 to 5.22). Note that for this outcome the right graph label favours ICM (experimental group).

1.12 Adverse event: 1a. Death - any cause

We found 14 relevant studies for this outcome, the data from which we divided into five subgroups according to different time to follow-up. We found similar results in mortality across different subgroups, none of which showed a significant difference between ICM and standard care for overall mortality.

1.12.1 By short term

We found two trials relevant to this subgroup, with a total of 161 participants. For this subgroup, two deaths occurred in the 81 people treated with ICM compared with two deaths in the 80 people treated with standard care ($n = 161$, 2 RCTs, RR 1.04, 95% CI 0.16 to 6.91; [Analysis 1.12](#)).

1.12.2 By medium term

There were six relevant trials in this subgroup (total $n = 901$). For this subgroup, five deaths occurred in 453 people treated with ICM compared with six deaths in 448 people treated with standard care ($n = 901$, 6 RCTs, RR 0.78, 95% CI 0.23 to 2.62; [Analysis 1.12](#)).

1.12.3 By long term

We found nine trials relevant to this subgroup, with a total of 1456 participants. For this subgroup, 24 deaths occurred in 741 people treated with ICM compared with 27 deaths in 715 people treated with standard care ($n = 1456$, 9 RCTs, RR 0.84, 95% CI 0.48 to 1.47; [Analysis 1.12](#)).

1.12.4 By medium-term FUP (3 years)

There was a single trial in this subgroup, in which six deaths occurred in 275 people treated with ICM compared with 10 deaths in 272 people treated with standard care, showing no significant difference between ICM and standard care ($n = 547$, 1 RCT, RR 0.59, 95% CI 0.22 to 1.61; [Analysis 1.12](#)).

1.12.5 By long-term FUP (8 years)

There was a single trial in this subgroup, in which 14 deaths occurred in 275 people treated with ICM compared with 15 deaths in 272 people treated with standard care, showing no significant difference between ICM and standard care ($n = 547$, 1 RCT, RR 0.92, 95% CI 0.45 to 1.88; [Analysis 1.12](#)).

1.13 Adverse event: 1b. Death - suicide

We found 12 relevant studies for this outcome and categorised data into four subgroups. Our results for mortality due to suicide were

similar to those found for mortality due to all causes, that is no significant difference in suicide rate between the two intervention groups.

1.13.1 By short term

Data by short term were available from two studies, where no suicides occurred in 62 people treated with ICM compared with two suicides in 65 people treated with standard care ($n = 127$, 2 RCTs, RR 0.35, 95% CI 0.04 to 3.27; [Analysis 1.13](#)).

1.13.2 By medium term

Data by medium term were available from four studies, where two suicides occurred in 412 people treated with ICM compared with two suicides in 407 people treated with standard care ($n = 819$, 4 RCTs, RR 0.98, 95% CI 0.17 to 5.60; [Analysis 1.13](#)).

1.13.3 By long term

Data by long term were available from nine studies, where 10 suicides occurred in 741 people treated with ICM compared with 14 suicides in 715 people treated with standard care ($n = 1456$, 9 RCTs, RR 0.68, 95% CI 0.31 to 1.51; [Analysis 1.13](#)).

1.13.4 By medium-term FUP (3 years)

Data by medium-term follow-up (3 years) were available from one study, where three suicides occurred in 275 people treated with ICM compared with four suicides in 272 people treated with standard care ($n = 547$, 1 RCT, RR 0.74, 95% CI 0.17 to 3.28; [Analysis 1.13](#)).

1.14 Global state: 1. Leaving the study early

We identified 21 studies relevant to this outcome and categorised data into five subgroups (in keeping with our protocol).

1.14.1 By short term

We included five short-term studies and found no significant differences between treatment groups for number of participants leaving the study early ($n = 598$, 5 RCTs, RR 0.79, 95% CI 0.44 to 1.41), but data were heterogeneous ($\text{Chi}^2 = 80.24$; $\text{df} = 4.0$; $P = 0.0$; $I^2 = 95\%$; [Analysis 1.14](#)).

1.14.2 By medium term

We included eight medium-term studies and found the risk of leaving the study early was lower for participants in the ICM group ($n = 1699$, 8 RCTs, RR 0.60, 95% CI 0.51 to 0.70; [Analysis 1.14](#)).

1.14.3 By long term

Data from 13 long-term studies confirmed data from medium-term studies, showing a significant advantage for ICM ($n = 1798$, 13 RCTs, RR 0.68, 95% CI 0.58 to 0.79; [Analysis 1.14](#)).

1.14.4 By medium-term FUP (3 years)

There was a single trial in this subgroup, showing no significant difference between ICM and standard care ($n = 547$, 1 RCT, RR 1.01, 95% CI 0.84 to 1.21; [Analysis 1.14](#)).

1.14.5 By long-term FUP (8 years)

We found one trial relevant to this subgroup, showing no significant difference between ICM and standard care ($n = 547$, 1 RCT, RR 0.88, 95% CI 0.7 to 1.09; [Analysis 1.14](#)).

1.15 Global state: 2. Average endpoint score (Global Assessment of Functioning Scale, high = good)

We identified five studies relevant to this outcome and categorised data into three subgroups. Note that for this outcome the right graph label favours ICM (experimental group).

1.15.1 By short term

There were four relevant trials in this subgroup (total $n = 797$). For this subgroup, the Global Assessment of Functioning Scale (GAF) score favoured ICM (MD 2.07, 95% CI 0.28 to 3.86; [Analysis 1.15](#)).

1.15.2 By medium term

Medium-term GAF data from three studies ($n = 722$, 3 RCTs, MD 0.09, 95% CI -3.11 to 3.28) showed no significant difference between groups. This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 4.42$; $\text{df} = 2.0$; $P = 0.11$; $I^2 = 54\%$; [Analysis 1.15](#)).

1.15.3 By long term

We found five trials relevant to this subgroup, with a total of 818 participants. For this subgroup, the GAF score favoured the ICM group (MD 3.41, 95% CI 1.66 to 5.16; [Analysis 1.15](#)).

1.16 Global state: 3. Not compliant with medication - by long term

We only found data from one long-term study, which favoured the ICM group ($n = 71$, 1 RCT, RR 0.35, 95% CI 0.15 to 0.81).

1.17 Social functioning: 1a. Contact with legal system (various measurements)

We found 11 relevant studies for this outcome and categorised data into six subgroups, according to different time to follow-up and different outcomes described.

1.17.1 By short term - contact with the police

We only found data from one study for short-term outcomes, describing the outcome 'contact with the police'. This study did not reveal any significant difference in the rate of contact with the police between treatment groups ($n = 61$, 1 RCT, RR 2.57, 95% CI 0.73 to 9.04; [Analysis 1.17](#)).

1.17.2 By medium term - arrested

We found three studies describing the outcome 'number of arrested'. These studies failed to show a significant difference between the two intervention groups ($n = 604$, 3 RCTs, RR 1.08, 95% CI 0.61 to 1.90; [Analysis 1.17](#)).

1.17.3 By medium term - contact with the police

Only one medium-term study was available providing data on 'contact with the police'. These data favoured the ICM group in reducing the number of contacts with the police ($n = 88$, 1 RCT, RR 0.23, 95% CI 0.09 to 0.55; [Analysis 1.17](#)).

1.17.4 By medium term - imprisoned

We found four medium-term studies describing 'number of imprisoned'. These studies showed no significant advantage for the ICM group ($n = 804$, 4 RCTs, RR 0.80, 95% CI 0.39 to 1.64). This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 6.21$; $\text{df} = 3.0$; $P = 0.1$; $I^2 = 51\%$; [Analysis 1.17](#)).

1.17.5 By long term - arrested

We found data from one study for long-term outcomes, describing the outcome 'number of arrested', and it showed no significant advantage for ICM ($n = 178$, 1 RCT, RR 0.66, 95% CI 0.32 to 1.37; [Analysis 1.17](#)).

1.17.6 By long term - imprisoned

We found also five long-term studies reporting data on 'number of imprisoned', again not showing any significant advantage for ICM in reducing the number of participants imprisoned by long term ($n = 908$, 5 RCTs, RR 0.86, 95% CI 0.45 to 1.65; [Analysis 1.17](#)).

1.18 Social functioning: 1b. Mean contacts with legal system (skewed data) - by medium term

Data were available from one medium-term trial, describing three different outcomes: bookings, jail days, and convictions. All these data were skewed and did not enter the analysis, therefore we have presented them in [Analysis 1.18](#). Data on booking and jail days suggested a trend favouring the ICM group, reducing contacts with legal system. Data on convictions did not show a trend favouring one group over the other.

1.19 Social functioning: 2. Employment status (various measurements)

We found six relevant studies for this outcome and categorised data into six subgroups, according to different time to follow-up and various outcomes described.

1.19.1 By medium term - not competitively employed at the end of the trial

One study reported data on 'not competitively employed at the end of the trial', and these data did not show a significant advantage for ICM in improving the number of competitively employed people ($n = 88$, 1 RCT, RR 1.00, 95% CI 0.91 to 1.10; [Analysis 1.19](#)).

1.19.2 By medium term - not employed at the end of the trial

We found four trials relevant to this subgroup; these also failed to show a significant difference between groups, although data did suggest a trend favouring ICM ($n = 1136$, 4 RCTs, RR 0.89, 95% CI 0.79 to 1.0). However, heterogeneity was present ($\text{Chi}^2 = 11.86$; $\text{df} = 3.0$; $P = 0.01$; $I^2 = 74\%$; [Analysis 1.19](#)).

1.19.3 By long term - not employed at the end of the trial

We found four trials relevant to this subgroup. As in the medium-term comparison, data failed to show a significant difference, although they suggested a trend favouring the ICM group ($n = 1129$, 4 RCTs, RR 0.70, 95% CI 0.49 to 1.00). However, again, there was considerable heterogeneity ($\text{Chi}^2 = 46.48$; $\text{df} = 3.0$; $P = 0.0$; $I^2 = 93\%$; [Analysis 1.19](#)).

1.19.4 By long term - not working/studying in the previous year

We found one trial relevant to this subgroup, with a total of 547 participants. Data showed a significant difference between groups, favouring ICM in reducing the risk of being 'not working or not studying' compared to standard care ($n = 547$, 1 RCT, RR 0.86, 95% CI 0.74 to 0.99). Heterogeneity for this outcome was high ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$; [Analysis 1.19](#)).

1.19.5 By medium-term FUP (3 years) - not working/studying in the previous year

There was a single trial in this subgroup. Data failed to show a significant difference between groups ($n = 547$, 1 RCT, RR 1.02, 95% CI 0.9 to 1.16; [Analysis 1.19](#)).

1.19.6 By long-term FUP (8 years) - not working/studying in the previous year

We found one trial relevant to this subgroup. Again, we did not find evidence of a clear difference between the two treatments ($n = 547$, 1 RCT, RR 0.99, 95% CI 0.88 to 1.11; [Analysis 1.19](#)).

1.20 Social functioning: 3a. Accommodation status (various measurements)

We found 10 relevant studies for this outcome, the data from which we divided into six subgroups according to different time to follow-up and various outcomes described.

1.20.1 By short term - homelessness

We found data on the outcome 'homelessness' from one short-term study. This small study revealed a significant reduction in the rate of homelessness in the ICM group ($n = 95$, 1 RCT, RR 0.04, 95% CI 0.00 to 0.70; [Analysis 1.20](#)).

1.20.2 By medium term - homelessness

Medium-term data on the outcome 'homelessness' were available from one small study. Data did not reveal any significant difference between groups in the rate of homelessness by the medium term ($n = 88$, 1 RCT, RR 0.32, 95% CI 0.03 to 2.95; [Analysis 1.20](#)).

1.20.3 By medium term - not living independently

We found five trials relevant to this subgroup. These data showed a significant advantage for ICM in reducing the number of participants not living independently ($n = 1303$, 5 RCTs, RR 0.80, 95% CI 0.66 to 0.97). Heterogeneity for this subgroup was moderately high ($\text{Chi}^2 = 5.81$; $\text{df} = 4.0$; $P = 0.21$; $I^2 = 31\%$; [Analysis 1.20](#)).

1.20.4 By long term - homelessness

We found 'homelessness' data in three long-term studies, which did not reveal any significant difference between intervention groups ($n = 418$, 3 RCTs, RR 0.78, 95% CI 0.34 to 1.82). This subgroup had moderate levels of heterogeneity ($\text{Chi}^2 = 3.27$; $\text{df} = 2.0$; $P = 0.19$; $I^2 = 38\%$; [Analysis 1.20](#)).

1.20.5 By long term - not living independently

There were four relevant trials in this subgroup. Data for this subgroup favoured the ICM group, where the incidence of not living independently was lower compared with the standard care group ($n = 1185$, 4 RCTs, RR 0.65, 95% CI 0.49 to 0.88). This subgroup had moderate levels of heterogeneity ($\text{Chi}^2 = 5.39$; $\text{df} = 3.0$; $P = 0.15$; $I^2 = 44\%$; [Analysis 1.20](#)).

1.20.6 By long term - not living in stable accommodation

The outcome 'not living in stable accommodation' was only available from one study. We found that data favoured the ICM group in reducing the number of participants not living in stable accommodation ($n = 168$, 1 RCT, RR 0.80, 95% CI 0.65 to 0.98; [Analysis 1.20](#)).

1.21 Social functioning: 3b. Accommodation status: mean number of days in supported house (skewed data, sample size # 200)

We identified only one study relevant to this outcome, providing data at different times, but always referring to the previous year of follow-up. Note that for this outcome the right graph label favours ICM (experimental group).

1.21.1 By long term (previous year)

There was no significant difference between ICM and standard care within this subgroup (n = 547, 1 RCT, MD 0.3, 95% CI -13.98 to 14.58; [Analysis 1.21](#)).

1.21.2 By medium-term FUP (3 years) (previous year)

We found evidence of a significant difference between ICM and standard care within this subgroup, with data favouring standard care over ICM (n = 547, 1 RCT, MD -22.2, 95% CI -38.47 to -5.93; [Analysis 1.21](#)).

1.21.3 By long-term FUP (8 years) (previous year)

We did not find evidence of a significant difference between the two treatments for this subgroup (n = 547, 1 RCT, MD -6.7, 95% CI -19.35 to 5.95; [Analysis 1.21](#)).

1.22 Social functioning: 3c. Accommodation status (various measurements, skewed data)

Data on this outcome were available from three studies; as all of these data were skewed and did not enter the analysis, we have presented them in [Analysis 1.22](#).

Two studies provided medium-term data on 'average days in stable accommodation', which showed a trend favouring the ICM group, consistent with results previously described for 'not living in stable accommodation' by long term.

Two studies provided long-term data on 'average days per month in sheltered homes'. These data were equivocal, as data from one study favoured ICM, whilst data from the second study favoured the standard care group.

1.23 Social functioning: 4a. Substance abuse

We identified only one study relevant to this outcome, providing various measures at different time of follow-up.

1.23.1 Alcohol abuse - by long term

We found one trial relevant to this subgroup (total n = 547). There was no significant difference between ICM and standard care within this subgroup (n = 547, 1 RCT, RR 0.55, 95% CI 0.26 to 1.17; [Analysis 1.23](#)).

1.23.2 Illicit drug abuse - by long term

As for alcohol abuse, data failed to show a significant difference between groups for this subgroup (n = 547, 1 RCT, RR 0.96, 95% CI 0.63 to 1.47; [Analysis 1.23](#)).

1.23.3 Substance abuse - by medium-term FUP (3 years)

We found one trial relevant to this subgroup (total n = 547). As for the two previous outcomes, data failed to show a significant difference between groups (RR 0.91, 95% CI 0.67 to 1.24; [Analysis 1.23](#)).

1.24 Social functioning: 4b. Substance abuse (Dartmouth Assessment of Lifestyle Interview (DALI), skewness not detectable) - by medium term

We were unable to enter two types of data into the analysis: medium-term data assessing alcohol and drug abuse on DALI scale. As the DALI scale averages values from positive to negative, skew is very difficult to detect, we did not enter these data in the analysis. These data tended to favour the standard care group for both the alcohol and drug abuse outcomes; we have presented them in [Analysis 1.25](#).

1.25 Social functioning: 4c. Substance abuse - days used per month (skewed data)

One study provided medium- and long-term data from the outcome 'days of substance use per month', which were equivocal, but skewed; we have therefore presented them in [Analysis 1.25](#).

1.26 Social functioning: 5a. Average endpoint score (various scales)

Three studies provided data from five different scales (Disability Assessment Scale (DAS), Interview Schedule for Social Interaction (ISSI), Role Functioning Scale (RFS), Social Adjustment Scale (SAS-adapted version), Strauss-Carpenter Outcome Scale) assessing social functioning by short, medium, and long term. As no more than one study used the same scale per time period, we did not enter more than one study per subgroup. Data from each available time period failed to show any significant difference between treatment groups, with the exception of two outcomes by long term (1.26.7 on ISSI and 1.26.8 on RFS), the first favouring the standard care group, and the second favouring the ICM group.

1.26.1 By short term (RFS, low = poor)

One trial providing data, no significant difference between groups (n = 80, 1 RCT, MD -0.62, 95% CI -2.23 to 0.99; [Analysis 1.26](#)).

1.26.2 By short term (SAS-adapted version, low = poor)

One trial providing data, no significant difference between groups (n = 80, 1 RCT, MD -3.34, 95% CI -7.55 to 0.87; [Analysis 1.26](#)).

1.26.3 By medium term - social role performance (DAS, high = poor)

One trial providing data, no significant difference between groups (n = 55, 1 RCT, MD 0.1, 95% CI -0.4 to 0.6; [Analysis 1.26](#)).

1.26.4 By medium term (RFS, low = poor)

One trial providing data, no significant difference between groups (n = 80, 1 RCT, MD -0.86, 95% CI -2.72 to 1.0; [Analysis 1.26](#)).

1.26.5 By medium term (SAS-adapted version, low = poor)

One trial providing data, no significant difference between groups (n = 80, 1 RCT, MD -3.3, 95% CI -7.83 to 1.23; [Analysis 1.26](#)).

1.26.6 By long term - social role performance (DAS, high = poor)

One trial providing data, no significant difference between groups (n = 58, 1 RCT, MD -0.2, 95% CI -0.67 to 0.27; [Analysis 1.26](#)).

1.26.7 By long term (ISSI, low = poor)

One trial providing data, showing a significant difference between groups favouring standard care over ICM (n = 62, 1 RCT, MD 3.2, 95% CI 0.11 to 6.29; [Analysis 1.26](#)).

1.26.8 By long term (RFS, low = poor)

One trial providing data, showing a significant difference between groups favouring ICM over standard care ($n = 80$, 1 RCT, MD -2.35, 95% CI -4.05 to -0.65; [Analysis 1.26](#)).

1.26.9 By long term (SAS-adapted version, low = poor)

One trial providing data, no significant difference between groups ($n = 80$, 1 RCT, MD -2.75, 95% CI -7.13 to 1.63; [Analysis 1.26](#)).

1.26.10 By long term (Strauss-Carpenter Outcome Scale, low = poor)

One trial providing data, no significant difference between groups ($n = 60$, 1 RCT, MD 0.1, 95% CI -1.17 to 1.37; [Analysis 1.26](#)).

1.27 Social functioning: 5b. Average endpoint score (various scales, skewed data)

Skewed data on SAS score were available by short, medium, and long term from two studies. These data were equivocal and not consistent between the two studies. One study provided long-term data on REHAB Scale score, which tended to favour the ICM group, but were also skewed. We have presented them in [Analysis 1.27](#).

1.28 Mental state: 1a. General symptoms - average endpoint score (various scales)

Two sets of data were available: i.) non-skewed data or skewed data from a sample size greater than or equal to 200 participants per study; entering analysis together; and ii.) skewed data: not entering analysis.

We identified four studies relevant to this outcome entering analysis, providing data from three different scales (Brief Psychiatric Rating Scale (BPRS-18 items), Brief Symptom Inventory (BSI), Colorado Symptom Index (CSI)) per different time period.

1.28.1 By short term (BPRS-18 items, high = poor)

We found two trials relevant to this subgroup. There was no significant difference between ICM and standard care within this subgroup ($n = 668$, 2 RCTs, MD -1.56, 95% CI -6.85 to 3.73), but data were heterogeneous ($\text{Chi}^2 = 12.58$; $\text{df} = 1.0$; $P = 0.0$; $I^2 = 92\%$; [Analysis 1.28](#)).

1.28.2 By short term (BSI, high = poor)

Short-term mental state scores assessed with the BSI were available from the same two studies providing BPRS short-term data. Again, data were not significantly different ($n = 668$, 2 RCTs, MD -0.06, 95% CI -0.19 to 0.06; [Analysis 1.28](#)); however, different from the BPRS results, these data were homogeneous.

1.28.3 By short term (CSI, low = poor)

One further trial was available providing short-term data on mental state assessed with the CSI. These data showed a significant difference between groups favouring the ICM group ($n = 125$, 1 RCT, MD -0.56, 95% CI -0.84 to -0.28; [Analysis 1.28](#)).

1.28.4 By medium term (BPRS-18 items, high = poor)

We found two trials relevant to this subgroup, with a total of 662 people. We did not find evidence of a significant difference between ICM and standard care within this subgroup (MD -0.96, 95% CI -2.42 to 0.51; [Analysis 1.28](#)).

1.28.5 By medium term (BSI, high = poor)

We found two trials relevant to this subgroup (total $n = 662$). We did not find evidence of a significant difference between ICM and standard care within this subgroup (MD -0.02, 95% CI -0.15 to 0.1; [Analysis 1.28](#)).

1.28.6 By medium term (CSI, low = poor)

There was a single trial in this subgroup. We found evidence favouring the ICM group over the standard care group ($n = 125$, 1 RCT, MD -0.35, 95% CI -0.65 to -0.05; [Analysis 1.28](#)).

1.28.7 By long term (BPRS-18 items, high = poor)

We found three trials relevant to this subgroup (total $n = 777$). There was no significant difference between ICM and standard care within this subgroup ($n = 777$, 3 RCTs, MD -1.48, 95% CI -3.69 to 0.74), but data were heterogeneous ($\text{Chi}^2 = 13.13$; $\text{df} = 2.0$; $P = 0.0$; $I^2 = 84\%$; [Analysis 1.28](#)).

1.28.8 By long term (BSI, high = poor)

We found two trials relevant to this subgroup, with data favouring the ICM group, in which participants reached a better mental state score by long term compared to the standard care group ($n = 647$, 2 RCTs, MD -0.18, 95% CI -0.31 to -0.06; [Analysis 1.28](#)).

1.29 Mental state: 1b. General symptoms - mean change from baseline (CSI, low = poor) - by long term

Finally, one study assessed the mean change from baseline on the CSI, with data showing no difference between groups ($n = 168$, 1 RCT, MD -0.32, 95% CI -0.53 to -0.11).

1.30 Mental state: 1c. General symptoms - average endpoint score (various scales, skewed data)

Skewed data were available from six studies assessing mental state by different time periods and with different scales (BPRS-18 items, BPRS-24 items, CPRS, PSE, SCL-90). Data failed to show a significant trend favouring one group over the other, this report being consistent across different studies and different rating scales. We considered these data to not be robust as they were skewed, but they were in accordance with short-, medium-, and long-term data. We have presented them in [Analysis 1.30](#).

1.31 Mental state: 2a. Specific symptoms - depression at follow-up interview

We found data on specific symptoms from only one study, which provided data on depression incidence per different time period. There was no significant difference between groups by medium term, long term, and medium-term follow-up (three years).

1.31.1 By medium term

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, RR 0.77, 95% CI 0.56 to 1.04; [Analysis 1.31](#)).

1.31.2 By long term

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, RR 0.83, 95% CI 0.57 to 1.21; [Analysis 1.31](#)).

1.31.3 By medium term FUP (3 years)

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, RR 1.25, 95% CI 0.91 to 1.72; [Analysis 1.31](#)).

1.32 Mental state: 2b. Specific symptoms - average endpoint score (various scales, skewed data, sample size # 200)

We identified only one study ($n = 547$) relevant to this outcome, providing data on two different dimensions (positive and negative symptoms) assessed at different times. Although skewed, data entered the analyses, as the sample size was greater than or equal to 200 participants per study. Only one comparison showed a significant advantage for the ICM group, in reducing risk of negative symptoms by long term.

1.32.1 By long term - positive symptoms (Scale for the Assessment of Positive Symptoms (SAPS), high = poor)

One trial providing data, showing no significant difference between groups, although tending to favour the ICM group ($n = 547$, 1 RCT, MD -0.22, 95% CI -0.45 to 0.01; [Analysis 1.32](#)).

1.32.2 By long term - negative symptoms (Scale for the Assessment of Negative Symptoms (SANS), high = poor)

One trial providing data, showing evidence of a significant difference between groups favouring ICM over standard care ($n = 547$, 1 RCT, MD -0.42, 95% CI -0.62 to -0.22; [Analysis 1.32](#)).

1.32.3 By medium-term FUP (3 years) - positive symptoms (SAPS, high = poor)

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, MD 0.12, 95% CI -0.15 to 0.39; [Analysis 1.32](#)).

1.32.4 By medium-term FUP (3 years) - negative symptoms (SANS, high = poor)

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, MD -0.1, 95% CI -0.33 to 0.13; [Analysis 1.32](#)).

1.32.5 By long-term FUP (8 years) - positive symptoms (SAPS, high = poor)

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, MD 0.03, 95% CI -0.21 to 0.27; [Analysis 1.32](#)).

1.32.6 By long-term FUP (8 years) - negative symptoms (SANS, high = poor)

One trial providing data, no significant difference between groups ($n = 547$, 1 RCT, MD 0.06, 95% CI -0.13 to 0.25; [Analysis 1.32](#)).

1.33 Mental state: 2c. Specific symptoms - average endpoint score (various scales, skewed data)

We found a second small study ($n = 70$) providing skewed data on depression symptoms assessed with the Beck Depression Inventory, and negative symptoms assessed with SANS. Neither data set was entered into the analysis. Skewed depression scores favoured the ICM group at medium and long term, whilst skewed negative symptoms scores by medium and long term were equivocal. We have reported these data in [Analysis 1.33](#).

1.34 Behaviour: 1. Specific behaviour - self harm

We found three relevant studies for this outcome providing data per different time period. We detected no significant difference between ICM and standard care in either reducing the risk for self harm or reducing the risk for attempting suicide.

1.34.1 By medium term

There were two relevant trials in this subgroup, in which 30 events occurred in 312 people treated with ICM compared with 30 events in 308 people treated with standard care. There was no significant difference in number of participants who committed self harm between the groups ($n = 620$, 2 RCTs, RR 0.99, 95% CI 0.61 to 1.59; [Analysis 1.34](#)).

1.34.2 By long term

There is a single relevant trial in this subgroup, in which 2 events occurred in 63 people treated with ICM compared with 2 events in 60 people treated with standard care. There was no significant difference in number of participants who committed self harm between the groups ($n = 123$, 1 RCT, RR 0.95, 95% CI 0.14 to 6.55; [Analysis 1.34](#)).

1.34.3 Attempted suicide - by long term (during last 12 months)

Long term data on self harm during the previous 12 months available from a single study confirmed medium- and long-term data ($n = 547$, 1 RCT, RR 0.81, 95% CI 0.47 to 1.38; [Analysis 1.34](#)), that is failing to show any significant difference between the two groups.

1.34.4 Attempted suicide - by medium-term FUP (during last 3 years)

The above data were again confirmed, from medium-term follow-up data on suicide attempts during the previous three years available from a single study. There was no significant difference between ICM and standard care ($n = 547$, 1 RCT, RR 0.95, 95% CI 0.56 to 1.62; [Analysis 1.34](#)).

1.35 Behaviour: 2. Social behaviour - average endpoint score (Social Behaviour Scale, high = poor)

Skewed data were available from one small study ($n = 70$) assessing behaviour with the Social Behaviour Scale by medium and long term. These data tended to favour the ICM group.

1.36 Quality of life: 1a. Average endpoint score (various scales)

We found seven studies assessing quality of life with various scales by different time periods, and categorised data into five subgroups. Note that for this outcome the right graph label favours ICM (experimental group).

1.36.1 By short term - general well-being (Lehman's Quality of Life Interview (QOLI), high = better)

The only significant result we found was by short term: data were available from a single study and showed a significantly higher quality of life in the ICM group as assessed on the QOLI general well-being subscale ($n = 125$, 1 RCT, MD 0.53, 95% CI 0.09 to 0.97; [Analysis 1.36](#)).

1.36.2 By medium term (Lancashire Quality of Life Profile (LQoLP), high = better)

Medium-term data assessing quality of life with LQoLP (one study) did not show a significant difference between groups ($n = 52$, 1 RCT, MD 0.09, 95% CI -0.60 to 0.78; [Analysis 1.36](#)).

1.36.3 By medium term (Manchester Short Assessment of Quality of Life (MANSA) - range 1 to 7, high = better)

Medium-term data assessing quality of life with MANSA (one study) did not show a significant difference between groups ($n = 81$, 1 RCT, MD 0.20, 95% CI -0.29 to 0.69; [Analysis 1.36](#)).

1.36.4 By long term (LQoLP, high = better)

As with the medium-term data, long-term data assessing quality of life with LQoLP (three studies) did not show a significant difference between groups ($n = 274$, 3 RCTs, MD -0.13 , 95% CI -0.38 to 0.12 ; [Analysis 1.36](#)).

1.36.5 By long term (QOLI, high = better)

Again, as with the medium-term data, long-term data assessing quality of life with QOLI (two studies) did not show a significant difference between groups ($n = 132$, 2 RCTs, MD 0.09 , 95% CI -0.24 to 0.42 ; [Analysis 1.36](#)).

1.37 Quality of life: 1b. Mean change from baseline (QOLI, high = better, skewed data) - by long term

We found one further study providing data by long term for this comparison, but as data were skewed, measuring mean change from baseline on the QOLI, the study was not entered into the analysis. These data tended to favour the ICM group. We have reported these data in [Analysis 1.37](#).

1.38 Participant satisfaction: 1a. Average endpoint score (Client Satisfaction Questionnaire (CSQ), high = better)

We found three relevant studies for this outcome, providing data per different time period. We found that participant satisfaction assessed with the CSQ was significantly greater in the ICM group compared with the standard care group in all three time period assessments. Note that for this outcome the right graph label favours ICM (experimental group).

1.38.1 By short term

Short-term data were available from only one small study and showed a significant difference between groups, favouring the ICM intervention ($n = 61$, 1 RCT, MD 6.2 , 95% CI 2.6 to 9.8 ; [Analysis 1.38](#)).

1.38.2 By medium term

Medium-term data from two studies confirmed the above results ($n = 500$, 2 RCTs, MD 1.93 , 95% CI 0.86 to 3.01 ; [Analysis 1.38](#)).

1.38.3 By long term

Long-term data also favoured the ICM group ($n = 423$, 2 RCTs, MD 3.23 , 95% CI 2.31 to 4.14 ; [Analysis 1.38](#)).

1.39 Participant satisfaction: 1b. Average endpoint score (CSQ, high = better, skewed data) - by short term

One further small trial provided short-term data, but the data were skewed: attrition in the standard care arm was higher than 50%. Participant satisfaction was assessed with the CSQ, and it tended to favour the ICM group. We have reported these data in [Analysis 1.39](#).

1.40 Participant need: 1. Average endpoint score (various scales, skewed data)

We found more skewed data from two studies assessing participant need on two other scales (Camberwell Assessment of Need Interview (CAN), Camberwell Assessment of Need Short Appraisal Schedule (CANSAS)). Medium-term data from one study assessed on CANSAS failed to show any difference between groups. Long-term data assessed in one study with the CAN tended to favour the ICM group. We have reported these data in [Analysis 1.40](#).

1.41 Costs: 1a. Direct costs of psychiatric hospital care - by medium term (unit cost = USD, fiscal year 1990)

Direct medium-term costs of psychiatric hospital care were available from two studies reporting skewed data, but with a sample size greater than 200 ([Chandler-California1 \(A\)](#); [Chandler-California1 \(B\)](#)). Data favoured ICM ($n = 426$, 2 RCTs, MD USD -143.74 , 95% CI -272.40 to -15.08 ; [Analysis 1.41](#)).

1.42 Costs: 1b. Direct costs of psychiatric hospital care - skewed data

Five additional studies did describe 'direct costs of psychiatric hospital care', but data were markedly skewed. Some of these data showed a trend favouring ICM, while some favoured standard care, therefore we could not highlight any trend confirming the findings from meta-analysis. We have presented these data in [Analysis 1.42](#).

1.43 Costs: 2a. Direct healthcare costs - by long term (unit cost = USD, fiscal year 1988)

Long-term data for direct healthcare cost were available from two studies; again studies reported skewed data, but with a sample size greater than 200, and so these data could be entered into a meta-analysis. These data were inconclusive ($n = 873$, 2 RCTs, MD USD -529.24 , 95% CI -2143.59 to 1085.1 ; [Analysis 1.43](#)), as they were highly heterogeneous ($\text{Chi}^2 = 17.83$; $\text{df} = 1.0$; $P = 0.0$; $I^2 = 94\%$) with inconsistency in direction of effect.

1.44 Costs: 2b. Direct healthcare costs - skewed data

Other skewed data from two studies with a sample size of less than 200 could not be entered into the meta-analysis. These studies assessed direct healthcare costs by medium term (one study) and by short-term follow-up (the other study). Medium-term data did not show any significant difference between interventions, whilst short-term FUP data seemed to favour standard care in reducing direct healthcare costs. We have reported these data in [Analysis 1.44](#).

1.45 Costs: 3. Direct costs - other data - skewed data

Five studies described direct costs for "all care" by short, medium, and long term, and one more study described direct costs for "specific" outcome (outpatient care and prison) by medium term. As these data were skewed and from studies with a sample size of less than 200, they could not be entered into the meta-analysis. We have presented these data in [Analysis 1.45](#).

Costs for all care by short term seemed to favour the ICM group, where costs were reduced (one study); by medium term one study favoured standard care (where costs were reduced), whilst the other study failed to show any difference between the two groups; and five studies provided data by long term: some of these data showed a trend favouring ICM, and some favoured standard care; these data were therefore inconclusive, and we could not highlight any trend.

Medium-term data from one study on cost for outpatient care showed costs were higher in the ICM group compared to standard care. Data from the same study on cost for prison showed costs were higher for the standard care group compared to ICM.

2. COMPARISON 2: INTENSIVE CASE MANAGEMENT versus NON-INTENSIVE CASE MANAGEMENT

Summary of findings 2. This comparison has 36 outcomes.

2.1 Service use: 1. Average number of days in hospital per month - by about 24 months

We found 21 relevant studies for this outcome and categorised data into two subgroups (skewed data but with a sample size greater

than or equal to 200, and skewed data with a sample size of less than 200). Overall, combining the two pools of studies, we found no clear difference between ICM and non-ICM ($n = 2220$, 21 RCTs, MD -0.08, 95% CI -0.37 to 0.21, Figure 10). A funnel plot did not show any significant reporting bias (Figure 11).

Figure 10. Forest plot of comparison: 2 Intensive Case Management versus non-Intensive Case Management, outcome: 2.1 Service use: 1. Average number of days in hospital per month - at about 24 months.

Figure 11. Funnel plot of comparison: 2 Intensive Case Management versus non-Intensive Case Management, outcome: 2.1 Service use: 1. Average number of days in hospital per month - by about 24 months.

2.1.1 Skewed data (sample size ≥ 200)

We found three studies reporting skewed data but with a sample size greater than or equal to 200. There was no significant difference between groups for reducing length of hospitalisation ($n = 694$, 3 RCTs, MD -0.58, 95% CI -1.93 to 0.76; [Analysis 2.1](#)). These findings were in accordance with the second subgroup analysis, skewed data from studies with a sample size of less than 200 participants.

2.1.2 Skewed data (sample size < 200)

There were 18 relevant trials in this subgroup, with a total of 1526 people. Again, these data did not show a significant difference between groups ($n = 1526$, 18 RCTs, MD -0.03, 95% CI -0.33 to 0.28; [Analysis 2.1](#)).

2.2 Service use: 1a. Average number of days in hospital per month - by medium/long-term follow-up (skewed data, sample size ≥ 200)

One study provided data by medium- and long-term follow-up, and as the sample size was greater than 200, skewed data entered the analysis.

2.2.1 By medium-term FUP (18 months)

One study provided data on medium-term follow-up (18 months), confirming the results described above by 24 months. There was no

clear difference between ICM and non-ICM within this subgroup ($n = 237$, 1 RCTs, MD 0.6, 95% CI -1.25 to 2.45; [Analysis 2.2](#)).

2.2.2 By long-term FUP (8.5 years)

The same study provided data on long-term follow-up (8.5 years), again showing no significant differences between interventions in reducing number of days in hospital ($n = 203$, 1 RCTs, MD 0.8, 95% CI -1.47 to 3.07; [Analysis 2.2](#)).

2.3 Service use: 2. Not remaining in contact with psychiatric services

We found four relevant studies for this outcome and categorised data into three subgroups, by different time period. Short-term data were not available. When we pooled studies from medium and long term, data did not show significant differences between interventions, but heterogeneity was substantial ($n = 1255$, 4 RCTs, RR 0.63, 95% CI 0.27 to 1.49, $I^2 = 81\%$, $P = 0.001$). We addressed this finding by checking again for correctness of data and explored heterogeneity by dropping each study out of the analysis. Only by removing both [Drake-NHamp 1998](#) and [UK700-UK 1999](#) was homogeneity restored. As we could not ascertain any clear reason for the heterogeneity, we have therefore chosen not to pool these data, as it could be misleading to quote an average value for the intervention effect - particularly in this case, when there is inconsistency in direction of effect. We did not use a funnel plot

for this outcome because there were fewer than 10 studies (see [Assessment of reporting biases](#)).

2.3.1 By medium term

One small study provided medium-term data showing a significant difference favouring the ICM group ($n = 73$, 1 RCT, RR 0.27, 95% CI 0.08 to 0.87; [Analysis 2.3](#)).

2.3.2 By long term

Long-term data were available from three studies. Pooled data were not statistically significant ($n = 1182$, 3 RCTs, RR 0.82, 95% CI 0.34 to 1.98), but data were heterogeneous ($\text{Chi}^2 = 10.86$; $\text{df} = 2.0$; $P = 0.0$; $I^2 = 81\%$) with inconsistency in direction of effect ([Analysis 2.3](#)).

2.3.3 By medium-term FUP (18 months)

One single trial provided data for this outcome, and we found no evidence of a clear difference between the two treatments ($n = 251$, 1 RCT, RR 0.42, 95% CI 0.17 to 1.05; [Analysis 2.3](#)).

2.4 Service use: 3a. Admitted to hospital - by long term

Binary data describing this outcome were available from three long-term studies, reporting 'number of admitted to hospital'. These data showed a non-significant difference in number of participants admitted to hospital between groups ($n = 1132$, 3 RCTs, RR 0.91, 95% CI 0.75 to 1.12; [Analysis 2.4](#)). Heterogeneity was high for this outcome ($\text{Chi}^2 = 5.26$; $\text{df} = 2.0$; $P = 0.07$; $I^2 = 62\%$).

2.5 Service use: 3b. Average number of admissions (skewed data - sample size # 200)

We identified two studies relevant to this outcome, one providing data by long term, the other by medium- and long-term follow-up. Data were skewed, but as the trial sample size were greater than or equal to 200, we entered these data in the analysis. Data from different time periods failed to show any significant differences between ICM and non-ICM in average number of admissions.

2.5.1 By long term (24 months)

Data from one long-term study failed to show any significant differences between groups ($n = 678$, 1 RCT, MD -0.18, 95% CI -0.41 to 0.05; [Analysis 2.5](#)).

2.5.2 By medium term FUP (18 months)

One single study provided data by medium-term follow-up (18 months). Data failed to show any significant differences between groups ($n = 237$, 1 RCT, MD -0.1, 95% CI -0.6 to 0.4; [Analysis 2.5](#)).

2.5.3 By long-term FUP (8.5 years)

One single study provided data by medium-term follow-up (8.5 years). Data failed to show any significant differences between groups ($n = 203$, 1 RCT, MD 1.0, 95% CI -0.25 to 2.25; [Analysis 2.5](#)).

2.6 Service use: 3c. Average number of admissions (skewed data) - by medium term

A trial that included fewer than 200 participants presented skewed data that could not be entered into the meta-analysis. Data were reported for the outcome 'average number of admissions' by medium term. As with previous findings, they failed to show any trend in effect between groups.

2.7 Adverse event: 1a. Death - any cause

We found seven relevant studies for this outcome and categorised data into five subgroups, by different time period.

2.7.1 By short term

Short-term data on mortality were available from one study ($n = 193$) reporting no deaths, therefore a measure of effect was not estimable ([Analysis 2.7](#)).

2.7.2 By medium term

Medium-term data were available from three studies, where 1 death occurred in 148 people treated with ICM, compared with no deaths in 146 people treated with non-ICM. There were no significant differences in mortality between groups ($n = 294$, 3 RCTs, RR 2.92, 95% CI 0.12 to 69.43; [Analysis 2.7](#)).

2.7.3 By long term

We found long-term data in five studies, reporting 16 deaths occurring in 816 people treated with ICM, compared with 18 deaths in 821 people treated with non-ICM. These data confirmed medium-term findings showing no differences in mortality between groups ($n = 1637$, 5 RCTs, RR 0.90, 95% CI 0.46 to 1.75; [Analysis 2.7](#)).

2.7.4 By medium-term FUP (18 months)

Medium-term follow-up data were available from one study, where 6 deaths occurred in 127 people treated with ICM, compared with 6 deaths in 124 people treated with non-ICM. These data confirmed the above results, showing no differences in mortality between groups ($n = 251$, 1 RCT, RR 0.98, 95% CI 0.32 to 2.95; [Analysis 2.7](#)).

2.7.5 By long-term FUP (8.5 years)

Long-term follow-up data were available from one study, where 20 deaths occurred in 127 people treated with ICM, compared with 17 deaths in 124 people treated with non-ICM. These data confirmed the above results, showing no differences in mortality between groups ($n = 251$, 1 RCT, RR 1.15, 95% CI 0.63 to 2.09; [Analysis 2.7](#)).

2.8 Adverse event: 1b. Death - suicide

We found eight relevant studies for this outcome and categorised data into four subgroups, by different time period.

2.8.1 By short term

Short-term data on suicide mortality were available from one study ($n = 193$), again reporting no deaths, and therefore a measure of effect was not estimable.

2.8.2 By medium term

Medium-term data were available from six studies, where 5 suicides occurred in 464 people treated with ICM, compared with 3 suicides in 465 people treated with non-ICM. There were no significant differences in the suicide rate between groups ($n = 929$, 6 RCTs, RR 1.61, 95% CI 0.26 to 9.85; [Analysis 2.8](#)).

2.8.3 By long term

Long-term data were available from three studies, reporting 6 suicides occurring in 577 people treated with ICM, compared with 7 suicides in 575 people treated with non-ICM. These data confirmed medium-term data on overall mortality and on suicide, with no

significant differences in the suicide rate between groups ($n = 1152$, 3 RCTs, RR 0.88, 95% CI 0.27 to 2.84; [Analysis 2.8](#)).

2.8.4 By medium-term FUP (18 months)

Medium-term follow-up data on suicide mortality were available from one study, reporting 1 suicide occurring in 127 people treated with ICM, compared with 3 suicides in 124 people treated with non-ICM. These data confirmed also in the follow-up period, medium- and long-term data on overall mortality and on suicide, with no significant differences in the suicide rate between groups ($n = 251$, 1 RCT, RR 0.33, 95% CI 0.03 to 3.09; [Analysis 2.8](#)).

2.9 Global state: 1. Leaving the study early

We found nine studies providing medium- and long-term data, but not short-term data. When pooling data from sub-groups for two time periods, we found data still significant, showing an advantage for ICM in reducing the number of participants lost to follow-up ($n = 2195$, 9 RCTs, RR 0.72, 95% CI 0.52 to 0.99). Although heterogeneity was reduced in comparison to the medium-term subgroup data, heterogeneity was still substantial ($\text{Chi}^2 = 19.58$; $\text{df} = 8.0$; $P = 0.01$; $I^2 = 59\%$) ([Analysis 2.9](#)).

2.9.1 By medium term

Medium-term data from two trials showed no treatment effect in reducing number of participants lost to follow-up ($n = 225$, 2 RCTs, RR 0.64, 95% CI 0.13 to 3.07), but these data presented a substantial level of heterogeneity ($\text{Chi}^2 = 6.38$; $\text{df} = 1.0$; $P = 0.01$; $I^2 = 84\%$). In addition, there was inconsistency in the direction of effect between the two studies ([Analysis 2.9](#)).

2.9.2 By long term

Long-term data were available from seven studies, and we found a significant advantage for ICM in reducing the number of participants lost to follow-up ($n = 1970$, 7 RCTs, RR 0.70, 95% CI 0.52 to 0.95). Different from the medium-term data, long-term subgroup analyses did not show substantial heterogeneity ($\text{Chi}^2 = 9.88$; $\text{df} = 6.0$; $P = 0.13$; $I^2 = 39\%$) ([Analysis 2.9](#)).

2.10 Global state: 2a. Average endpoint score (Health of the Nation Outcome Scale (HoNOS), high = poor) - by long term

One study reported long-term data on global state assessed with HoNOS. These data were skewed, but as the study sample size was greater than or equal to 200 participants they entered the analysis. Data failed to show a significant difference between interventions ($n = 239$, 1 RCT, MD -0.40, 95% CI -1.77 to 0.97; [Analysis 2.10](#)).

2.11 Global state: 2b. Average endpoint score (HoNOS, high = poor) - skewed data

We found skewed data describing global state with HoNOS by medium and long term from one trial. These data tended to favour the standard care group ([Analysis 2.11](#)).

2.12 Global state: 3a. Not compliant with medication - by medium term

One study reported medium-term data for the binary outcome 'number of participants not compliant with medication'. There was no significant difference between groups ($n = 73$, 1 RCT, RR 1.14, 95% CI 0.42 to 3.05; [Analysis 2.12](#)).

2.13 Global state: 3b. Compliance with medication - average endpoint subscale score (Rating of Medication Influences (ROMI)) - by long term

Long-term compliance scores assessed with the ROMI compliance and non-compliance subscales were not significantly different (compliance subscale: $n = 239$, 1 RCT, MD 0.60, 95% CI -0.05 to 1.25; non-compliance subscale: $n = 239$, 1 RCT, MD -0.60, 95% CI -1.63 to 0.43), although both subscale scores tended to favour ICM. Note that for the compliance subscale (high = good), the right side of the graph favours experimental (ICM).

2.13.1 Compliance subscale (high = good)

There was a single trial in this subgroup, with a total of 239 people. There was no clear difference between ICM and non-ICM within this subgroup (MD 0.6, 95% CI -0.05 to 1.25; [Analysis 2.13](#)).

2.13.2 Non-compliance subscale (high = poor)

There was a single trial in this subgroup, with a total of 239 people. There was no clear difference between ICM and non-ICM within this subgroup (MD -0.6, 95% CI -1.63 to 0.43). This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$) ([Analysis 2.13](#)).

2.14 Global state: 3c. Compliance with medication - average endpoint subscale score (ROMI, score 1 to 3, skewed data)

Medium- and long-term skewed data were available from one study assessing compliance scores with the ROMI compliance and non-compliance subscales. These data tended to favour standard care, where participants had a higher level of compliance ([Analysis 2.14](#)).

2.15 Social functioning: 1. Contact with legal system (various measurements)

We identified three studies relevant to this outcome, providing data on different time periods and different measures.

2.15.1 By medium term - contact with the police

Medium-term data were available from one study reporting 'contact with the police'. We found no significant difference between groups ($n = 73$, 1 RCT, RR 0.32, 95% CI 0.04 to 2.97; [Analysis 2.15](#)).

2.15.2 By long term - imprisoned

Long-term data were available on both binary outcomes of 'imprisoned' and 'arrested'. We found two studies reporting the outcome 'imprisoned', and data failed to show any difference in the number of people imprisoned ($n = 959$, 2 RCTs, RR 1.15, 95% CI 0.64 to 2.08; [Analysis 2.15](#)).

2.15.3 By long term - arrested

Only one study provided data on the outcome 'arrested'. Again, there was no clear difference between groups ($n = 251$, 1 RCT, RR 0.87, 95% CI 0.53 to 1.42; [Analysis 2.15](#)).

2.15.4 By medium-term FUP (18 months) - imprisoned

We found one trial relevant to this subgroup, with a total of 251 participants. There was no clear difference between ICM and non-ICM within this subgroup ($n = 251$, 1 RCT, RR 1.07, 95% CI 0.47 to 2.44; [Analysis 2.15](#)).

2.15.5 By long-term FUP (8.5 years) - imprisoned

There was a single trial in this subgroup. There was no clear difference between ICM and non-ICM within this subgroup ($n = 214$, 1 RCT, RR 0.70, 95% CI 0.43 to 1.14; [Analysis 2.15](#)).

2.16 Social functioning 2. Employment status (various measurements)

We identified two studies relevant to this outcome: one medium-term study, reporting 'participant who spent more than one day employed' and 'participants on paid employment', and one long-term follow-up study, reporting 'unemployed'. Both medium-term outcomes showed no significant difference between groups. The long-term follow-up outcome confirmed medium-term data, showing no significant difference between ICM and non-ICM in employment status.

2.16.1 Spent > 1 day employed - by medium term

There was no significant difference between ICM and non-ICM in increasing number of days of employment ($n = 73$, 1 RCT, RR 1.46, 95% CI 0.45 to 4.74; [Analysis 2.16](#)).

2.16.2 On paid employment - by medium term

There was no significant difference between ICM and non-ICM in increasing the chance of being on paid employment by medium term ($n = 73$, 1 RCT, RR 0.97, 95% CI 0.14 to 6.54; [Analysis 2.16](#)).

2.16.3 Unemployed - by long-term FUP (8.5 years)

There was no significant difference between ICM and non-ICM in decreasing the risk of unemployment ($n = 214$, 1 RCT, RR 1.10, 95% CI 0.91 to 1.34; [Analysis 2.16](#)).

2.17 Social functioning: 3a. Accommodation status (various measurements)

We found two relevant studies for this outcome, one providing data only for the outcome 'living in supported accommodation' by medium term. The second study provided data for all of the other outcomes, using different measures to assess accommodation status. The data failed to show significant differences between groups at any time period.

2.17.1 By medium term - living in supported accommodation

The outcome 'living in supported accommodation' was only available for the medium term from one study. Data failed to show a significant difference between groups ($n = 73$, 1 RCT, RR 2.59, 95% CI 0.75 to 9.01; [Analysis 2.17](#)).

2.17.2 By long term - homelessness

The outcome 'homelessness' was available for the long term from one study. There were no significant differences between treatment groups in the number of people who were homeless ($n = 251$, 1 RCT, RR 0.69, 95% CI 0.34 to 1.38; [Analysis 2.17](#)).

2.17.3 By medium-term FUP (18 months) - living independently

One study provided data and failed to show a significant difference between groups ($n = 251$, 1 RCT, RR 0.98, 95% CI 0.84 to 1.13; [Analysis 2.17](#)).

2.17.4 By medium-term FUP (18 months) - living in supported accommodation

One study provided data and failed to show a significant difference between groups ($n = 251$, 1 RCT, RR 0.83, 95% CI 0.38 to 1.77). This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$; [Analysis 2.17](#)).

2.17.5 By medium-term FUP (18 months) - homelessness

One study provided data and failed to show a significant difference between groups ($n = 251$, 1 RCT, RR 0.84, 95% CI 0.47 to 1.49). Heterogeneity was high for this outcome ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$; [Analysis 2.17](#)).

2.17.6 By long-term FUP (8.5 years) - living in supported accommodation

One study provided data and failed to show a significant difference between groups ($n = 214$, 1 RCT, RR 1.05, 95% CI 0.75 to 1.48; [Analysis 2.17](#)).

2.17.7 By long-term FUP (8.5 years) - homelessness

One study provided data and failed to show a significant difference between groups ($n = 214$, 1 RCT, RR 0.92, 95% CI 0.55 to 1.53; [Analysis 2.17](#)).

2.18 Social functioning: 3b. Accommodation status - average days per month in stable accommodation

The continuous outcome 'average days per month in stable accommodation' was available for short, medium, and long term (2 RCTs). Data did not show significant differences between groups at any time period.

2.18.1 By short term

One trial was relevant to this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 203$, 1 RCT, MD -0.2, 95% CI -2.48 to 2.08; [Analysis 2.18](#)).

2.18.2 By medium term

One trial was relevant to this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 203$, 1 RCT, MD 0.1, 95% CI -2.15 to 2.35). This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$; [Analysis 2.18](#)).

2.18.3 By long term

We found two trials relevant to this subgroup (total $n = 901$). We did not find evidence of a clear difference between ICM and non-ICM within this subgroup ($n = 901$, 2 RCTs, MD -0.19, 95% CI -1.37 to 1.0; [Analysis 2.18](#)).

2.19 Social functioning: 4a. Substance abuse - by long term

We found two relevant studies for this outcome. Long-term binary data on 'substance abuse' differentiated between 'alcohol abuse' and 'illicit drug abuse'. Data did not show significant differences between groups with any measures.

2.19.1 Alcohol abuse

There was no difference between ICM and non-ICM in the number of people abusing alcohol ($n = 251$, 1 RCT, RR 1.10, 95% CI 0.67 to 1.83; [Analysis 2.19](#)).

2.19.2 Illicit drug abuse

There was no difference between ICM and non-ICM in the number of people abusing illicit drugs ($n = 251$, 1 RCT, RR 1.08, 95% CI 0.69 to 1.71; [Analysis 2.19](#)).

2.19.3 Alcohol - remission from alcohol use disorder (Alcohol Use Scale (AUS) score < 3)

Binary data on 'remission from alcohol use disorder' (defined AUS score < 3) also did not show any significant difference between groups by long term ($n = 223$, 1 RCT, RR 0.86, 95% CI 0.65 to 1.14; [Analysis 2.19](#)).

2.20 Social functioning: 4b. Substance abuse - average endpoint score (Substance Abuse Treatment Scale (SATS), low = poor)

Short-, medium-, and long-term continuous data were available from one study, assessing substance abuse with the SATS. These data failed to show a significant difference between groups at any time period assessment.

2.20.1 By short term

We did not find evidence of a clear difference between ICM and non-ICM within this subgroup ($n = 203$, 1 RCT, MD 0.07, 95% CI -0.28 to 0.42; [Analysis 2.20](#)).

2.20.2 By medium term

We did not find evidence of a clear difference between ICM and non-ICM within this subgroup ($n = 203$, 1 RCT, MD -0.11, 95% CI -0.55 to 0.33; [Analysis 2.20](#)).

2.20.3 By long term

We did not find evidence of a clear difference between ICM and non-ICM within this subgroup ($n = 203$, 1 RCT, MD 0.11, 95% CI -0.41 to 0.63). This subgroup had important levels of heterogeneity ($\text{Chi}^2 = 0.0$; $\text{df} = 0.0$; $P = 0.0$; $I^2 = 100\%$; [Analysis 2.20](#)).

2.21 Social functioning: 4c. Alcohol - abuse (various measurements, skewed data)

Skewed data were available from one study assessing 'days using alcohol' and 'AUS score' by short, medium, and long term. Data on 'days using alcohol' showed a trend towards a higher alcohol consumption in the ICM group in each assessed time period. This trend was confirmed by the short- and medium-term findings on the AUS, where the ICM group rating had a worse outcome than the non-ICM group; however, long-term data showed a worse outcome in the non-ICM group ([Analysis 2.21](#)).

2.22 Social functioning: 5a. Average endpoint score (Life Skill Profile (LSP), high = poor) - by long term

We found the LSP social functioning score did not favour one group over the other by long term ($n = 239$, 1 RCT, MD 4.0, 95% CI -0.61 to 8.61).

2.23 Social functioning: 5b. Average endpoint score (Social Functioning Questionnaire (SFQ), high = poor) - skewed data

Skewed data on SFQ social functioning scores showed equivocal results by medium term, and a worse outcome in the ICM group by long term. We entered these data as 'other' data ([Analysis 2.23](#)).

2.24 Mental state: 1a. General symptoms - average endpoint score (various scales)

We identified two studies relevant to this outcome, assessing 'mental state: general symptoms' on two different scales (BPRS-24 items and CPRS) at different time periods. We found BPRS mental state scores favoured neither group during the short-, medium-, and long-term analysis. These data were confirmed by long-term findings on the CPRS, where there was no significant difference between ICM and non-ICM.

2.24.1 By short term (BPRS-24 items, high = poor)

The single trial in this subgroup showed no difference between the two treatments ($n = 203$, 1 RCT, MD -0.65, 95% CI -3.99 to 2.69; [Analysis 2.24](#)).

2.24.2 By medium term (BPRS-24 items, high = poor)

The single trial in this subgroup showed no difference between the two treatments ($n = 203$, 1 RCT, MD -1.62, 95% CI -4.76 to 1.52; [Analysis 2.24](#)).

2.24.3 By long term (BPRS-24 items, high = poor)

The single trial in this subgroup showed no difference between the two treatments ($n = 203$, 1 RCT, MD -0.22, 95% CI -3.32 to 2.88; [Analysis 2.24](#)).

2.24.4 By long term (CPRS, high = poor)

The single trial in this subgroup showed no difference between the two treatments ($n = 595$, 1 RCT, MD 0.40, 95% CI -1.83 to 2.63; [Analysis 2.24](#)).

2.25 Mental state: 1b. General symptoms - average endpoint scores (various scales, skewed data)

Medium- and long-term skewed data from the Krawiecka Scale and long-term skewed data from the BPRS scale could not be entered into meta-analysis. These data, provided from two different trials, consistently suggested a better mental state outcome in the non-ICM group.

2.26 Mental state: 2a. Specific symptoms: negative symptoms - average endpoint score (SANS, high = poor) - by long term

Long-term continuous data on negative symptoms from one long-term trial did not favour either group ($n = 593$, 1 RCT, MD 0.20, 95% CI -2.32 to 2.72).

2.27 Mental state: 2b. Specific symptoms - average endpoint scores (various scales, skewed data)

Skewed data were available on anxiety and depression symptoms assessed with the Hospital Anxiety and Depression Scale (HADS) anxiety and depression subscale by medium and long term. These data, provided by the same study, were not consistent between medium and long term, as they showed a better outcome in the ICM group by medium term and a worse outcome in the ICM group by long term, compared with the non-ICM group ([Analysis 2.27](#)).

2.28 Behaviour: 1. Specific behaviour (various measurements)

We found three relevant studies for this outcome, assessing the outcome at different time periods and using different measures. Data failed to show a significant difference between groups at any time period for any outcomes.

2.28.1 By medium term - harm to self or others

Medium-term data reporting 'harm to self or others' did not show a significant difference between groups ($n = 73$, 1 RCT, RR 0.88, 95% CI 0.4 to 1.9; [Analysis 2.28](#)).

2.28.2 By long term - self-harm

We found two trials relevant to this subgroup. There was no clear difference between ICM and non-ICM within this subgroup ($n = 959$, 2 RCTs, RR 1.00, 95% CI 0.69 to 1.46; [Analysis 2.28](#)).

2.28.3 By long term - injury/assault to others

We found two trials relevant to this subgroup. There was no clear difference between ICM and non-ICM within this subgroup ($n = 959$, 2 RCTs, RR 1.09, 95% CI 0.85 to 1.4; [Analysis 2.28](#)).

2.28.4 By medium-term FUP (18 months) - self harm

There was a single trial in this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 251$, RR 0.85, 95% CI 0.44 to 1.67; [Analysis 2.28](#)).

2.28.5 By medium-term FUP (18 months) - injury/assault to others

There was a single trial in this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 251$, 1 RCT, RR 1.35, 95% CI 0.87 to 2.1; [Analysis 2.28](#)).

2.28.6 By long-term FUP (8.5 years) - self harm

There was a single trial in this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 214$, 1 RCT, RR 0.81, 95% CI 0.51 to 1.27; [Analysis 2.28](#)).

2.28.7 By long-term FUP (8.5 years) - injury/assault to others

There was a single trial in this subgroup. We did not find evidence of a clear difference between the two treatments ($n = 214$, 1 RCT, RR 0.95, 95% CI 0.83 to 1.09; [Analysis 2.28](#)).

2.29 Quality of life: 1. Average endpoint score (various scales)

We found three studies assessing quality of life with three different scales (LQoLP, MANSA, QOLI) at different time periods. There were no significant differences between ICM and non-ICM in any of these measures at any time period. Data on QOLI scores were available by short and medium term from one study. Long-term data were available from three different studies measuring quality of life with three different scales, therefore not entering the analysis together. No results showed any significant difference between groups. Note that for this outcome the right graph label favours ICM (experimental group).

2.29.1 By short term - overall life satisfaction (QOLI, high = better)

One study provided data, showing no difference between groups ($n = 203$, 1 RCT, MD -0.02, 95% CI -0.43 to 0.39; [Analysis 2.29](#)).

2.29.2 By medium term - overall life satisfaction (QOLI, high = better)

One study provided data, showing no difference between groups ($n = 203$, 1 RCT, MD -0.04, 95% CI -0.43 to 0.35; [Analysis 2.29](#)).

2.29.3 By long term (LQoLP, high = better)

One study provided data, showing no difference between groups ($n = 526$, 1 RCT, MD 0.03, 95% CI -0.10 to 0.16; [Analysis 2.29](#)).

2.29.4 By long term (MANSA, range 1 to 7, high = better)

One study provided data, showing no difference between groups ($n = 166$, 1 RCT, MD 0.10, 95% CI -0.19 to 0.39).

2.29.5 By long term - overall life satisfaction (QOLI, high = better)

One study provided data, showing no difference between groups ($n = 203$, 1 RCT, MD 0.1, 95% CI -0.25 to 0.45; [Analysis 2.29](#)).

2.30 Participant satisfaction/need: 1. Average endpoint scores (various scales) - by long term

Long-term data were available from one study, assessing participant need with CAN, and participant satisfaction with health service scale. There were no significant differences between groups as assessed with the two scales.

2.30.1 Patient need: CAN (high = poor)

One study provided data, showing no difference between groups ($n = 585$, 1 RCT, MD -0.29, 95% CI -0.69 to 0.11; [Analysis 2.30](#)).

2.30.2 Patient Satisfaction With Health Services (high = poor)

One study provided data, showing no difference between groups ($n = 490$, 1 RCT, MD -0.4, 95% CI -1.25 to 0.45; [Analysis 2.30](#)).

2.31 Participant need: 1. Average endpoint scores (various scales, skewed data)

One study provided data suggesting a difference between interventions in participant need as assessed with CAN scores, showing a worse outcome in the ICM group in the medium and long term, but these data were skewed. A second study provided data on participant need, assessed with CANSAS by long term. These data failed to show any difference between groups. We have presented these data as 'other' data ([Analysis 2.31](#)).

2.32 Participant satisfaction: 1. Average endpoint scores (CSQ-modified, high = better, skewed data) - by long term

Skewed data from a different study suggested long-term better satisfaction with treatment for the ICM group (data assessed with CSQ). We have reported these data as 'Other' data, ([Analysis 2.32](#)).

2.33 Costs: 1. Direct costs of psychiatric hospital care (skewed data)

Costs were assessed measuring 'direct costs of psychiatric hospital care' and 'direct cost of all care'. No data were available on 'direct healthcare costs'.

Skewed data on direct costs of psychiatric hospital care were available from two studies by medium and long term. Medium- and long-term data from one study found no significant difference between groups, whilst the second long-term study data found costs were significantly lower for the ICM group. The latter study was small ([Quinlivan-California 1995](#), $n = 60$), where the former one was larger ([Harrison-Read-UK 2000](#), $n = 193$). We have presented these data as 'Other' data, ([Analysis 2.33](#)).

2.34 Costs: 2a. Direct costs of all care - by long term (2 years) - unit cost GBP, fiscal year 1997/98

Direct costs of all care were available from one study reporting skewed data ([UK700-UK 1999](#)), but with a sample size greater than 200. There was no significant difference between groups for

reducing direct costs of all care ($n = 667$, 1 RCT, MD 77.00, 95% CI -66.63 to 220.63), but findings showed a trend suggesting greater cost in the ICM group. This trend suggested a cost increase of GBP 77 per person per month by long term, referred to as fiscal year 1997/98.

2.35 Costs: 2b. Direct costs of all care (skewed data) - by medium term

One study ($n = 58$) reported skewed data on the same outcome (direct costs of all care) (Johnston-Australia 1998). This data set showed no significant differences between groups by medium term, substantially confirming data by long term. We have reported these data as 'Other' data, (Analysis 2.35).

2.36 Costs: 3. Total costs of care per patient - unit cost GBP

Total costs of care were available from two studies reporting skewed data (REACT-UK 2002; UK700-UK 1999), but with a sample size greater than 200. Total costs of care included direct and indirect costs (i.e. informal care, prison, court, probation officer, police custody, etc.).

2.36.1 By 24 months, fiscal year 1997/1998

There was no significant difference between groups for reducing total costs of care ($n = 667$, 1 RCT, MD 1849.00, 95% CI -1598.23 to 5296.23), but findings showed a trend suggesting greater cost in the ICM group (Analysis 2.36).

2.36.2 By 18 months, fiscal year 2003/2004 (GBP 1 = USD 1.58)

There was no significant difference between groups for reducing total costs of care ($n = 243$, 1 RCT, MD 4031.00, 95% CI -2724.13 to 10,786.13), but findings showed a trend suggesting greater cost in the ICM group (Analysis 2.36).

3. SENSITIVITY ANALYSES

As anticipated in the Methods section (see Methods, Sensitivity analysis), we performed the following sensitivity analyses.

3.1 Implication of randomisation

3.1.1 COMPARISON 1: INTENSIVE CASE MANAGEMENT versus STANDARD CARE

All of the included studies were described as randomised, and none were described in a way as to imply randomisation, therefore we did not include any trials in a sensitivity analysis.

3.1.2 COMPARISON 2: INTENSIVE CASE MANAGEMENT versus NON-INTENSIVE CASE MANAGEMENT

All of the included studies were described as randomised, and none were described in a way as to imply randomisation, therefore we did not include any trials in a sensitivity analysis.

3.2 Standard care caseload is over 20

3.2.1 COMPARISON 1: INTENSIVE CASE MANAGEMENT versus STANDARD CARE

Among studies reporting on our primary outcomes, only six studies reported the ratio of staff to participants, and for each study it was greater than 1:20 (Bond-Chicago1 1990; Bond-Indiana1 1988; Herinckx-Oregon 1996; Jerrell-SCarolina1 1991; OPUS-Denmark 1999; Sytema-Netherlands 1999).

When we entered these studies (where standard care group caseload was greater than 20) in the analysis, the first primary outcome 'average days per month in hospital' showed a significantly favourable effect in the ICM group in reducing the length of hospitalisation ($n = 951$, 7 RCTs/study centres, MD -2.01, 95% CI -3.36 to -0.67), but heterogeneity was substantial ($I^2 = 70\%$, $P = 0.003$). These findings confirm those obtained when all studies were entered in the analysis, regardless of caseload in the standard care comparison group.

The second primary outcome 'not remaining in contact with psychiatric services' showed that participants in the ICM group were significantly less likely to lose contact with psychiatric services than participants in the standard care group by medium term, long term, and overall ($n = 931$, 4 RCTs, MD 0.38, 95% CI 0.23 to 0.63), but heterogeneity was substantial ($I^2 = 67\%$, $P = 0.03$). These findings confirm those obtained when all studies were entered in the analysis, regardless of caseload in the standard care comparison group, however data in the sensitivity analysis showed a substantial level of heterogeneity not present when all studies were entered in the analysis.

3.3 Assumptions for lost binary data

3.3.1 COMPARISON 1: INTENSIVE CASE MANAGEMENT versus STANDARD CARE

No assumptions needed to be made regarding people lost to follow-up for the primary binary outcome 'not remaining in contact with psychiatric services' for this comparison, therefore we did not include any trials in a sensitivity analysis.

3.3.2 COMPARISON 2: INTENSIVE CASE MANAGEMENT versus NON-INTENSIVE CASE MANAGEMENT

For the second comparison, we needed to make assumptions regarding people lost to follow-up for the primary binary outcome 'not remaining in contact with psychiatric services' for one trial (REACT-UK 2002). When we compared the findings of the outcome when we used our assumption to when we used completer data only, results did not differ substantially.

3.4 Assumptions for lost continuous data (for meta-regression)

We undertook sensitivity analysis, removing 13 out of 52 trials originally entering meta-regression. These were trials where primary outcome standard deviation was imputed (see Table 3). Meta-regression was therefore run on the remaining pool of 39 non-imputed studies. Results no longer reached significance for both variables 'organisation fidelity subscore' and 'baseline hospital use' as P is at trend ~ 0.07 ('organisation fidelity subscore': regression coefficient -0.2, 95% CI -0.48 to 0.02, $P = 0.067$; 'baseline hospital use': regression coefficient -0.18, 95% CI -0.39 to 0.02, $P = 0.077$). Removing a high-influence outlier (Rosenheck-USA-NP (C)), significance returns for the effect of 'baseline hospital use' (-0.26, 95% CI -0.51 to -0.01, $P = 0.046$), but not for 'organisation fidelity'. When combining the two variables within the model ('organisation fidelity subscore' and 'baseline hospital use'), the pattern of results did not change for the non-imputed studies.

DISCUSSION

Summary of main results

1. COMPARISON 1: INTENSIVE CASE MANAGEMENT versus STANDARD CARE

1.1 Service use

1.1.1 Service use: Average number of days in hospital per month - at about 24 months

ICM does seem to reduce length of hospitalisation when compared with standard care (by 0.86 day per month over 24 months). However, these data were low quality and from a heterogeneous analysis; when certain studies are removed from the analysis, the now-homogeneous result suggests that the saving is in the region of 0.6 days per month. We were unsure which of the two figures was the most reliable, but in any event trial findings suggest a saving of time in hospital per person of between about 7 and 10 days in hospital per year.

What is important, however, is that there was a high duration of hospital stay for these people in the two previous years (averaging 6 days per month). This was higher than for those in the ICM versus non-ICM comparison (averaging 3.4 days per month), which found no difference between groups (see [Figure 10](#)). The impressive saving of time in hospital for ICM was greater than that of standard care, but the saving in standard care was also considerable (absolute decline for ICM was about 3 days, standard care was 1.8 days). Well-organised standard care, for people with what would seem to be a history of considerable periods spent in hospital over the last 24 months, does seem to reduce the time in hospital for the ensuing two years. However, ICM adds more than an extra day to that gain.

The meta-regression is a tool of limited power, employed on weak data. However, the results were in keeping with the results of one other review ([Burns 2007](#)), which suggests that the gain of ICM was not so much linked with the total fidelity score, the staff subscale, or the comparison group. It did suggest a link with the organisational subscore of the Index of Fidelity to Assertive Community Treatment (IFACT) scale (0.36 day per month out of hospital gained by each point increase of this subscore). It also suggested that ICM effect is linked to length of hospitalisation during the previous two years (0.2 day per month out of hospital gained by each day increase in the day in hospital per month during previous two years).

In other words, this means that:

- if the ICM team ratio staff:client is less than 1:20 (calculated dividing the number of active clients on the caseload by the number of full-time equivalents of direct service staff on the team), then it makes no difference how much the caseload is lower than 1:20;
- the ICM team size does not matter (calculated as the number of full-time clinical staff equivalents, as defined earlier);
- the availability of a psychiatrist on the team is not pivotal; and/or
- the availability of a nurse on the team is not pivotal.

It also suggested that gains in IFACT scores can reduce average hospital stay. [McGrew 1994](#) and [McGrew 1995](#) suggest that gain can be mediated by:

- ensuring that the ICM team performed the role of primary therapist for the client (the primary therapist role designates the person within the local mental health system with primary clinical and record keeping (e.g. treatment plans) responsibility for the client);
- the ICM team's offices being located in a separate building from the parent agency's main offices (i.e. usually away from the hospital site);
- the ICM team sharing caseloads (rated as the degree to which all staff members on the team had contact with all clients on a regular basis, e.g. through rotation), in contrast to individual caseloads in which specific staff workers are responsible for specific clients;
- the ICM team meeting as a group each weekday to discuss their entire caseload;
- the ICM team's supervisor devoting at least half time to client contacts, either conjointly during supervision of team members, or individually as part of his or her duties as a member of the team;
- the ICM team providing 24-hour direct access to the team (if access to the ICM team was triaged through the community mental health centre emergency 24-hour on-call service, intermediate score of 0.5 is obtained, therefore the advantage on decreasing days in hospital per month would be halved (-0.2 days in hospital per month)); and/or
- the ICM team serving clients without any expectation of transferring them to another programme.

1.1.2 Service use: Average number of days in hospital per month - by follow-up

When the same outcome 'average number of days in hospital per month' was assessed on medium- and long-term follow up, data did not confirm the effect of ICM in reducing length of hospitalisation assessed by 24 months. These data were provided by one large study ($n = 547$), where during the follow-up period all participants received the control intervention (standard care). These data are suggestive of a loss of effect on reducing number of days in hospital over time, if ICM intervention is discontinued.

1.1.3 Service use: Not remaining in contact with psychiatric services

Overall, we found ICM to be better than standard care for retaining people in psychiatric services ($n = 1633$, 9 RCTs, RR 0.43, 95% CI 0.30 to 0.61). However, this effect was not seen for the short-term analysis ($n = 95$, 1 RCT, RR 0.54, 95% CI 0.28 to 1.05), although confidence intervals were compatible with an effect favouring ICM ($P = 0.07$). Medium-term findings did suggest an overall effect of ICM being better in reducing loss to follow-up to psychiatric service contact ($n = 1063$, 3 RCTs, RR 0.51, 95% CI 0.36 to 0.71). In the longer term, this same effect was heterogeneous, due to an outlying finding of a single study ([Herinckx-Oregon](#)). This trial had a peculiar definition for this outcome, which was different from the other studies. In [Herinckx-Oregon](#) 'not remaining in contact with psychiatric services' did not include refusing re-interview, moving out, and death, whereas for the other trials it did. If we exclude [Herinckx-Oregon](#), and only five long-term trials are retained in the analysis, then ICM appears to be effective in preventing loss to follow-up ($n = 475$, 5 RCTs, RR 0.27, 95% CI 0.11 to 0.66).

The result of a better retention in care for the ICM group strengthens the relevance of the result for the first primary outcome (i.e. ICM decreasing time in hospital). ICM decreases days of hospitalisation

in a severe mentally ill population where patients are kept in close contact with services, therefore the ICM effect on reducing days in hospital might not be dissipated by a higher rate of loss to follow-up.

1.1.4 Service use: Use of hospital

We found that ICM reduced the number of people admitted to hospital more than standard care, at least in the medium term ($n = 1303$, 5 RCTs, RR 0.85, 95% CI 0.77 to 0.93). Skewed data for 'average number of admissions in the medium term' were in accordance with these first findings, whilst skewed data for 'average number of admissions in the long term' failed to show any trend in the effect of intervention. Synthesis of short- and long term studies in this outcome produced heterogeneous findings. The short-term data were from only two studies, and when the most positive one is removed ([Bond-Indiana1](#)), the finding becomes clearly null. The long-term data was from 11 trials; removing the three clearly outlying studies, [Curtis-New York](#), [Macias-Utah](#), and [Test-Wisconsin](#), also restores homogeneity and moves the finding squarely towards the null. One small study provided inconclusive data on the unplanned admission to the emergency department, an outcome describing only one option of psychiatric admission; for this reason, and because these data come from a single small study, we considered this finding weak.

Overall, the effect of ICM on admission to hospital is not strong. Whereas the time spent in hospital does seem to be less if allocated ICM - at least for those whose baseline use of hospital was high - the number of admissions is not greatly changed. Admissions are shorter, but not by much, if any less frequent.

1.1.5 Service use: Use of services outside of mental health provision

More outcomes were available describing 'use of services outside of mental health provision'. Studies did not report a convincing difference in 'use of emergency room', 'rate of use of emergency room', 'use of day hospital care', or 'rate of outpatient visits'. Only 'rate of home visits' was higher for the ICM group. However, we did not consider these data very robust, as they were based on single studies providing data per each outcome or on skewed data that were very difficult to interpret.

1.2 Adverse event

1.2.1 Death - all cause and suicide

This review did not find any difference in mortality either due to all causes or to suicide in the short, medium, and long term and in medium- and long-term follow-up. Although death is a rare adverse event, the duration of the longer studies (~ 24 months) means that some deaths would have been expected to occur and did (3.2% ICM versus 3.8% standard care). This difference was not statistically significant, but is homogeneous, and suggests a trend in terms of risk reduction (RR 0.84, 95% CI 0.48 to 1.47), partly confirmed in one large study on medium-term follow-up (RR 0.59, 95% CI 0.22 to 1.61). The same trend was confirmed in the ICM effect on mortality due to suicide by long term (suicide rate 1.3% ICM versus 2% standard care). Again, this difference was not statistically significant, but is homogeneous, and stronger compared to death due to all causes. If the suicide risk is in actuality so much reduced (RR 0.68, 95% CI 0.31 to 1.51), this would be a very important finding, although the quality of the evidence is low ([Summary of findings table 1](#)).

Few things have changed the outcome of death for people with schizophrenia. If, for this group of people, set in the context of a standard care with a high baseline risk of admission, ICM could decrease death, and by so much, this would be a strong argument in favour of ICM. These data on suicide are the findings of nine studies with only a total number of participants of 1456 and low-quality evidence. A single larger trial might be able to confirm this important suggestion.

1.3 Global state

1.3.1 Global state: Relapse

No data were provided for the important outcome of relapse.

1.3.2 Global state: Leaving the study early

ICM data regarding number of participants lost to follow-up for the short term were heterogeneous. However, we found ICM to be more advantageous than standard care in reducing rate of lost to follow-up both in the medium term ($n = 1699$, 8 RCTs, RR 0.60, 95% CI 0.51 to 0.70) and long term ($n = 1798$, 13 RCTs, RR 0.68, 95% CI 0.58 to 0.79, *low-quality evidence*). The impression remains that ICM, and again with the proviso that these findings may apply most specifically to a group with high baseline admission, holds on to people more tightly across time. This may not significantly lower admission rate, but loss to follow-up and length of admission may decrease. Overall, these data were not of high quality ([Summary of findings table 1](#)), but there is a belief that ICM is advantageous over standard care for the higher-risk groups. For example, in groups with only 10% loss to follow-up across the long term, only 3 more people are not lost for every 100 given ICM. However, with more realistic figures of 50% loss to follow-up, this figure rises to 15 more people out of every 100 who are kept in care compared with those allocated standard care.

1.3.3 Global state: Global Assessment of Functioning Scale (GAF)

Short-term studies indicated a better improvement in GAF endpoint score for participants in the ICM group compared with those allocated standard care (short term: $n = 797$, 4 RCTs, MD 2.07, 95% CI 0.28 to 3.86). This effect was confirmed by the long-term data ($n = 818$, 5 RCTs, MD 3.41, 95% CI 1.66 to 5.16). Whilst this is favourable for those allocated ICM, we are unsure of the clinical meaning of these data, as changes of two or three points on a scale that runs to 100 does not seem to be much. We have found no reference to the clinical meaning of such small changes.

1.3.4 Global state: Not compliant with medication

Only one long-term study provided data on compliance with medication, and these indicated a higher compliance level in those allocated to ICM compared with those in the standard care group ($n = 71$, 1 RCT, RR 0.35, 95% CI 0.15 to 0.81). Again, this is an important finding and should be replicated. We are surprised that such easily recorded data are not reported in more studies.

1.4 Social functioning

1.4.1 Social functioning: Contact with legal system

Studies measuring contact with legal system used different definitions over varying time periods, which makes interpretation difficult. There was no real suggestion that ICM either increases or decreases the measures of this outcome. The 'arrested' and 'imprisoned' outcomes were the only ones with some consistency. They showed no significant difference in the intervention effect

between groups. The 'contact with the police' outcome findings were from only one study and were not significant in the short term, but became significantly different in the medium term (favouring the ICM group). Overall, the legal outcomes were not convincing, and there is a need for more consistency in approach to this area of research.

1.4.2 Social functioning: Employment status

This review did not reveal any significant difference between ICM and standard care in employment status, as measured by different outcomes. Medium-term findings on 'number of people not competitively employed' were based on only one trial. Both medium- and long-term data reporting 'not employed' tended to favour ICM, although data were heterogeneous, and overall the quality of the evidence was very low ([Summary of findings table 1](#)). Data from one large trial on medium- and long-term follow-up failed to show any difference between interventions. Again, this is an important outcome for which more data are needed before firm conclusions can be drawn.

1.4.3 Social functioning: Accommodation status

Data on the outcome 'homelessness' were not convincing by short, medium, or long term, but were mostly derived from just a few trials.

The outcome 'not living in stable accommodation' was scarcely reported, available from only one long-term study.

Regarding the 'not living independently' outcome, we found that people allocated to ICM were more likely to live independently compared with those allocated standard care - in the medium term, and even more so in the long term. This is another important finding of this review. If the risk of not living independently is in actuality substantially reduced by this ICM package (18% ICM versus 26% standard care, long term), at least for people with high baseline risk of admission, and if this is a desired outcome for this particular client group, then, combined with the other moderate but cumulative advantages, this finding further highlights the advantage of ICM over standard care.

Only one large study reported the outcome 'days in supported house', assessing it by long term and by medium- and long-term follow-up. The advantage for standard care reported on medium-term follow-up was not confirmed on long term or on long-term follow-up, failing to show a significant trend of effect.

1.4.4 Social functioning: Substance abuse

Only one study ($n = 547$) reported usable binary data for alcohol and drug abuse. A long-term single study failed to show any advantage for participants treated with ICM compared to standard care. Skewed data were supplied by [Sytema-Netherlands](#) ($n = 81$), with Dartmouth Assessment of Lifestyle Interview scores tending to favour the ICM group for both drug use and alcohol consumption. However, we are unsure of the clinical meaning of these scores. [Morse-Missouri3](#) ($n = 103$) reported skewed data on days substances were used per month. There was no indication of any difference between groups. There is currently no compelling evidence that ICM affects abuse of substances or alcohol.

1.4.5 Social functioning: Various scales

Few studies reported usable data for social functioning scale, and outcome data were complicated by the use of different scales

within single studies, making meta-analysis impossible. In this confusion of evidence, we see no advantage for participants treated with ICM compared to those treated with standard care in terms of social functioning measures. This does not seem to concur with other findings on independent living. It could be that the fine-grain measures of functioning are picking up subtle parameters of social function not effected by the package. It could also be that the measures are not sensitive enough to broad and important issues of social function.

1.5 Mental state

Rating of mental state in these trials illustrates the confusion of how such symptoms are recorded in randomised studies. Timings of use of the scales differ, and the findings are so problematic to interpret from the clinical perspective that we are left to make safe but bland conclusions.

No data were provided for the important outcome 'mental state: not improved to an important extent', and there does not seem to be any compelling evidence that, in this group of people, set where the baseline risk of admission is high, ICM in actuality substantially affects a person's mental state.

1.6 Behaviour: self harm

Based on findings from the larger of the studies, self harm was not convincingly reduced by use of the ICM model. The mortality finding discussed above, however, does seem to suggest that ICM reduced the risk of death. These findings are a little at odds with each other, although not entirely, providing all the more reason to continue to research into this area for these, the simplest of outcomes.

1.7 Quality of life

Few studies reported relevant outcomes. Short- and medium-term outcome data were complicated by the use of different scales within single studies, making meta-analysis impossible. We found that one short-term study ($n = 125$) showed a better quality of life in the ICM group on the Lehman's Quality of Life Interview scale, but more medium- and long-term data failed to show any advantage for participants treated in the ICM group compared with standard care. The few skewed data seem to concur with the impression that for quality of life measures used in trials, ICM confers no advantage over standard care.

1.8 Participant satisfaction/need

Participants administered ICM were more satisfied with their treatment compared with those administered standard care in these trials. These findings were based on data that were quite strong (short term, $n = 61$; medium term, $n = 500$; long term, $n = 423$). More satisfaction with care could enhance medication compliance, the will to keep in services, housing status, and a host of other variables. We are left doubting the size and meaning of the overall finding. We are unsure how encouraged we should be that these packages of care deliver an average of a two- to three-point improvement in the Client Satisfaction Questionnaire.

Several of the smaller trials did measure need and unmet need. These skewed data were difficult to interpret, but did not seem to convincingly favour either of the groups.

1.9 Costs

With respect to cost of inpatient psychiatric care, ICM was consistently superior to standard care for the outcome 'direct costs of psychiatric hospital care', suggesting a saving of money per person of about USD 144 per month (fiscal year 1990). Two studies taking part in the same multicentre trial provided these data. Skewed data were contradictory, neither showing a trend confirming nor disputing these data.

We found no difference between groups with respect to direct healthcare costs (where skewed data were contradictory and provided by only two small studies). Results on 'direct costs of all care' were inconclusive, as data were skewed and different trials reported contradictory effects.

2. COMPARISON 2: INTENSIVE CASE MANAGEMENT versus NON-INTENSIVE CASE MANAGEMENT

2.1 Service use

2.1.1 Service use: Average number of days in hospital per month - at about 24 months

Moderate quality evidence from this review showed no significant advantage of ICM in reducing the average length of hospitalisation when compared with non-ICM. This could be an important finding, and we see no good reason not to trust this result. The implications from this finding could be that if services are already providing non-ICM, there is no point in investing in further intensiveness. We currently know of no review comparing non-ICM with standard care and reporting relevant outcomes. This should be undertaken. It is possible that there are other features of ICM that may improve outcome, but we are not stipulating that we should specifically investigate for these. What was different between the two sets of comparisons was the baseline risk of admission in the previous two years (about 6 days per month for Comparison 1 versus about 3.4 days per month for Comparison 2). This was highlighted by the meta-regression process. This generates further hypotheses. Baseline hospital risk is linked to service provision, service culture, severity of illness, and other issues. We do not have the sophistication of data to investigate these. What we are left with is the possibility that in a situation where people with severe mental illness have a duration in hospital of less than 4 days per month in the two years preceding the ICM package of care, the increased intensity of approach may not be justified.

2.1.2 Service use: Average number of days in hospital per month - at follow-up

Data on medium- and long-term follow-up from one study ($n = 237$) failed to show a significant advantage of ICM in reducing the average length of hospitalisation when compared with non-ICM. During the follow-up period participants could remain in the originally allocated intervention or be transferred to the control one. These data on follow-up confirmed the data at 24 months discussed above.

2.1.3 Service use: Not remaining in contact with psychiatric service

We found ICM to be more effective in increasing the number of people retained in contact with psychiatric service in the medium term, but we did not consider these findings robust as they were based only on one small trial ($n = 73$). We found no difference between interventions in the long term, but data were heterogeneous. Overall, when pooling medium- and long-term

data, we found no advantage for participants treated with ICM compared to non-ICM for better retention in psychiatric service but, again, these data were heterogeneous, and we found no obvious explanation for the heterogeneity ($n = 1255$, 4 RCTs). Medium-term (18 months) follow-up data showed a trend favouring ICM in increasing the number of people retained in contact with psychiatric service.

2.1.4 Service use: Admissions

We found no difference between groups in the risk of being admitted to hospital in the long term ($n = 1132$, 3 RCTs, RR 0.91, 95% CI 0.75 to 1.12). These findings were confirmed by data from one long-term study ($n = 678$) and one medium-term study ($n = 68$) on the average number of admissions, where no advantage was shown between treatments in reducing number of admissions in the long term (moderate-quality evidence, [Summary of findings 2](#)) or in the medium- and long-term follow-up. Data on frequency of admission and on length of hospitalisation therefore consistently show no effect of ICM for both outcomes.

2.2 Adverse events

2.2.1 Death due to all causes and to suicide

This review did not find provide strong evidence on mortality rate either due to all causes or to suicide in the short, medium, and long term, or in the medium- and long-term follow-up. These data are quite informative, especially those from long-term studies, where the study length might balance the rarity of the event in detecting any difference between intervention effects. Some deaths occurred in the long-term studies (2.0% ICM versus 2.2% non-ICM) ($n = 1634$, 5 RCTs, RR 0.90, 95% CI 0.46 to 1.75). This impression was confirmed for studies reporting suicide only, as shown in [Summary of findings 2](#), where low-quality evidence also showed no difference between groups.

2.3 Global state

2.3.1 Global state: Relapse

No data were provided for this important outcome.

2.3.2 Global state: Leaving the study early

No studies were available for the short-term outcome.

Data showed no difference between interventions by the medium term, but these data were not strong as they came from a small sample of two studies ($n = 225$) and were heterogeneous with inconsistency of effect.

We found ICM to be more advantageous than non-ICM in reducing rate of lost to follow-up by the long term.

Overall, pooling studies from subgroups for two time points, we found heterogeneous data, but substantially confirming homogeneous data obtained by long term. ICM was confirmed to be more advantageous than non-ICM in reducing rate of lost to follow-up ($n = 2195$, 9 RCTs, RR 0.72, 95% CI 0.52 to 0.99). If we consider this outcome as proxy of a better retention in care, it might overcome the inconsistency of data on 'number of people remaining in contact with psychiatric service' (see Discussion - 2.1.3 Service use: Not remaining in contact with psychiatric service). ICM therefore seems to positively reduce number of lost to follow-up, but does not affect length and frequency of admission. These data

were of low quality ([Summary of findings 2](#)), but it appears that ICM has an advantage over non-ICM for the higher-risk groups. For example, in groups with only 10% loss to follow-up across the long term, only three more people are not lost for every 100 given ICM. However, with a more realistic figure of 50% loss to follow-up, this rises to 14 more people out of every 100 are kept in care compared with those allocated standard care.

2.3.3 Global state: Health of the Nation Outcome Scale (HoNOS)

Not enough studies were available to run a meta-analysis on data derived from the HoNOS or from any other scales assessing global state. Considering the comprehensiveness of the scale assessment of other outcomes, it appears that global state as an outcome is under-recorded by trialists, despite being informative and relevant from a clinical point of view.

2.3.4 Global state: Compliance with medication

As for the previous outcome, not enough studies were available to run a meta-analysis. Again, a very meaningful outcome from a clinical point of view is neglected.

2.4 Social functioning

2.4.1 Social functioning: Contact with legal system

As for studies included in Comparison 1, studies measuring contact with legal system used different definitions over a variety of time periods. This makes interpretation difficult. In addition, only a few studies addressed this outcome (three trials overall). There was no real suggestion that ICM either increases or decreases the measures of this outcome. The 'imprisoned' outcome was the only one with some consistency, showing no significant difference in the intervention effect between groups. The 'contact with the police' and 'arrested' outcome findings were from only one study each and were not significant in the short and long term, respectively. Overall, the legal outcomes were not convincing, and there is a need for more consistency in approach to this area of research.

2.4.2 Social functioning: Employment status

Data available for this outcome were substantially inconclusive, reported by only one small trial ($n = 73$). This trial measured employment status according to two different definitions: 'spent more than one day employed' and 'on paid employment'. Both findings were not significant in the medium term, and overall quality of evidence was low ([Summary of findings 2](#)). One larger study ($n = 214$) provided data on long-term follow-up (8.5 years after the randomised allocation was broken), showing no difference between the two groups. These data did not add much to the understanding of the impact of ICM on employment status compared to non-ICM. Again, this is an important outcome underestimated in the current studies, and at this stage more data are needed before firm conclusions can be drawn.

2.4.3 Social functioning: Accommodation status

Available data on this outcome were surprisingly scarce, as this outcome was reported in just four studies. Two studies described this outcome with binary data: one measuring just 'living in supported accommodation' by medium term, the second measuring 'living in supported accommodation', 'homelessness', and 'living independently' by long term and on follow-up. All data on different measures at different time periods were based on only one trial and they were not significant.

Two more studies described this outcome with continuous data on 'average days per months in stable accommodation', again failing to show any difference between the two groups. Findings seemed to point at a non-significant difference in effects of intervention, although these findings were inconclusive due to the scarcity of available data, despite being easily recorded and very relevant from the perspective of a community-based service.

2.4.4 Social functioning: Substance abuse

Only two studies measured substance abuse, and they described this outcome as binary and continuous measures, and not consistently across studies. This makes interpretation difficult and findings unconvincing, as a single study entered each measurement, and we therefore could not carry out any meta-analysis. As far as we could assess, there was no indication of any long-term difference between groups in 'number of people abusing alcohol', 'number of people abusing illicit drug', or 'remission from alcohol use disorder' (defined as Alcohol Use Scale score less than 3). These findings were confirmed by those continuous data, assessing the substance abuse with Substance Abuse Treatment Scale. These data failed to show a significant difference between groups at any time period assessment. As for the first comparison, currently there is no compelling evidence that ICM affects abuse of substances or alcohol.

2.4.5 Social functioning: Scale data

Findings were equivocal on scale data measuring social functioning, as provided by only one study. We do not think that future studies should address this outcome by use of scale measurement. Scales are not sensitive measures of social functioning. More effort should be placed on consistent and wide measurements of the main issues of social functioning (such as accommodation status, employment status, contact with legal system, rate of permanent social benefits).

2.5 Mental state: General symptoms and specific symptoms

Again, outcomes measured on scales were substantially inconclusive, as the data were spread across single studies on different scales and at different time periods, making meta-analysis impossible. According to the low-quality data available, there does not seem to be any compelling evidence that ICM substantially affects mental state. No data were available for the significant outcome of 'important improvement in mental health'.

2.6 Behaviour: Self harm and injury to others

This review did not reveal any long-term significant difference between ICM and non-ICM in risk of committing self harm or injury to others. These data were based on findings from two studies ($n = 959$), one of which is the largest study ([UK700-UK 1999](#)), and the other the only study providing data on medium- and long-term follow-up ([REACT-UK 2002](#)). These findings are consistent with the mortality findings discussed above, where no significant difference was shown in death rate between groups, either for suicide and for all causes. Although these data are suggestive of no difference of effects between interventions, they are still quite weak due to limited sample size. More trials should address this outcome, one of the simplest ones to collect.

2.7 Quality of life

Quality of life rating in these trials illustrates the confusion of how such symptoms are recorded in randomised studies. The scales differ, and the timings of use of the scales also differ. There was such an inconsistency in approach to this area of research to make meta-analysis impossible. None of the available findings showed any significant difference between interventions. There does not seem to be any compelling evidence that ICM substantially affects the quality of life of a person with severe mental illness.

2.8 Participant satisfaction/need

Findings tended to favour the ICM group in being better satisfied with health services and in reducing need. However, this difference was not significant, and both findings were based on data from the same trial, the largest one ([UK700-UK 1999](#), $n = 585$). We therefore cannot draw any conclusions, but highlight a possible favourable effect in the ICM group, which needs to be confirmed.

2.9 Costs

Studies assessed 'direct costs of psychiatric hospital care', 'direct cost of all care', and 'total cost of care'. Regarding the first outcome, findings were based on skewed data, provided by one small trial ([Quinlivan-California 1995](#), $n = 60$) and one larger one ([Harrison-Read-UK 2000](#), $n = 193$). There did not appear to be any compelling evidence that ICM substantially affects 'direct costs of psychiatric hospital care', either by medium or long term. Also, findings on long-term 'direct cost of all care' did not show any difference between interventions. Again, findings on 'total cost of care' failed to show any difference between ICM and non-ICM.

Overall completeness and applicability of evidence

1. Completeness

1.1 Duration of follow-up

The majority of studies presented long-term data, that is over one year of follow-up. This is a reasonable length of time to sensibly assess any difference in the intervention effects.

Two studies, one in the first comparison (ICM versus standard care) and one in the second comparison (ICM versus non-ICM) presented long-term follow-up (from 18 months to 8 years), assessing outcomes after the active intervention was discontinued or after participants could choose to which arm they were allocated.

1.2 Coverage of outcomes

As the experimental intervention is a service organisation model, its realisation involves health policy and research should account for efficacy and cost evaluation. The outcomes reported were mainly service use and social functioning oriented. No studies reported data on relapse (see [Summary of findings for the main comparison](#), [Summary of findings 2](#)), carer satisfaction and family burden. Participant satisfaction was scarcely reported and in a fragmented way, therefore available data are only partially informative on the effects of these approaches. Few studies provided cost data.

2. Applicability

2.1 Origin

The origin of the data has changed in the last decade since the two original reviews ([Marshall 2000a](#); [Marshall 2000b](#)). There are

now more included trials from Europe, whereas in the past the data source was largely North America, with a few trials from Australia. Thirty per cent of the total sample included in the current review comprises randomised people from Europe. These studies add power to the result for the primary outcome, narrowing the confidence intervals, but otherwise not substantially changing the findings. As only one study was from China, and all the remaining included studies were from Europe, North America, and Australia, the findings of this review still lack applicability to low-income countries and, more generally, to countries where mental health systems are not community based.

2.2 People

Studies included people presenting a variability that we feel is likely to reflect the heterogeneous population a clinician faces in daily practice when treating people affected by severe mental illness. This variability was in terms of diagnosis (where participants were affected by a wide diagnostic group including schizophrenic, affective, and personality disorder); comorbidity (where four studies included dually diagnosed participants) ([Drake-NHamp 1998](#); [Essock-Connecticut 2006](#); [Morse-Missouri 2005](#); [Muller-Clemm-Canada 1996](#)); and social characteristics (where eight trials included homeless participants). On average, studies included people with a long history of illness; only [OPUS-Denmark 1999](#) included participants with a first episode of psychotic illness. This fits with the concept of severe mental illness, where this label includes certain criteria relating to length of illness.

2.3 Interventions

Some studies showed a greater applicability because the experimental intervention was provided by pre-existing team, therefore closer to the real world and less contaminated by the experimental setting.

The majority of new included trials from the 2010 update compared ICM with non-ICM (8 out of 14 trials), and they are all from Europe, Australia, and North America. This confirms the trend of psychiatric services in those particular areas to increasingly include some elements of the original model, but also to dilute and contaminate them with the current organisation. What we call 'standard care' is therefore converging toward non-ICM. The two studies newly included from the 2015 update compare ICM with standard care: one is from the USA and assesses ICM adapted to the forensic setting, and the other is from China, where only recently community care is catching on. For those of us who practice in Europe, the second of the two comparisons in this review may well be more applicable to everyday care. Importantly, this comparison did not illustrate a substantial difference between ICM and non-ICM.

Quality of the evidence

As illustrated in [Figure 1](#), it appears there is an overall unclear risk of bias in these trials. This would therefore mean there is a moderate risk of overestimate of positive effect. Also, making difficult judgements about quality has been greatly helped by a discernable improvement in reporting of methodology.

Potential biases in the review process

There were several potential biases. We have worked mainly with published reports, and only in few cases with unpublished material. By doing this we may be perpetuating a reporting and

publishing bias. It would have been better to have much more original individual participant data. This review follows from two past Cochrane reviews (Marshall 2000a; Marshall 2000b), as well as much work already published in paper format (Burns 2007). The conduct of these reports has influenced this document, and it is possible that we have failed to identify systematic biases in the way we have conducted the reviews across time.

An author of this review is an active pioneer in the development and implementation of the experimental intervention model across the scientific community and clinical world (MM), and one included study is his (Marshall-UK 1995). As a team, we tried to ensure that decisions were made by rational consensus, and not to have an expert in the team would have been an inadvisable omission.

In some cases, protocol rules were unclear, and need for subsequent clarification arose and post hoc decisions had to be taken (see [Differences between protocol and review](#)). This could have affected the review process in various cases. This has probably lowered the quality of the data included in the review, but to not include so much, for example, skewed data, would have omitted much information. Also, by breaking down studies into their centres, many fell below the 200-participant cutoff point. We have included these data in the 'less than 200' category, whereas in previous versions of the review they would have been in the 'greater than 200' category. Due to the overall effect of the changes in protocol, it appears that we have a more inclusive review, with data that are more heterogeneous and also more favourable for the experimental interventions than otherwise would have been the case should we have used a more limited data set. Nevertheless, we did feel it important to present all of these data for the reader to consider.

We prespecified what characteristics of studies could be associated with heterogeneity, and therefore we stated in the protocol what variables were to be explored in the meta-regression before inspecting the results of the studies. Despite this prespecification, we were not blind to what variables were probably more related to heterogeneity, as we were familiar with some study results previously published. The undertaken exploration of heterogeneity might therefore at best lead to generation of hypothesis, but it cannot provide reliable conclusions.

Agreements and disagreements with other studies or reviews

This review merges two older Cochrane reviews, fully bringing up to date how these data should be considered. This version does not disagree with the older reviews; it simply replaces them with a more current viewpoint of the data. A major improvement in this version is data on duration of admission, which were previously lacking from past reviews. Other research in this area do not provide a full summary of available evidence on ICM effects across various outcomes (Burns 2007). This Cochrane review does not disagree with the paper version; it is just much more comprehensive. Regarding the meta-regression, this review substantially confirms the hypothesis stated elsewhere that baseline hospital use and fidelity to the model affects outcome (Burns 2007).

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with severe mental illnesses

We found ICM to be effective in ameliorating many outcomes relevant to people with severe mental illness. Compared to standard care, ICM may reduce hospitalisation and increase retention in care. In fact, ICM was shown to reduce hospitalisation, in terms of less frequent and shorter admission to hospital; increase retention in care; probably reduce the risk of death and suicide; and globally improve social functioning in terms of a better accommodation status, employment status, and showing a trend in reducing contact with legal system. Although its effect on mental state and quality of life remains unclear, ICM seems to significantly help global state compared with standard care. However, it is unclear what gain ICM provides on top of a less formal non-ICM approach. The latter may better suit some people with severe mental illness than the more intensive full-ICM model. Data on satisfaction with care for ICM versus non-ICM were very few and difficult to interpret.

2. For clinicians

ICM formalises a holistic approach to care of people with severe mental illness in the era of limiting hospital admissions and subsequent hospital closure. This review suggests that this formalising is helpful across several outcomes over and above standard care, the latter largely based in outpatient departments, and that this seems acceptable to people with severe mental illness. However, when the fully formal holistic approach (ICM) is compared with the less formal, but also holistic non-ICM, the differences are not so clear. This could be seen as encouraging, as for various reasons many clinicians are unlikely to rigidly apply full ICM. This does not abrogate the need to know and apply key components of the model of care within ICM.

3. For policymakers

We know at this juncture that ICM is of value at least to people with severe mental illness in the subgroup with a high level of hospitalisation (about 4 days per month in past 2 years). The intervention should be performed close to the original model, therefore training should be planned for relevant mental health workers. Data on costs are still scarce, and we could not draw conclusions on cost-effectiveness. Where ICM features are already available in the community psychiatric service (the non-ICM intervention), it is unclear if additional full development to the rigid model of ICM is of value. The results of this review could guide policies on the introduction of such an ICM service in those countries where a community psychiatric service is already set up but ICM is not in use, and in countries where a shift from hospital-based care in favour of a more community-focused approach has still to be developed. Particular consideration should be given to the setting where ICM is to be developed, as its value was shown where the level of hospitalisation is high. It is unclear whether the introduction of some but not all of the ICM features (the non-ICM intervention) is of value compared with community-based standard care, as more research is needed to clarify the effects of non-ICM versus those of standard care.

Implications for research

1. General

First, as we have said previously, reporting of research does seem to have improved across time, and as a result the details of the practice of modern studies are much easier to understand.

However, this review illustrates how scale measurements are much more widespread than simple clinical questions for assessing clinical outcomes. We suggest that binary data are less ambiguous than continuous. There were many scales for the same outcome, further complicating matters: we found many studies assessing the same outcome on different scales and therefore did not feel justified to run a meta-analysis. For example, there was need for consistency in approach regarding social functioning outcomes. Heterogeneous measurements were used to describe the same outcome. This is not very informative - but this review illustrates opportunities lost by researchers. As it is possible that the time for more studies has past, by not having consistency, we will always be left in doubt about important effects of care. Finally, we presume that the use of scales may discourage any worker committed to patient care from taking part in an experimental study.

More attention should be placed on patient and family perspectives, in terms of detecting patient and carer satisfaction, quality of life, and family burden.

2. Specific

2.1 More reviews

We currently know of no review comparing non-ICM with standard care and reporting relevant outcomes. This should be undertaken. In addition, we excluded several good studies from this review as they evaluated mixed models of care, or models plus other interventions such as cognitive behavioural therapy. These studies do merit further attention from reviewers and could help clarify further ways by which either the ICM model develops or new and yet more holistic approaches evolve.

2.2 Developing this review

A full data set with all individual participant data would help in avoiding some biases and allow re-analysis using unified definitions of outcome. Any relevant studies in this area should

make a provision for prospectively providing data compatible with this review.

2.3 More trials

We do not think that more trials comparing current ICM with standard care or non-ICM are justified. We do think that the features of ICM that may improve outcome should be researched, as it may be that the model of intervention is effective only because of some of its features. This work may involve more observational studies in order to evolve the ICM model to new and better packages of care.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Aberg-Wistedt-Sweden 1995

Methods	Allocation: randomised. Design: single centre. Duration: 24 months. Country: Stockholm, Sweden.
Participants	Diagnosis: schizophrenic disorder (DSM-III-R). N = 40. Setting: community setting.

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Aberg-Wistedt-Sweden 1995 (Continued)

Age: 25 to 55 years, mean ~ 38 years.
Sex: 65% M (26M, 14F).
Ethnicity: not reported.
History: recently admitted to ward or currently in outpatient department.

Interventions	1. ICM: interdisciplinary-team based. Caseload: 1:2.5. N = 20. 2. Standard care: multidisciplinary psychiatric outpatient team, specialised in people with schizophrenia. Caseload: ~ 1:10/15. N = 20.
Outcomes	Global state: leaving the study early. Unable to use - Service use: average number of days in hospital per month and number of emergency visits (no mean, no SD). Quality of life: (no mean, no SD). Social network size: (measure validated on children only, no mean, no SD). Burden of care: (no mean, no SD).

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service utilisation (emergency and inpatient services): data collected from patient records. Blinding not reported. Participant's quality of life, size of social networks, and their relatives' burden of care self reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study did not address this outcome.
Selective reporting (reporting bias)	High risk	Most outcomes of interest are reported incompletely.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Audini-UK 1994

Methods	Allocation: randomised. Design: single centre. Duration: 15 months. Country: London, UK.
Participants	Diagnosis: serious mental illness (30% schizophrenia according DSM-III-R). N = 66. Setting: psychiatric community services. Age: 18 to 64 years, median ~ 37 years. Sex: 45% M (30M, 36F). Ethnicity: 26% Afro-Caribbean. History: mean ~ 0.2 admissions in last year; completed at least 18 months in ACT programme*. Excluded: primary addiction, primary organic brain damage.
Interventions	1. ICM: ACT (Stein and Test model). Caseload: 1:12. N = 33**. 2. Standard care: routine care from psychiatric services, as outpatients or inpatients, or both as necessary, with community support services. N = 33.
Outcomes	Service use: average number of days in hospital per month***. Admitted to hospital. Average number hospital admissions***. Death: suicide. Global state: leaving the study early. GAF. Social functioning: SAS, employment status. Mental state: BPRS 24-item, PSE. Participant satisfaction: CSQ. Costs: costs of all care. Unable to use - Carer satisfaction: Relative's Satisfaction (scale not peer reviewed, attrition > 50%).
Notes	Loss to follow-up: 12.1% *Participants in this study were recruited from the treatment arm of a trial on ACT 20 to 30 months long. **Authors report that "the team became depleted and demoralised" in the course of this trial. ***Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - Unclear. No details provided.

Audini-UK 1994 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Clinical (mental state) and social function assessed by independent raters. Blinding not tested. Participant's and relative's satisfaction self reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number and reasons for attrition reported. Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	All listed outcomes are reported completely.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Bjorkman-Sweden 2002

Methods	Allocation: randomised. Design: single centre. Duration: 36 months. Country: Lund, Sweden.
Participants	Diagnosis*: serious mental illness, according to DSM-III-R. N = 77. Setting: community psychiatric service. Age*: 19 to 55 years, mean ~ 37 years. Sex: 36M, 41F. Ethnicity: not reported. History: i. serious mental illness for > 2 yrs, ii. impairment due to illness (social-relationship, housing, or work situation) for more than 2 yrs, iii. no primary diagnosis of substance- or alcohol-related disorders, iv. informed consent given.
Interventions	1. ICM: Case Management service based on the Strength Model. Caseload: ~ 1:9. N = 33. 2. Standard care: comprehensive psychiatric service with joint management for outpatient, inpatient, and day care facilities. N = 44.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services, admitted to hospital. Death: suicide. Global state: leaving the study early, GAF. Social functioning: Strauss-Carpenter Scale, social network (ISSI). Mental state: general symptoms, SCL-90. Quality of life: LQoLP. Participant satisfaction: CAN. Unable to use - Client satisfaction: questionnaire by the Swedish Institute for Health Services Development (modified version, not peer reviewed).
Notes	*51.9% schizophrenia-like disorder. **ICM group significantly older than standard care group (5 yrs older on average).

Bjorkman-Sweden 2002 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised: used a computer random number generator.
Allocation concealment (selection bias)	Unclear risk	Random selection performed by one of the trialist. No further details.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcomes: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - Unclear. Interviewers formally blind to participant group allocation. Not tested.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Clinical (mental state) and social function assessed by independent raters. Blinding not tested. Service utilisation. Blinding not reported. Participant's and relative's satisfaction self reported, not blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analysis performed on an ITT basis, but "clients who were not available for or refused contact at follow-up were excluded from the respective analysis on an individual basis".
Selective reporting (reporting bias)	Low risk	All listed outcomes of interest reported.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Bond-Chicago1 1990

Methods	Allocation: randomised. Design: single centre. Duration: 12 months. Country: Chicago, Illinois, USA.
Participants	Diagnosis*: serious mental illness (schizophrenia, schizoaffective disorder, affective disorder, personality disorder) according to RDC and SADS. N = 88. Setting: private psychiatric rehabilitation agency. Age: > 18 years, mean ~ 34 years. Sex: 56.8% M (50M, 38F). Ethnicity: non-white 36%. History**: i. 3 admissions in the last 2 years or total of 5 admissions in life, ii. had no prior contact of more than 1 month's duration with either study programme, iii. informed consent given.
Interventions	1. ICM***: a large-city adaptation of ACT model according to Stein and Test. Caseload 1:10. N = 45. 2. Standard care***: provided from drop-in centre (day treatment, central meeting place, no requirement for frequent contacts). Caseload: 1 : ≥ 20 . N = 43.

Bond-Chicago1 1990 (Continued)

Outcomes	<p>Service use: average number of days in hospital per month, not remaining in contact with psychiatric services, admitted to hospital, average number of admissions.</p> <p>Death: all causes, suicide.</p> <p>Global state: leaving the study early.</p> <p>Social functioning: police contact, arrested, imprisoned, accommodation status.</p> <p>Unable to use -</p> <p>Global functioning: GAS (no SD, no sample size providing data).</p> <p>Social functioning: Areas of Difficulty Checklist (ADC) (scale not peer reviewed, no SD).</p> <p>Quality of life: Life Satisfaction Checklist (LSC) (scale not peer reviewed, no SD).</p> <p>Satisfaction with care: Satisfaction with Services (SWS), author-modified version of CSQ (not peer reviewed, no SD).</p> <p>Cost: no SD, no sample size.</p>
Notes	<p>*Schizophrenia ~ 37%; primary or secondary diagnosis of substance abuse = 26% .</p> <p>**At the time of study admission, 62% in ICM group and 54% in SC group were in a psychiatric hospital.</p> <p>***Author reporting: "ACT had been in existence for 6 yrs, SC service for 2 yrs. In both programmes staff were enthusiastically committed to the respective programme philosophy".</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	Random assignment achieved by individual sealed envelopes (not specified if opaque), the assignment was carried out by a person unconnected to research programme.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: most are clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Interviewer was not blind to treatment condition.
Incomplete outcome data (attrition bias) All outcomes	High risk	Missing outcome data not balanced in numbers across intervention groups, but similar reasons for missing data across groups.
Selective reporting (reporting bias)	High risk	Some outcomes of interest are reported incompletely and are not usable (due to missing SD or sample size providing data).
Other bias	Low risk	Publicly funded (by the State Department of Mental Health). No further details. No evidence of the presence of other bias.

Bond-Indiana1 (A)

Methods	Methods: see above Bond-Indiana1 1988 .
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Bond-Indiana1 (A) *(Continued)*

Participants	Participants: see above Bond-Indiana1 1988 . N = 61.
Interventions	Interventions: see above Bond-Indiana1 1988 . 1. ICM: N = 29. 2. Standard care: N = 32.
Outcomes	Service use: average number of days in hospital per month*. Death: suicide. Social functioning: contact with the police. Unable to use - Costs: total inpatient cost, total treatment cost (no SD).
Notes	*Variance not reported - data from another study used.

Bond-Indiana1 (B)

Methods	Methods: see above Bond-Indiana1 1988 .
Participants	Participants: see above Bond-Indiana1 1988 . N = 64.
Interventions	Interventions: see above Bond-Indiana1 1988 . 1. ICM: N = 34. 2. Standard care: N = 30.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Variance not reported - data from another study used.

Bond-Indiana1 (C)

Methods	Methods: see above Bond-Indiana1 1988 .
Participants	Participants: see above Bond-Indiana1 1988 . N = 42.
Interventions	Interventions: see above Bond-Indiana1 1988 . 1. ICM: N = 21. 2. Standard care: N = 21.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Variance not reported - data from another study used.

Bond-Indiana1 1988

Methods	Allocation: randomised. Design: multicentre, 3 centres (3 CMHCs)*. Duration: 6 months. Country: Indiana, USA.
Participants	Diagnosis ^{**} : psychotic disorder (DSM-III). N = 67. Setting: CMHCs. Age: > 17 years, mean ~ 35 years. Sex: 61.6% M (103M, 64F). Ethnicity: black (understood to be African-American) 34%. History ^{***} : high risk of hospitalisation, described as: i. discharged within last year and either rehospitalised ≥ 3 times in previous 2 years or determined by mental health services staff to be at high risk for readmission, ii. committed or awaiting commitment to hospitals, iii. presenting for admission at CMHC inpatient unit and having ≥ 4 psychiatric hospitalisations in last 2 years.
Interventions	1. ICM: Assertive Case Management, according to the ACT model (Stein and Test), in addition to all other available mental health programmes. Caseload: 1:8-12. N = 84. 2. Standard care: as provided at CMHCs (including case management services with large caseload). N = 83.
Outcomes	Service use: average number of days in hospital per month ^{****} , (data available for single centre, see below); admitted to hospital. Death: all causes (data from centre A only). Global state: leaving the study early. Social functioning: contact with the police (data from centre A only). Unable to use - Quality of life: self report instrument (no data, scale not peer reviewed, compiled by the therapist). Global state: compliance with medication (data not reported). Costs: available only for centre A (no SD).
Notes	*Among client groups at the 3 centres, significant differences were found in: age, gender, race, education, employment, diagnosis, and history at baseline. **Schizophrenia-like disorder: 61%; substance abuse: 39%. ***Average 8.8 lifetime hospitalisation and 1.5 hospitalisation in the previous year. ****Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised for single centre. No further details.
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: most are clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details

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Bond-Indiana1 1988 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of lost to follow-up reported, but no reasons for missing data provided.
Selective reporting (reporting bias)	High risk	Prespecified outcomes not reported (medication compliance) or reported incompletely (days in hospital: SD missing).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Bush-Georgia 1990

Methods	Allocation: randomised. Design: single site. Duration: 12 months. Country: Atlanta, USA.
Participants	Diagnosis*: severe mental illness. N = 28. Age: 25 to 56 years. Sex: 57% M (16M, 12F). Ethnicity: 50% African-American. History: high rates of hospital readmissions (2 to 18 previous admissions), difficulty in community living.
Interventions	1. ICM: clinical case management, providing intensive support and outreach (according to the Stein and Test model TCL). N = 14. 2. non-ICM: standard care providing case management at a lower level of intensity and rehabilitation services. N = 14.
Outcomes	Service use: average number of days in hospital per month**. Death: all causes, suicide. Unable to use - Service use: number of hospital admissions (no individual group data); emergency room visits (no individual group data). Global state: compliance: adherence to service and medication plan (incompletely reported data). Social functioning: appropriate living status (incompletely reported data). Costs: no individual group data.
Notes	*86% schizophrenia. **Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias)	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear.

Intensive case management for severe mental illness (Review)

Bush-Georgia 1990 (Continued)

All outcomes		Secondary outcome: leaving the study early - clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use and appropriate living conditions collected from records. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	High risk	Outcomes not pre-stated. Most of the reported outcomes are reported incompletely (data not usable).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Chan-Hong Kong 2000

Methods	Allocation: randomised. Design: single site. Duration: 11 months (5-month intervention period, 6-month follow-up). Country: Hong Kong.
Participants	Diagnosis: chronic schizophrenia. N = 62. Setting: recruited from a community mental hospital. Age: 21 to 65 years. Sex: 71% female. Ethnicity: not reported. History: suffered from schizophrenia for 2 or more years; had 3 or more hospitalisations in the past 24 months before admission; required supervision in living skills; unemployed for 3 or more months; and unreliable in compliance to treatment.
Interventions	1. ICM: based on the developed case management model, with a community psychiatric nurse case manager co-ordinating care. Caseload 1:3. N = 31. 2. Standard care: traditional community psychiatric nursing care. Caseload 1:3. N = 31.
Outcomes	All of the usable outcomes are provided at the 6 months' follow-up. Service use: unplanned admission through the Accident and Emergency Department; day hospital care; outpatient visits; home visits. Costs: direct healthcare costs. Unable to use - SD or equivalent not reported: BPRS; Specific Level of Functioning scale (SLOF); Patient Satisfaction Instrument (PSI). Average number of days in hospital per month: it may have been possible to calculate this outcome (imputing SD), but we decided not to use it as the study reports data only on "unplanned admission", therefore the available data misses data on overall admission (planned and unplanned).

Chan-Hong Kong 2000 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients who met the inclusion criteria and provided consent were randomised to case management or conventional care after recruitment"; no further details were provided.
Allocation concealment (selection bias)	Unclear risk	No details on allocation concealment were reported.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No details reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Details on blinding participants and personnel were not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Details on blinding outcome assessors were not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analyses were reported as ITT; it was not reported whether any participants left early.
Selective reporting (reporting bias)	High risk	For many of the outcome scales, only items that had a significant difference between experimental and control groups were reported.
Other bias	Low risk	The study seems to be free of other bias. The study reports that baseline characteristics were similar, although only age and gender were reported.

Chandler-California1 (A)

Methods	Site A: Long Beach. Methods: see above Chandler-California1 1991 .
Participants	Participants: see above Chandler-California1 1991 . N = 256.
Interventions	Interventions: see above Chandler-California1 1991 . ICM = 127. SC = 129.
Outcomes	Service use: average number of days per month in hospital, not remaining in contact with psychiatric services, admitted to hospital. Global state: leaving the study early. Social functioning: employment status, arrested, imprisoned, accommodation status. Costs: direct costs of psychiatric hospital care.

Chandler-California1 (A) (Continued)

Notes

Chandler-California1 (B)

Methods	Site B: Stanislaus County. Methods: see above Chandler-California1 1991 .
Participants	Participants: see above Chandler-California1 1991 . N = 260.
Interventions	Interventions: see above Chandler-California1 1991 . ICM = 125. SC = 135.
Outcomes	Service use: average number of days per month in hospital, not remaining in contact with psychiatric services, admitted to hospital. Global state: leaving the study early. Social functioning: employment, arrested, imprisoned, accomodation status. Costs: direct costs of psychiatric hospital care.
Notes	

Chandler-California1 1991

Methods	Allocation: randomised. Design: multicentre, 2 sites*** (site A: Long Beach, urban site; site B: Stanislaus County, rural site). Duration: 36 months. Country: California, USA.
Participants	Diagnosis: serious and persistent mental illness (DSM-III-R). N = 516. Setting: 1 urban, 1 rural but integrated service agencies. Age: 30% > 45 years. Sex: 52% M. Ethnicity: 26% non-white. History**: i. functional impairment due to mental disorder, ii. eligibility for public assistance, iii. not a primary diagnosis of substance abuse, iv. informed consent given.
Interventions	1. ICM***: ACT provided by integrated service agencies, according to Training in Community Living Programme (Stein and Test). Caseload: 1:10. N = 252. 2. Standard care: usual mental health service (i.e. outpatients: day treatment, case management; inpatients: minimal rehabilitation services). N = 264.
Outcomes	Service use: average number of days in hospital per month Following outcomes available for single centre. Service use: not remaining in contact with psychiatric services, admitted to hospital. Global state: leaving the study early. Social functioning: employment, arrested, imprisoned, accomodation status. Costs: cost of psychiatric hospital care. Unable to use -

Chandler-California1 1991 (Continued)

Mental state: general symptoms: Colorado Symptom Index (no data reported).
Self esteem: New York Self Esteem Scale (no data reported).
Quality of life: Lehman's Quality of Life Instrument (no data reported).
Social functioning: level of social activities (scale not peer reviewed).
Family burden: subscales adapted from Tessler's Family Burden Interview (not peer reviewed, attrition > 50%).
Participant satisfaction: scale for overall satisfaction with mental health services (scale not peer reviewed).
Costs: direct costs of health care and of all care (no SD), all mental health care (not listed as review outcome of interest).

Notes

*61% schizophrenia
**28% admitted in previous year
***Intervention programme in 2 sites slightly different: Site A puts more emphasis on employment services and social and therapeutic activities. Site B emphasises avoiding hospitalisation through use of crisis house.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised for single centre. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Employment, arrest, conviction, homelessness, and service use (hospitalisation) were compiled from state and local databases. Blinding not reported. For mental state (symptomology), independent research staff conducted interviews. Blinding not reported. Quality of life and personal safety self reported. Not blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of lost to follow-up reported, but reasons for missing data not provided. LOCF for continuous data.
Selective reporting (reporting bias)	High risk	Listed outcomes of interest not reported (continuous data from scales not reported; days in hospital reported only for site A, no SD).
Other bias	Low risk	Publicly funded (California Department of Mental Health, NIMH). No details. No evidence of the presence of other bias.

Curtis-New York 1992

Methods Allocation: randomised.

Curtis-New York 1992 (Continued)

Design: single centre.
Duration: 14 months.
Country: New York, USA.
Follow-up*: range of 18 to 52 months.

Participants	<p>Diagnosis**: not stated, DSM-III. N = 292. Setting: Harlem Hospital Center (HHC). Age: age 18 to 54 years, mean $\pm$ SD 35.9 $\pm$ 12.1 yrs (N = 430). Sex: 59% F. Ethnicity: 91% black (understood to be African-American). History***: i. about to be discharged from hospital, ii. local residents, iii. without a sole diagnosis of substance abuse or organic mental disorder, iv. inpatients for > 7 days, and not eligible for the "Community Support System" programme - that is no psychiatric admission of > 6 months duration/3 admissions of > 10 days within the last 2 years, v. informed consent given.</p>
Interventions	<p>1. ICM: intensive outreach case management from a multidisciplinary team at HHC, which implemented a discharge treatment plan and monitored clinical and social problems. The team did not "assume direct responsibility for care but [...] help[ed] the patient enrol in a day hospital programme, adult mental health clinic, rehabilitation programme, or alcohol treatment programme". Caseload: 1:17. N = 147.</p> <p>2. Standard care: routine aftercare, within the discharge treatment plan prescribed for each patient by HHC; "most received at least initial treatment from various divisions of the departments of psychiatry within the Health and Hospitals Corporation". N = 145.</p>
Outcomes	<p>Service use: average number of days in hospital per month, admitted to hospital. Death: all causes and suicide.</p> <p>Unable to use - Use of ambulatory services: this outcome is not listed as an outcome of interest for the review. Quality of life: measuring instrument written by trialists for this particular trial and was not published in peer-reviewed journal (EAF - Evaluation Aftercare Form).</p>
Notes	<p>*Follow-up period variable, depending on date of participant's entry into the study. **Schizophrenia 38%; alcohol or drug abuse or dependence 39%. ***Mean number of previous admissions > 1.</p> <p>Some more severely ill clients not included in this part of study as they were eligible for "Community Support System" programme group.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: some are clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.

Curtis-New York 1992 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use (rehospitalisations, hospital-based ambulatory services) and mortality derived from the shared medical billings systems. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data are not addressed.
Selective reporting (reporting bias)	Low risk	Listed outcomes are reported completely.
Other bias	Low risk	Funded by public institution (New York City Health and Hospitals Corporation and foundations). No details. No evidence of the presence of other bias.

Cusack-North Carolina

Methods	Allocation: randomised. Design: single site. Duration: 24 months. Country: USA. Duration: 2 years.
Participants	Diagnosis: DSM-IV axis I major mental disorder. N = 134. Setting: Harlem Hospital Center (HHC). Age: 37 (SD 10) years. Sex: 59% male. Ethnicity: 63% Caucasian (understood to be white participants). History: detained in county prison at enrolment and diagnosed with major mental disorder. Comorbid substance abuse (66%) or additional mental disorder diagnosis were not excluded. Candidates ever charged with a serious, violent offence, or "third strike" candidates were excluded.
Interventions	1. ICM: Forensic Assertive Community Treatment (FACT)*, with team-based mental health and substance abuse services, as well as support for housing, employment assistance, benefits applications, advocacy, and a full-time peer recovery specialist and a full-time probation officer. Caseload: < 20. N = 72. 2. Standard care: treatment as usual (TAU): services routinely available in the county-operated public behavioural health system, such as psychiatric assessment, psychiatric medications in both outpatient and inpatient general hospital settings, outpatient mental health and substance abuse counselling, and case management. N = 62.
Outcomes	Service use: mean number of outpatient visits. Social functioning: contact with legal system (bookings, jail days, convictions). Costs: direct costs of psychiatric hospital care; direct costs for outpatient care, jail. Not used - Service use: mean number of hospital days (could not be converted to average number of days per month), crisis contacts.
Notes	*With high fidelity to the ACT model, DACTS scores 4.5 and 4.6.

Risk of bias

Cusack-North Carolina (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using a random number table, assignment in blocks of 2.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment details were not reported.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No details
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details on blinding participants and personnel were reported.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Results relied on external administrative data.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All analyses were ITT; outcomes were observed regardless of active or continued participation.
Selective reporting (reporting bias)	Low risk	Listed outcomes are reported completely.
Other bias	Low risk	No indication of other bias; baseline characteristics similar between groups, except, on average, participants in the FACT group were nearly 4.5 years older than participants in the TAU condition. However, after adjusting for age, the results were essentially the same.

Drake-NHamp (A)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 23.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 11. 2. Standard care: N = 12.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp (B)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data:

Drake-NHamp (B) *(Continued)*

N = 23.

Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 10. 2. Standard care: N = 13.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp (C)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 25.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 14. 2. Standard care: N = 11.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp (D)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 60.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 30. 2. Standard care: N = 30.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp (E)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 32.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 17. 2. Standard care: N = 15.

Drake-NHamp (E) *(Continued)*

Outcomes	Service use: average days per month in hospital.
Notes	

Drake-NHamp (F)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 17.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 9. 2. Standard care: N = 8.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp (G)

Methods	Methods: see above Drake-NHamp 1998 .
Participants	Participants: see above Drake-NHamp 1998 . For this centre, sample providing data: N = 16.
Interventions	Interventions: see above Drake-NHamp 1998 . For this centre, sample providing data: 1. ICM: N = 7. 2. Standard care: N = 9.
Outcomes	Service use: average number of days in hospital per month.
Notes	

Drake-NHamp 1998

Methods	Allocation: randomised. Design: multicentre (7 sites(CHMCs), 2 in urban areaand 5 in rural area). Duration: 36 months. Country: New Hampshire, USA.
Participants	Diagnosis: schizophrenia, schizoaffective or bipolar disorder (DSM-III-R) and active substance user disorder within past 6 months (DSM-III-R)*. N = 225. Setting: CHMCs. Age: 18 to 60 years, mean ~ 34 years. Sex: 74.4% M (167M, 58F). Ethnicity: ethnic minority 3.4%. History: i. no mental retardation or medical conditions that would prevent participation, ii. written informed consent given.

Drake-NHamp 1998 (Continued)

Interventions	<p>1. ICM: ACT teams with special training in substance abuse treatment. Caseload: 1:12. N = 109.</p> <p>2. Non-ICM: standard non-Intensive Case Management, incorporating most of the ACT principle, but providing less individual service for substance abuse. Caseload: 1:25. N = 114.</p>
Outcomes	<p>Service use: average number of days in hospital per month, not remaining in contact with psychiatric services.</p> <p>Death: all causes.</p> <p>Global state: leaving the study early.</p> <p>Mental state: BPRS-24 item.</p> <p>Social functioning: average days in stable accommodation, Alcohol Use Scale (AUS), Substance Abuse Treatment Scale (SATS), alcohol use days (TLFB), remission from alcohol use disorder.</p> <p>Quality of life: QOLI.</p> <p>Unable to use -</p> <p>Substance abuse: drug use scale (DUS), drug use days (TLFB) and not in remission: attrition > 50%, Addiction Severity Index (ASI) (data not reported).</p> <p>Service use: Service Utilization Interview (data not reported).</p> <p>Costs: direct costs of psychiatric hospital care (no SD), average total study cost (not listed as outcome of interest in the review).</p>
Notes	*53% schizophrenia, 22% schizoaffective, 24% bipolar disorder, 72.6% alcohol abuse, 41.8% drug abuse.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: some are clinician/participant mediated - rating - Unclear, some are interviewer rated - rating - Unclear. Interviewer blind, not tested.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Independent raters, blind to study condition, separately rated alcohol and drug use as well as substance abuse treatment. Service use was obtained from outpatient records and hospital records, blinding not reported. Blinding not reported for mental state, quality of life, or homelessness.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of lost to follow-up is reported, but reasons for missing data are not reported for each randomised treatment group (reported overall, information not usable).
Selective reporting (reporting bias)	Low risk	Prespecified outcomes of interest are reported.
Other bias	Low risk	No information available. No evidence of the presence of other bias.

Essock-Connecticut1 1995

Methods	Allocation: randomised. Design*: multicentre, 3 sites, all in city area (data for single centre not available). Duration: 18 months. Country: Connecticut, USA.
Participants	Diagnosis**: major depression, bipolar disorder, schizophrenia, schizoaffective disorder according to DSM-III-R. N = 262. Age: mean ~ 41 years. Sex: 64% M. History***: high level of service use (defined as: i. ≥ 2 psychiatric hospitalisations in last 2 years, ii. 1 psychiatric hospitalisation longer than 180 days in last yr, or iii. ≥ 2 contacts with crisis services in last 2 years) and significant difficulties meeting the demands of everyday life (defined as: 1. homeless in past year, or ii. requiring extensive supervision or assistance at least weekly to meet personal-care needs), informed consent given.
Interventions	1. ICM: Assertive Community Treatment teams (Stein and Test model), but having a richer staff and achieving 24-hour coverage. Caseload: 1:5-7. N = 130****. 2. Non-ICM: generalist model, but providing mobile case managers. Caseload: 1:25-30. N = 132****.
Outcomes	Service use: average number of days in hospital per month. Death: all causes. Global state: leaving the study early. Unable to use - Mental state: modified version of SCL-90 (no peer-reviewed scale, no SD). Social functioning: accomodation status, number of days homeless (no SD), imprisoned (not reported). Quality of life: modified version of QOLI (no peer-reviewed scale, no SD). Carer satisfaction: Family Burden Interview (no SD). Costs: data reported incompletely.
Notes	*Authors state that the same treatments provided in different sites were not identical ("different styles of providing services were used at different sites"), but single-centre data not available. **67% schizophrenia or schizoaffective disorder. ***62% participants had lifetime history of substance abuse or dependence and 25% participants were hospitalised at the study entry.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. Randomisation counterbalanced "so that within each site clients had 50% likelihood of being assigned to either ICM or non-ICM and counterbalanced so that clients hospitalised at the time of assignment had 50% likelihood of being assigned to either ICM or non-ICM."
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: leaving the study early - clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias)	Unclear risk	Blinding not reported.

Essock-Connecticut1 1995 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use (hospitalisation), housing (homelessness, temporary housing): source of data and blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Number and reasons for missing data clearly reported. Missing outcome data balanced across intervention groups.
Selective reporting (reporting bias)	High risk	Listed outcome of interest not reported or reported incompletely.
Other bias	Low risk	Funded by public health institutes and private foundation. No other details provided. No evidence of the presence of other bias.

Essock-Connecticut2 2006

Methods	Allocation: randomised. Design: multicentre, 2 urban sites (data for single centre not available). Duration: 36 months. Country: Bridgeport, Connecticut, USA.
Participants	Diagnosis*: schizophrenia, schizoaffective disorder, depression with psychotic features, bipolar disorder according to DSM-III-R. N** = 198 (randomised to site A: N = 100, to site B: N = 98). Setting: 2 state-operated outpatient CMHCs. Age: mean 36.5 years (SD 7.8 years). Sex: 72% M (143M, 55F). Ethnicity: African-American 55%; Hispanic 14%. History: i. active substance use disorder (abuse or dependence on alcohol or other drugs previous 6 months), ii. high service use previous 6 months (≥ 2 between: psychiatric hospitalisation, stays in a psychiatric crisis or respite programme, emergency department visit, or incarceration), iii. homeless or unstably housed, iv. poor independent living skills, v. no pending legal charge, vi. no medical condition or mental retardation, vii. written informed consent given.
Interventions	1. ICM***: Assertive Case Management. Caseload: 1:10-15. N = 99. 2. Non-ICM***: Clinical Case Management provided by clinicians. Caseload: 1:20-30. N = 99.
Outcomes	Service use: average number of days in hospital per month. Unable to use - Global state: leaving the study early, GAS (N for single intervention group not reported). Social functioning: days in stable accommodation (N for single intervention group not reported), imprisoned (days in jail reported with days in hospital). Social functioning: SATS, AUS, DUS (scales rated by clinicians), days of alcohol/drug use (N for single intervention group not reported). Mental state: BPRS-24 item (N for single intervention group not reported). Client satisfaction: General Life Satisfaction (N for single intervention group not reported). Costs: not reported.
Notes	*76% schizophrenia or schizoaffective disorder; 17% mood disorder; 74% alcohol disorder; 81% substance use disorder. **Original randomised sample N = 205. 7 participants left for administrative reason. Authors did not report to which group they were assigned. ***Both interventions addressed substance use disorders.

Essock-Connecticut2 2006 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using separate computer-generated randomisation stream for each site.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No details
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of missing data (number and reasons for missing data reported for the total sample, not for each intervention group). 7 randomised participants were lost due to administrative reason, but their intervention allocation was not reported.
Selective reporting (reporting bias)	High risk	Listed outcomes of interest are fully reported for each site, but authors did not provide sample size.
Other bias	Low risk	Publicly funded. No further details. No evidence of the presence of other bias.

Ford-UK 1995

Methods	Allocation: randomised. Design: single centre (multisite study, but randomisation is used in only one site; we have reported data from this site). Duration: 18 months. Country: North Southwark, London, UK.
Participants	Diagnosis*: psychotic illness, severely and persistently mentally ill (criteria not reported). N = 77. Setting: Centre for Mental Health. Age: mean ~ 46 years. Sex: 47% M. Ethnicity: 30% ethnic minority. History: i. either: recent inpatient admission, or impairment in social functioning, or problems in compliance with medication/treatment regimens, or problem in receiving help from multi-agency; ii. no primary diagnosis of organic psychosis, personality disorder, drug/alcohol abuse, learning difficulty.
Interventions	1. ICM: multidisciplinary team, providing Assertive Community Care not following any specific model of case management. Caseload: < 15 clients per case manager. ICM provided in addition to standard mental health service. N = 39. 2. Standard care: provided by psychiatric services. N = 38.

Ford-UK 1995 (Continued)

Outcomes	<p>Service use: average number of days in hospital per month, admitted to hospital.</p> <p>Death*: all causes and suicide.</p> <p>Global state: leaving the study early, compliance with medication.</p> <p>Social functioning: imprisoned.</p> <p>Mental state: BPRS-18 item.</p> <p>Quality of life: objective quality of life through QOLI.</p> <p>Costs: direct costs of psychiatric hospital care, direct costs of all care.</p> <p>Unable to use -</p> <p>Social functioning: Life Skill Profile (LSP) (rated by the therapist, not independent rater).</p> <p>Social support: data not reported due to "high level of missing data".</p>
Notes	<p>*Schizophrenia 81%.</p> <p>**Difference of 1 death (all causes) between 2 reports (3 to 4 deaths reported in ICM group). (Number of suicide consistent between reports). Reported lowest number of death here.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised. Sequence of random number generated by computer program.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: some are clinician/participant mediated - rating - Unclear, some are interviewer rated - rating - Unclear. No details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use, costs, convictions/imprisonment, and mortality were collected by independent researchers. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	Number and reasons for missing dichotomous outcome data reported; imbalance in numbers and reasons for missing data across intervention groups, which is not addressed for continuous outcome data.
Selective reporting (reporting bias)	Low risk	Listed outcome of interest reported, or if not reported, reason is provided (i.e. social support data are not reported due to high level of missing data).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Hampton-Illinois (A)

Methods	<p>Site A - Bridge West.</p> <p>Methods: see above Hampton-Illinois 1992.</p>
Participants	<p>Participants: see above Hampton-Illinois 1992.</p> <p>Site A provided the following information:</p>

Hampton-Illinois (A) *(Continued)*

Diagnosis: 78% (74/95) primary diagnosis of major mental illness (schizophrenia, affective disorder, other psychosis), ~ 13% (12/95) have primary diagnosis of alcohol or substance abuse.
N = 95.
Sex: 80% M (76M, 19F).
Ethnicity: non-white: 50.5% (48/95).
Age: average ~ 38 years.
History: average age at first psychiatric contact ~ 23.5 years, average duration of homeless before entering the study ~ 44.6 months.

Interventions	Interventions: see also above Hampton-Illinois 1992 . Site A provided the following information: 1. ICM: N = 48. 2. Standard care: provided by psychiatric services, including traditional office-based outpatient care and case management. N = 47.
Outcomes	Service use: average number of days in hospital per month*, not remaining in contact with psychiatric services. Death: all causes. Global state: leaving the study early. Social functioning: accomodation status. Unable to use - Service use: mean number of admissions (data not reported). Social functioning: imprisoned (data not reported).
Notes	*Variance not reported - data from another study used.

Hampton-Illinois (B)

Methods	Site B - Bridge South. Methods: see above Hampton-Illinois 1992 .
Participants	Participants: see above Hampton-Illinois 1992 . Site B provided the following information: Diagnosis: 54% (38/70) have primary diagnosis of schizophrenia, 27% (19/70) have primary diagnosis of affective disorder, 1% (1/70) have primary diagnosis of substance abuse. N = 70. Sex: 71% M (M59/70). Age: average ~ 35 years. History: average age at first psychiatric contact ~ 23 years, average homeless before entering the study ~ 18 months.
Interventions	Interventions: see above Hampton-Illinois 1992 . Site B provided the following information: 1. ICM: N = 34. 2. Standard care: N = 36.
Outcomes	Service use: average number of days in hospital per month*. Global state: leaving the study early. Unable to use** - Service use: not remaining in contact with psychiatric services. Death: all causes. Social functioning: accomodation status, imprisoned.

Hampton-Illinois (B) (Continued)

Notes	<p>*Variance not reported - data from another study used.</p> <p>**Data excluded due to an incomplete report (figures in project report do not add up; > than total N in study).</p>
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Hampton-Illinois 1992

Methods	<p>Allocation: randomised.</p> <p>Design: multicentre (2 centres: Site A - Bridge West; Site B - Bridge South).</p> <p>Duration: 12 months.</p> <p>Country: Chicago, USA.</p>
Participants	<p>Diagnosis*: serious mental illness.</p> <p>N = 165.</p> <p>Setting: community mental health service.</p> <p>Age: ≥ 18 years, mean ~ 37 years.</p> <p>Sex: 77% M (127M, 38F).</p> <p>Ethnicity: 55.7% black (understood to be African-American).</p> <p>History: i. admitted to inpatient units of 2 state hospitals, ii. homeless on admission or at risk of homelessness on discharge, iii. informed consent given (site A).</p>
Interventions	<p>1. ICM: Assertive Case Management (Stein and Test model). Caseload: $\sim 1:10$. N = 82.</p> <p>2. Standard care: provided by psychiatric services. N = 83. (Site A included traditional office-based outpatient care and case management.)</p>
Outcomes	<p>Outcomes from different centres are reported separately; we assumed a single-centre randomisation procedure. See below in Hampton-Illinois (A) and Hampton-Illinois (B).</p>
Notes	<p>*Schizophrenia 42%.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	<p>Randomised. No further details.</p> <p>Although this was not explicit, we assumed an independent randomisation for each centre. Authors reported: "Project staff recruited clients on varying days to reduce bias". We interpreted this as meaning that different days were used for recruitment to the whole study, and not that group of allocation was determined by day.</p>
Allocation concealment (selection bias)	Unclear risk	<p>Described as "blinded randomisation".</p> <p>No further details.</p>
Blinding (performance bias and detection bias) All outcomes	Unclear risk	<p>Primary outcome: clinician/participant mediated - rating - Unclear.</p> <p>Secondary outcomes: some clinician/participant mediated - rating - Unclear.</p>
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details
Blinding of outcome assessment (detection bias)	Unclear risk	No details

Hampton-Illinois 1992 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions to permit judgement.
Selective reporting (reporting bias)	High risk	In both centres, Hampton-Illinois (A) and Hampton-Illinois (B) , some listed outcomes of interest were not reported or were reported incompletely (i.e. days spent in hospital: no SD).
Other bias	Unclear risk	Publicly funded (National Institute of Mental Health). It is unclear whether the study was interrupted earlier in Hampton-Illinois (B) . Authors reported: "The study sample for Site B was inadequate due to late start, implementation problems and high dropout rate"; for this reason, they reported data only by 6 months.

Harrison-Read-UK 2000

Methods	Allocation: randomised. Design: single centre. Duration: 24 months. Country: London, UK.
Participants	Diagnosis*: "heavy psychiatric service users", no diagnostic criteria reported. N = 193. Setting: community psychiatric services. Age: 16 to 64 years, mean ~ 39 years. Sex: 53% M (102M, 91F). History: admitted within the last 3 years and had at least 2 admissions in the last 6.5 years. Excluded: participants who were continuously hospitalised during 8 months' recruitment.
Interventions	1. ICM: enhanced community management on ACT principles (Stein model) provided by dedicated multiprofessional team. Caseload: 1:8-15. N = 97. 2. Non-ICM: locality-based community psychiatric services using the UK Care Programme Approach. Caseload: 1 ≥ 20 . N = 96.
Outcomes	Service use: average number of days in hospital per month. Death: all causes, suicide. Global state: leaving the study early, compliance, Rating of Medication Influences (ROMI). Social functioning: Social Functioning Questionnaire (SFQ). Mental state: Krawiecka Scale (KS), Health of the Nation Outcome Scale (HoNOS), Hospital Anxiety and Depression Scale (HADS). Participant satisfaction: Camberwell Assessment of Need (CAN). Costs: direct costs of psychiatric hospital care. Unable to use - Mental state: general symptoms, Well-being Questionnaire (W-BQ) (not peer-reviewed scale and modified from the original).
Notes	*Schizophrenia ~ 65%. **Median number of 5 admissions over 6.5 years.

Risk of bias

Bias	Authors' judgement	Support for judgement
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Harrison-Read-UK 2000 (Continued)

Random sequence generation (selection bias)	Low risk	Random sequence generated by computer program.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: some are interviewer rated - rating - No. Interviewers are not blind to treatment assignment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Interviewers were not blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of lost to follow-up reported, but reasons for attrition not reported. Number of lost to follow-up balanced between 2 groups. Some participants were excluded after randomisation, but reasons for exclusion not stated.
Selective reporting (reporting bias)	Low risk	Listed outcomes of interest are fully reported.
Other bias	Low risk	Publicly funded (National Health Service). No further details. No evidence of other bias.

Herinckx-Oregon 1996

Methods	Allocation: randomised. Design: single centre. Duration: 29 months. Country: Portland, Oregon, USA.
Participants	Diagnosis: schizophrenia, major affective disorder, paranoid disorder, or another severe mental disorder; diagnostic criteria not reported. N = 178. Setting: community. Age: > 18 years, mean 36.5 ± 10.3 years (N = 163). Sex: 61% M (N = 163). Ethnicity: 18% black (understood to be African-American). *History: i. chronically mentally ill, ii. history of persistent psychotic symptoms not due to substance abuse, iii. impaired functioning in > 2 of (i) social role, (ii) daily living, (iii) social acceptability, iv. no mental retardation. In process of being discharged from hospital or transferring to new service providers within community.
Interventions	1. ICM*: Assertive Community Treatment from combined teams staffed by consumers (N = 58) and not staffed by consumers (N = 59). ACT following the Stein and Test model. Caseload: 1:10. N = 117. 2. Standard care***: provided by 1 of 4 CMHCs and a number of smaller, more specialised agencies (none providing assertive outreach). Average caseload ~ 1:27. N = 61.
Outcomes	Service use: not remaining in contact with psychiatric services****, admitted to hospital, number visits to emergency room. Social functioning: accommodation status, arrests.

Herinckx-Oregon 1996 (Continued)

Unable to use -
Social functioning: employment status, illicit drug use (not reported).
Mental state: general symptoms (not reported).
Quality of life: measurement instrument not specified (data not reported).
Satisfaction with services: measurement instrument not specified (not reported).

Notes *60% psychotic disorders, 40% affective disorders, 33% severe alcohol or drug use comorbidity, 61% 2+ admissions in last 6 months.
 **Staff members were self identified mental health consumers DSM-III-R axis I diagnosis (~ 50% of staff had a diagnosis of bipolar disorder).
 ***In the standard care group: caseload ~ 1:15 is provided to ~ 33% participants.
 ****Disengagement does not include who moved out, who refused to be re-interviewed, death.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. Ratio randomisation between interventions: ICM:SC = 2:1. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Source of data not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Missing data are not addressed.
Selective reporting (reporting bias)	High risk	Not all listed outcomes of interest are reported.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Holloway-UK 1996

Methods Allocation: randomised.
 Design: single centre.
 Duration: 18 months.
 Country: East Lambeth, London, UK.

Participants Diagnosis*: hospital diagnosis of functional psychosis (no diagnostic criteria stated).
 N = 70.
 Setting: community psychiatric service.
 Age: 16 to 64 years, mean ~ 35 years.
 Sex: 66% M (46M, 24F).

Holloway-UK 1996 (Continued)

Ethnicity: not available.

History*: referred by teams as being "hard to treat" (previous non-compliance with treatment, frequent readmission or poor symptomatic response to conventional management), ii. live locally, iii. informed consent given.

Interventions	1. ICM: intensive team-based Case Management. "Continuing care team" providing Assertive Case Management (according to the Clinical Case Management Model. Caseload: 1:8. N = 35. 2. Standard care: provided by community psychiatric nursing service. N = 35.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services, admitted to hospital. Death: all causes and suicide. Global state: leaving the study early. Social functioning: Disability Assessment Scale (DAS). Mental state: Comprehensive Psychopathological Rating Scale (CPRS), Schedule for the Assessment of Negative Symptoms (SANS), depression, Beck Depression inventory (BDI). Quality of life: Lancashire Quality of Life Profile (LQoLP). Behaviour: Social Behaviour Scale (SBS). Unable to use - Participant satisfaction: satisfaction interview (not peer reviewed, scale developed by the research team).
Notes	*66% schizophrenia/schizoaffective disorder; 26% bipolar disorder. **All had 1 or more psychiatric admission, years since onset of illness = mean 11 years.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	Randomisation by sealed envelopes (not stated if opaque).
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: most are interviewer rated - rating - No. Interviewers are not blind to treatment condition.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Source of data and blinding not reported for mortality and service use. Raters were not blinded for mental state and social functioning outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	YES - Primary outcomes: average number of days in hospital per month; not remaining in contact with psychiatric services. No missing data. NO - Secondary outcomes: imbalance in numbers for missing data across intervention groups.
Selective reporting (reporting bias)	Low risk	All listed outcomes of interest are fully reported.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Intensive case management for severe mental illness (Review)

Jerrell-SCarolina1 1991

Methods	Allocation: randomised. Design: single-centre trial. Duration: 18 months. Country: South Carolina, USA.
Participants	Diagnosis*: psychotic or major affective disorders (DSM-III-R, according to the Computer based Diagnostic Interview Schedule Revised (C-DIS-R)). N = 122. Age: 18 to 59 years, 55% > 34 years. Sex: 68M, 54F. Ethnicity: ~ 28% non-white. Setting: large urban mental health service. History: i. participants were being discharged from the most recent of 2+ inpatient admissions in last year or subacute care episodes or lengthy residential treatment and repeated emergency psychiatric visits; ii. 2+ years of poor work history, eligible for public assistance, poor living skills, poor social support, history of inappropriate behaviour.
Interventions	1. **ICM (1): Programme Assertive Community Treatment (PACT) adaptation. Caseload: 1:15/20. N = 40. 2. **ICM (2): Intensive Broker Case Management Model. Caseload: 1:15/18. N = 42. 3. Standard care: from 1 of 4 multidisciplinary psychiatric teams. Clinical approach according to a generalist model with supplemental case management provided to ~ 25% of the most unstable clients. Caseload: 1:35 to 1:45. N = 40.
Outcomes	Service use: average number of days in hospital per month***, average visits to emergency room***. Social functioning: Social Adjustment Scale-II (SAS-II), Role Functioning Scale (RFS). Unable to use - Mental state: not reported with the psychometric measurement instrument. Social functioning: use of alcohol and drug, legal system involvement (not reported). Participant satisfaction: satisfaction with service (instrument not stated, data not reported). Satisfaction with Life Scale (SLS) (not reported). Costs: direct costs of psychiatric inpatient care (no SD).
Notes	*Schizophrenia ~ 75%. **Both intervention (1) and intervention (2) would fit into the definition of Intensive Case Management as described in this review, hence they could be considered as a single intervention. But as they were reported separately in the original study, it was not possible to present data from these two samples combined (it is not possible to sum up SD data). We decided to present only data from intervention (1) versus standard care. ***Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No information
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - Unclear. No information.

Jerrell-SCarolina1 1991 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Cost-of-care data were based on both public and private mental health services. Blinding not reported. Blinding for interviewers for social adjustment, mental state not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of randomised participants is not stated; only number of randomised participants completing the study period is reported.
Selective reporting (reporting bias)	High risk	Listed outcome of interest not reported or reported incompletely (i.e. service use: no SD).
Other bias	Low risk	Publicly funded (National Institute of Mental Health). No details. No evidence of the presence of other bias.

Johnston-Australia 1998

Methods	Allocation: randomised. Design: single centre. Duration: 12 months. Country: Sydney, Australia. Setting: Eastern Suburb Mental Health Service (ESMHS).
Participants	Diagnosis*: schizophrenia, bipolar disorder (diagnostic criteria not reported). N = 73. Setting: Eastern Suburb Mental Health Service (ESMHS). Age: 16 to 70 years, mean ~ 42 years. Sex: 56% M (41M, 32F). History: at least 3 of: i. high relapse rate over previous 2 years, ii. poor compliance, iii. disturbing behaviour, iv. frequent changes of accommodation, v. poor budgeting skills, vi. low quality of life, vii. difficulty to manage in existing service. Resident of the ESMHS catchment area. No primary diagnosis of substance misuse, organic brain disorder, or intellectual disability.
Interventions	1. ICM**: Caseload: 1:8-10. N = 37. 2. Non-ICM: Caseload: 1:20-40. N = 36.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services, admission to hospital. Death: all causes. Global state: leaving the study early, compliance with medication. Social functioning: accommodation status, number living in supported accommodation, employment, participants spending at least 1 day employed, participants on paid employment, number of participants having contact with police or legal system. Behaviour: number of participants having incident of self harm or harm to others. Costs: direct costs of all care. Unable to use - Service use: number admitted to hospital (not reported), use of general practitioner (not listed as review outcome of interest). Global state: clinically significant improvement (as Life Skill Profile (LSP) improvement ≥ 18 points/12 months) (scale assessment completed by the therapist, not reported what measurement used). Social functioning: accommodation changes (not listed as review outcome of interest), LSP (assessment completed by the therapist).

Johnston-Australia 1998 (Continued)

Costs: direct costs of psychiatric hospital care (no SD).

Notes	*Schizophrenia 89%. **Main difference between teams was in ratio of staff to participant. Both are multidisciplinary, co-ordinate and provide a variety of services, have access to inpatient, rehabilitation, and 24-hour crisis service.
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: most are clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use (hospitalisations), social functioning (accommodation status, employment, police and legal involvement), behaviour (self harm and harm to others): collected and reported by the case manager. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	YES - Primary outcomes: average number of days in hospital per month, not remaining in contact with psychiatric services. Numbers and reasons for missing data clearly reported and balanced between groups. NO - Secondary outcomes: imbalance in numbers for missing data across intervention groups.
Selective reporting (reporting bias)	Low risk	All listed outcomes of interest are fully reported.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Lehman-Maryland1 1994

Methods	Allocation: randomised. Design: single centre. Duration: 12 months. Country: Baltimore, Maryland, USA.
Participants	Diagnosis*: severe mental disorder (schizophrenia, schizoaffective disorder, or any other diagnosis axis I and extensive prior hospitalisation history, according to the DSM-III-R). N = 152. Setting: CMHCs. Age: 18 to 64 years, mean ~ 37 years. Sex: 67% M (102M, 50F). History**: i. homeless***, ii. severe mental disorder****, iii. written consent given.

Lehman-Maryland1 1994 (Continued)

Interventions	<p>1. ICM: Programme of Assertive Community Treatment (Stein and Test model). Caseload: 1:10-12. N = 77.</p> <p>2. Standard care: care from community mental health centres and emergency facilities, though also a small amount of non-ICM. N = 75.</p>
Outcomes	<p>Service use: average number of days in hospital per month, admitted to hospital, average number of admissions to emergency room (mean adjusted for race as covariate).</p> <p>Global state: leaving the study early.</p> <p>Social functioning: not living independently, days in stable accommodation.</p> <p>Mental state: Colorado Symptom Index (CSI) (mean adjusted for race as covariate).</p> <p>Quality of life: Lehman's Quality of Life Index (QOLI), satisfaction with general well-being (mean adjusted for race as covariate).</p> <p>Costs: direct cost of psychiatric hospital, direct costs of all health care.</p> <p>Unable to use -</p> <p>Social functioning: days in prison (reported data are not complete).</p> <p>Quality of life: specific items reported from Quality of Life Scale (QOLS) (not global assessments).</p> <p>Social functioning: objective QOLS (no data), days homeless (split reporting of different types of homelessness, no SD).</p> <p>General health: Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) (mean adjusted for race as covariate) (not listed as outcome of interest for the review).</p>
Notes	<p>*Schizophrenia-like disorder: 58%, bipolar disorder 20%, major depression 8%, comorbid for substance use disorders 71%.</p> <p>**74% homeless for at least 1 year in total; 34% homeless for ≥ 4 years.</p> <p>***Homeless defined as: on street or shelter for ≥ 5 days last 45 or ≥ 14 last 180, or in temporary accommodation with ≥ 2 residential moves in last 6 months.</p> <p>****Severe mental disorder: defined as diagnosis of schizophrenia or schizophrenia-like illness or receiving benefit because of mental disorder or had another axis I disorder and either: > 2 hospitalisations of > 21 days in past 3 years or a total of > 42 days prior to current hospitalisation or ≥ 90 days in psychiatric hospital or nursing home in past 3 years or mental disability lasting > 1 year during which unable to spend > 75% of time in some gainful activity.</p> <p>Note complex inclusion criteria.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised (stratified random assignment). No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: those interviewer rated - rating - Unclear. No details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Source of data not reported for service use (hospitalisations, emergency room visits, outpatient visits for general medical care), social functioning (homelessness, incarceration). Blinding not reported for mental state. Quality of life and health survey self reported.

Lehman-Maryland1 1994 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusion (no reasons for missing data provided).
Selective reporting (reporting bias)	High risk	Not all listed outcomes of interest are reported completely.
Other bias	Low risk	Publicly funded (Center for Mental Health Services, Maryland). No details. No evidence of the presence of other bias.

Macias-Utah 1994

Methods	Allocation: randomised. Design: single centre. Duration: 18 months. Country: Utah, USA.
Participants	Diagnosis*: serious and persistent mental disorder. N = 41. Setting: mental health centre. Age: not reported. Sex: 56% M. Ethnicity: 100% Caucasian (understood to be white). History: unclear, no primary diagnosis of mental retardation or substance abuse.
Interventions	1. ICM: psychosocial rehabilitation programme at CMHC + Case Management (CM is modelled as Strengths CM). Caseload: 1:20. N = 20. 2. Standard care: psychosocial rehabilitation programme** at CMHC. N = 21.
Outcomes	Service use: admitted to hospital. Global state: leaving the study early. Unable to use - Mental state: Brief Psychological Well-Being Index (BPWI) (unpublished scales, designed by authors especially for the population under study). Global state: Self Report Inventory (SRI) (unpublished scales, designed by authors especially for the population under study). Carer satisfaction: Utah Family Burden Scale (unpublished, designed by authors especially for the population under study). Social functioning: Utah Case Management Consumer Assessment Record (not independently rated, no summary score, no SD).
Notes	*Schizophrenia 46%, major depression 22%. **Described as "a high quality rehabilitation program that informally provides many services typical of case management". It is not a specific package of care and does not refer to a specific intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details

Macias-Utah 1994 (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusion (no reasons for missing data provided).
Selective reporting (reporting bias)	Unclear risk	One listed outcome of interest is not reported completely (Utah Case Management Consumer Assessment Record: no summary report, no SD).
Other bias	Low risk	Funded by public institution (NIMH). No details. No evidence of the presence of other bias.

Marshall-UK 1995

Methods	Allocation: randomised. Design: single centre. Duration: 14 months. Country: Oxford, UK.
Participants	Diagnosis*: severe persistent psychiatric disorder. N = 80. Setting: Oxford Social Service. Age: 20 to over 60 years, mean ~ 48 years. Sex: 85% M (68M, 12F). Ethnicity: not reported. History**: i. either homeless, at risk of homelessness, living in supported, temporary or poor-quality accommodation, experiencing social isolation, or causing disturbances, ii. not already receiving case management, iii. informed consent given.
Interventions	1. ICM: Case Management from team of social services case managers (case managers are free to choose how much time to offer each patient, but at minimum provided some intervention). Caseload: ~ 1:10. N = 40. 2. Standard care: provided by CMHTs. N = 40.
Outcomes	Service use: average number of days in hospital per month, admitted to hospital. Death: all causes. Global state: leaving the study early. Social functioning: REHAB scale, imprisonment, employment. Quality of life: Quality of Life Index. Costs: costs of all care per week (including accommodation). Unable to use - Need for care: Medical Research Council (MRC) Needs for Care Schedule (version modified by authors). Behaviour: Social Integration Questionnaire (not published in peer-reviewed journal). Social functioning: accommodation status (the definition of "better" and "worse" accommodation status was not clearly stated), employment (no mean and SD reported).

Intensive case management for severe mental illness (Review)

Marshall-UK 1995 (Continued)

Costs: direct cost of psychiatric hospital care and of health care (no SD).

Notes *Schizophrenia and related disorder 74%.
 **40% illness > 1 yr, 85% previous psychiatric admission.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by permuted block. No further details.
Allocation concealment (selection bias)	Unclear risk	Randomisation by sealed envelopes (not stated if opaque).
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: those interviewer rated - rating - Unclear. No details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data for service use (hospitalisation), costs, social functioning (employment; accommodation), non-psychiatric health care, psychiatric health care provided by the respective healthcare providers. Blinding not reported. Mental state and social functioning (social behaviour measured by REHAB) rated by a trained observer. Blinding not reported. Social functioning and quality of life self reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusion (no reasons for missing data provided). Lost to follow-up reported at 7 months, not at 14 months. Reasons for attrition reported only for the experimental sample.
Selective reporting (reporting bias)	Low risk	Listed outcomes reported completely.
Other bias	Low risk	No details. No evidence of the presence of other bias.

McDonel-Indiana (A)

Methods	McDonel-Indiana (A) refers to 4 centres grouped together, providing data on service use. Methods: see above McDonel-Indiana 1997.
Participants	Participants: see above McDonel-Indiana 1997. N = 160.
Interventions	Interventions: see above McDonel-Indiana 1997. 1. ICM: N = 80. 2. Non-ICM: N = 80.
Outcomes	Service use: average number of days in hospital per month.

McDonel-Indiana (A) *(Continued)*

Notes

McDonel-Indiana (B)

Methods	<p>McDonel-Indiana (B) refers to the 5th centre alone, providing data on service use.</p> <p>Methods: see above McDonel-Indiana 1997.</p>
Participants	<p>Participants: see above McDonel-Indiana 1997.</p> <p>N = 40.</p>
Interventions	<p>Interventions: see above McDonel-Indiana 1997.</p> <p>1. ICM: N = 20. 2. Control group: N = 20.</p>
Outcomes	Service use: average number of days in hospital per month.
Notes	

McDonel-Indiana 1997

Methods	<p>Allocation: randomised.</p> <p>Design: multicentre (5 rural sites).</p> <p>Duration: 24 months.</p> <p>Country: Indiana, USA.</p>
Participants	<p>Diagnosis*: severe mental illness (DSM-III-R coded between 295 and 301.99).</p> <p>N = 200 (40 participants for each site).</p> <p>Setting: 5 rural CMHCs.</p> <p>Age: > 18 years, mean ~ 38.1 years (SD 11.1).</p> <p>Sex: 43% M (86M, 114F).</p> <p>Ethnicity: 98% Caucasian (understood to be white).</p> <p>History**: i. poor utilisation of community mental health services and frequent use of psychiatric hospital or emergency room, ii. difficulties with the legal system or in maintaining stable housing, iii. more than 1 episode of intensive psychiatric care lasting > 2 months, iv. impaired role functioning on a continuing or intermittent basis for at least 2 years.</p>
Interventions	<p>1. ICM: Assertive Community Treatment (1 site had addition of Rhinelander model to ACT). Caseload: 1:10. N = 100.</p> <p>2. Non-ICM: provided by the mental health services: office-based; subscribed to the tradition of individual Case Management (including day treatment, partial hospitalisation, outpatient therapy, residential services). Caseload: 1:30 to 1:60. N = 100.</p>
Outcomes	<p>Service use: average number of days in hospital per month (provided for 2 groups of centres, see below in McDonel-Indiana 1997 A and McDonel-Indiana 1997 B).</p> <p>Global state: leaving the study early.</p> <p>Unable to use -</p> <p>Service use: admission (sample size not reported).</p> <p>Global functioning: Global Assessment of Functioning (GAF) (rated by the therapist), compliance with medication on 11-item client-rated checklist (not a peer-reviewed scale).</p> <p>Social functioning: Indiana Level of Functioning (Indiana LOF) (rated by the therapist), accommodation quality and employment scale (not a peer-reviewed scale).</p>

McDonel-Indiana 1997 (Continued)

Social functioning: days in jail, number of police contacts (sample size not reported).
Mental state: Brief Psychiatric Rating Scale (BPRS) (rated by the therapist).
Quality of life: scale modified by the trialist (not a peer-reviewed scale).
Satisfaction with services: satisfaction with service scale (not peer-reviewed scale).

Notes *Schizophrenia 48%, affective disorder 32%. N = 153.
 **Mean lifetime hospitalisation: 8.4 (SD 7.5), mean hospitalisation in the previous years: 1.3 (SD 1.1). N = 153.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcome: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use (hospitalisation) was obtained from agency records and the state Department of Mental Health database. Blinding not reported. Accommodation, legal involvement, and education outcomes were self reported and verified by case managers. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusion (number of missing data is reported, but no reasons provided). Number of participants randomised to each group not clearly reported (some participants refused to participate and they were not clearly accounted for in each group).
Selective reporting (reporting bias)	High risk	Some listed outcomes of interest are reported incompletely (sample size not reported for social functioning and admission).
Other bias	Low risk	Publicly funded (NIMH grant). No details. No evidence of the presence of other bias.

Morse-Missouri1 1992

Methods	Allocation: randomised. Design: single site. Duration: 12 months. Country: Missouri, USA.
Participants	Diagnosis*: psychiatric diagnosis (DSM-III-R). N = 178** Setting: community (drop-in daytime centres for homeless in St Louis area, mental health clinic operated by Missouri Department of Mental Health). Age: mean ~ 33.7 years.

Morse-Missouri1 1992 (Continued)

Sex: 58% M (103M, 75F).

Ethnicity: 52.5% non-white, mostly African-American.

History***: i. serious psychiatric disorder defined as a) previous psychiatric hospitalisation or b) above 90th centile on Global Severity Index or c) above 90th centile on psychoticism, paranoid ideation, or depression subscales of the Brief Symptom Inventory severity index, ii. currently homeless, iii. plans to stay in the study area for its duration, iv. no serious violent behaviour.

Interventions	<p>1. ICM: clinical case management based on ACT principles (TCL model). Caseload: 1:10. N = 52.</p> <p>2. Standard care: traditional outpatient treatment provided at local mental health clinic (offered psychotherapy, medication, and assistance in obtaining social services). N = 64.</p> <p>3. Drop-in centres****: 2 daytime centres made available, 1 exclusively for women. Centre offered respite when other emergency shelters closed. Provided food, clothing, showers, some recreational activity. Social workers available for referrals to other social services, staff-client ratio 1:40. N = 62.</p>
Outcomes	<p>Global state: leaving the study early.</p> <p>Unable to use -</p> <p>Social functioning: Personality and Social Network Adjustment Scale (N for treatment groups not presented).</p> <p>Social functioning: mean number of days spent homeless in past month (N for treatment groups not presented), monthly quantity and frequency of alcohol consumption based on form developed by the National Institute on Alcohol Abuse and Alcoholism (N for treatment groups not presented).</p> <p>Mental state: global severity index of Brief Symptom Inventory (N for treatment groups not presented).</p> <p>Participant satisfaction: measuring instrument not reported (N for treatment groups not presented).</p> <p>Self esteem: Rosenberg's Self Esteem Scale (not peer reviewed, N for treatment groups not presented).</p> <p>Costs: mean monthly income (not described as a review outcome of interest, N for treatment groups not presented).</p>
Notes	<p>*30.1% schizophrenia, 21% major depression, 8% bipolar, 5% other psychotic disorder, 12% alcohol abuse, 4% other drug abuse, 15% other axis I disorder, 5% no diagnosis. Of those with major axis I disorder, 23% had dual diagnosis with substance abuse. N = 155 (as for remaining 23 participants, it was not possible to assess diagnosis).</p> <p>**Initially 50 people assigned to each treatment group, but if they were lost to follow-up within the first month after entering the study, they were replaced by random assignment.</p> <p>***Mean length of time since last stable address 16.6 months, 71.9% had previous psychiatric hospitalisation.</p> <p>****Data from the drop-in centre arm were not presented as the intervention provided did not fit the inclusion criteria for any of the interventions addressed in this review.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details. Participants lost to follow-up within first month were replaced, replacement was performed through random allocation.
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.

Morse-Missouri1 1992 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number and reasons for lost to follow-up incompletely reported.
Selective reporting (reporting bias)	High risk	All data presented but not usable due to N for treatment groups missing.
Other bias	Low risk	Publicly funded (grants from National Institute of Mental Health). No further details. No evidence of the presence of other bias.

Morse-Missouri3 2005

Methods	Allocation: randomised. Design: single site. Duration: 24 months. Country: Missouri, USA.
Participants	Diagnosis*: severe mental illness and substance abuse disorder (according to DSM-IV). N = 196. Age: 18 to 66 years, mean ~ 40 years. Sex: ~ 80% M. Ethnic: 73% African-American, 25% Caucasian (understood to be white), 2% other minority. History**: currently homeless and severely mentally ill, not already enrolled in an Intensive Case Management programme.
Interventions	1. ICM: clinical team trained to deliver psychiatric care package following ACT principles and practices. Caseload: 1:10. Treatment of participant's substance abuse via referral to other community providers for outpatient or individual substance abuse services, 12-step group. N = 46. 2. Standard care: participants shown a list of community agencies that provided mental health and/or substance abuse treatment***. Team also provided linkage assistance to help participants access these services. N = 49. 3. Integrated Community Treatment: combination of Integrated Treatment Services and Assertive Community Treatment (IACT), clinical team trained to deliver psychiatric care package following ACT principles and practices. Also trained to follow Integrated Treatment principles and practices. Substance abuse services provided directly via counselling and bi-weekly treatment groups. Substance abuse specialist part of IACT team. N = 54****.
Outcomes	Social functioning: number of days homeless per month, mean number of days used substances. Costs: inpatient psychiatric costs, healthcare costs, costs of all care. Unable to use - Service use: contacts with treatment programme - not clearly defined (not described as a review outcome of interest). Global state: leaving the study early (overall loss given, no individual group data). Mental state: 24-item BPRS (data reported are not likely to be obtained through the stated measurement instrument, as rating scores reported are not consistent with this scale). Satisfaction: client satisfaction (modified scale used; not peer reviewed). Social functioning: substance abuse rating score (scale not described or referenced). Costs: emergency shelter costs (not described as a review outcome of interest).

Morse-Missouri3 2005 (Continued)

Notes

*48% schizophrenia, 19% schizoaffective disorder, 11% atypical psychotic disorder, 11% bipolar, 9% major depression-recurrent disorder, 2% delusional disorder.

**Mean 12.5 days homeless in previous month.

***Most agencies specialised in either mental health treatment or substance abuse treatment, but not both.

****Data from this group not used in final analysis, as ACT plus another treatment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, but no description given.
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcomes: interviewer rated - rating - Unclear. Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use data were obtained from service agencies, claim records, and participant self report. Services provided. Blinding not reported. Homelessness, income, alcohol consumption self reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition described for the total sample and analysed for effect on outcome. Number and reasons for loss to follow-up not reported for single arm.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	No details. No evidence of the presence of other bias.

Muijen-UK2 1994

Methods	Allocation: randomised. Design: single centre. Duration: 18 months. Country: Greenwich Health District, London, UK.
Participants	Diagnosis*: severe mental illness: psychotic disorder (schizophrenia or affective psychosis) (diagnostic criteria not reported). N = 82. Setting: Health District. Age: 18 to 64 years, mean ~ 37 years. Sex: 56% M (46M, 36F). Race: 23.1% African/Afro-Caribbean. History**: schizophrenia or affective psychosis lasting > 2 years, ≥ 2 hospital admissions last 2 years, about to be discharged, no primary organic disorder.

Muijen-UK2 1994 (Continued)

Interventions	<p>1. ICM: Case Management approach provided by a Community Support Team (community psychiatric nurses and team leader). The team acts as advocate, practical assistance with welfare benefits and housing, no-discharge policy. Caseload: 1:8-11 for the first 15 months (until April 1990), then increased to caseload: 1:20-25 for the last 3 months, until the end of the trial. N = 41.</p> <p>2. Standard care: provided by community psychiatric nurses (CPNs) working independently and based in primary care. N = 41.</p>
Outcomes	<p>Service use: average number of days in hospital per month.</p> <p>Death: all causes and suicide.</p> <p>Global state: leaving the study early.</p> <p>Mental state: BPRS 24-item, PSE.</p> <p>Social functioning scale: GAS, SAS, imprisoned.</p> <p>Participant satisfaction (by short term).</p> <p>Costs: direct costs of all care.</p> <p>Unable to use -</p> <p>Social functioning: accomodation (authors reported data on "patients using hostel accommodations"; it is unclear what is included in this definition).</p> <p>Participant satisfaction (by medium and long term).</p> <p>Client Satisfaction Questionnaire (CSQ) (attrition > 50%).</p> <p>Carer satisfaction (attrition > 50%).</p> <p>Costs: other costs (no SD).</p>
Notes	<p>*Schizophrenia-like disorder 83%; mania 12%; psychotic depression 0.5%.</p> <p>**Baseline mean number of admissions: 5.7.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: those interviewer rated - rating - Unclear. No details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use, income, and accomodation data were collected using the Client Service Receipt Interview. Information was also taken from case records on frequency and duration of input from CPNs. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of lost to follow-up is stated, but reason for attrition is reported generically, referred to the entire sample size and not the single intervention sample.
Selective reporting (reporting bias)	High risk	All listed outcomes of interest are fully reported (but some economic outcomes missing any variance measurement).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Muller-Clemm-Canada 1996

Methods	Allocation: randomised. Design: multicentre (2 sites: Site A, New West; Site B, Surrey - individual centre data not reported). Duration: 24 months. Country: British Columbia, Canada.
Participants	Diagnosis*: majority of participants affected by schizophrenic disorder, others any DSM-III axis I or axis II (including dual diagnosis). N = 123. Setting: CMHC. Ethnicity: data not available. Age: 19 to 64 years (randomised sample age not reported). Sex: 49.5% M (61M, 62F). History: i. serious and persistent mental illness with impaired role functioning, ii. about to be discharged from hospital, iii. high risk of rehospitalisation, iv. no primary diagnosis of substance abuse, organic brain disease, or developmental disorder, v. no recent history of severe violence, vi. informed consent to participate.
Interventions	1. ICM: care from a CMHC plus additional Assertive Case Management according to Stein and Test model. Caseload: ~ 1:10. N = 63. 2. Standard care: care from a CMHC. N = 60.
Outcomes	Service use: average number of days in hospital per month**, number of admissions**. Death: all causes and suicide. Global state: leaving the study early. Unable to use - Quality of life: scale (not peer reviewed).
Notes	*Schizophrenia-like disorder (60.2%). **Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcome: those clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Hospitalisation based on hospital records. Blinding not reported. Quality of life self reported.

Muller-Clemm-Canada 1996 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number randomised not clearly reported, as authors declared that "Clients who withdrew from the study within the first 6 months were replaced by other clients".
Selective reporting (reporting bias)	High risk	Outcome length of hospitalisation reported incompletely (no SD).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Okpaku-Tennessee 1997

Methods	Allocation: randomised. Design: single centre. Duration*: 4 months. Country: Nashville, Tennessee, USA.
Participants	Diagnosis**: mental illness causing significant impairment. No further information provided. N = 152. Setting: urban mental health centres. Age: 18 to 55 years, mean ~ 36.8 years (SD 9.1). Sex: 59% M. Ethnicity: 40% non-white. History: i. clients of mental health centres, ii. serious mental illness as judged by eligibility for disability benefits.
Interventions	1. ICM***: employment-oriented case management provided by psychiatric vocational rehabilitation specialists, supervised by the multidisciplinary team, vocational rehabilitation specialists. Caseload: 1:10. N = 73. 2. Non-ICM: standard case management services from CMHC. Caseload: 1:40 to 90. N = 79.
Outcomes	Global state: leaving the study early. Unable to use - Service use: admission data (not reported). Social functioning: employment status (data are reported referring to the full trial length, although intervention was provided for only first 4 months)*. Costs: insufficient data reported.
Notes	*Variable follow-up period - all received 4 months' intervention and one 3-month follow-up interview, some participants were followed up for as long as 24 months (intervention duration was 4 months). We reported data from only 4 months' follow-up. **Schizophrenia 23%, mood disorder 21%, 33% no current diagnosis according to SCID diagnostic criteria. ***The psychiatric vocational rehabilitation specialist intervention was provided for 4 months. The project specialist engaged the clients in therapeutic and rehabilitation activities and assisted mental health workers to obtain services more expeditiously, the psychiatrist was available 24 hours a day for consultation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.

Okpaku-Tennessee 1997 (Continued)

Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcome: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Hospitalisation, employment, income, illegal activity self reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusion to permit judgement (number for missing to follow-up is reported, but reason is not reported).
Selective reporting (reporting bias)	High risk	More listed outcomes of interest are reported incompletely.
Other bias	Low risk	Publicly funded (grant from the Social Security Administration). No further details. No evidence of the presence other bias.

OPUS-Denmark 1999

Methods	Allocation: randomised. Design: multicentre (5 centres, in Copenhagen and Aarhus, data not available for single centres). Duration: 24 months of active treatments after randomisation. Follow-up: 5 and 10 years after randomisation (i.e. 3 and 8 years after the active intervention was provided). Starting from 2 years after randomisation, all participants received standard care (both those randomised to the experimental intervention and those randomised to standard care). Country: Copenhagen and Aarhus, Denmark.
Participants	Diagnosis*: schizophrenia or schizophrenia-like psychosis (according to ICD-10) (main diagnosis and comorbidity based on SCAN 2.0 and SCAN 2.1). N = 547. Setting: public mental health service. Age: 18 to 45 years, mean 26.6 years. Sex: 59% M (323M, 224F). Ethnicity: not reported. History**: i. prior treatment of mental disorder has not been adequate (i.e. ≤ 12 weeks of continuous antipsychotic medication in antipsychotic dosage), ii. absence of learning disability, organic mental disorder, and psychotic condition due to psychoactive substance use, iii. Danish speaker, iv. written informed consent, v. legal residence in the catchment area, vi. the use of psychoactive drug did not cause exclusion.
Interventions	1. ICM***: modified Assertive Community Treatment (including individual case manager, recommendation of antipsychotic medications, psycho-educational family treatment****, and social skill training). Caseload: 1:15. N = 275. 2. Standard care***: treatment in a CMHC. Caseload: 1:20-30. N = 272.
Outcomes	Service use: average number of days in hospital per month; not in contact with service, defined as "an unplanned break of at least 30 days in treatment or between treatment regimens or status (i.e. from

OPUS-Denmark 1999 (Continued)

discharge to outpatient status"); admitted to hospital (during previous 12 months); proportion not hospitalised; proportion without outpatient contacts; proportion without psychiatric emergency room contacts.

Death: all causes, suicide.

Global state: leaving the study early.

Social functioning: not working or in education, not living independently, alcohol and drug abuse diagnosed with SCAN, contact with the legal system - imprisonment (2-year treatment and 3-year follow-up), number of days in supported housing, number of days in a homeless shelter.

Mental state, specific symptoms: positive symptoms (Scale for Assessment of Positive Symptoms - SAPS), negative symptoms (Scale for Assessment of Negative Symptoms - SANS), comorbidity with depression.

Participant satisfaction: Client Satisfaction Questionnaire (CSQ).

Behaviour: specific behaviour, self harm (measured by self reporting of suicide attempts).

Unable to use -

Global state: compliance with medications: defined "good compliance" as having taken the prescribed antipsychotic medications in the recommended doses regularly during previous 3 months (not reported), GAF (reported only subscale data, not global score).

Social functioning: Social Network Size (not published measure instrument), Social Network Schedule (SNS); various outcomes on accommodation status (as proportion spending at least 1 day in supported housing or in homeless shelter): not listed as a review outcome of interest.

Mental state, specific symptoms: disorganised dimension (not stated how it is measured) and suicidal ideation (not listed as a review outcome of interest).

Quality of life: not reported.

Participant satisfaction: Camberwell Assessment of Need (CAN) (not reported).

Relative satisfaction: Client Satisfaction Questionnaire 8-item, adapted version (not reported).

Behaviour: Social Behaviour Assessment Schedule (SBAS) (reported only score on subscale).

Use of coercive measure: not listed as a review outcome of interest.

Assessment of expressed emotion: not listed as a review outcome of interest.

Notes

*Schizophrenia 66%; schizotypal disorder ~ 15%; schizoaffective disorder ~ 5%.

**Median duration of untreated psychosis ~ 50 weeks.

***In both interventions use of antipsychotics followed the guidelines from the Danish Psychiatry Society (recommending a low-dose strategy for patients with first-episode psychosis and the use of second-generation drugs as first choice).

****Family treatment followed McFarlane's manual for psychoeducational treatment for multiple-family group (18 months' treatment, 1.5 hours twice a week, in a multiple-family group with 2 therapists and 4 to 6 patients with their families). Focus on problem solving and development of skills to cope with illness.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised. In Copenhagen, allocation sequence was computer generated. In Aarhus, a secretary drew a lot among 5 red and 5 white lots from a black box. Central randomisation. Randomisation was 1:1, in block of 6, stratified for each of the 5 centres.
Allocation concealment (selection bias)	Low risk	In Copenhagen, randomisation was carried out through centralised telephone allocation. In Aarhus, researchers were informed on the randomisation assignment after they had finished the entry assessment. Block sizes were unknown to investigator.
Blinding (performance bias and detection bias)	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear.

OPUS-Denmark 1999 (Continued)

All outcomes		Secondary outcome: those interviewer rated - rating - No. Reported: "Investigators were not blind to treatment allocation".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use based on official registers, blinding not reported. Interviewers for mental state unblinded. Client satisfaction, suicide attempts, and suicidal ideation self reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Numbers and reasons for missing data are clearly reported. Analysis was conducted on an ITT basis.
Selective reporting (reporting bias)	High risk	Authors reported change of primary outcome stated in the protocol (from "relapse and positive symptoms" to "psychotic and negative symptoms"), as high attrition occurred in the former outcome measurements. Some listed outcomes of interest are not reported.
Other bias	Low risk	Publicly funded. No declaration of interest. No further details. No evidence of the presence of other bias.

Pique-California 1999

Methods	Allocation: randomised. Design: single centre. Duration: 24 months. Country: San Francisco, USA.
Participants	Diagnosis: severe and persistent mental illness (psychiatric disorder as the primary source of disability). N = 37. Setting: Department of Psychiatry, San Francisco General Hospital. Age: ≥ 18 years. Sex: not reported. Ethnicity: European (understood to be white) or African-American. History: high user of intensive treatment care who had experienced an unsatisfactory quality of life in the community, i. recently hospitalised; ii. no primary diagnosis of (a) organic brain disease, (b) substance abuse disorder with no other psychiatric disorder, or (c) learning disability; iii. no history of violence not due to treatable psychiatric symptoms; iv. written informed consent.
Interventions	1. ICM: standard care + Assertive Community Treatment according to Stein and Test model, culturally focused on needs of Afro-American population. Caseload: 1:10. N = 22. 2. Standard care: Caseload: 1:30. N = 15.
Outcomes	Global state: leaving the study early. Unable to use - Service use: average number of days in hospital per month (not reported). Global functioning: GAF (attrition 57%). Costs: reported incompletely (no mean, no SD).
Notes	

Pique-California 1999 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised. Stratified by sex, ethnicity, recruitment centre, assignment to intervention 2:1. Randomisation sequence constructed by independent investigator using a table of random permutation.
Allocation concealment (selection bias)	Unclear risk	Randomisation sequence in sealed, opaque envelopes, unused assignment envelopes kept in a locked container (available to the recruiter psychiatrists).
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcome: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use data were obtained from the county database. Costs were obtained from billing records. Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Author did not address this outcome. Reasons for missing outcome data not reported.
Selective reporting (reporting bias)	High risk	Listed outcome of interest reported incompletely (costs: no mean, no SD).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Quinlivan-California 1995

Methods	Allocation: randomised. Design: single centre. Duration: 24 months. Country: San Diego, California, USA.
Participants	Diagnosis*: major disorder DSM-III-R axis I. N = 90. Setting: San Diego County Mental Health Service. Age: > 18 years, 33% > 40 years, mean ~ 37 years. Sex: 44% M (40M, 50F). Ethnicity: 43% non-white (18% African-American). History: ≥ 3 hospitalisations last 2.5 years.
Interventions	1. ICM: Assertive Community Treatment according to Stein and Test model. Caseload: 1:15. N = 30. 2. Non-ICM: traditional CM programme, no team approach. Caseload: 1:40-60. N = 30. 3. Standard care: services offered by the public mental health system. N = 30.
Outcomes	Service use: average number of days in hospital per month. Costs: direct costs of psychiatric hospital care. Unable to use -

Quinlivan-California 1995 (Continued)

Service use: other service use than hospital (reported incompletely).
Global state: leaving the study early (not reported).
Costs: direct costs of other psychiatric care (outcomes relevant to this review not directly examined).

Notes	*56% schizophrenia; 23% bipolar disorder. This is a 3-arm study, data from the study are included in both comparisons addressed by the review: ICM versus non-ICM and ICM versus standard care.
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details.
Allocation concealment (selection bias)	Unclear risk	No information
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: - rating - Yes. No information provided, but available outcomes are not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Hospitalisation data were obtained from the county mental health services division's management information system. Costs were based on budgeted unit cost of each service multiplied by the total number of units as reported in the management information system.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study did not address this outcome.
Selective reporting (reporting bias)	Low risk	Listed outcomes of interest are reported completely.
Other bias	Low risk	No data provided. No evidence of the presence of other bias.

REACT-UK 2002

Methods	Allocation: randomised. Design: multicentre (2 centres, information for single centre not available). Duration: 18 months. During this period, participants remained allocated in their trial arm. Follow-up: 36 months and 10 years after randomisation (i.e. 18 months and 8.5 years after the active intervention was provided). During the follow-up period, participants could remain in the originally allocated intervention (ICM) or be transferred to the control one. Country: London, UK.
Participants	Diagnosis*: SMI (schizophrenia, schizoaffective disorder, other chronic psychosis, bipolar affective disorder). N = 251. Setting: community services in 2 inner London boroughs (Camden and Islington).

REACT-UK 2002 (Continued)

Age: mean 39 years (SD 11).
Sex: 58% M.
Ethnicity: African-Caribbean 36%.
History: i. living independently or in low-supported accommodation, ii. under the care of CMHT ≥ 12 months and having difficulty engaging with standard community care, iii. recent high use of inpatient care (i.e. ≥ 100 consecutive inpatient days or ≥ 5 admissions during previous 2 years, or ≥ 50 consecutive inpatient days or ≥ 3 admissions previous 1 year), iv. substance misuse or personality disorder eligible if these were secondary diagnosis, v. no organic brain damage.

Interventions	1. ICM: Assertive Community Treatment (as described by McGrew 1995). Caseload: 1:12. N = 127. 2. Non-ICM: services offered by CMHT (according to Care Programme Approach). Caseload: 1:35. N = 124.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services (defined as no face-to-face contacts between staff and client in previous 3 months), average admission, admitted to hospital. Death: all causes and suicide. Global state: leaving the study early, Health of the Nation Outcome Scale (HoNOS), Rating of Medication Influence scale (ROMI). Social functioning: arrested, imprisoned, number homeless, living independently, living in supported accommodation, Life Skill Profile (LSP), substance abuse: assessed through various scales (Alcohol Use Scale - AUS, Drug Use Scale - DUS, Substance Abuse Treatment Scale - SATS), but reported as binary outcome. Mental state: Brief Psychiatric Rating Scale (BPRS-24 item). Behaviour: self harm, injury to others. Quality of life: Manchester Short Assessment of Quality of Life (MANSA). Participant satisfaction: Client Satisfaction Questionnaire modified version (CSQ-modified), Camberwell Assessment Need abbreviated form (CAN). Unable to use - Use of Mental Health Act (not listed as review outcome of interest). Quality of engagement: adapted form of Homeless Engagement Acceptance Scale (HEAS) (not listed as review outcome of interest).
Notes	*53% schizophrenia; 13% schizoaffective; 4% bipolar; 26% illicit drug misuse; 25% alcohol misuse.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised: permuted block randomisation with a block size of 8 ensuring parity between CMHT in proportions randomised to ICM.
Allocation concealment (selection bias)	Low risk	The interviewer contacted an administrator at the trial centre who opened the appropriate numbered envelope communicating the outcome of randomisation. Participants and referrers were informed of the treatment assignment by letter.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - No. Interviewers were independent of clinical care, but not blind.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Source of service use data not reported.

REACT-UK 2002 (Continued)

		Self harm, violence, contact with legal services, quality of life, compliance with medication, and mental state were obtained from interviews with clients. Other scales were completed by care co-ordinators. All additional data were collected from case notes. Assessors not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	YES - Primary outcomes: average number of days in hospital per month. No missing data (except death, balanced in numbers across groups). YES - Secondary outcomes: number and reasons for missing data are reported. Analysis carried out on an ITT basis.
Selective reporting (reporting bias)	Low risk	All of the listed outcomes of interest are completely reported.
Other bias	Low risk	Publicly funded (Camden and Islington Health Authority; King's Fund; Department of Health). Competing interests declared: none. No further details. No evidence of the presence of other bias.

Rosenheck-USA 1993

Methods	Allocation: randomised. Design: multicentre. 10 sites: 6 General Medical and Surgical centres (GMS) and 4 Neuropsychiatric (NP) centres. Data available both for single centre and for 2 pooled centre groups (GMS and NP). See below. Duration: 24 months. Country: Northeastern United States
Participants	Diagnosis*: primary psychiatric disorder. N = 873. Setting: community-based psychiatric care - Department of Veterans Affairs (VA). Age: 48% > 45 years, mean 47.6 years. Sex: 100% M. Ethnicity: 20% non-white. History: i. current inpatient in VA psychiatric unit, ii. no primary diagnosis of substance abuse or organic brain disease, iii. recent high user of psychiatric care (definition varied between GMS and NP centres), iv. written consent.
Interventions	1. ICM: Intensive Psychiatric Community Care programme, providing ACT intervention according to Stein and Test model. Caseload: average 1:7-15. N = 454. 2. Standard care**: routine care from psychiatric services provided by Veterans Affairs, including inpatient and outpatient psychiatric treatment, psychopharmacological treatment, and rehabilitation service. N = 419.
Outcomes	Service use: average number of days in hospital per month (both pooled data for GMS and NP centres and data for single centre available; see below)***. Global state: GAS (authors reported results pooled for GMS and NP centres; see below). Mental state: BPRS-18 item, BSI (authors reported results pooled for GMS and NP centres; see below). Costs: total healthcare cost (authors reported results pooled for GMS and NP centres; see below). Unable to use - Global state: self reported measure (not published, not peer reviewed). Participant satisfaction: satisfaction with service (measurement instrument not published, not peer reviewed). Social functioning: Addiction Severity Index (ASI) (reported only a subscale, not the overall score). Costs: non-healthcare costs (not listed as an outcome of interest in the review).
Notes	*Schizophrenia 50.5%, dual diagnosis 28%, bipolar disorder 10%. **Standard care provided by both types of centre did not differ programme wise.

Intensive case management for severe mental illness (Review)

Rosenheck-USA 1993 (Continued)

***Pooled data for GMS and NP entered the meta-analysis; data for single centre entered in meta-regression.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised through coin tossing.
Allocation concealment (selection bias)	Unclear risk	No details (reported only that the assignment by coin tossing was performed by an independent researcher).
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - Unclear. Authors report that interviewers are independent, but it is not stated whether they are blind to participant assignment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Service use (hospital and nursing home service use) was derived from the VA's national computerised workload monitoring systems. Blinding not reported. Costs were determined using VA's standardised Cost Distribution Report.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study did not address this outcome.
Selective reporting (reporting bias)	High risk	Some listed outcomes of interest are not reported completely (i.e. substance abuse, which is reported only as a subscale score and not general score).
Other bias	Low risk	No details. No evidence of the presence of other bias.

Rosenheck-USA-GMS

Methods	<p>Rosenheck-USA-GMS refers to 6 General Medical and Surgical centres (GMS) pooled together (centre A, B, D, F, I, J).</p> <p>Methods: see above Rosenheck-USA 1993.</p>
Participants	<p>Participants: see above Rosenheck-USA 1993.</p> <p>Following data are specific for Rosenheck-USA-GMS: N = 528. Setting: Department of Veterans Affairs (VA) - 6 GMS centres enrolled in the Intensive Psychiatric Community Care programme. GMS centres are located in urban centres, provide shorter-term, crisis-oriented, inpatient care. History: i. current inpatient in VA psychiatric unit, ii. no primary diagnosis of substance abuse or organic brain disease, iii. recent high user of psychiatric care (defined as i. ≥ 40 days in hospital or ii. ≥ 2 admissions in the previous year), iv. written consent.</p>
Interventions	<p>1. ICM*: Intensive Psychiatric Community Care programme, providing ACT intervention according to Stein and Test model. Caseload: average 1:7-15. N = 271.</p>

Rosenheck-USA-GMS (Continued)

2. Standard care: routine care from psychiatric services provided by Veterans Affairs, including inpatient and outpatient psychiatric treatment, psychopharmacological treatment, and rehabilitation service. N = 257.

Outcomes	Service use: average number of days in hospital per month**. Global state: GAS. Mental state: BPRS-18 item, BSI. Costs: costs of health care.
Notes	*Centre J: caseload 1:44. **Entered in the meta-analysis.

Rosenheck-USA-GMS (A)

Methods	Rosenheck-USA-GMS (A) is a GMS centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . N = 79.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . 1. ICM: N = 44. 2. Standard care: N = 35.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-GMS (B)

Methods	Rosenheck-USA-GMS (B) is a GMS centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . N = 94.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . 1. ICM: N = 47. 2. Standard care: N = 47.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-GMS (D)

Methods	Rosenheck-USA-GMS (D) is a GMS centre.
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Rosenheck-USA-GMS (D) *(Continued)*

Methods: see above [Rosenheck-USA 1993](#) and [Rosenheck-USA-GMS](#).

Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . N = 102.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . 1. ICM: N = 49. 2. Standard care: N = 53.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-GMS (F)

Methods	Rosenheck-USA-GMS (F) is a GMS centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . N = 78.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . 1. ICM: N = 43. 2. Standard care: N = 35.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-GMS (I)

Methods	Rosenheck-USA-GMS (I) is a GMS centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . N = 88.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-GMS . 1. ICM: N = 44. 2. Standard care: N = 44.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-NP

Methods	<p>Rosenheck-USA-NP refers to 4 Neuropsychiatric centres (NP) pooled together (centre C, E, G, H).</p> <p>Methods: see above Rosenheck-USA 1993.</p>
Participants	<p>Participants: see above Rosenheck-USA 1993.</p> <p>Following data are specific for Rosenheck-USA-NP: N = 345. Setting: Department of Veterans Affairs (VA) - 4 NP centres enrolled in the Intensive Psychiatric Community Care programme. NP centres are large facilities providing long-term mental health care in sub-urban or rural settings. History*: i. current inpatient in VA psychiatric unit, ii. no primary diagnosis of substance abuse or organic brain disease, iii. recent high user of psychiatric care (defined as i. ≥ 180 days in hospital or ii. ≥ 4 admissions in the previous year), iv. written consent.</p>
Interventions	<p>1. ICM: Intensive Psychiatric Community Care programme, providing ACT intervention according to Stein and Test model. Caseload: average 1:7-15. N = 183. 2. Standard care: routine care from psychiatric services provided by Veterans Affairs, including inpatient and outpatient psychiatric treatment, psychopharmacological treatment, and rehabilitation service. N = 162.</p>
Outcomes	<p>Service use: average number of days in hospital per month**. Global state: GAS. Mental state: BPRS-18 item, BSI. Costs: direct costs of health care.</p>
Notes	<p>*Characteristic at baseline differs between NP sites regarding inpatient days before programme entry. Difference was attributable to site C. To compensate for this imbalance, the authors made an adjustment. The adjusted value was used in all the calculations, but the results they yielded did not differ substantially from those obtained with unadjusted value. **Entered in the meta-analysis.</p>

Rosenheck-USA-NP (C)

Methods	<p>Rosenheck-USA-NP (C) is a NP centre.</p> <p>Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-NP.</p>
Participants	<p>Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-NP.</p> <p>N = 93.</p>
Interventions	<p>Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-NP.</p> <p>1. ICM: N = 50. 2. Standard care: N = 43.</p>
Outcomes	<p>Service use: average number of days in hospital per month*.</p>
Notes	<p>*Entered in the meta-regression.</p>

Rosenheck-USA-NP (E)

Methods	<p>Rosenheck-USA-NP (E) is a NP centre.</p>
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Rosenheck-USA-NP (E) *(Continued)*

Methods: see above [Rosenheck-USA 1993](#) and [Rosenheck-USA-NP](#).

Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . N = 67.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . 1. ICM: N = 34. 2. Standard care: N = 33.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-NP (G)

Methods	Rosenheck-USA-NP (G) is a NP centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-NP .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . N = 71
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . 1. ICM: N = 40. 2. Standard care: N = 31.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Rosenheck-USA-NP (H)

Methods	Rosenheck-USA-NP (H) is a NP centre. Methods: see above Rosenheck-USA 1993 and Rosenheck-USA-NP .
Participants	Participants: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . N = 114.
Interventions	Interventions: see above Rosenheck-USA 1993 and Rosenheck-USA-NP . 1. ICM: N = 59. 2. Standard care: N = 55.
Outcomes	Service use: average number of days in hospital per month*.
Notes	*Entered in the meta-regression.

Salkever-SCarolina 1999

Methods	Allocation: randomised. Design: single centre. Duration: 18 months. Country: Charleston, South Carolina, USA.
Participants	Diagnosis*: schizophrenia, schizoaffective disorder, bipolar disorder or other psychotic disorder (DSM-III-R). N = 173. Setting: Charleston and Darchester CMHCs. Age: 18 to 65 years, mean $\approx$ 35.5 yrs. Sex: 54.8% M. (N = 114). Ethnicity: 62.5% non-white. (N = 114). History: i. history or high risk for high services use patterns (i.e. long-term or multiple hospitalisation), ii. difficulty with treatment compliance, independent living, or activities of daily living, iii. no primary diagnosis of personality disorder or substance abuse or organic brain syndrome, iv. no need for 24-hour supervision, v. no assault behaviour in the previous year not associated with psychosis.
Interventions	1. ICM**: Programme of Assertive Community Treatment (PACT) provided by 2 different locations (treatment based in CMHC and treatment run by nonprofit organisation located near CMHC). Caseload: ranging during the trial duration from 1:6.5 to 1:13. N = 104. 2. Non-ICM: standard care from CMHC, providing primarily office-based case management programme. Caseload: decreased during the trial duration from 1:68 to 1:34. N = 69.
Outcomes	Service use: average number of days in hospital per month***; admitted to hospital. Global state: leaving the study early. Unable to use - Costs: direct costs of psychiatric hospital care (no SD).
Notes	*N = 114, 81.5% schizophrenia or schizoaffective disorder, 50.8% secondary diagnosis of substance abuse disorder. **PACT provided by the 2 sites did not differ. ***Variance not reported - data from another study used.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details

Salkever-SCarolina 1999 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of missing data (number for missing data is provided, but reason is provided for the whole sample, is not stated for single intervention group).
Selective reporting (reporting bias)	High risk	Listed outcomes of interest are fully reported, but any variance measurements are missing.
Other bias	Low risk	Publicly funded (by NIMH and grant from universities and university centres for research). No further details. No evidence of the presence of other bias.

Shern-USA1 2000

Methods	Allocation: randomised. Design: single centre. Duration: 24 months. Country: New York, USA.
Participants	Diagnosis*: severe mental illness causing severe disability (definition not clearly reported). N = 168. Setting: community services. Age: ≥ 18 years, mean ~ 40 years, range 21 to 66 years. Sex: 76% M (128M, 40F). Ethnicity: 61% black (understood to be African-American). History: i. homeless for 7 of last 14 nights, ii. no primary diagnosis of substance abuse or learning disability, iii. not considered dangerous to self or others, iv. informed consent given.
Interventions	1. ICM: from the CHOICE programme, which aims to develop "housing readiness" (i.e. compliance with psychiatric treatment and period of sobriety). The main features are: i. drop-in centre, ii. Case Management intervention modelled according to main principles of the ACT model. Caseload: $\sim 1:13$. N = 91. 2. Standard care**: homelessness and specialty mental health services provided from a variety of agencies (including drop-in centres, outreach services, mental health and health services, soup kitchen, shelters). It could involve non-ICM. N = 77.
Outcomes	Social functioning: not living in stable accommodation. Mental state: Colorado Symptom Index. Quality of Life: Lehman's Quality of life Index (QOLI). Unable to use - Service use: hospital use (data partially reported). Social functioning: police contact - imprisoned, arrested (data partially reported), change in proportion of time spent in residential setting (incompletely reported). Self esteem: Rosenberg's Self Esteem Scale (not peer reviewed). Coping: Pearlin and Schooler's Mastery Scale (not listed as a review outcome of interest). Participant satisfaction: unmet needs (measurement instrument not described).
Notes	* $\sim 9\%$ no major mental illness. **People randomised to standard care were just "provided informations by the research interviewers about local homelessness service programmes". No attempts were made to arrange the first contact to available local services.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. No further details.

Intensive case management for severe mental illness (Review)

Shern-USA1 2000 (Continued)

Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	High risk	Primary outcome: not provided. Secondary outcomes: interviewer mediated - rating - No. Not clearly stated, but it is implicitly not blind.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Service use and housing status were assessed in face-to face interviews, protocols were used. Interviewers not blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors declared "using alternative techniques for accommodate missing observations". Our main concern was regarding the high attrition rate the authors declared, but was not clearly reported as presented data were already transformed through statistician techniques accounting for missing observation.
Selective reporting (reporting bias)	High risk	Some listed outcomes of interest are not usable due to incomplete reporting (service use, social functioning, quality of life outcomes).
Other bias	Low risk	Publicly funded (NIMH). No further details. No evidence of the presence of other bias.

Solomon-Pennsylvania 1994

Methods	Allocation: randomised. Design: single centre. Duration: 12 months. Country: Philadelphia, Pennsylvania, USA. Not entering meta-regression.
Participants	Diagnosis*: seriously mentally ill (schizophrenia, affective or personality disorder according to DSM-III-R). N = 200. Setting: CMHC. Age: mean 35.2 years (SD 9.4). Sex: 86.5% M. Ethnicity: Afro-American 81% History: i. about to be released from prison, ii. homeless (i.e. situational, episodically, or chronically without a domicile or if jail detention resulted in the loss of a stable housing situation), iii. state hospitalisation ≥ 60 days in previous 2 years or a significant amount of outpatient treatment, iv. GAF ≤ 40 or GAF ≤ 60 if age ≤ 35 years, v. written informed consent.
Interventions	1**. ICM: Assertive Community Treatment according to the Stein and Test model. Caseload: 1:8-12. N = 60. 2**. ICM: Intensive Case Management provided from an individual forensic case manager who worked at CMHC, but as individual rather than as part of a treatment team. Caseload: not available. N = 60. 3. Standard care: from local CMHC (2 clients received ICM services at times during the year in the study). N = 80.
Outcomes	Global state: leaving the study early.

Intensive case management for severe mental illness (Review)

Solomon-Pennsylvania 1994 (Continued)

Social functioning: imprisonment***.

Unable to use -

Service use: days in hospital, hospitalisation (data not available); drug and alcohol use Addiction Severity Index (data not available); accommodation, employment, arrest (data not available), Pattison Psychosocial Network Inventory (data not available).

Mental state: BPRS (data not available).

Quality of life: Lehman's Quality of Life Interview (objective and subjective components).

Notes

*Schizophrenia 82.5%, major affective disorder 10%, other (unspecified psychotic disorder and personality disorder) 3%, substance abuse disorder 52%. N = 200.

**We considered both arms as a single intervention.

***Attrition in the control group > 50%.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised. Authors reported that "slightly higher number of clients were assigned to the control treatment", but it is not clear if it was a stratified randomisation. No further details provided.
Allocation concealment (selection bias)	Unclear risk	No details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: not available. Secondary outcome: clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete reporting of missing data (number of missing data is reported, but reasons not provided).
Selective reporting (reporting bias)	High risk	Some listed outcomes of interest are not reported (i.e. service use, quality of life, etc.).
Other bias	Low risk	No evidence of the presence of other bias.

Sytema-Netherlands 1999

Methods	Allocation: randomised. Design: single centre. Duration*: follow-up variable (minimum 12 months, maximum 24 months). Country: Netherlands.
Participants	Diagnosis**: severe mental illness (diagnostic criteria not reported). N = 118***. Setting: rural catchment area, community mental health service.

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Sytema-Netherlands 1999 (Continued)

Age: mean ~ 41.5 yrs (SD ~ 11 years).
Sex: 68.6% M.
Ethnicity: not reported.
History: Health of the Nation Outcome Scale (HoNOS) $\geq$ 15.

Interventions	1. ICM: ACT model according to a fidelity scale (DACTS). Caseload: 1:10. N = 59. 2. Standard care: provided by CMHT. Caseload: 1:40. N = 59.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services (defined by authors as "not having any registered contact with the mental health services during the last 12 months of observation"), average number of admissions per month. Death: all causes, suicide. Social functioning: homeless at the end of the trial, average days per month in sheltered houses, Dartmouth Assessment of Lifestyle Interview (DALI). Mental state: BPRS-24 item. Participant satisfaction: Client Satisfaction Questionnaire (CSQ), Camberwell Assessment of Needs Short Appraisal Schedule (CANSAS). Unable to use - Social functioning: Social Functioning Scale (SFS) (data not clearly reported).
Notes	*Participant inclusion in the study started April 2004 and was closed at 1 June 2005. All participants were followed up until August 2006. **Schizophrenia 51.7%, major depression 13.5%, bipolar 3%. ***The number of participants randomised was 119, but 1 participant was excluded from sample because he or she moved to another area directly after randomisation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised, based on block design (block size of 5).
Allocation concealment (selection bias)	Low risk	Participant included in the study received ID number from service administration. The new ID number was emailed to a researcher who had a pre-arranged list of ID numbers randomised.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - No. Open-label.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	YES - Primary outcomes: service use data. No missing data (but 1 participant excluded from sample because he or she moved to another area directly after randomisation). UNCLEAR - Secondary outcomes: number of missing data is provided, but reasons not stated.

Sytema-Netherlands 1999 (Continued)

Selective reporting (reporting bias)	Low risk	All listed outcomes of interest are completely reported.
Other bias	Low risk	Publicly funded (grant from The Netherlands Organisation for Health Research and Development). No further details. No evidence of the presence of other bias.

Test-Wisconsin 1985

Methods	Allocation: randomised. Design: single centre. Duration: total duration of the trial 12 years, participants were followed at least 5 years, extended to 12 years for those who first entered the study. Some data available at 4 years, some at 24 months. Country: Dane County, Wisconsin, USA.
Participants	Diagnosis*: schizophrenia or schizoaffective disorder (according to RDC), or schizotypal personality (according to DSM-III). N = 122. Setting: CMHS. Age: 18 to 30 years. Sex: 67.2% M (82M, 40F). Ethnicity: white 95.9%. History**: i. resident of Dane County, ii. < 12 months total prior time spent in psychiatric and penal institutions, iii. no primary diagnosis of mental retardation, organic brain syndrome, or alcoholism, iv. informed consent.
Interventions	1. ICM: Assertive Community Treatment according to Stein and Test model. Caseload: ~1:9. N = 75. 2. Standard care: routine care from Dane County psychiatric services - included an unspecified degree of case management. N = 47.
Outcomes	Service use: average number of days in hospital per month, not remaining in contact with psychiatric services, admitted to hospital. Death: all causes, suicide. Global state: leaving the study early. Social functioning: number homeless or living in sheltered accommodation (at least 1 day), not living independently, imprisoned. Unable to use - Mental state: BPRS, BSI (no data). Social functioning: days homeless (no SD), days in jail (no SD), Community Adjustment Form (scale not peer reviewed, no data). Quality of life: Satisfaction with Life Scale (scale not peer reviewed, no data).
Notes	*Schizophrenia 73.8%; schizoaffective disorder ~ 23%. **Average age first contact with mental health system: 19.02 yrs.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised (randomised assignment to experimental and control intervention on a ratio 6:4), no further details.
Allocation concealment (selection bias)	Unclear risk	No details

Test-Wisconsin 1985 (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: most are clinician/participant mediated - rating - Unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Problematic to blind participants and those providing the intervention in studies comparing ICM intervention with standard care.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number and reasons for missing data are not clearly reported.
Selective reporting (reporting bias)	High risk	Listed outcomes of interest not reported or reported incompletely, BPRS and BSI (not reported), days in jail and days in hospital (no SD).
Other bias	Low risk	Publicly funded (grant by NIMH). No further details. No evidence of the presence of other bias.

UK700-UK (A)

Methods	Centre: St. George's - London. Methods: see above UK700-UK 1999 .
Participants	Participants: see above UK700-UK 1999 . N = 196.
Interventions	Methods: see above UK700-UK 1999 . Sample size providing data: 1. ICM: N = 96. 2. Non-ICM: N = 99.
Outcomes	Service use: average number of days in hospital per month.
Notes	

UK700-UK (B)

Methods	Centre: King's - London. Methods: see above UK700-UK 1999 .
Participants	Participants: see above UK700-UK 1999 . N = 153.
Interventions	Methods: see above UK700-UK 1999 . Sample size providing data: 1. ICM: N = 77.

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UK700-UK (B) *(Continued)*

2. Non-ICM: N = 74.

Outcomes	Service use: average number of days in hospital per month.
Notes	

UK700-UK (C)

Methods	Centre: Manchester. Methods: see above UK700-UK 1999 .
Participants	Participants: see above UK700-UK 1999 . N = 158.
Interventions	Methods: see above UK700-UK 1999 . 1. ICM: N = 79. 2. Non-ICM: N = 79.
Outcomes	Service use: average number of days in hospital per month.
Notes	

UK700-UK (D)

Methods	Centre: St. Mary's* - London. Methods: see above UK700-UK 1999 .
Participants	Participants: see above UK700-UK 1999 . N = 201.
Interventions	Methods: see above UK700-UK 1999 . Sample size providing data: 1. ICM: N = 99. 2. Non-ICM: N = 101.
Outcomes	Service use: average number of days in hospital per month.
Notes	*In St. Mary's centre staff were randomly assigned to ICM or non-ICM position.

UK700-UK 1999

Methods	Allocation: randomised. Design: multicentre (4 sites, 3 in London and 1 in Manchester). Duration: 24 months. Country: UK.
Participants	Diagnosis*: psychotic illness (diagnosed through OPCRIT). N = 708.

UK700-UK 1999 (Continued)

Setting: inner-city mental health services.
Age: 18 to 65 years, mean ~ 37.3 years.
Sex: 57% M (404M, 304F).
Ethnicity: Afro-Caribbean 28%.
History: i. psychotic illness for at least 2 years, ii. ≥ 2 previous hospital admissions, 1 within past 2 years, iii. no organic brain disease or primary diagnosis of substance misuse, iv. written informed consent.

Interventions	1. ICM**: Caseload: 1:10-15. N = 353. 2. Non-ICM: Caseload: 1:30-35. N = 355.
Outcomes	<p>Service use: average number of days in hospital per month (available for single centre, see below), not remaining in contact with psychiatric services (reported as not remaining in contact with case manager), admitted to hospital, mean number of admissions. Death: all causes and suicide. Global state: leaving the study early. Social functioning: time in independent living accommodation (reported as time spent in stable accommodation), imprisoned, Camberwell Assessment of Need (CAN). Mental state: general symptoms CPRS, negative symptoms (SANS). Behaviour: self harm, harm to others. Quality of life: Lancashire Quality of Life Profile (LQoLP). Participant satisfaction: Patients' satisfaction with health services questionnaire. Costs: direct costs of all care.</p> <p>Unable to use - Social functioning: DAS (scale adapted by the trialist, not peer reviewed). Mental state: subscale of CPRS for depression (Montgomery-Åsberg Depression Rating Scale) and for psychotic symptoms (no SD), for anxiety and for behavioural disturbance (no SD, not peer-reviewed scale). Carer satisfaction: Experience of Caregiving Inventory, 12-Item General Health Questionnaire (attrition 83.6%). Costs: direct costs of health care and of psychiatric hospital care (no SD). Adverse drug effects: Abnormal Involuntary Movement Scale (not listed as outcome of interest of the review).</p>
Notes	<p>*Schizophrenia 38%, schizoaffective 49%, mania or bipolar 5%. **The team organisation varied slightly across centres.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, randomisation stratified by centre. No further details.
Allocation concealment (selection bias)	Low risk	Randomised allocation assigned by telephone or fax by an independent statistical centre.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Primary outcome: clinician/participant mediated - rating - Unclear. Secondary outcomes: interviewer rated - rating - No. (Researchers were not masked to treatment allocation.)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported.
Blinding of outcome assessment (detection bias)	Unclear risk	Blinding not reported.

UK700-UK 1999 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	Number and reasons for attrition stated. Analysis performed on an ITT basis.
Selective reporting (reporting bias)	Unclear risk	Most of the listed outcomes are reported completely (the only exception is for CPRS subscale: SD missing).
Other bias	Low risk	Publicly funded (grants from the UK Department of Health and NHS research and development programme). No further details. No evidence of the presence of other bias.

ACT - Assertive Community Treatment

CM - Case Management

CMHC - Community Mental Health Center

CMHT - Community Mental Health Team

CPA - Care Programme Approach: the CPA is a combination of non-Intensive Case Management and care from a CMHT, introduced in England in the mid-1990s and becoming standard care thereafter

CPNS - Community Psychiatric Nursing Service

DSM-III-R - Diagnostic and Statistical Manual of Mental Disorders, 3rd Edition, Revised ([APA 1987](#))

DSM IV - Diagnostic and Statistical Manual of Mental Disorders, 4th Edition ([APA 1994](#))

F - female

ICD-10 - International Statistical Classification of Diseases and Related Health Problems 10th Revision ([WHO 1992](#))

ICM - Intensive Case Management

ITT - intention to treat

LOCF - last observation carried forward

M - male

N - number

NIMH - National Institute of Mental Health (USA)

non-ICM - non-Intensive Case Management

OPCRIT - Operational Criteria ([McGuffin 1991](#))

OPD - outpatient department

PACT - Programme of Assertive Community Treatment

P/T - part time

RDC - Research Diagnostic Criteria ([Spitzer 1978](#))

SADS - Schedule for Affective Disorders and Schizophrenia interview ([Endicott 1978](#))

SC - standard care

SCAN 2.0 - 2.1: Schedule for Clinical Assessment in Neuropsychiatry (SCAN 2.0 in 1998, SCAN 2.1 since 1999) ([WHO 1998](#))

SCID - Structured Clinical Interview for DSM-IV ([First 1997](#))

SD - standard deviation

SMI - severe mental illness

TCL - Training in Community Living

VA - Veterans administration

Yrs - years

Scales

ACL - Adjective Checklists

ASI - Addiction Severity Index

AUS - Alcohol Use Scale

BDI - Beck Depression Inventory

BPRS - Brief Psychiatric Rating Scale

BSI - Brief Symptom Inventory

CAN - Camberwell Assessment of Need Interview

CANSAS - Camberwell Assessment of Need Short Appraisal Schedule

CPRS - Comprehensive Psychopathological Rating Scale

C-DIS-R - Computer-based Diagnostic Interview Schedule Revised

CSI - Colorado Symptom Index

CSQ - Client Satisfaction Questionnaire

CSRI - Client Service Receipt Inventory

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DALI - Dartmouth Assessment of Lifestyle Interview
 DACTS - Dartmouth Assertive Community Treatment Scale
 DAS - Disability Assessment Scale
 DUS - Drug Use Scale
 GAF - Global Assessment of Functioning Scale
 GAS - Global Assessment Scale
 GSI - Global Severity Index
 HADS - Hospital Anxiety and Depression Scale
 HEAS - Homeless Engagement Acceptance Scale
 HoNOS - Health of the Nation Outcome Scale
 IMPS - Inpatient Multidimensional Psychiatric Scale
 Indiana LOF - Indiana Level of Functioning
 ISSI: Interview Schedule for Social Interaction
 KS - Krawiecka Scale
 LQoLP - Lancashire Quality of Life Profile
 LSP - Life Skill Profile
 MANSA - Manchester Short Assessment of Quality of Life
 PANSS - Positive and Negative Syndrome Scale
 PSE - Present State Examination
 PSNAS - Personality and Social Network Adjustment Scale
 QOLI - Lehman's Quality of Life Interview
 REHAB - a scale of social functioning (REHAB GB: general behaviour); (REHAB DB: deviant behaviour)
 ROMI - Rating of Medication Influences
 RSES - Rosenberg Self Esteem Scale
 SAI - Scale for the Assessment of Insight
 SAI-E - Scale for the Assessment of Insight-expanded
 SANS - Scale for the Assessment of Negative Symptoms
 SAPS - Scale for the Assessment of Positive Symptoms
 SAS - Social Adjustment Scale
 SATS - Substance Abuse Treatment Scale
 SBS - Social Behaviour Scale
 SCL-90: Hopkins Symptoms Check List-90
 SCRS - Short Clinical Rating Scale
 SFQ - Social Functioning Questionnaire
 SLS - Satisfaction with Life Scale
 TLFB - Timeline Followback
 W-BQ - Well-being Questionnaire

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

Study	Reason for exclusion
Agius-Croatia 2007	Allocation: not randomised (cohort study).
An 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Community-based follow-up interventions. 2. Care as usual. Not ICM.
An Qi 2013	Allocation: randomised. Participants: primary schizophrenia. Interventions: 1. Family intervention. 2. Care as usual.

Study	Reason for exclusion
	Not ICM.
Bao 2012	Allocation: unclear. Not RCT.
Bao-China 2005	Allocation: randomised. Participants: people with schizophrenia. Intervention: 1. Family intervention, community based. Not ICM. 2. Standard care.
Barbic 2009	Allocation: randomised. Participants: people who met DSM-IV diagnostic criteria for schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder, or bipolar disorder. Intervention: No relevant comparison: ACT vs ACT + Recovery Workbook.
Barekatin-Iran 2014	Allocation: randomised. Participants: age 18 to 65 years. DSM-IV diagnosis of bipolar I disorder (mania or mixed), schizophrenia, or schizoaffective disorder. Intervention: 1. Psychoeducation program for families, explicitly operationalised, provided within a package of care close to the ICM model (caseload 1:12). 2. Standard care: routine psychiatric treatments. Caseload not reported. N = 62.
Bigelow-Oregon 1991	Allocation: not randomised, quasi-experimental design.
Bond-Chicago2 1989	Allocation: not randomised, matched-groups design. Interventions: 2 types of crisis housing.
Bond-Indiana2 1991	Allocation: not randomised, allocation to ACT and reference group was not random in 1 of the 3 participating centres. The study could be included if separate data can be obtained from the 2 centres where randomisation took place.
Borland-Washington 1989	Allocation: not randomised.
Borras 2009	Allocation: randomised. Participants: all meeting ICD-10 criteria for a diagnosis of schizophrenia or other non-affective psychoses. Interventions: no relevant comparison: traditional psychiatric outpatient care or case management vs traditional psychiatric outpatient care or case management + self esteem module.
Botha 2014	Allocation: randomised. Participants: adults with severe mental illness. Intervention: 1. Modified assertive intervention. 2. Standard care. Caseload > 20.
Burns 2013	Allocation: randomised.

Study	Reason for exclusion
	<p>Participants: adult patients diagnosed with psychosis.</p> <p>Interventions: 1. Community treatment orders (CTOs): program for patient who needs supervision after a period of involuntary hospital treatment and who, without it, is highly likely to relapse and be readmitted involuntarily. Not ICM.</p> <p>2. Section 17 leave: a well-established rehabilitation practice, used for brief periods to assess the stability of a patient's recovery after or during a period of involuntary hospital treatment.</p>
Burns-UK 1993	<p>Allocation: randomised.</p> <p>Participants: people who were (a) aged between 18 and 74 years, (b) from the appropriate catchment area of Psychiatric Service, (c) not in treatment during the preceding 12 months, (d) able to be interviewed in English.</p> <p>Intervention: multidisciplinary team home treatment, not ICM.</p>
Champney-Ohio 1992	<p>Allocation: randomised.</p> <p>Participants: adults with severe mental disabilities.</p> <p>Intervention: all 4 comparison groups received some form of case management, no ACT. Neither standard care nor non-ICM in the comparison group.</p>
Chandler 1999	<p>Allocation: randomised.</p> <p>Participants: volunteers randomly assigned to ACT.</p> <p>Not exclusively community setting.</p>
Chandler 2000	<p>Allocation: randomised.</p> <p>Participants: not clear, described as "high cost inpatient users".</p> <p>Intervention: no relevant comparison: ACT + social skills training vs ACT.</p>
Chandler-California2 2006	<p>Allocation: randomised.</p> <p>Participants: current serious mental illness and substance use disorder.</p> <p>Intervention: 1. In-custody standard care + brief aftercare + Integrated Dual Disorders Treatment. Postcustody treatment includes ICM and specific intervention addressing substance abuse disorder. Not exclusively community setting; not only ICM.</p> <p>2. Service as usual: in-custody standard care + usual postcustody services + 60 days of postrelease case management and housing assistance. Not exclusively community setting.</p>
Chang 2013	<p>Allocation: randomised.</p> <p>Participants: 18 to 35 years with a diagnosis of schizophrenia, non-affective psychosis, affective disorders with psychotic features, or delusional disorder.</p> <p>Intervention: 1. Community-based case management (n = 79).</p> <p>2. Standard care: general psychiatric care with all auxiliary care options unchanged (n = 77).</p> <p>All participants had been enrolled in the Early Assessment Service for Young People with Early Psychosis (EASY) for 2 years before starting this trial.</p> <p>Not ICM, caseload 1:80.</p>
Chatterjee 2014	<p>Allocation: randomised.</p> <p>Participants: patients aged 16 to 60 years with a primary diagnosis of schizophrenia according to the ICD-10 Diagnostic Criteria for Research (DCR).</p>

Study	Reason for exclusion
	Intervention: 1. Collaborative community-based care plus facility-based care. 2. Facility-based care alone. Not ICM.
Chen XZ 2012	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Home visit. 2. Education. Not ICM.
Chen-China 2007	Allocation: randomised. Participants: adults with schizophrenia (non-acute). Intervention: 1. Antipsychotic + Digital Network + Community Support Network. 2. Antipsychotic + Community Support Network. Digital Network involves providing online consultation to patients, emailing them periodically, providing online health education. Community Support Network involves providing physical, psychological, and rehabilitation treatment to non-acute patients. Not ICM.
COAST-UK 2004	Allocation: randomised. Participants: those with any functional psychosis. Interventions: 1. ICM: Assertive Outreach Team model; caseload: 1:12. Also includes individual therapy for residual positive symptoms of psychosis (CBT) and family intervention, if appropriate. Not only ICM. 2. Non-ICM: usual services available to a local multidisciplinary team (according to Care Programme Approach); caseload: 1:35. Does not include any specialised psychological interventions.
COMO-UK 2003	Allocation: cluster randomisation. Participants: case manager providing care to patients with psychosis and comorbid substance misuse ("dual diagnosis"). Interventions: 1. Training in dual-diagnosis intervention (i.e. i. treatment manual; ii. 5-day training course in assessment and management of dual diagnosis; iii. subsequent monthly supervision). Not ICM. 2. CMHT management as usual.
Cook 2013	Allocation: randomised. Participants: patients with serious mental illness as defined by federal Public Law 102-321 specifying diagnosis, duration, and level of disability (schizophrenia, schizoaffective, bipolar, depressive, other); age ≥ 18 years. Interventions: 1. Wellness Recovery Action Planning: an evidence-based practice that consisted of 9, 2.5-hour group sessions that were facilitated free of charge by 2 trained and certified instructors in recovery from mental illness, with backup instructors available as needed. Not ICM. 2. Choosing Wellness: Healthy Eating Curriculum: a nutrition education intervention holistically focused on wellness.
CORE 2014	Allocation: randomised. Participants: patients diagnosed with bipolar disorder, anxiety disorder, major depressive disorder, schizophrenia, personality disorder, panic disorder, age 16 to 64 years.

Study	Reason for exclusion
	Intervention: 1. Co-design technique to optimise psychosocial recovery. Not ICM. 2. Waiting list.
Cosden-California 2005	Allocation: randomised. Participants: offenders with serious mental illness. Interventions: 1. ICM + non-adversarial court proceeding. 2. Non-ICM + adversarial court proceeding. 2 arms are provided with different intervention between groups in addition to ICM and non-ICM.
CRIMSON-UK 2008	Allocation: randomised. Participants: diagnosis of psychotic illness; ≥ 1 admission to a psychiatric inpatient service during previous 2 yrs. Interventions: 1. Joint Crisis Plan: aims to empower the client and to facilitate early detection and treatment of relapse. Plan contains client's treatment preferences for any future psychiatric emergency, when the client may be too unwell to express clear views. Not ICM. 2. Standard treatment: as provided by CMHT.
Cui 2012	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Case management. 2. Outpatient visits. Not ICM.
De Cangas-Canada 1994	Allocation: randomised. Intervention: hospital-based care for those in control group, not community-based ICM.
Dean-UK1 1990	Allocation: not randomised.
Dean-UK2 1993	Allocation: not randomised, quasi-experimental study.
Dekker-Netherlands 2002	Allocation: randomised, but randomisation is compromised because after initial randomisation control group were combined with control group from another study that experienced problems. Participants: chronic psychiatric patients with a history of several admissions. Interventions: 1. ACT; caseload: 1:30. Not ICM. 2. Standard care.
Deng-China 2006	Allocation: quasi-randomised (randomisation according to hospital admission number). Participants: admitted to hospital for a first-onset schizophrenia. Interventions: hospital based, not community based.
Dharwadkar-Victoria 1994	Allocation: not randomised, before-and-after design.
Dinitz 1965	Allocation: randomised. Participants: acutely mentally ill patients in a hospital setting.
Er 2013	Allocation: randomised. Participants: chronic schizophrenia. Interventions: 1. Antipsychotics + family education, and rehabilitation instruction 2. Care as usual. Not ICM.

Study	Reason for exclusion
Fenton-Canada 1978	Allocation: randomised. Participants: people with schizophrenia, acutely ill, requiring immediate hospital admission. Intervention: home-care community-based treatment vs hospital care. Not ICM in the experimental group; comparison group not community based.
Franklin-Texas 1987	Allocation: randomised. Participants: people who at least had 2 discharges from mental hospital. Intervention: Assertive Community Treatment caseload over 30. Not ICM.
Gao 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Hospital-community-family integrated management. 2. Care as usual. Caseload not reported.
Gaughran 2013	Allocation: randomised. Participants: patients with a ICD-10 diagnosis of psychotic disorder (F20-29, F31.2, F31.5). Intervention: 1. Improving physical health and reducing substance use in psychosis (IM-PACT)-Health Promotion Intervention. Not ICM. 2. Standard care.
Glick-New York 1986	Allocation: randomised. Intervention: day hospital care vs outpatient group therapy, not ICM.
Godley-Illinois 1994	Allocation: randomised. Participants: major psychiatric and substance abuse diagnosis. Intervention: 1. ICM: specialised case management. Caseload ~ 1:15. 2. Standard care. Outcome: incomplete data reporting. Not providing usable outcomes.
Goering-Canada 1988	Allocation: not randomised, used historical controls.
Gold-SCarolina 2006	Allocation: randomised. Participants: adults with severe mental illness. Intervention: ACT + Individual Placement and Support (integrated supported employment programme). Not only ICM. 2. Traditional programme: providing mental health and brokered case management services in parallel to vocational services. Not only standard-care services. 2 arms are provided with different interventions between groups in addition to ACT and standard care.
Gong 2014	Allocation: randomised. Participants: adults with severe mental illness. Interventions: 1. Case management provided by village doctors. 2. Usual care. Not ICM.
Grawe-Norway 2005	Allocation: randomised. Participants: people with recent-onset schizophrenia. Interventions: 1. Integrated treatment: package of care provided by a multidisciplinary team with management caseload ~ 1:10; cognitive-behavioural family treatment and home-based crisis management. Not only ICM.

Study	Reason for exclusion
	2. Standard treatment: clinical-based case management caseload ~ 1:10 and crisis inpatient treatment.
Gu-China 2010	Allocation: randomised (multicentre trial; 4 centres). Participants: patients suffering from schizophrenia. 1. Integrated training: the intervention includes life skill training, occupational skill training, communication training, psycho-education, and family visiting. Delivered by nurses. Caseload is probably 1<20. 2. Standard care. Routine training, no more details. Not ICM in the intervention.
Han SH 2012	Allocation: randomised. Participants: primary schizophrenia. Interventions: 1. Antipsychotics, psycho-education, family visit, and instruction. 2. Antipsychotics and psycho-education. Not ICM.
Hargreaves-California	Allocation: not randomised.
Havassy-California 2000	Allocation: randomised. Participants: seriously mentally ill adults with and without substance dependence. Interventions: 1. Intensive Clinical Case Management community-based. 2. Expanded brokerage case management program (data on caseload not available; it could be either ICM or non-ICM), hospital based, providing intensive support during the initial postdischarge period, with a maximum of 60 days. Outcome: poor reporting data results, not usable. 2 reasons for exclusion: intervention (not clear if the comparison intervention is ICM or non-ICM) and not providing usable data (comparison is between the 2 subgroups "with or without substance dependence", not between the 2 interventions).
He-China 2004	Allocation: quasi-randomised (randomised allocation according to register number).
Hornstra-Kansas 1993	Allocation: not randomised, historical controls.
Hoult-Australia 1981	Allocation: randomised. Participants: people with schizophrenia, acutely ill, requiring immediate hospital admission. Interventions: ICM vs acute admission to a psychiatric hospital.
Huang 2012	Allocation: unclear. Not RCT.
Huang 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Community nursing intervention and rehabilitation training. 2. Treatment as usual. Not ICM.

Study	Reason for exclusion
Hui 2014	<p>Allocation: randomised.</p> <p>Participants: patients diagnosed with schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief psychotic disorder, psychotic disorder not otherwise specified, or manic episodes with psychotic features (DSM-IV); age 22 to 55 years.</p> <p>Interventions: 1. Early Intervention Program: specialised and individualised case management as well as community-based group programmes. Caseload > 20.</p> <p>2. Standard care.</p>
Hurlburt-California 1996	<p>Allocation: randomised.</p> <p>Participants: severe mental illness.</p> <p>Interventions:</p> <ol style="list-style-type: none"> 1. Non-ICM: comprehensive case management; caseload 1:22. Not ICM. 2. Non-ICM: traditional case management; caseload 1:40. Not ICM. 3. Non-ICM: comprehensive case management; caseload 1:22 + high-level access to independent housing. Not ICM. 4. Non-ICM: traditional case management; caseload 1:40 + high-level access to independent housing. Not ICM.
ISRCTN73683215	<p>Allocation: randomised.</p> <p>Participants: adults with severe mental illness who received mental health care in clinical settings.</p> <p>Interventions: Not ICM. Boston Psychiatric Rehabilitation Approach versus treatment as usual.</p>
Jerrell-California 1989	<p>Allocation: randomised. Randomisation is compromised because number of people excluded after randomisation is not reported (patients were excluded if they refused to participate after randomisation or if they had not been discharged from hospital within 6 months of entering the study).</p> <p>Participants: severe mental illness.</p> <p>Intervention: 1. ICM, according to the ACT Stein and Test model. 2. Standard care: provided in the community setting.</p>
Jerrell-SCarolina2 1994	<p>Allocation: randomised.</p> <p>Interventions: ACT vs 12-step recovery programme and behavioural skills training + standard care. Not standard care only in the comparison group.</p>
Jiang 2012	<p>Allocation: randomised.</p> <p>Participants: primary schizophrenia</p> <p>Interventions: 1. Family intervention plus antipsychotics.</p> <p>2. Antipsychotics alone.</p> <p>Not ICM.</p>
Jiang 2013	<p>Allocation: randomised.</p> <p>Participants: chronic schizophrenia.</p> <p>Interventions: 1. Intergrated community-based intervention.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Jorgensen 2012	<p>Allocation: randomised.</p>

Study	Reason for exclusion
	<p>Participants: patients meeting the criteria for schizophrenia according to ICD10 F.20.09 or schizoaffective disorder according to ICD10 F.25.09; age 18 to 70 years.</p> <p>Interventions: 1. Guided Self Determination: 21 worksheets designed to guide patient and mental health professionals through autonomy-supportive problem solving. The worksheets are filled in by the patient before and between conversations with their community nurse over 10 sessions, each approximately 1 hour. Not ICM.</p> <p>2. Waiting list</p> <p>*Trial status: ongoing (trial registration form only).</p>
Kane-Virginia 2004	Not randomised.
Kilbourne 2014	<p>Allocation: randomised.</p> <p>Participants: Adult Veterans Administration (VA) Center patients diagnosed with an ICD-9 diagnosis of schizophrenia or related disorder or bipolar disorder who was lost to care.</p> <p>Interventions: 1. Re-Engage: a national VA outreach program consisting of risk assessment (i.e. identifying the patient's current status, including clinical care needs and current disposition) and outreach services (i.e. attempting to contact patients and invite them back to receive health services). Not ICM.</p> <p>2. Standard care.</p>
Klotz-California 2001	Wrote to author for further information. Received email from D. Innes-Gomberg on 4 January 2016 stating that there is no data. Consequently, this study is excluded.
Knight-California 1990	Allocation: not randomised, quasi-experimental design.
Kuldau-California 1977	<p>Allocation: randomised.</p> <p>Interventions: rapid discharge vs hospital care, not ICM.</p>
Lafave-Canada 1996	<p>Allocation: randomised.</p> <p>Intervention: hospital-based care for control group, not community-based care. Neither standard care nor non-ICM in the comparison group.</p>
Langley 2009	<p>Allocation: randomised</p> <p>Participants: diagnosed with a DSM-IV axis 1 disorder.</p> <p>Interventions: ACT vs ICM. No relevant comparison: both interventions types of ICM.</p>
Langsley-Colorado 1968	<p>Allocation: randomised.</p> <p>Interventions: outpatient family crisis management vs hospital admission. Not ICM.</p>
Lehman-Maryland ² 1993	<p>Allocation: randomised.</p> <p>Participants: dually diagnosed people.</p> <p>Interventions: 1. ICM + experimental group treatment Being Sober Group (addressing the specific problems of dually diagnosed adults). 2. Non-ICM. In the experimental group: not only ICM.</p>
LEO-UK 1994	<p>Allocation: randomised.</p> <p>Participants: people with non-affective psychosis.</p> <p>Interventions: 1. ICM: Assertive Outreach model; caseload ~ 1:7. Including also: i. CBT based on manualised protocol; ii. family counselling and vocational strategies based on established protocols. Not only ICM.</p> <p>2. Non-ICM: delivered by the sector community mental health teams (according to Care Programme Approach). No CBT, no family counselling and vocational strategies.</p>

Study	Reason for exclusion
Li 2011	<p>Study design: randomised.</p> <p>Participants: inpatients with schizophrenia (Chinese Classification of Mental Disorders (CCMD-3)).</p> <p>Interventions: hospital-based intervention, not community based.</p> <p>Assessed by Sai Zhao.</p>
Li 2012	<p>Allocation: randomised.</p> <p>Participants: primary schizophrenia.</p> <p>Interventions: 1. Community comprehensive intervention.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Li 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Care package involving family intervention, psycho-education, and drug therapy.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Li JX 2013	<p>Allocation: randomised.</p> <p>Participants: primary schizophrenia.</p> <p>Interventions: 1. Individulised rehabilitation training.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Li MD 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Family intervention plus usual care.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Li Ning 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Community-based comprehensive intervention.</p> <p>2. Standard community intervention.</p> <p>Caseload not reported.</p>
Li WX 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Community-based interventions.</p> <p>2. Long-term hospitalisation.</p>

Study	Reason for exclusion
	Not ICM.
Li-China 2004	Not community setting: hospital setting. In Chinese. Assessment by Tao Yuan Li Jun and Chunbo Lee.
Liang 2009	Allocation: not randomised. The author randomly selected 188 participants and divided them into 2 groups. Participants: schizophrenia. Interventions: talking therapy and instruction for medication. Assessed by Sai Zhao.
Liang 2012	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Family intervention and antipsychotic medication. 2. Antipsychotics alone. Not ICM.
Liao 2010	Study design: RCT. Participants: inpatients with schizophrenia. Interventions: hospital-based intervention included psycho-education, social skills training, family education, etc. Assessed by Sai Zhao.
Lichtenberg-Israel 2008	Allocation: randomised. Participants: people with at least 3 psychiatric admissions during the previous 2 yrs. Diagnosis is not stated. Interventions: 1. Non-ICM; caseload 1:30. Not ICM. 2. Standard care: provided by the mental healthcare centres.
Lin-China 1998	Allocation: not randomised.
Liu 2010	Study design: RCT. Participants: inpatients with schizophrenia. Interventions: hospital-based group psycho-education. Assessed by Sai Zhao.
Lloyd 2000	Allocation: not randomised.
Lu 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Hospital-community integrated management model. 2. Care as usual. Caseload not reported.
Malm-Sweden 2003	Allocation: randomised. Participants: diagnosed according to DSM-IV schizophrenia, schizophreniform, schizoaffective, or delusion disorders. Intervention: 1. "Integrated Care" vs 2. "Rational Rehabilitation". Both of the compared treatment programmes were delivered in the context of clinical case management by CMHTs. They actively incorporated some key features of ACT; caseloads ~ 1:40.

Study	Reason for exclusion
	The additional component in the Integrated Care programme was the continuous social network resource group for each patient. Not ICM.
Martin-Delaware 1993	Allocation: not randomised.
Martin-UK 2005	Allocation: randomised. Participants: people with intellectual disability and mental illness.
Marx-Wisconsin 1973	Allocation: randomised. Interventions: hospital-based care for control group, not community-based care. Neither standard care nor non-ICM in the comparison group.
McDonell 2013	Allocation: randomised. Participants: patients meeting Mini International Neuropsychiatric Interview criteria for schizophrenia, schizoaffective disorder, bipolar I or II disorder, or recurrent major depressive disorder and methamphetamine, amphetamine, or cocaine dependence who had used stimulants during the past 30 days. Intervention: 1. Contingency management for stimulant abstinence. Not ICM. 2. Treatment as usual.
McFarlane-New York 1992	Allocation: unclear if randomised. Interventions: ACT vs Family-Aided Assertive Community Treatment (FACT). Neither standard care nor non-ICM in the comparison group.
McGowan-California 1995	Allocation: unclear if randomised; control and treatment groups were "randomly selected" from a population already receiving ACT or standard care.
McGrew-Indiana 1994	Allocation: not randomised (study was a before-and-after design examining the effects of implementing ACT teams in 6 sites in Indiana).
McHugo-Washington DC 2004	Allocation: randomised. Participants: adults with severe mental illness at high risk for homelessness. Intervention: 1. Parallel housing services programme: including ICM - caseload 1:15, implemented by mobile ACT team, and housing by routine community-based landlords. Not only ICM. 2. Integrated housing services programme: including ICM - caseload 1:15; case management and housing services were provided by teams within a single agency and were closely co-ordinated. Neither standard care nor non-ICM in the comparison group.
MECCA-Europe 2002	Allocation: cluster randomisation. Participants: people with functional psychosis. Intervention: 1. Treatment as usual + "outcome management". The latter is an innovative treatment where every 2 months a key-worker assesses patient's subjective quality of life, treatment satisfaction, and wishes for additional/different support using a questionnaire (MECCA). It is expected that the results will directly feed into the therapeutic dialogue and be discussed by the patient and key-worker together. Not ICM. 2. Treatment as usual.
Meneghelli-Italy 2000	Allocation: not randomised.
Merson-UK 1992	Allocation: randomised. Interventions: multidisciplinary team home treatment vs emergency assessment at hospital. Neither standard care nor non-ICM in the comparison group.
Modcrin-Kansas 1988	Allocation: randomised. Participants: chronically mentally ill.

Study	Reason for exclusion
	Interventions: strengths model of case management versus standard case management. As caseload is not reported for either group, it is unclear if experimental intervention could be considered ICM and comparison group could be considered standard care or non-ICM. The study could be included if more data can be obtained on caseload.
Morse-Missouri 1997	Allocation: randomised. Participants: homeless people with severe mental illness. Interventions: 1. ICM: ACT, caseload 1:10; vs 2. Non-ICM: Brokered Case Management, caseload 1:85; vs 3. ACT plus community worker support, caseload 1:10. Outcomes: unable to use data, numbers for treatment groups not presented.
Morthorst 2012	Allocation: randomised. Participants: patients admitted after a suicide attempt to acute emergency units, intensive care units, paediatric units, and psychiatric emergency rooms: age: ≥ 12 (subgroup analysis according to age reported). Excluded patients who had been diagnosed with severe mental illness (i.e. schizophrenia spectrum disorders, severe depression, severe bipolar disorder).
Mosher-California 1975	Allocation: not randomised, alternative assignment.
Muijen-UK1 1992	Allocation: randomised. Participants: those with severe mental illness requiring immediate emergency admission. Interventions: ICM vs acute admission to a psychiatric hospital.
Mulder-Missouri 1985	Allocation: randomised, but data from randomised and non-randomised patients not reported separately. Participants: people with schizophrenia, acutely ill, presenting for psychiatric hospital admission. Interventions: 1. ICM: modelled according to the PACT model (as an alternative to current hospitalisation). 2. Standard care: usual hospital admission procedure, and at discharge the usual aftercare case management services.
NCT00781079	Allocation: randomised. Participants: must have serious mental illness and must be working with Veterans Affairs ICM team. Interventions: No relevant comparison: ICM + peer specialists vs ICM only.
NCT01597141	Allocation: randomised. Participants: aged 12 to 35 years, with prodromal schizophrenia, psychotic disorders, severe bipolar disorder with psychotic features, or severe major depression with psychotic features. Interventions: 1. Family-Aided Assertive Community Treatment (FACT) (a combination of family psycho-education, ACT, supported education/employment, and psychotropic medication). 2. Enhanced standard treatment: the participants will receive the same psychotropic drugs, but will receive individual case management, family education, and crisis intervention. Not ICM vs standard care or ICM vs non-ICM.
Nieves 2002	Allocation: not a randomised study: "quasi-experimental design with a matched-groups comparison of outcomes achieved by patients in two community mental health centers in the South Bronx area of New York City".
Odom 2005	Allocation: non-randomised, post-hoc analysis of RCT.

Study	Reason for exclusion
Pai-India 1982	Allocation: not randomised, alternative assignment.
Pioli 2006	Allocation: randomised. Participants: aged between 18 and 65 years; affected by severe mental illness. Intervention: generic rehabilitation interventions, not ICM. Setting: conducted partially in residential rehabilitation centre.
Polak-Colorado 1976	Allocation: randomised. Participants: not clearly specified. Interventions: admission to small "community-based therapeutic environments" vs standard hospital care. Not ICM.
PRISM-UK 1998	Allocation: not randomised.
Ren-China 2004	Allocation: not clearly stated if randomised. Participants: people with chronic schizophrenia, admitted to rehabilitation hospital. Interventions: rehabilitation hospital based, not community based.
Roldan-Merino 2012	Allocation: randomised Participants: patients diagnosed with schizophrenia with an evolution of 2 or more years since the moment of the diagnosis. Interventions: 1. Personalised in-home nursing care plan: periodic home visits, with maximum intervals of 21 days between visits. Not ICM. 2. Standard care.
Rossler-Germany1 1992	Allocation: not randomised, case control study.
Rossler-Germany2 1995	Allocation: not randomised, case control study.
Rutter-UK	Allocation: randomised. Participants: severe mental illness. Interventions: 1. ICM: case management provided by a case manager internal to the CMHT; caseload 1:15. 2. ICM: case management provided by a case manager outside the CMHT; caseload 1:15. The comparison group was neither standard care nor non-ICM.
Salyers 2010	Allocation: randomised. Participants: adults with severe mental illness. Interventions: Not ICM. Illness Management and Recovery (IMR) vs intensive problem solving. IMR: psycho-education, cognitive behavioural approaches, relapse prevention, social skills training, and coping skills training.
Salyers 2014	Allocation: randomised. Participants: patients diagnosed with schizophrenia or schizoaffective disorder, currently receiving (or newly admitted to) mental health services at a Veterans Administration (VA) or community mental health centre; age 18 or older. Interventions: 1. Group-based Illness Management and Recovery (IMR) program: developed to incorporate effective strategies including psycho-education, cognitive behavioural approaches to medication adherence, relapse prevention, social skills training, and coping skills training.

Study	Reason for exclusion
	2. Equally intensive problem-solving (PS) control group. Not ICM and irrelevant comparison.
Santiago-Arizona 1985	Allocation: randomised. Participants: those with serious mental illnesses, recently admitted to hospital and ready for discharge. Intervention: 1. Treatment Network Team provided both in community- and hospital-based setting. Caseload not stated. Not ICM. 2. Standard care. Unable to use all outcomes.
Sato 2012	Allocation: randomised. Participants: hospitalised patients.
Schmidt 2005	Not randomised: retrospective cohort design using an approximation of random assignment.
Segal 2010	Allocation: randomised. Participants: adults with severe mental illness. Interventions: 1. Community Mental Health Agencies (CMHA) treatment vs 2. CMHA treatment and Self-Help Agencies. Not ICM.
Segal 2011	Allocation: randomised. Participants: adults with serious mental illness (schizophrenia or schizoaffective disorder, major affective disorder). Interventions: 1. CMHA outpatient treatment. Not ICM. 2. A combination of CMHA outpatient treatment and consumer-operated service programs (COSP).
Sha 2010	Allocation: randomised. Participants: inpatients with schizophrenia (Chinese Classification of Mental Disorders (CCMD-3)). Interventions: hospital-based intervention, not community based. Assessed by Sai Zhao.
Shen WW 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Hospital-community-family integrated management. 2. Care as usual. Caseload not reported.
Shern-USA2	Allocation: randomised. Participants: serious and persistent mental health disorder + homelessness. Interventions: 1. Pathways to Housing: supporting housing programme, providing permanent, independent housing + ACT (according to Stein and Test model); caseload 1:10. Not only ICM. 2. Standard care: provided by social agencies (i.e. outreach teams, drop-in centres). If participant has no current affiliation to service providers, information was given about where services could be obtained. No active engagement.
Shern-USA3	Allocation: randomised.

Study	Reason for exclusion
	Participants: severe mental illness, co-occurring addiction and homelessness. Interventions: 1. Housing First programme: providing permanent, independent housing without prerequisites for sobriety and treatment + ACT; vs 2. Standard care. Not only ACT.
Shern-USA4	Allocation: randomised. Participants: homeless mentally ill population. Interventions: 1. Pathways to Housing: supporting-housing programme, providing permanent, independent housing; vs 2. Standard residential treatment. Not ICM.
Solomon 2014	Intervention: Not ICM: Transitional Care Model is a time-limited (90 days), transitional intervention from release from acute hospitalisation to full engagement with community mental health care 1. Transitional Care with case management: nurse practitioner managing risk factors to prevent further cognitive or emotional decline, managing problem behaviours, assessing and managing physical symptoms, preventing functional decline; promoting adherence to therapies, assuring proper medical management and continuity of care, and helping case managers understand the integrated mental and physical care approach. 2. Usual case management: a case manager was assigned to the participant and a psychiatrist provided medication management.
Solomon-Pennsylvania1	Allocation: randomised. Intervention: 1 type of case management vs another. Neither standard care nor non-ICM in the comparison group.
Somers 2013	Allocation: randomised Participants: homelessness or precarious housing participants with current mental disorder status meeting Mini-International Neuropsychiatric Interview criteria for major depressive episode, manic or hypomanic episode, post-traumatic stress disorder, mood disorder with psychotic features, and psychotic disorder. Interventions: 1. Housing First + ICM. Not ICM alone. 2. Usual care.
Song 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Family psychological care plus social skills training and antipsychotics. 2. Antipsychotics alone. Not ICM.
Stein 1974	Allocation: randomised Participants: adults with severe mental illness; age 18 to 62 years. Interventions: 1. Training in community living. 2. Hospital care. Control group not in community.
Stein-Wisconsin	Allocation: randomised. Participants: those with severe mental illness requiring immediate emergency admission. Intervention: ICM (according to the ACT model) vs acute admission to a psychiatric hospital.
Stultz 2014	Allocation: randomised

Study	Reason for exclusion
	<p>Participants: patients in need for acute psychiatric inpatient care</p> <p>Intervention: 1. Community treatment (not specified).</p> <p>2. Hospital admission and inpatient treatment. Control group not community treated.</p> <p>*Trial status: ongoing (trial registration form only).</p>
Sungur 2011	<p>Allocation: randomised.</p> <p>Participants: between the ages of 18 and 45 years; a DSM-IV diagnosis of schizophrenia confirmed by Structured Clinical Interview for DSM-IV (SCID-IV) interviews; duration of illness of less than 10 years; living with a family member the year prior to admission; a resident of Ankara; completed written informed consent approved by the ethics committee (caregivers were also required to provide written informed consent).</p> <p>Intervention: 1. Optimal case management. Caseload: 4:50.</p> <p>2. Routine case management. Caseload: 4:50.</p>
Supereden 2012	<p>Allocation: randomised</p> <p>Participants: patients with nonaffective psychosis who had been with Early Intervention Service (EIS) between 1 and 2 years and who showed a low level of structured activity after at least 1 year of treatment (defined as 30 hours or less per week).</p> <p>Interventions: 1. Social recovery-oriented cognitive behavioural therapy + standard care. Not ICM.</p> <p>2. Standard care.</p>
Susser-New York 1997	<p>Allocation: randomised.</p> <p>Participants: severe mental illness.</p> <p>Interventions: 1. "Critical time intervention": a time-limited approach aimed at stabilising the patient's social support network, designed for transitions from various institutions to the community; the goal is to enhance continuity of care, strengthening the individual's long-term ties to services. Not ICM.</p> <p>2. Standard care: community-based services.</p>
Tang 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Carers-provided home-based rehabilitation intervention.</p> <p>2. Professional-provided home visit.</p> <p>Not ICM.</p>
Tao-China 2004	<p>Allocation: randomised.</p> <p>Participants: people with schizophrenia, admitted to hospital.</p> <p>Intervention: provided pre-discharging. Hospital, not community, based.</p>
Teague-New Hampshire 1995	Allocation: not randomised.
Thornicroft-Maryland 1991	Allocation: not randomised.
Tomita 2011	<p>Allocation: randomised.</p> <p>Participants: 150 previously homeless individuals with severe and persistent mental illness after discharge from inpatient treatment.</p>

Study	Reason for exclusion
	Intervention: Critical Time Intervention (primarily designed to prevent homelessness) is not ICM; it is transitional care from hospital to full engagement with community mental health services.
Toro-New York 1997	Allocation: randomised. Participants: a minority of the participants suffered from severe mental illness; around 80% were simply homeless.
Tyrer-UK 1995	Allocation: randomised Participants: psychotic illness. Intervention: 1. ICM. 2. Standard treatment: provided by social and psychiatric services. The case managers for the treatment group were also the case managers for the control group (see Excluded studies section).
van Meijel 2003	Allocation: randomised Participants: adults with severe mental illness. Interventions: 1. Relapse Prevention Plan: includes detecting the early signs of difficulty and actions that could be taken when psychotic relapse threatens (not ICM). 2. Usual care.
Vesterager 2011	Allocation: randomised, parallel-group clinical trial. Participants: outpatients, aged 18 to 35 years, diagnosed with first-episode psychosis or schizotypal disorder within F2 spectrum in ICD-10. Participants were in a postacute phase of illness, had sufficient comprehension of Danish (i.e. did not need an interpreter), and provided written informed consent. Intervention: 1. OPUS + cognitive training vs 2. OPUS only. OPUS consists of affiliation with a primary contact person, involvement of family, possibility of psycho-education and social skills training. Depending on individual needs, patients are can take part in group therapy, either social skills training or cognitive behavioural therapy. No relevant comparison.
Vincent-Ohio 1977	Allocation: not randomised, alternative assignment.
Wang 2008a	Not randomised.
Wang F 2012	Allocation: randomised. Participants: chronic schizophrenia. Interventions: 1. Family rehabilitation intervention. 2. Care as usual. Not ICM.
Wang FY 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Family rehabilitation intervention. 2. Care as usual. Not ICM.
Wang YL 2012	Allocation: randomised.

Study	Reason for exclusion
	<p>Participants: schizophrenia.</p> <p>Interventions: 1. Family nursing intervention.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Wang YQ 2010a	<p>Allocation: randomised.</p> <p>Participants: inpatients with schizophrenia.</p> <p>Interventions: hospital-based intervention.</p> <p>Assessed by Sai Zhao.</p>
Wang Z 2012	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Family intervention plus antipsychotics.</p> <p>2. Antipsychotics alone.</p> <p>Not ICM.</p>
Wen 2010	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: family interventions; the nurses made an individualised treatment plan for each participant, then implemented intervention according to the plan. The effects of the intervention on outcomes were evaluated and treatments revised according to specific problems of the participant.</p> <p>Assessed by Sai Zhao.</p>
Wirshing 2006	<p>Allocation: randomised.</p> <p>Participants: all with a diagnosis of DSM-IV schizophrenia or schizoaffective disorder.</p> <p>Interventions: not ICM (Community Re-Entry Program), not outpatient/community setting (delivered during brief hospitalisations).</p>
Wood-New Zealand 1994	<p>Allocation: not randomised, case control study.</p>
Wu 2013	<p>Allocation: randomised.</p> <p>Participants: schizophrenia.</p> <p>Interventions: 1. Group psychotherapy combined with family intervention.</p> <p>2. Care as usual.</p> <p>Not ICM.</p>
Wunderink 2015	<p>Allocation: randomised.</p> <p>Participants: severely mentally ill patients.</p> <p>Interventions: 1. Enhanced Assertive Community Treatment: ACT enhanced with evidence-based interventions.</p> <p>2. Standard care.</p> <p>*Trial status is ongoing (trial registration form only).</p>

Study	Reason for exclusion
Xing 2013	Allocation: randomised. Participants: chronic schizophrenia. Interventions: 1. Rehabilitation training. 2. Control group. Not ICM.
Yang 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Rehabilitation training. 2. Treatment as usual. Not ICM.
Yao 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Case management model. 2. No case management. Not ICM.
Yao 2014	Allocation: randomised. Participants: chronic schizophrenia. Interventions: 1. Day nursing care in community. 2. Care as usual. Not ICM.
Yu 2011	Study design: not randomised. Allocation based on admission sequences. Assessed by Sai Zhao.
Yuan 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Case management model. 2. Conventional community management model. Caseload not reported.
Zhang SY 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Enhanced family nursing intervention. 2. Conventional family intervention. Not ICM.

Study	Reason for exclusion
Zhang YF 2012	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Community visit and antipsychotics. 2. Antipsychotics alone. Not ICM.
Zhang YM 2013	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Comprehensive intervention (family visit, medicine compliance intervention, family intervention, crisis intervention). 2. Telephone follow-up. Not ICM.
Zhao HM 2013	Allocation: randomisation. Participants: schizophrenia. Intervention: 1. Comprehensive community rehabilitation intervention. 2. Standard drug therapy. Caseload not reported.
Zhu 2009	Allocation: not randomised. Allocation based on admission sequences. Assessed by Sai Zhao.
Zhu DP 2012	Allocation: randomised. Participants: schizophrenia. Interventions: 1. Family intervention plus antipsychotics. 2. Antipsychotics alone. Not ICM.

ACT - Assertive Community Treatment

CBT - cognitive behavioural therapy

CMHA - Community Mental Health Agencies

CMHT: Community Mental Health Team

CPA - Care Programme Approach: the CPA is a combination of non-ICM and care from a CMHT, introduced in England in the mid-1990s and becoming standard care thereafter

DSM - Diagnostic and Statistical Manual of Mental Disorders

ICD-10 - 10th revision of the International Statistical Classification of Diseases and Related Health Problems

ICM - Intensive Case Management

non-ICM - non-Intensive Case Management

PACT - Programme of Assertive Community Treatment

RCT - randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Bonsack-Switzerland

Methods	Allocation: randomised.
Participants	Aged 18 to 65 years, following psychiatric hospitalisation.
Interventions	1. Transitional Case Management. 2. Standard care.
Outcomes	Adherence to outpatient care; working alliance; number of readmissions; degree of psychiatric symptoms (SCL-90 R); etc.
Notes	ClinicalTrials.gov (clinicaltrials.gov/ct2/show/NCT02258737): "This study has been completed."; no results posted or publication announced. Written to investigator for clarification.

ChiCTR-TRC-13003407

Methods	Allocation: randomised.
Participants	Adults with severe mental illness.
Interventions	1. Assertive Community Treatment. 2. Standard community service.
Outcomes	
Notes	Insufficient information in trial registry entry to determine inclusion/exclusion. Written to investigator for clarification.

Dick-UK 2000

Methods	Allocation: randomised.
Participants	People with chronic functional psychosis.
Interventions	Community rehabilitation programme.
Outcomes	
Notes	Not available as full report, written to investigator for clarification, awaiting response.

Guo-China 2003

Methods	Allocation: randomised, no further details.
Participants	Participants: people with schizophrenia (CCMD-3), living in the community.
Interventions	Intervention: community-based.

Guo-China 2003 (Continued)

1. Experimental intervention: provided by team composed by nurses, social worker; caseload 1:10. Providing: i. Expressed Emotion intervention; ii. psycho-education (how to prevent relapse, how to deal with adverse effects); iii. daily living activity.

2. Standard care. Awaiting further information on comparison treatment.

Outcomes	Outcomes: awaiting for data extraction.
Notes	In Chinese. Written to investigator for clarification.

Kawanishi-Japan 2014

Methods	Allocation: randomised; multicentre.
Participants	People with mental health problems who have attempted suicide.
Interventions	1. Assertive case management 2. Enhanced usual care.
Outcomes	
Notes	Caseload not reported. Written to investigator for clarification.

Kossobudzka-Poland 2001

Methods	Allocation: randomised.
Participants	People with chronic psychoses, mostly schizophrenia; N = 107.
Interventions	1. Mobile community teams. 2. Traditional psychiatric care.
Outcomes	
Notes	To be assessed, in Polish.

Li 2010

Methods	Allocation: randomised.
Participants	People with chronic schizophrenia.
Interventions	Interventions: community-based integrated intervention includes supportive psychosocial therapy, family therapy, rehabilitation training, and antipsychotics. Caseload: the author did not state the caseload.

Li 2010 (Continued)

Outcomes

Notes	In Chinese. Assessed by Sai Zhao. (Li 2010). Insufficient information to determine inclusion or exclusion; written to investigator.
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Linszen-Netherlands 2002

Methods	Allocation: randomised.
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Participants	Young patients with recent-onset psychosis.
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Interventions	
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Outcomes	
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Notes	Not enough information in the published conference abstracts to determine intervention or age of participants (described as "young"). Written to authors for more published reports.
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Manuel 2009

Methods	
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Participants	
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Interventions	
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Outcomes	
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Notes	To be assessed. PDF not yet retrieved.
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O'Donnell-Australia 1999

Methods	Allocation: randomised.
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Participants	Clients with schizophrenia and bipolar disorder, 18 to 65 years of age, referred for case management by community health services.
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Interventions	1. Standard case management. 2. Client-focused case management. 3. Client-focused case management plus consumer advocacy.
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Outcomes	
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Notes	Written to authors asking for caseload.
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Rivera-New York 2007

Methods	Allocation: randomised.
Participants	203 clients with severe and persistent mental illness.
Interventions	ICM vs peer-enhanced ICM vs clinic-based ICM.
Outcomes	
Notes	Written to authors asking for caseload.

Ruggeri-Italy

Methods	Allocation: randomised.
Participants	Adults with severe mental illness.
Interventions	1. Multi-element psychosocial intervention. 2. Standard care.
Outcomes	
Notes	Caseloads not reported. Unclear whether intervention is ICM. Written to authors for clarification.

Sells-Connecticut 2006

Methods	Allocation: randomised. Design: multicentre (2 cities in Connecticut, not stated which ones). Duration: 12 months. Country: Connecticut, USA. Not entering meta-regression.
Participants	Diagnosis*: severe mental illness (schizophrenia spectrum disorder, major mood disorder, or both). N = 137. Setting: public mental health centres, urban site. Age: 20 to 63 years, mean 41 yrs (SD 9 years). Sex: 61% M. Ethnicity: African-American 28.5%. History: i. treatment disengagement, ii. informed consent provided.
Interventions	1. ICM**: Case management services from peer providers partnered with ACT teams. Peer case manager. Caseload: 1:10-12. N = 68. 2. Non-ICM***: regular case management from regular providers. Caseload: ~ 1:20-24. N = 69.
Outcomes	Unable to use - Service use: 26-item self reported measure of service use (not peer reviewed). Level of engagement: rated using 1 item of Level of Care Utilization System (subscale not validated). Social functioning: subscale from Addiction Severity Index (ASI) (subscale not peer reviewed, data not reported).

Sells-Connecticut 2006 (Continued)

Client-counsellor relationship: modified version of Barrett-Lennard Relationship Inventory (BLRI) (not peer reviewed, modified by authors).

Notes	<p>*61% psychiatric disorder; 63% major mood disorder; 72% substance abuse disorder; 70% co-occurring disorder (psychotic disorder, mood disorder, or both plus substance abuse disorder).</p> <p>**All peer staff had publicly disclosed histories of severe mental illness and some of co-occurring drug use disorder. They received broad-based training concerning the provision of case management service.</p> <p>***Regular providers worked alongside peer providers on the same treatment teams.</p> <p>1 additional paper requested.</p>
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Sharifi-Iran 2009

Methods	Allocation: randomised.
Participants	People with severe mental disorders. N = 120.
Interventions	<p>1. Home aftercare service: home visits by multidisciplinary teams, including general practitioners, nurses, and social workers supervised by psychiatrists.</p> <p>2. Treatment as usual.</p>
Outcomes	
Notes	<p>Conference abstract, not enough information to determine inclusion/exclusion.</p> <p>Written to authors for clarification.</p>

Su-China 2008

Methods	Allocation: randomised.
Participants	People with schizophrenia.
Interventions	<p>Interventions: community-based integrated intervention includes rehabilitation consultant, develop individualised rehabilitation plan, telephone follow-up, and family psycho-education.</p> <p>Caseload: the author did not state the caseload.</p>
Outcomes	
Notes	In Chinese. To be assessed.

Tan-China 2005

Methods	Allocation: randomised, no further details.
Participants	Diagnosis: schizophrenia.
Interventions	<p>1. Experimental intervention: provided by team, caseload not reported. Providing: i. antipsychotic drug treatment; ii. family intervention; iii. occupational intervention; iv. rehabilitation intervention.</p>

Tan-China 2005 *(Continued)*

2. Control intervention: no details provided.

Outcomes	Awaiting further information from author about experimental intervention caseload.
Notes	In Chinese. To be assessed.

Verhaegh-Netherlands 2006

Methods	Allocation: unclear.
Participants	People with first-episode psychosis, 18 to 35 years of age.
Interventions	1. ACT with different modalities. 2. Care as usual.
Outcomes	
Notes	Unclear if this is a randomised study (caseload is also unclear). Main paper in Dutch to be assessed. Written to authors for clarification.

Wang 2009

Methods	Allocation: randomised.
Participants	People with schizophrenia.
Interventions	Interventions: community-based integrated intervention includes psycho-education, direction on use of medication, social rehabilitation training, psychological intervention, and crisis intervention. Caseload: the author did not state the caseload.
Outcomes	
Notes	In Chinese. Assessed by Sai Zhao. (Wang 2009). Insufficient information to determine inclusion or exclusion; written to investigator.

Zhang 2009

Methods	Allocation: randomised.
Participants	People with schizophrenia.
Interventions	Interventions: community-based integrated intervention includes psycho-education, life skill training, and cognitive therapy. Caseload: the author did not state the caseload.
Outcomes	
Notes	In Chinese. Assessed by Sai Zhao. (Zhang 2009).

Zhang 2009 (Continued)

Insufficient information to determine inclusion or exclusion; written to investigator.

Zoeteman-Netherlands

Methods	Allocation: randomised.
Participants	Homeless patients with severe mental illness.
Interventions	1. ACT. 2. Case management.
Outcomes	
Notes	Trial completed, but no results or publication found. Caseload unclear. Written to investigator for clarification.

ACT - Assertive Community Treatment
CCMD-3 - Chinese Classification of Mental Disorders
ICM - Intensive Case Management
SD - standard deviation

Characteristics of ongoing studies [ordered by study ID]

Koike-Japan

Trial name or title	Comprehensive early intervention for patients with first-episode psychosis in Japan (J-CAP): study protocol for a randomised controlled trial.
Methods	Allocation: randomised. Blinding: Only assessors blinded.
Participants	People who received a diagnosis of F2 or F3 (ICD-10), with psychotic symptoms.
Interventions	1. Comprehensive community-based care. 2. Standard care. N = expected 150. Age: 15 to 35 years.
Outcomes	Primary outcome: Global Assessment of Functioning (GAF-F) scores at the first endpoint. Secondary outcomes: GAF-F at the second and last endpoints, symptom domain of Global Assessment of Functioning (GAF-S), PANSS, the World Health Organization Quality of Life 26-item version (WHOQOL-BREF), Brief Evaluation of Medication Influences and Beliefs (BEMIB), care satisfaction of participants and their families, educational and vocational recovery rates, remission rate, readmission rate, lost to follow-up rate, self harm and suicide attempt rate, suicide rate, engagement behaviour, and direct and indirect costs at each endpoint.
Starting date	March 2011.
Contact information	skoike-tky@umin.ac.jp; nishida-at@igakuken.or.jp

Koike-Japan (Continued)

Notes The University Hospital Medical Information Network Clinical Trials Registry (No. UMIN000005092).
Expected completion date: September 2017.

Lutgens 2015

Trial name or title	A five-year randomized parallel and blinded clinical trial of an extended specialized early intervention vs. regular care in the early phase of psychotic disorders.
Methods	Allocation: randomised.
Participants	People with first-episode psychosis.
Interventions	1. Extended Specialized Early Intervention: modified assertive case management; psycho-education for families; multiple-family intervention; cognitive behavioural therapy; and substance abuse treatment and monitoring. 2. Regular care.
Outcomes	Primary outcomes: proportion of participants in complete remission and mean length of remission achieved. Secondary outcomes: relapse, functioning, quality of life.
Starting date	
Contact information	Danyael Lutgens: Danyael.Lutgens@douglas.mcgill.ca
Notes	

Malla-Canada

Trial name or title	Extending specialized early intervention service from 2 to 5 years: a randomised controlled trial.
Methods	Allocation: randomised.
Participants	Adults with severe mental illness.
Interventions	1. Extended Specialized Early Intervention. 2. Usual care.
Outcomes	Rates of sustained engagement, length of remission, health economic indices.
Starting date	
Contact information	Ashok Malla: ashok.malla@mcgill.ca
Notes	Conference abstracts with brief interim results only.

NCT01313052

Trial name or title	Forensic Assertive Community Treatment: an emerging model of service delivery (FACT).
Methods	Allocation: randomised, open, and parallel.
Participants	Individuals diagnosed with any psychotic disorder such as schizophrenia, schizoaffective disorder, bipolar disorder with psychotic features, depressive disorder with psychotic features, and psychotic disorder, not otherwise specified, who currently face misdemeanor or violation charges and have not yet been sentenced; N = 53.
Interventions	<p>1. Forensic Assertive Community Treatment (FACT): services of an Assertive Community Treatment team and close supervision of a judge trained in the FACT model.</p> <p>2. Enhanced treatment as usual: expedited appointment at a clinic specialising in the treatment of psychotic disorders; services of a therapist, psychiatrist, and case manager.</p>
Outcomes	Jail recidivism; mental health service utilisation.
Starting date	May 2008.
Contact information	Steven Lamberti, University of Rochester.
Notes	<p>Completed, no results posted, no publications found.</p> <p>Written to author for further information. Received email from S. Lamberti on 30 December 2015 stating that they are unable to share the results at this time as they are being prepared for publication. Awaiting publication.</p>

RISE - Ethiopia

Trial name or title	RISE (Rehabilitation Intervention for People With Schizophrenia in Ethiopia).
Methods	Cluster randomised trial.
Participants	Adults with a diagnosis of schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder, or schizophreniform disorder) using (DSM-IV) criteria.
Interventions	<p>1. Communitybased rehabilitation: delivered to participants and their caregivers at their home, comprising psycho-education, adherence support, rehabilitation (including self care and social skills), family support groups, and accessing existing community organisations. The intervention also involves community awareness raising and education and mobilisation of community leaders; antipsychotic medication prescribed by a nurse or clinical officer in a health centre; and basic psycho-education.</p> <p>2. Facility-based usual care: antipsychotic medication prescribed by a nurse or clinical officer in a health centre and basic psycho-education.</p>
Outcomes	Disability, symptom severity, Clinical Global Impression, relapse, functioning, economic activity of participant (employment, income, and household work), medication adherence, engagement with facility-based care, proportion with human rights problems, nutritional status (BMI), serious adverse events, etc.
Starting date	September 2015.
Contact information	<p>Mary De Silva, PhD MSc, London School of Hygiene and Tropical Medicine.</p> <p>Abewaw Fekadu, Addis Ababa University Department of Psychiatry.</p>

RISE - Ethiopia (Continued)

Notes Currently recruiting.

Walsh-Connecticut

Trial name or title	Specialized Treatment Early in Psychosis (STEP).
Methods	Allocation: randomised. Blinding: open label.
Participants	Diagnosis: schizophrenia spectrum psychosis or affective psychosis (DSM-IV, SCID). N = expected 200. Age: 16 to 45 years. History: ≤ 8 weeks of received antipsychotic treatment lifetime, informed consent, no psychosis believed due to substance use.
Interventions	1. Specialised early treatment: including individual case management, antipsychotic prescription, multifamily group therapy, group cognitive behavioural therapy, and cognitive remediation. 2. Standard care: usual referral to CMHC.
Outcomes	Primary outcomes: service use: rehospitalisation (measured every 6 months for 5 yrs). Secondary outcomes: relapse, overall functioning, quality of life, education and employment status, treatment satisfaction, adherence, substance use, adverse effects (including self harm and violence), medication side effect, economic measures.
Starting date	March 2006.
Contact information	barbara.walsh@yale.edu; vinod.srihari@yale.edu
Notes	ClinicalTrials.gov identifier: NCT00309452 Expected completion: September 2011. NOTE: Results are available in Srihari VH, Tek C, Kucukgoncu S, Phutane VH, Breitborde NJ, Pollard J, Ozkan B, Saksa J, Walsh BC, Woods SW. First-episode services for psychotic disorders in the U.S. public sector: a pragmatic randomized controlled trial. Psychiatric Services 2015 Jul;66(7):705-12.

BMI - body mass index

CMHC - Community Mental Health Centre

DSM - Diagnostic and Statistical Manual of Mental Disorders

ICD-10 - International Statistical Classification of Diseases and Related Health Problems 10th Revision

PANSS - Positive and Negative Syndrome Scale

SCID - Structured Clinical Interview for DSM-IV (First 1997)

DATA AND ANALYSES

Comparison 1. Intensive Case Management versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Service use: 1. Average number of days in hospital per month - by about 24 months	24	3595	Mean Difference (IV, Random, 95% CI)	-0.86 [-1.37, -0.34]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 skewed data (sample size $\geq$ 200)	5	1812	Mean Difference (IV, Random, 95% CI)	-0.46 [-0.95, 0.03]
1.2 skewed data (sample size < 200)	19	1783	Mean Difference (IV, Random, 95% CI)	-1.01 [-1.74, -0.28]
2 Service use: 1a. Number of days in hospital - by follow-up (skewed data, sample size $\geq$ 200)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 by medium term FUP (3 years) (previous year)	1	547	Mean Difference (IV, Random, 95% CI)	0.10 [-10.26, 10.46]
2.2 by long term FUP (8 years) (previous year)	1	547	Mean Difference (IV, Random, 95% CI)	4.30 [-4.63, 13.23]
3 Service use: 2. Not remaining in contact with psychiatric services	9	1633	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.30, 0.61]
3.1 by short term	1	95	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.28, 1.05]
3.2 by medium term	3	1063	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.36, 0.71]
3.3 by long term	5	475	Risk Ratio (M-H, Random, 95% CI)	0.27 [0.11, 0.66]
4 Service use: 3a. Admitted to hospital	16		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 by short term	2	244	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.22, 1.69]
4.2 by medium term	5	1303	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.77, 0.93]
4.3 by long term	11	1516	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.74, 1.23]
4.4 by long term- during previous 12 months	1	547	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.52, 0.86]
4.5 by short term FUP - unplanned admission through Emergency Department	1	62	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.07, 15.28]
5 Service use: 3b. Average number of admissions per month (skewed data)			Other data	No numeric data
5.1 by medium term			Other data	No numeric data
5.2 by long term			Other data	No numeric data
6 Service use: 4a. Admitted to ER - by long term	1	178	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.72, 1.76]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7 Service use: 4b. Average number of admissions to ER (skewed data) - by medium term			Other data	No numeric data
8 Service use: 5a. Received day hospital care - by short term FUP	1	62	Risk Ratio (M-H, Random, 95% CI)	2.0 [0.19, 20.93]
9 Service use: 5b. Outpatient visits - by short term FUP (6 months)	1	62	Mean Difference (IV, Random, 95% CI)	0.29 [-0.14, 0.72]
10 Service use: 5c. Outpatient visits - by medium term (skewed data)			Other data	No numeric data
11 Service use: 5d. Received home visits - by short term FUP	1	62	Mean Difference (IV, Random, 95% CI)	4.32 [3.42, 5.22]
12 Adverse event: 1a. Death - any cause	14		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12.1 by short term	2	161	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.16, 6.91]
12.2 by medium term	6	901	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.23, 2.62]
12.3 by long term	9	1456	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.48, 1.47]
12.4 by medium term FUP (3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.59 [0.22, 1.61]
12.5 by long term FUP (8 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.45, 1.88]
13 Adverse event: 1b. Death - suicide	12		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
13.1 by short term	2	127	Risk Ratio (M-H, Random, 95% CI)	0.35 [0.04, 3.27]
13.2 by medium term	4	819	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.17, 5.60]
13.3 by long term	9	1456	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.31, 1.51]
13.4 by medium term FUP (3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.17, 3.28]
14 Global state: 1. Leaving the study early	21		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
14.1 by short term	5	598	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.44, 1.41]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14.2 by medium term	8	1699	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.51, 0.70]
14.3 by long term	13	1798	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.58, 0.79]
14.4 by medium term FUP (3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.84, 1.21]
14.5 by long term FUP (8 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.70, 1.09]
15 Global state: 2. Average endpoint score (GAF, high = good)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
15.1 by short term	4	797	Mean Difference (IV, Random, 95% CI)	2.07 [0.28, 3.86]
15.2 by medium term	3	722	Mean Difference (IV, Random, 95% CI)	0.09 [-3.11, 3.28]
15.3 by long term	5	818	Mean Difference (IV, Random, 95% CI)	3.41 [1.66, 5.16]
16 Global state: 3. Not compliant with medication - by long term	1	71	Risk Ratio (M-H, Random, 95% CI)	0.35 [0.15, 0.81]
17 Social functioning: 1a. Contact with legal system (various measurements)	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
17.1 by short term - contact with the police	1	61	Risk Ratio (M-H, Random, 95% CI)	2.57 [0.73, 9.04]
17.2 by medium term - arrested	3	604	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.61, 1.90]
17.3 by medium term - contact with the police	1	88	Risk Ratio (M-H, Random, 95% CI)	0.23 [0.09, 0.55]
17.4 by medium term - imprisoned	4	804	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.39, 1.64]
17.5 by long term - arrested	1	178	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.32, 1.37]
17.6 by long term - imprisoned	5	908	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.45, 1.65]
18 Social functioning: 1b. Mean contacts with legal system (skewed data) - by medium term			Other data	No numeric data
18.1 Bookings			Other data	No numeric data
18.2 Jail days			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
18.3 Convictions			Other data	No numeric data
19 Social functioning: 2. Employment status (various measurements)	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
19.1 by medium term - not competitively employed at the end of the trial	1	88	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.91, 1.10]
19.2 by medium term - not employed at the end of the trial	4	1136	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.79, 1.00]
19.3 by long term - not employed at the end of the trial	4	1129	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.49, 1.00]
19.4 by long term - not working/studying in the previous year	1	547	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.74, 0.99]
19.5 by medium term FUP (3 years) - not working/studying in the previous year	1	547	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.90, 1.16]
19.6 by long term FUP (8 years) - not working/studying in the previous year	1	547	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.88, 1.11]
20 Social functioning: 3a. Accommodation status (various measurements)	10		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
20.1 by short term - homelessness	1	95	Risk Ratio (M-H, Random, 95% CI)	0.04 [0.00, 0.70]
20.2 by medium term - homelessness	1	88	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.03, 2.95]
20.3 by medium term - not living independently	5	1303	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.66, 0.97]
20.4 by long term - homelessness	3	418	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.34, 1.82]
20.5 by long term - not living independently	4	1185	Risk Ratio (M-H, Random, 95% CI)	0.65 [0.49, 0.88]
20.6 by long term - not living in stable accommodation	1	168	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.65, 0.98]
21 Social functioning: 3b. Accommodation status: mean number of days in supported house (skewed data, sample size $\geq$ 200)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
21.1 by long term (previous year)	1	547	Mean Difference (IV, Random, 95% CI)	0.30 [-13.98, 14.58]
21.2 by medium term FUP (3 years) (previous year)	1	547	Mean Difference (IV, Random, 95% CI)	-22.20 [-38.47, -5.93]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
21.3 by long term FUP (8 years) (previous year)	1	547	Mean Difference (IV, Random, 95% CI)	-6.70 [-19.35, 5.95]
22 Social functioning: 3c. Accommodation status (various measurements, skewed data)			Other data	No numeric data
22.1 by medium term - average days per month in stable accommodation			Other data	No numeric data
22.2 by long term - average days per month in sheltered homes			Other data	No numeric data
23 Social functioning: 4a. Substance abuse	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
23.1 alcohol abuse - by long term	1	547	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.26, 1.17]
23.2 illicit drug abuse - by long term	1	547	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.63, 1.47]
23.3 substance abuse - by medium term FUP (3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.67, 1.24]
24 Social functioning: 4b. Substance abuse (DALI, skewness not detectable) - by medium term			Other data	No numeric data
24.1 alcohol abuse (DALI, -4 to + 6, high = worse)			Other data	No numeric data
24.2 drug abuse (DALI, - 4 to + 4, high = worse)			Other data	No numeric data
25 Social functioning: 4c. Substance abuse - days used per month (skewed data)			Other data	No numeric data
25.1 by medium term			Other data	No numeric data
25.2 by long term			Other data	No numeric data
26 Social functioning: 5a. Average end-point score (various scales)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
26.1 by short term (RFS, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-0.62 [-2.23, 0.99]
26.2 by short term (SAS-adapted version, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-3.34 [-7.55, 0.87]
26.3 by medium term - social role performance (DAS, high = poor)	1	55	Mean Difference (IV, Random, 95% CI)	0.10 [-0.40, 0.60]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
26.4 by medium term (RFS, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-0.86 [-2.72, 1.00]
26.5 by medium term (SAS-adapted version, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-3.30 [-7.83, 1.23]
26.6 by long term - social role performance (DAS, high = poor)	1	58	Mean Difference (IV, Random, 95% CI)	-0.20 [-0.67, 0.27]
26.7 by long term (ISSI, low = poor)	1	62	Mean Difference (IV, Random, 95% CI)	3.20 [0.11, 6.29]
26.8 by long term (RFS, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-2.35 [-4.05, -0.65]
26.9 by long term (SAS-adapted version, low = poor)	1	80	Mean Difference (IV, Random, 95% CI)	-2.75 [-7.13, 1.63]
26.10 by long term (Strauss-Carpenter Scale, low = poor)	1	60	Mean Difference (IV, Random, 95% CI)	0.10 [-1.17, 1.37]
27 Social functioning: 5b. Average endpoint score (various scales, skewed data)			Other data	No numeric data
27.1 by short term (SAS, high = poor)			Other data	No numeric data
27.2 by medium term (SAS, high = poor)			Other data	No numeric data
27.3 by long term (SAS, high = poor)			Other data	No numeric data
27.4 by long term (REHAB, high = poor)			Other data	No numeric data
28 Mental state: 1a. General symptoms - average endpoint score (various scales)	4		Mean Difference (IV, Random, 95% CI)	Subtotals only
28.1 by short term (BPRS-18 items, high = poor)	2	668	Mean Difference (IV, Random, 95% CI)	-1.56 [-6.85, 3.73]
28.2 by short term (BSI, high = poor)	2	668	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.19, 0.06]
28.3 by short term (CSI, low = poor)	1	125	Mean Difference (IV, Random, 95% CI)	-0.56 [-0.84, -0.28]
28.4 by medium term (BPRS-18 items, high = poor)	2	662	Mean Difference (IV, Random, 95% CI)	-0.96 [-2.42, 0.51]
28.5 by medium term (BSI, high = poor)	2	662	Mean Difference (IV, Random, 95% CI)	-0.02 [-0.15, 0.10]
28.6 medium term (CSI, low = poor)	1	125	Mean Difference (IV, Random, 95% CI)	-0.35 [-0.65, -0.05]
28.7 by long term (BPRS-18 items, high = poor)	3	777	Mean Difference (IV, Random, 95% CI)	-1.48 [-3.69, 0.74]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
28.8 by long term (BSI, high = poor)	2	647	Mean Difference (IV, Random, 95% CI)	-0.18 [-0.31, -0.06]
29 Mental state: 1b. General symptoms - mean change from baseline (CSI, low = poor) - by long term	1	168	Mean Difference (IV, Random, 95% CI)	-0.32 [-0.53, -0.11]
30 Mental state: 1c. General symptoms - average endpoint score (various scales, skewed data)			Other data	No numeric data
30.1 by short term (BPRS-24 items, high = poor)			Other data	No numeric data
30.2 by short term (PSE, high = poor)			Other data	No numeric data
30.4 by medium term (BPRS-24 items, high = poor)			Other data	No numeric data
30.5 by medium term (CPRS, high = poor)			Other data	No numeric data
30.6 by medium term (PSE, high = poor)			Other data	No numeric data
30.8 by long term (BPRS-18 items, high = poor)			Other data	No numeric data
30.9 by long term (BPRS-24 items, high = poor)			Other data	No numeric data
30.10 by long term (CPRS, high = poor)			Other data	No numeric data
30.11 by long term (PSE, high = poor)			Other data	No numeric data
30.12 by long term (SCL-90, high = poor)			Other data	No numeric data
31 Mental state: 2a. Specific symptoms - depression at follow up interview	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
31.1 by medium term	1	547	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.56, 1.04]
31.2 by long term	1	547	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.57, 1.21]
31.3 by medium term FUP (3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.91, 1.72]
32 Mental state: 2b. Specific symptoms - average endpoint score (various scales, skewed data, sample size ≥ 200)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
32.1 by long term - positive symptoms (SAPS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	-0.22 [-0.45, 0.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
32.2 by long term - negative symptoms (SANS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	-0.42 [-0.62, -0.22]
32.3 by medium term FUP (3 years) - positive symptoms (SAPS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	0.12 [-0.15, 0.39]
32.4 by medium term FUP (3 years) - negative symptoms (SANS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.33, 0.13]
32.5 by long term FUP (8 years) - positive symptoms (SAPS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	0.03 [-0.21, 0.27]
32.6 by long term FUP (8 years) - negative symptoms (SANS, high = poor)	1	547	Mean Difference (IV, Random, 95% CI)	0.06 [-0.13, 0.25]
33 Mental state: 2c. Specific symptoms - average endpoint score (various scales, skewed data)			Other data	No numeric data
33.3 by medium term - depression symptoms (BDI, high = poor)			Other data	No numeric data
33.4 by medium term - negative symptoms (SANS, high = poor)			Other data	No numeric data
33.7 by long term - depression symptoms (BDI, high = poor)			Other data	No numeric data
33.11 by long term - negative symptoms (SANS, high = poor)			Other data	No numeric data
34 Behaviour: 1. Specific behaviour - self-harm	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
34.1 by medium term	2	620	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.61, 1.59]
34.2 by long term	1	123	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.14, 6.55]
34.3 attempted suicide - by long term (during last 12 months)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.47, 1.38]
34.4 attempted suicide - by medium term FUP (3 years) (during last 3 years)	1	547	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.56, 1.62]
35 Behaviour: 2. Social behaviour - average endpoint score (SBS, high = poor)			Other data	No numeric data
35.1 by medium term			Other data	No numeric data
35.2 by long term			Other data	No numeric data
36 Quality of life: 1a. Average endpoint score (various scales)	7		Mean Difference (IV, Random, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
36.1 by short term - general well-being (QOLI, high = better)	1	125	Mean Difference (IV, Random, 95% CI)	0.53 [0.09, 0.97]
36.2 by medium term (LQoLP, high = better)	1	52	Mean Difference (IV, Random, 95% CI)	0.09 [-0.60, 0.78]
36.3 by medium term (MANSA - range 1-7, high = better)	1	81	Mean Difference (IV, Random, 95% CI)	0.20 [-0.29, 0.69]
36.4 by long term (LQoLP, high = better)	3	274	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.38, 0.12]
36.5 by long term (QOLI, high = better)	2	132	Mean Difference (IV, Random, 95% CI)	0.09 [-0.24, 0.42]
37 Quality of life: 1b. Mean change from baseline (QOLI, high = better, skewed data) - by long term			Other data	No numeric data
38 Participant satisfaction: 1a. Average endpoint score (CSQ, high = better)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
38.1 by short term	1	61	Mean Difference (IV, Random, 95% CI)	6.20 [2.60, 9.80]
38.2 by medium term	2	500	Mean Difference (IV, Random, 95% CI)	1.93 [0.86, 3.01]
38.3 by long term	2	423	Mean Difference (IV, Random, 95% CI)	3.23 [2.31, 4.14]
39 Participants satisfaction: 1b. Average endpoint score (CSQ, high = better, skewed data) - by short term			Other data	No numeric data
40 Participants need: 1. Average endpoint score (various scales, skewed data)			Other data	No numeric data
40.1 by medium term - met needs (CANSAS, high = better)			Other data	No numeric data
40.2 by medium term - unmet needs (CANSAS, high = poor)			Other data	No numeric data
40.4 by long term (CAN, high = poor)			Other data	No numeric data
41 Costs: 1a. Direct costs of psychiatric hospital care - by medium term (Unit cost = USD, fiscal year 1990)	2	426	Mean Difference (IV, Random, 95% CI)	-143.74 [-272.40, -15.08]
42 Costs: 1b. Direct costs of psychiatric hospital care - skewed data			Other data	No numeric data
42.1 by medium term			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
42.2 by long term			Other data	No numeric data
43 Costs: 2a. Direct healthcare costs - by long term (Unit cost = USD, fiscal year 1988)	2	873	Mean Difference (IV, Random, 95% CI)	-529.24 [-2143.59, 1085.10]
44 Costs: 2b. Direct healthcare costs - skewed data			Other data	No numeric data
44.1 by medium term			Other data	No numeric data
44.2 by short term FUP			Other data	No numeric data
45 Costs: 3. Direct costs - other data - skewed data			Other data	No numeric data
45.1 all care - by short term			Other data	No numeric data
45.2 all care - by medium term			Other data	No numeric data
45.3 all care - by long term			Other data	No numeric data
45.4 specific - outpatient care - by medium term			Other data	No numeric data
45.5 specific - prison - by medium term			Other data	No numeric data

Analysis 1.1. Comparison 1 Intensive Case Management versus standard care, Outcome 1 Service use: 1. Average number of days in hospital per month - by about 24 months.

Study or subgroup	INTENSIVE CASE MANAGEMENT		STANDARD CARE		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		
1.1.1 skewed data (sample size ≥ 200)							
Chandler-California1 (A)	102	0.5 (2.3)	101	0.8 (1.8)		6.82%	-0.31[-0.89,0.27]
Chandler-California1 (B)	115	0.7 (2.6)	114	1 (2.1)		6.77%	-0.29[-0.89,0.31]
OPUS-Denmark 1999	263	5.1 (7.7)	244	6.6 (8.7)		4.72%	-1.46[-2.9,-0.02]
Rosenheck-USA-GMS	271	4 (4.1)	257	4.2 (4.6)		6.46%	-0.13[-0.87,0.61]
Rosenheck-USA-NP	183	8.9 (10.5)	162	11.7 (12.4)		2.79%	-2.75[-5.19,-0.31]
Subtotal ***	934		878			27.56%	-0.46[-0.95,0.03]
Heterogeneity: Tau ² =0.11; Chi ² =6.36, df=4(P=0.17); I ² =37.08%							
Test for overall effect: Z=1.85(P=0.06)							
1.1.2 skewed data (sample size < 200)							
Audini-UK 1994	33	1 (2.8)	33	0.9 (2)		5.34%	0.02[-1.17,1.21]
Bjorkman-Sweden 2002	33	0.8 (3.1)	44	2.2 (4.1)		4.29%	-1.32[-2.94,0.3]
Bond-Chicago1 1990	42	3.2 (4.6)	40	5.3 (5.4)		3.21%	-2.08[-4.25,0.09]
Bond-Indiana1 (A)	29	1.3 (3.2)	32	7.7 (9)		1.82%	-6.44[-9.76,-3.12]
Bond-Indiana1 (B)	34	2.7 (4.5)	30	3.6 (5.2)		2.83%	-0.9[-3.32,1.52]
Bond-Indiana1 (C)	21	0.1 (1.9)	21	3.4 (5)		3.04%	-3.33[-5.61,-1.05]
					-20 -10 0 10 20	Favours control	
					Favours treatment

Analysis 1.2. Comparison 1 Intensive Case Management versus standard care, Outcome 2 Service use: 1a. Number of days in hospital - by follow -up (skewed data, sample size ≥ 200).

Analysis 1.3. Comparison 1 Intensive Case Management versus standard care, Outcome 3 Service use: 2. Not remaining in contact with psychiatric services.

Analysis 1.4. Comparison 1 Intensive Case Management versus standard care, Outcome 4 Service use: 3a. Admitted to hospital.

Analysis 1.5. Comparison 1 Intensive Case Management versus standard care, Outcome 5 Service use: 3b. Average number of admissions per month (skewed data).

Service use: 3b. Average number of admissions per month (skewed data)

Study	Intervention	Mean	SD	Total	Note
by medium term					
Bond-Chicago1 1990	1. ICM	0.16	0.15	42	
Bond-Chicago1 1990	2. Standard care	0.26	0.23	40	
by long term					
Audini-UK 1994	1. ICM	0.02	0.05*	33	
Audini-UK 1994	2. Standard care	0.03	0.06*	33	* Carried over from Sytema-Netherlands.
Muller-Clemm-Canada 1996	1. ICM	0.09	0.05*	61	
Muller-Clemm-Canada 1996	2. Standard care	0.08	0.06*	57	* Carried over from Sytema-Netherlands.
Sytema-Netherlands 1999	1. ICM	0.05	0.05	58	
Sytema-Netherlands 1999	2. Standard care	0.05	0.06	57	

Analysis 1.6. Comparison 1 Intensive Case Management versus standard care, Outcome 6 Service use: 4a. Admitted to ER - by long term.

Analysis 1.7. Comparison 1 Intensive Case Management versus standard care, Outcome 7 Service use: 4b. Average number of admissions to ER (skewed data) - by medium term.

Service use: 4b. Average number of admissions to ER (skewed data) - by medium term

Study	Intervention	Mean	SD	Total	Note
Jerrell-SCarolina1 1991	1. ICM	0.85	1.7*	40	
Jerrell-SCarolina1 1991	2. Standard care	0.73	3.3*	40	* Carried over from Lehman-Maryland1.
Lehman-Maryland1 1994	1. ICM	0.9	1.7	77	
Lehman-Maryland1 1994	2. Standard care	2	3.3	75	

Analysis 1.8. Comparison 1 Intensive Case Management versus standard care, Outcome 8 Service use: 5a. Received day hospital care - by short term FUP.

Analysis 1.9. Comparison 1 Intensive Case Management versus standard care, Outcome 9 Service use: 5b. Outpatient visits - by short term FUP (6 months).

Analysis 1.10. Comparison 1 Intensive Case Management versus standard care, Outcome 10 Service use: 5c. Outpatient visits - by medium term (skewed data).

Service use: 5c. Outpatient visits - by medium term (skewed data)					
Study	Intervention	Mean	SD	Total	Note
Cusack-North Carolina	ICM	95.9	57.1	72	-
Cusack-North Carolina	Standard care	43.3	47.9	62	-

Analysis 1.11. Comparison 1 Intensive Case Management versus standard care, Outcome 11 Service use: 5d. Received home visits - by short term FUP.

Analysis 1.12. Comparison 1 Intensive Case Management versus standard care, Outcome 12 Adverse event: 1a. Death - any cause.

Analysis 1.13. Comparison 1 Intensive Case Management versus standard care, Outcome 13 Adverse event: 1b. Death - suicide.

Analysis 1.14. Comparison 1 Intensive Case Management versus standard care, Outcome 14 Global state: 1. Leaving the study early.

Analysis 1.15. Comparison 1 Intensive Case Management versus standard care, Outcome 15 Global state: 2. Average endpoint score (GAF, high = good).

Analysis 1.16. Comparison 1 Intensive Case Management versus standard care, Outcome 16 Global state: 3. Not compliant with medication - by long term.

Analysis 1.17. Comparison 1 Intensive Case Management versus standard care, Outcome 17 Social functioning: 1a. Contact with legal system (various measurements).

Analysis 1.18. Comparison 1 Intensive Case Management versus standard care, Outcome 18 Social functioning: 1b. Mean contacts with legal system (skewed data) - by medium term.

Social functioning: 1b. Mean contacts with legal system (skewed data) - by medium term				
Study	Intervention	Mean	SD	Total
Bookings				
Cusack-North Carolina	1. ICM	0.64	1.2	72
Cusack-North Carolina	2. Standard care	1.42	1.86	62
Jail days				
Cusack-North Carolina	1. ICM	18.5	45.3	72
Cusack-North Carolina	2. Standard care	35.3	56.9	62
Convictions				
Cusack-North Carolina	1. ICM	0.75	0.77	72
Cusack-North Carolina	2. Standard care	0.85	1.03	62

Analysis 1.19. Comparison 1 Intensive Case Management versus standard care, Outcome 19 Social functioning: 2. Employment status (various measurements).

Analysis 1.20. Comparison 1 Intensive Case Management versus standard care, Outcome 20 Social functioning: 3a. Accommodation status (various measurements).

**Analysis 1.21. Comparison 1 Intensive Case Management versus standard care, Outcome 21 Social functioning:
3b. Accommodation status: mean number of days in supported house (skewed data, sample size ≥ 200).**

**Analysis 1.22. Comparison 1 Intensive Case Management versus standard care, Outcome
22 Social functioning: 3c. Accommodation status (various measurements, skewed data).**

Social functioning: 3c. Accommodation status (various measurements, skewed data)				
Study	Intervention	Mean	SD	Total
by medium term - average days per month in stable accommodation				
Lehman-Maryland1 1994	1. ICM	17.5	9	77
Lehman-Maryland1 1994	2. Standard care	13.34	9	75
Morse-Missouri3 2005	1. ICM	5.77	7.42	54
Morse-Missouri3 2005	2. Standard care	5.02	8.62	49
by long term - average days per month in sheltered homes				
Morse-Missouri3 2005	1. ICM	17.78	12.68	54
Morse-Missouri3 2005	2. Standard care	12.59	13.27	49
Sytema-Netherlands 1999	1. ICM	2.8	7.4	58
Sytema-Netherlands 1999	2. Standard care	3.6	9.2	57

Analysis 1.23. Comparison 1 Intensive Case Management versus standard care, Outcome 23 Social functioning: 4a. Substance abuse.

Analysis 1.24. Comparison 1 Intensive Case Management versus standard care, Outcome 24 Social functioning: 4b. Substance abuse (DALI, skewness not detectable) - by medium term.

Social functioning: 4b. Substance abuse (DALI, skewness not detectable) - by medium term				
Study	Intervention	Mean	SD	Total
alcohol abuse (DALI, -4 to +6, high = worse)				
Sytema-Netherlands 1999	1. ICM	-0.8	2.7	45
Sytema-Netherlands 1999	2. Standard Care	-1.2	2.4	36
drug abuse (DALI, -4 to +4, high = worse)				
Sytema-Netherlands 1999	1. ICM	-1.4	1.3	45
Sytema-Netherlands 1999	2. Standard Care	-1.8	1.3	36

Analysis 1.25. Comparison 1 Intensive Case Management versus standard care, Outcome 25 Social functioning: 4c. Substance abuse - days used per month (skewed data).

Social functioning: 4c. Substance abuse - days used per month (skewed data)				
Study	Intervention	Mean	SD	Total
by medium term				
Morse-Missouri3 2005	1. ICM	6.25	7.84	54
Morse-Missouri3 2005	2. Standard care	6.34	7.52	49
by long term				
Morse-Missouri3 2005	1. ICM	6.77	8.86	54
Morse-Missouri3 2005	2. Standard care	6.42	7.84	49

Analysis 1.26. Comparison 1 Intensive Case Management versus standard care, Outcome 26 Social functioning: 5a. Average endpoint score (various scales).

Analysis 1.27. Comparison 1 Intensive Case Management versus standard care, Outcome 27 Social functioning: 5b. Average endpoint score (various scales, skewed data).

Social functioning: 5b. Average endpoint score (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by short term (SAS, high = poor)				
Muijen-UK2 1994	1. ICM	3.9	1.1	35
Muijen-UK2 1994	2. Standard care	3.9	1.6	29
by medium term (SAS, high = poor)				
Muijen-UK2 1994	1. ICM	4.3	1.6	29
Muijen-UK2 1994	2. Standard care	3.7	1.5	25
by long term (SAS, high = poor)				
Audini-UK 1994	1. ICM	3.0	1.6	30
Audini-UK 1994	2. Standard care	2.9	1.1	28
Muijen-UK2 1994	1. ICM	3.6	1.4	24
Muijen-UK2 1994	2. Standard care	4.2	1.4	22
by long term (REHAB, high = poor)				
Marshall-UK 1995	1. ICM	31.7	29.3	31
Marshall-UK 1995	2. Standard care	40.83	19.65	30

Analysis 1.28. Comparison 1 Intensive Case Management versus standard care, Outcome 28 Mental state: 1a. General symptoms - average endpoint score (various scales).

Analysis 1.29. Comparison 1 Intensive Case Management versus standard care, Outcome 29 Mental state: 1b. General symptoms - mean change from baseline (CSI, low = poor) - by long term.

Analysis 1.30. Comparison 1 Intensive Case Management versus standard care, Outcome 30 Mental state: 1c. General symptoms - average endpoint score (various scales, skewed data).

Mental state: 1c. General symptoms - average endpoint score (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by short term (BPRS-24 items, high = poor)				
Audini-UK 1994	1. ICM	39.1	10.0	31
Audini-UK 1994	2. Standard Care	39.5	12.0	30
Muijen-UK2 1994	1. ICM	42.4	16.8	36
Muijen-UK2 1994	2. Standard Care	43.1	15.2	32
by short term (PSE, high = poor)				
Audini-UK 1994	1. ICM	7.2	7.2	31
Audini-UK 1994	2. Standard Care	8.4	9.3	30
Muijen-UK2 1994	1. ICM	19.9	19.5	35
Muijen-UK2 1994	2. Standard Care	17.3	15.8	32
by medium term (BPRS-24 items, high = poor)				
Audini-UK 1994	1. ICM	42.3	14.8	30
Audini-UK 1994	2. Standard Care	41.4	12.2	28
Muijen-UK2 1994	1. ICM	45.7	15.2	32
Muijen-UK2 1994	2. Standard Care	43.1	12.7	26
Sytema-Netherlands 1999	1. ICM	38	10	45
Sytema-Netherlands 1999	2. Standard Care	42	11	36
by medium term (CPRS, high = poor)				
Holloway-UK 1996	1. ICM	20.6	12.1	22
Holloway-UK 1996	2. Standard Care	21.3	14.0	22
by medium term (PSE, high = poor)				
Muijen-UK2 1994	1. ICM	18.7	15.9	35
Muijen-UK2 1994	2. Standard Care	14.4	15	27
by long term (BPRS-18 items, high = poor)				
Ford-UK 1995	1. ICM	12.8	9.6	36
Ford-UK 1995	2. Standard Care	13.5	11.9	32
by long term (BPRS-24 items, high = poor)				
Muijen-UK2 1994	1. ICM	44.4	13.3	31
Muijen-UK2 1994	2. Standard Care	51.8	18.8	26
by long term (CPRS, high = poor)				
Holloway-UK 1996	1. ICM	21.6	12.9	21
Holloway-UK 1996	2. Standard Care	22.4	14.5	19
by long term (PSE, high = poor)				
Audini-UK 1994	1. ICM	7.6	8.2	30
Audini-UK 1994	2. Standard Care	10.6	12.2	28
Muijen-UK2 1994	1. ICM	20.3	13.7	28
Muijen-UK2 1994	2. Standard Care	27.6	23.5	25

Mental state: 1c. General symptoms - average endpoint score (various scales, skewed data)

Study	Intervention	Mean	SD	Total
by long term (SCL-90, high = poor)				
Bjorkman-Sweden 2002	1. ICM	102	68.5	27
Bjorkman-Sweden 2002	2. Standard Care	81.4	55.1	33

Analysis 1.31. Comparison 1 Intensive Case Management versus standard care, Outcome 31 Mental state: 2a. Specific symptoms - depression at follow up interview.

Analysis 1.32. Comparison 1 Intensive Case Management versus standard care, Outcome 32 Mental state: 2b. Specific symptoms - average endpoint score (various scales, skewed data, sample size ≥ 200).

Analysis 1.33. Comparison 1 Intensive Case Management versus standard care, Outcome 33 Mental state: 2c. Specific symptoms - average endpoint score (various scales, skewed data).

Mental state: 2c. Specific symptoms - average endpoint score (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by medium term - depression symptoms (BDI, high = poor)				
Holloway-UK 1996	1. ICM	11.5	8.9	23
Holloway-UK 1996	2. Standard care	18.5	13.9	19
by medium term - negative symptoms (SANS, high = poor)				
Holloway-UK 1996	1. ICM	7.3	4	26
Holloway-UK 1996	2. Standard care	6.3	4.4	22
by long term - depression symptoms (BDI, high = poor)				
Holloway-UK 1996	1. ICM	12.8	8.1	25
Holloway-UK 1996	2. Standard care	14.8	11.5	17
by long term - negative symptoms (SANS, high = poor)				
Holloway-UK 1996	1. ICM	7.3	3.7	26
Holloway-UK 1996	2. Standard care	7.1	4.1	20

Analysis 1.34. Comparison 1 Intensive Case Management versus standard care, Outcome 34 Behaviour: 1. Specific behaviour - self-harm.

Analysis 1.35. Comparison 1 Intensive Case Management versus standard care, Outcome 35 Behaviour: 2. Social behaviour - average endpoint score (SBS, high = poor).

Behaviour: 2. Social behaviour - average endpoint score (SBS, high = poor)				
Study	Intervention	Mean	SD	Total
by medium term				
Holloway-UK 1996	1. ICM	3.2	2.8	33
Holloway-UK 1996	2. Standard Care	2.4	2.9	30
by long term				
Holloway-UK 1996	1. ICM	3.3	2.8	34
Holloway-UK 1996	2. Standard Care	2.7	2.2	26

Analysis 1.36. Comparison 1 Intensive Case Management versus standard care, Outcome 36 Quality of life: 1a. Average endpoint score (various scales).

Analysis 1.37. Comparison 1 Intensive Case Management versus standard care, Outcome 37 Quality of life: 1b. Mean change from baseline (QOLI, high = better, skewed data) - by long term.

Quality of life: 1b. Mean change from baseline (QOLI, high = better, skewed data) - by long term					
Study	Intervention	Mean	SD	Total	
Shern-USA1 2000	1. ICM	1.19	1.99	91	
Shern-USA1 2000	2. Standard Care	-0.02	1.65	77	

Analysis 1.38. Comparison 1 Intensive Case Management versus standard care, Outcome 38 Participant satisfaction: 1a. Average endpoint score (CSQ, high = better).

Analysis 1.39. Comparison 1 Intensive Case Management versus standard care, Outcome 39 Participants satisfaction: 1b. Average endpoint score (CSQ, high = better, skewed data) - by short term.

Participants satisfaction: 1b. Average endpoint score (CSQ, high = better, skewed data) - by short term					
Study	Intervention	Mean	SD	Total	Note
Muijen-UK2 1994	1. ICM	26	5.4	30	
Muijen-UK2 1994	2. Standard Care*	22	7.5	13	* Attrition >50%.

Analysis 1.40. Comparison 1 Intensive Case Management versus standard care, Outcome 40 Participants need: 1. Average endpoint score (various scales, skewed data).

Participants need: 1. Average endpoint score (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by medium term - met needs (CANSAS, high = better)				
Sytema-Netherlands 1999	1. ICM	8.5	4.5	45
Sytema-Netherlands 1999	2. Standard Care	8.6	4.7	36
by medium term - unmet needs (CANSAS, high = poor)				
Sytema-Netherlands 1999	1. ICM	1.4	1.9	45
Sytema-Netherlands 1999	2. Standard Care	1.6	1.7	36
by long term (CAN, high = poor)				
Bjorkman-Sweden 2002	1. ICM	3.2	1.8	28
Bjorkman-Sweden 2002	2. Standard Care	4.6	3.8	36

Analysis 1.41. Comparison 1 Intensive Case Management versus standard care, Outcome 41 Costs: 1a. Direct costs of psychiatric hospital care - by medium term (Unit cost = USD, fiscal year 1990).

Analysis 1.42. Comparison 1 Intensive Case Management versus standard care, Outcome 42 Costs: 1b. Direct costs of psychiatric hospital care - skewed data.

Costs: 1b. Direct costs of psychiatric hospital care - skewed data					
Study	Intervention	Mean	SD	Total	Note
by medium term					
Cusack-North Carolina	1. ICM*	5,530	12,414	72	* Unit cost US \$, Inpatient costs Time period: 12 months.
Cusack-North Carolina	2. Standard care*	8,827	19,289	62	* Unit cost US \$, Inpatient costs Time period: 12 months.
Lehman-Maryland ¹ 1994	1. ICM*	2,619	4,440	77	
Lehman-Maryland ¹ 1994	2. Standard care*	4,662	6,034	75	* Unit cost US \$, fiscal year 1994. t-value=2.34 Time period: 12 months.
Morse-Missouri ³ 2005	1. ICM*	624	2,314	54	
Morse-Missouri ³ 2005	2. Standard care*	439	1,596	49	* Unit cost US \$, fiscal year 2001. "No main effect of treatment condition for inpatient costs, F(2, 146)=0.10, p=0.9, η ² =0.01" Time period: 6 months.
by long term					
Ford-UK 1995	1. ICM*	378	846	39	
Ford-UK 1995	2. Standard care*	237	492	38	* Unit cost £, fiscal year not reported, study base year 1990. ** No statistical analysis available from the paper. Time period: 18 months.
Morse-Missouri ³ 2005	1. ICM*	855	2,356	54	
Morse-Missouri ³ 2005	2. Standard care*	455	1,065	49	* Unit cost US \$, fiscal year 2001. ** "No main effect of treatment condition for inpatient costs, F(2, 146)=0.10, p=0.9, η ² =0.01" Time period: 6 months.
Quinlivan-California 1995	1. ICM*	301	397	30	

Costs: 1b. Direct costs of psychiatric hospital care - skewed data

Study	Intervention	Mean	SD	Total	Note
Quinlivan-California 1995	2. Standard care*	1,636	2,593	30	* Unit cost US \$, fiscal year not reported, but study was carried on from April 1990 to March 1992. ** "Costs significantly lower for the ICM group ($F=4.32$, $df=2.87$, $p=0.02$.)" Time period: 24 months.

Analysis 1.43. Comparison 1 Intensive Case Management versus standard care, Outcome 43 Costs: 2a. Direct healthcare costs - by long term (Unit cost = USD, fiscal year 1988).

Analysis 1.44. Comparison 1 Intensive Case Management versus standard care, Outcome 44 Costs: 2b. Direct healthcare costs - skewed data.

Costs: 2b. Direct healthcare costs - skewed data

Study	Intervention	Mean	SD	Total	Note
by medium term					
Lehman-Maryland1 1994	1. ICM*	4,229	5,058	77	
Lehman-Maryland1 1994	2. Standard care*	5,540	6,368	75	* Unit cost US \$, fiscal year 1994. ** 'Total per-case cost did not reach statistical significance ($p = 0.07$). Transformation of total costs per case to account for non-normality (square root of total costs, t -test= 0.77 , $df=1,134$, NS) and non-parametric analysis (Wilcoxon test for ranks, $Z=0.146$, NS) also were non-significant.' Time period 12 months.
by short term FUP					
Chan-Hong Kong 2000	1. ICM	14,833	1,539	31	
Chan-Hong Kong 2000	2. Standard care	11,230	7,979	31	HK \$ (HK\$8=US\$1, at time of study publication, 2000). Statistically significant difference ($P = 0.017$).

Analysis 1.45. Comparison 1 Intensive Case Management versus standard care, Outcome 45 Costs: 3. Direct costs - other data - skewed data.

Costs: 3. Direct costs - other data - skewed data					
Study	Intervention	Mean	SD	Total	Note
all care - by short term					
Audini-UK 1994	1. ICM*	4,264	1,768	33	
Audini-UK 1994	2. Standard care*	7,202	5,564	29	* Unit cost £, fiscal year 1996/7. ** 'Bivariate cost comparisons (after log transformation) revealed significant advantage for ICM group (p=0.001)'. ***Time period: missing (it is not the monthly cost per patient).
all care - by medium term					
Marshall-UK 1995	1. ICM*	1,044	425.3	31	
Marshall-UK 1995	2. Standard care*	1,108	530.4	30	* Unit cost £, fiscal year 1994. ** 'No significant differences between two groups were found.' ***Time period: mean weekly cost.
Morse-Missouri3 2005	1. ICM*	2,946.8	3,219.3	54	
Morse-Missouri3 2005	2. Standard care*	1,899.5	3,629.6	49	* Unit cost US \$, fiscal year 2001. ** 'There was a main effect of treatment condition on total costs, $F(2, 146)=4.00$, $p=0.02$, $\eta^2=0.05$. Standard care condition had significantly lower costs than ICM.' ***Time period: 6 months
all care - by long term					
Audini-UK 1994	1. ICM*	10,192	3,900	32	
Audini-UK 1994	2. Standard care*	15,288	17,160	28	* Unit cost £, fiscal year 1996/7. ** 'Bivariate cost comparisons (after log transformation) did not reveal significant advantage for ICM group (p=0.09)'. ***Time period: missing (it is not the monthly cost per patient).
Ford-UK 1995	1. ICM*	1,813	1,347	39	
Ford-UK 1995	2. Standard care*	717	768	38	* Unit cost £, fiscal year not reported, study base year 1990. ** 'ANOVA analysis carried on, revealing significant advantage for ICM group (p<0.05)'. ***Time period: 12 months.
Marshall-UK 1995	1. ICM*	996	398	31	
Marshall-UK 1995	2. Standard care*	1,088	562.4	30	* Unit cost £, fiscal year 1994. ** 'No significant differences between two groups were found.' ***Time period: mean weekly cost.

Costs: 3. Direct costs - other data - skewed data					
Study	Intervention	Mean	SD	Total	Note
Morse-Missouri3 2005	1. ICM*	3,190	3,441	54	
Morse-Missouri3 2005	2. Standard care*	1,467	2,173	49	* Unit cost US \$, fiscal year 2001. ** There was a main effect of treatment condition on total costs, $F(2, 146)=4.00$, $p=0.02$, $\eta^2=0.05$. Standard care condition had significantly lower costs than ICM. ***Time period: 6 months.
OPUS-Denmark 1999	1. ICM*	111,924	100,862	151	
OPUS-Denmark 1999	2. Standard Care*	137,638	147,570	150	*Unit cost Euro €, fiscal year 2009. **No significant difference between the groups. ***Time period: FUP 3 years.
specific - outpatient care - by medium term					
Cusack-North Carolina	1. ICM*	13,481	9,547	72	* Unit cost US \$. **Time period: 12 months.
Cusack-North Carolina	2. Standard care*	5,118	6,184	62	* Unit cost US \$. **Time period: 12 months.
specific - prison - by medium term					
Cusack-North Carolina	1. ICM*	1,848	4,533	72	* Unit cost US \$. **Time period: 12 months.
Cusack-North Carolina	2. Standard care*	3,530	5,690	62	* Unit cost US \$. **Time period: 12 months.

Comparison 2. Intensive Case Management versus non-Intensive Case Management

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Service use: 1. Average number of days in hospital per month - by about 24 months	21	2220	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.37, 0.21]
1.1 skewed data (sample size ≥ 200)	3	694	Mean Difference (IV, Random, 95% CI)	-0.58 [-1.93, 0.76]
1.2 skewed data (sample size < 200)	18	1526	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.33, 0.28]
2 Service use: 1a. Average number of days in hospital per month - by medium/long term follow up (skewed data, sample size ≥ 200)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 by medium term FUP (18 months)	1	237	Mean Difference (IV, Random, 95% CI)	0.60 [-1.25, 2.45]
2.2 by long term FUP (8.5 years)	1	203	Mean Difference (IV, Random, 95% CI)	0.80 [-1.47, 3.07]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Service use: 2. Not remaining in contact with psychiatric services	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 by medium term	1	73	Risk Ratio (M-H, Random, 95% CI)	0.27 [0.08, 0.87]
3.2 by long term	3	1182	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.34, 1.98]
3.3 by medium term FUP (18 months)	1	251	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.17, 1.05]
4 Service use: 3a. Admitted to hospital - by long term	3	1132	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.75, 1.12]
5 Service use: 3b. Average number of admissions (skewed data -sample size $\geq$ 200)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 - by long term (24 months)	1	678	Mean Difference (IV, Random, 95% CI)	-0.18 [-0.41, 0.05]
5.2 by medium term FUP (18 months)	1	237	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.60, 0.40]
5.3 by long term FUP (8.5 years)	1	203	Mean Difference (IV, Random, 95% CI)	1.0 [-0.25, 2.25]
6 Service use: 3c. Average number of admissions (skewed data) - by medium term			Other data	No numeric data
7 Adverse event: 1a. Death - any cause	7		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
7.1 by short term	1	193	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
7.2 by medium term	3	294	Risk Ratio (M-H, Random, 95% CI)	2.92 [0.12, 69.43]
7.3 by long term	5	1637	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.46, 1.75]
7.4 by medium term FUP (18 months)	1	251	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.32, 2.95]
7.5 by long term FUP (8.5 years)	1	251	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.63, 2.09]
8 Adverse event: 1b. Death - suicide	8		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
8.1 by short term	1	193	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.2 by medium term	6	929	Risk Ratio (M-H, Random, 95% CI)	1.61 [0.26, 9.85]
8.3 by long term	3	1152	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.27, 2.84]
8.4 by medium term FUP (18 months)	1	251	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.03, 3.09]
9 Global state: 1. Leaving the study early	9	2195	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.52, 0.99]
9.1 by medium term	2	225	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.13, 3.07]
9.2 by long term	7	1970	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.52, 0.95]
10 Global state: 2a. Average endpoint score (HoNOS, high = poor) - by long term	1	239	Mean Difference (IV, Random, 95% CI)	-0.40 [-1.77, 0.97]
11 Global state: 2b. Average endpoint score (HoNOS, high = poor) - skewed data			Other data	No numeric data
11.1 medium term			Other data	No numeric data
11.2 long term			Other data	No numeric data
12 Global state: 3a. Not compliant with medication - by medium term	1	73	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.42, 3.05]
13 Global state: 3b. Compliance with medication - average endpoint sub-scale score (ROMI) - by long term	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
13.1 compliance sub-scale (high = good)	1	239	Mean Difference (IV, Random, 95% CI)	0.60 [-0.05, 1.25]
13.2 non-compliance sub-scale (high = poor)	1	239	Mean Difference (IV, Random, 95% CI)	-0.60 [-1.63, 0.43]
14 Global state: 3c. Compliance with medication - average endpoint sub-scale score (ROMI, score 1-3, skewed data)			Other data	No numeric data
14.1 medium term - compliance sub-scale (high = good)			Other data	No numeric data
14.2 medium term - non-compliance sub-scale (high = poor)			Other data	No numeric data
14.3 long term - compliance sub-scale (high = good)			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14.4 long term - non-compliance sub-scale (high = poor)			Other data	No numeric data
15 Social functioning: 1. Contact with legal system (various measurements)	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
15.1 by medium term - contact with the police	1	73	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.04, 2.97]
15.2 by long term - imprisoned	2	959	Risk Ratio (M-H, Random, 95% CI)	1.15 [0.64, 2.08]
15.3 by long term - arrested	1	251	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.53, 1.42]
15.4 by medium term FUP (18 months) - imprisoned	1	251	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.47, 2.44]
15.5 by long term FUP (8.5 years) - imprisoned	1	214	Risk Ratio (M-H, Random, 95% CI)	0.7 [0.43, 1.14]
16 Social functioning 2. Employment status (various measurements)	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
16.1 spent >1 day employed - by medium term	1	73	Risk Ratio (M-H, Random, 95% CI)	1.46 [0.45, 4.74]
16.2 on paid employment - by medium term	1	73	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.14, 6.54]
16.3 unemployed - by long term FUP (8.5 years)	1	214	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.91, 1.34]
17 Social functioning: 3a. Accommodation status (various measurements)	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
17.1 by medium term - living in supported accommodation	1	73	Risk Ratio (M-H, Random, 95% CI)	2.59 [0.75, 9.01]
17.2 by long term - homelessness	1	251	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.34, 1.38]
17.3 by medium term FUP (18 months) - living independently	1	251	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.84, 1.13]
17.4 by medium term FUP (18 months) - living in supported accommodation	1	251	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.38, 1.77]
17.5 by medium term FUP (18 months) - homelessness	1	251	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.47, 1.49]
17.6 by long term FUP (8.5 years) - living in supported accommodation	1	214	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.75, 1.48]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17.7 by long term FUP (8.5 years) - homelessness	1	214	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.55, 1.53]
18 Social functioning: 3b. Accommodation status - average days per month in stable accommodation	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
18.1 by short term	1	203	Mean Difference (IV, Random, 95% CI)	-0.20 [-2.48, 2.08]
18.2 by medium term	1	203	Mean Difference (IV, Random, 95% CI)	0.10 [-2.15, 2.35]
18.3 by long term	2	901	Mean Difference (IV, Random, 95% CI)	-0.19 [-1.37, 1.00]
19 Social functioning: 4a. Substance abuse - by long term	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
19.1 alcohol abuse	1	251	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.67, 1.83]
19.2 illicit drug abuse	1	251	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.69, 1.71]
19.3 alcohol - remission from alcohol use disorder (AUS score < 3)	1	223	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.65, 1.14]
20 Social functioning: 4b. Substance abuse - average endpoint score (SATS, low = poor)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
20.1 by short term	1	203	Mean Difference (IV, Random, 95% CI)	0.07 [-0.28, 0.42]
20.2 by medium term	1	203	Mean Difference (IV, Random, 95% CI)	-0.11 [-0.55, 0.33]
20.3 by long term	1	203	Mean Difference (IV, Random, 95% CI)	0.11 [-0.41, 0.63]
21 Social functioning: 4c. Alcohol - abuse (various measurements, skewed data)			Other data	No numeric data
21.1 short term - days using alcohol during previous 6 months (TLFB)			Other data	No numeric data
21.2 short term - average endpoint score (AUS, high = poor)			Other data	No numeric data
21.3 medium term - days using alcohol during previous 6 months (TLFB)			Other data	No numeric data
21.4 medium term - average endpoint score (AUS, high = poor)			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
21.5 long term - days using alcohol during previous 6 months (TLFB)			Other data	No numeric data
21.6 long term - average endpoint score (AUS, high = poor)			Other data	No numeric data
22 Social functioning: 5a. Average endpoint score (LSP, high = poor) - by long term	1	239	Mean Difference (IV, Random, 95% CI)	4.0 [-0.61, 8.61]
23 Social functioning: 5b. Average endpoint score (SFQ, high = poor) - skewed data			Other data	No numeric data
23.1 by medium term			Other data	No numeric data
23.2 by long term			Other data	No numeric data
24 Mental state: 1a. General symptoms - average endpoint score (various scales)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
24.1 by short term (BPRS-24 items, high = poor)	1	203	Mean Difference (IV, Random, 95% CI)	-0.65 [-3.99, 2.69]
24.2 by medium term (BPRS-24 items, high = poor)	1	203	Mean Difference (IV, Random, 95% CI)	-1.62 [-4.76, 1.52]
24.3 by long term (BPRS-24 items, high = poor)	1	203	Mean Difference (IV, Random, 95% CI)	-0.22 [-3.32, 2.88]
24.4 by long term (CPRS, high = poor)	1	595	Mean Difference (IV, Random, 95% CI)	0.40 [-1.83, 2.63]
25 Mental state: 1b. General symptoms - average endpoint scores (various scales, skewed data)			Other data	No numeric data
25.1 by medium term (Krawiecka Scale, high = poor)			Other data	No numeric data
25.2 by long term (Krawiecka Scale, high = poor)			Other data	No numeric data
25.3 by long term (BPRS 24-items, high = good)			Other data	No numeric data
26 Mental state: 2a. Specific symptoms: negative symptoms - average endpoint score (SANS, high = poor) - by long term	1	593	Mean Difference (IV, Random, 95% CI)	0.20 [-2.32, 2.72]
27 Mental state: 2b. Specific symptoms - average endpoint scores (various scales, skewed data)			Other data	No numeric data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
27.1 medium term - anxiety (HADS, high = poor)			Other data	No numeric data
27.2 medium term - depression (HADS, high = poor)			Other data	No numeric data
27.3 long term - anxiety (HADS, high = poor)			Other data	No numeric data
27.5 long term - depression (HADS, high = poor)			Other data	No numeric data
28 Behaviour: 1. Specific behaviour (various measurements)	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
28.1 by medium term - harm to self or others	1	73	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.40, 1.90]
28.2 by long term - self-harm	2	959	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.69, 1.46]
28.3 by long term - injury/assault to others	2	959	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.85, 1.40]
28.4 by medium term FUP (18 months) - self harm	1	251	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.44, 1.67]
28.5 by medium term FUP (18 months) - injury/assault to others	1	251	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.87, 2.10]
28.6 by long term FUP (8.5 years) - self harm	1	214	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.51, 1.27]
28.7 by long term FUP (8.5 years) - injury/assault to others	1	214	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.83, 1.09]
29 Quality of life: 1. Average endpoint score (various scales)	3		Mean Difference (IV, Random, 95% CI)	Subtotals only
29.1 by short term - overall life satisfaction (QOLI, high = better)	1	203	Mean Difference (IV, Random, 95% CI)	-0.02 [-0.43, 0.39]
29.2 by medium term - overall life satisfaction (QOLI, high = better)	1	203	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.43, 0.35]
29.3 by long term (LQoLP, high = better)	1	526	Mean Difference (IV, Random, 95% CI)	0.03 [-0.10, 0.16]
29.4 by long term (MANSA, range 1-7, high = better)	1	166	Mean Difference (IV, Random, 95% CI)	0.10 [-0.19, 0.39]
29.5 by long term - overall life satisfaction (QOLI, high = better)	1	203	Mean Difference (IV, Random, 95% CI)	0.10 [-0.25, 0.45]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
30 Participant satisfaction/need: 1. Average endpoint scores (various scale) - by long term	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
30.1 Patient need: CAN (high = poor)	1	585	Mean Difference (IV, Random, 95% CI)	-0.29 [-0.69, 0.11]
30.2 Patient Satisfaction with Health Services (high = poor)	1	490	Mean Difference (IV, Random, 95% CI)	-0.40 [-1.25, 0.45]
31 Participants need: 1. Average endpoint scores (various scales, skewed data)			Other data	No numeric data
31.1 by medium term (CAN, high = poor)			Other data	No numeric data
31.2 by long term (CAN, high = poor)			Other data	No numeric data
31.3 by long term (CANSAS, high = poor)			Other data	No numeric data
32 Participant satisfaction: 1. Average endpoint scores (CSQ-modified, high = better, skewed data) - by long term			Other data	No numeric data
33 Costs: 1. Direct costs of psychiatric hospital care (skewed data)			Other data	No numeric data
33.3 by medium term			Other data	No numeric data
33.4 by long term			Other data	No numeric data
34 Costs: 2a. Direct costs of all care - by long term (2 years). Unit cost GBP, fiscal year 1997/98	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
35 Costs: 2b. Direct costs of all care - by medium term (skewed data)			Other data	No numeric data
36 Costs: 3. Total costs of care per patient - Unit cost GBP	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
36.1 by 24 months, fiscal year 1997/98	1	667	Mean Difference (IV, Fixed, 95% CI)	1849.0 [-1598.23, 5296.23]
36.2 by 18 months, fiscal year 2003/2004 (GBP 1 = USD 1.58)	1	243	Mean Difference (IV, Fixed, 95% CI)	4031.00 [-2724.13, 10786.13]

Analysis 2.1. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 1 Service use: 1. Average number of days in hospital per month - by about 24 months. **Analysis 2.2. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 2 Service use: 1a. Average number of days in hospital per month - by medium/long term follow up (skewed data, sample size ≥ 200).**

Analysis 2.3. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 3 Service use: 2. Not remaining in contact with psychiatric services.

Analysis 2.4. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 4 Service use: 3a. Admitted to hospital - by long term. **Analysis 2.5. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 5 Service use: 3b. Average number of admissions (skewed data -sample size ≥ 200).** **Analysis 2.6. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 6 Service use: 3c. Average number of admissions (skewed data) - by medium term.**

Service use: 3c. Average number of admissions (skewed data) - by medium term					
Study	Intervention	Mean	SD	Total	
Johnston-Australia 1998	1. ICM	1.6	2	35	
Johnston-Australia 1998	2. non-ICM	1.9	2.4	33	

Analysis 2.7. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 7 Adverse event: 1a. Death - any cause.

Analysis 2.8. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 8 Adverse event: 1b. Death - suicide.

Analysis 2.9. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 9 Global state: 1. Leaving the study early.

Analysis 2.10. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 10 Global state: 2a. Average endpoint score (HoNOS, high = poor) - by long term.

Analysis 2.11. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 11 Global state: 2b. Average endpoint score (HoNOS, high = poor) - skewed data.

Global state: 2b. Average endpoint score (HoNOS, high = poor) - skewed data				
Study	Intervention	Mean	SD	Total
medium term				
Harrison-Read-UK 2000	1. ICM	12	6.8	54
Harrison-Read-UK 2000	2. non-ICM	11.4	6.4	64
long term				
Harrison-Read-UK 2000	1. ICM	11.9	5.9	60
Harrison-Read-UK 2000	2. non-ICM	10.4	6.4	59

Analysis 2.12. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 12 Global state: 3a. Not compliant with medication - by medium term.

Analysis 2.13. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 13 Global state: 3b. Compliance with medication - average endpoint sub-scale score (ROMI) - by long term.

Analysis 2.14. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 14 Global state: 3c. Compliance with medication - average endpoint sub-scale score (ROMI, score 1-3, skewed data).

Global state: 3c. Compliance with medication - average endpoint sub-scale score (ROMI, score 1-3, skewed data)				
Study	Intervention	Mean	SD	Total
medium term - compliance sub-scale (high = good)				
Harrison-Read-UK 2000	1. ICM	1.8	0.4	49
Harrison-Read-UK 2000	2. non-ICM	2.0	0.5	61
medium term - non-compliance sub-scale (high = poor)				
Harrison-Read-UK 2000	1. ICM	1.3	0.3	49
Harrison-Read-UK 2000	2. non-ICM	1.2	0.3	61
long term - compliance sub-scale (high = good)				
Harrison-Read-UK 2000	1. ICM	1.8	0.4	62
Harrison-Read-UK 2000	2. non-ICM	1.9	0.5	60
long term - non-compliance sub-scale (high = poor)				
Harrison-Read-UK 2000	1. ICM	1.2	0.3	63
Harrison-Read-UK 2000	2. non-ICM	1.2	0.3	61

Analysis 2.15. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 15 Social functioning: 1. Contact with legal system (various measurements).

Analysis 2.16. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 16 Social functioning 2. Employment status (various measurements).

Analysis 2.17. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 17 Social functioning: 3a. Accommodation status (various measurements).

Analysis 2.18. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 18 Social functioning: 3b. Accommodation status - average days per month in stable accommodation.

Analysis 2.19. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 19 Social functioning: 4a. Substance abuse - by long term.

Analysis 2.20. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 20 Social functioning: 4b. Substance abuse - average endpoint score (SATS, low = poor).

Analysis 2.21. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 21 Social functioning: 4c. Alcohol - abuse (various measurements, skewed data).

Social functioning: 4c. Alcohol - abuse (various measurements, skewed data)				
Study	Intervention	Mean	SD	Total
short term - days using alcohol during previous 6 months (TLFB)				
Drake-NHamp 1998	1. ICM	56.8	56.4	75
Drake-NHamp 1998	2. non-ICM	47.5	58.4	68
short term - average endpoint score (AUS, high = poor)				
Drake-NHamp 1998	1. ICM	3.09	1.02	83
Drake-NHamp 1998	2. non-ICM	2.91	1.08	73
medium term - days using alcohol during previous 6 months (TLFB)				
Drake-NHamp 1998	1. ICM	59.1	53.3	75
Drake-NHamp 1998	2. non-ICM	42.8	52.9	68
medium term - average endpoint score (AUS, high = poor)				
Drake-NHamp 1998	1. ICM	3.11	1.05	83
Drake-NHamp 1998	2. non-ICM	2.8	1.13	73
long term - days using alcohol during previous 6 months (TLFB)				
Drake-NHamp 1998	1. ICM	46.4	53.6	75
Drake-NHamp 1998	2. non-ICM	43.6	57.3	68
long term - average endpoint score (AUS, high = poor)				
Drake-NHamp 1998	1. ICM	2.64	1.12	83
Drake-NHamp 1998	2. non-ICM	2.77	1.18	73

Analysis 2.22. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 22 Social functioning: 5a. Average endpoint score (LSP, high = poor) - by long term.

Study or subgroup	INTENSIVE CASE MANAGEMENT		NON-INTENSIVE CASE MANAGEMENT		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)			
REACT-UK 2002	124	119 (16.4)	115	115 (19.7)	Random, 95% CI	100%	4[-0.61,8.61]
Total ***	124		115			100%	4[-0.61,8.61]
Heterogeneity: Not applicable Test for overall effect: Z=1.7(P=0.09)							
					Favours experimental	-20 -10 0 10 20	Favours control

Analysis 2.23. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 23 Social functioning: 5b. Average endpoint score (SFQ, high = poor) - skewed data.

Social functioning: 5b. Average endpoint score (SFQ, high = poor) - skewed data				
Study	Intervention	Mean	SD	Tot
by medium term				
Harrison-Read-UK 2000	1. ICM	7.3	5.3	49
Harrison-Read-UK 2000	2. non-ICM	7.5	5.1	62
by long term				
Harrison-Read-UK 2000	1. ICM	8.9	4.9	57
Harrison-Read-UK 2000	2. non-ICM	7.9	4.9	58

Analysis 2.24. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 24 Mental state: 1a. General symptoms - average endpoint score (various scales).

Analysis 2.25. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 25 Mental state: 1b. General symptoms - average endpoint scores (various scales, skewed data).

Mental state: 1b. General symptoms - average endpoint scores (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by medium term (Krawiecka Scale, high = poor)				
Harrison-Read-UK 2000	1. ICM	8.8	5.6	57
Harrison-Read-UK 2000	2. non-ICM	8	4.5	65
by long term (Krawiecka Scale, high = poor)				
Harrison-Read-UK 2000	1. ICM	9.2	5.5	47
Harrison-Read-UK 2000	2. non-ICM	7.9	4.5	57
by long term (BPRS 24-items, high = good)				
REACT-UK 2002	1. ICM	32.9	9	91
REACT-UK 2002	2. non-ICM	33.5	8.6	75

Analysis 2.26. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 26 Mental state: 2a. Specific symptoms - negative symptoms - average endpoint score (SANS, high = poor) - by long term.

Analysis 2.27. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 27 Mental state: 2b. Specific symptoms - average endpoint scores (various scales, skewed data).

Mental state: 2b. Specific symptoms - average endpoint scores (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
medium term - anxiety (HADS, high = poor)				
Harrison-Read-UK 2000	1. ICM	6.5	4.9	52
Harrison-Read-UK 2000	2. non-ICM	6.7	4.6	61
medium term - depression (HADS, high = poor)				
Harrison-Read-UK 2000	1. ICM	6.4	5.4	52
Harrison-Read-UK 2000	2. non-ICM	6.6	4.9	61
long term - anxiety (HADS, high = poor)				
Harrison-Read-UK 2000	1. ICM	7.5	5.3	56
Harrison-Read-UK 2000	2. non-ICM	6.4	4.6	58
long term - depression (HADS, high = poor)				
Harrison-Read-UK 2000	1. ICM	7.3	5.4	56
Harrison-Read-UK 2000	2. non-ICM	6.8	5.6	58

Analysis 2.28. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 28 Behaviour: 1. Specific behaviour (various measurements).

Analysis 2.29. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 29 Quality of life: 1. Average endpoint score (various scales).

Analysis 2.30. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 30 Participant satisfaction/need: 1. Average endpoint scores (various scale) - by long term.

Analysis 2.31. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 31 Participants need: 1. Average endpoint scores (various scales, skewed data).

Participants need: 1. Average endpoint scores (various scales, skewed data)				
Study	Intervention	Mean	SD	Total
by medium term (CAN, high = poor)				
Harrison-Read-UK 2000	1. ICM	7.3	3.7	49
Harrison-Read-UK 2000	2. non-ICM	6.1	4	60
by long term (CAN, high = poor)				
Harrison-Read-UK 2000	1. ICM	6.6	3.6	54
Harrison-Read-UK 2000	2. non-ICM	5.6	3.8	59
by long term (CANSAS, high = poor)				
REACT-UK 2002	1. ICM	3.3	2.7	91
REACT-UK 2002	2. non-ICM	3.4	2.9	75

Analysis 2.32. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 32 Participant satisfaction: 1. Average endpoint scores (CSQ-modified, high = better, skewed data) - by long term.

Participant satisfaction: 1. Average endpoint scores (CSQ-modified, high = better, skewed data) - by long term				
Study	Intervention	Mean	SD	Total
REACT-UK 2002	1. ICM	77.2	20	91
REACT-UK 2002	2. non-ICM	70	20.6	75

Analysis 2.33. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 33 Costs: 1. Direct costs of psychiatric hospital care (skewed data).

Costs: 1. Direct costs of psychiatric hospital care (skewed data)					
Study	Intervention	Mean	SD	Total	Note
by medium term					
Harrison-Read-UK 2000	1. ICM*	501	967.4	97	* Unit cost £, fiscal year 1995/6. ** 'No significant difference between groups. Statistical analysis on non-parametric data were performed using bootstrap methods'. ***Time period: 12 months.
Harrison-Read-UK 2000	2. Low ICM*	527	753	96	
by long term					
Harrison-Read-UK 2000	1. ICM*	414	777.8	97	* Unit cost £, fiscal year 1995/6. ** 'No significant difference between groups. Statistical analysis on non-parametric data
Harrison-Read-UK 2000	2. Low ICM*	478	890	96	

Costs: 1. Direct costs of psychiatric hospital care (skewed data)

Study	Intervention	Mean	SD	Total	Note
Quinlivan-California 1995	1. ICM*	301	396.6	30	were performed using bootstrap methods'. ***Time period: 12 months.
Quinlivan-California 1995	2. Low ICM*	959	1,572.7	30	* Unit cost US \$, fiscal year not reported, but study was carried on from April 1990 to March 1992. ** 'Costs significantly lower for the ICM group ($F=4.32$, $df=2.87$, $p=0.02$.)' ***Time period: 24 months

Analysis 2.34. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 34 Costs: 2a. Direct costs of all care - by long term (2 years). Unit cost GBP, fiscal year 1997/98.

Study or subgroup	INTENSIVE CASE MANAGEMENT		NON-INTENSIVE CASE MANAGEMENT		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)			
UK700-UK 1999	335	1023 (975.3)	332	946 (916.7)	Random, 95% CI	0%	77 [-66.63, 220.63]

Analysis 2.35. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 35 Costs: 2b. Direct costs of all care - by medium term (skewed data).
Costs: 2b. Direct costs of all care - by medium term (skewed data)

Study	Intervention	Mean	SD	Total	Note
Johnston-Australia 1998	1. ICM*	2,408	2,581.4	33	
Johnston-Australia 1998	2. Non-ICM*	1,762	1,872	25	* Unit cost Aus \$, fiscal year 1991/2. ** 'The significance test on the cost of care per patient was performed on transformed means. No significant differences were found between groups'. ***Time period: 12 months.

Analysis 2.36. Comparison 2 Intensive Case Management versus non-Intensive Case Management, Outcome 36 Costs: 3. Total costs of care per patient - Unit cost GBP.

Study or subgroup	INTENSIVE CASE MANAGEMENT		NON-INTENSIVE CASE MANAGEMENT		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		
2.36.1 by 24 months, fiscal year 1997/98							
UK700-UK 1999	335	24553 (23408)	332	22704 (22000)		100%	1849[-1598.23,5296.23]
					Favours [ICM]		Favours [NON- ICM]

ADDITIONAL TABLES

Table 1. Case Management and Assertive Community Treatment

1. Case Management (CM)

The key principle of case management is that a single person - the 'case manager' - takes primary responsibility for a defined group of patients in the community. The case manager is responsible for (Holloway 1991):

- assessing the patient's needs;
- developing a care plan;
- arranging suitable care from community services;
- keeping contact with the patient.

Initially, in its simplest form (referred to as 'brokerage'), case managers were not mental health professionals, did not provide any direct care, and worked independently.

2. Assertive Community Treatment (ACT)

Assertive Community Treatment should be practiced according to a defined and validated model (Stein 1980), based on the consensus of an international panel of ACT experts (McGrew 1994; McGrew 1995). A key aspect of ACT is that it is a team-based approach, characteristically a multidisciplinary team including social workers, nurses, and psychiatrists, caring exclusively for a defined group of patients (McGrew 1995; Olfson 1990). Team members share responsibility for their clients, so it is common for several team members to work together in treating the same patient. Other characteristics of ACT are (Stein 1980):

- provide all necessary care themselves, rather than arranging for it to be provided by other services;
- provide care at home or in workplaces;
- carry low caseloads (usually 10 to 15 patients per member);
- practice 'assertive outreach', meaning that they persist in attempts to engage unco-operative clients;
- place particular emphasis on medication compliance;
- provide 24-hour emergency cover.

Table 2. Average number of days in hospital per month - at about 24 months - entering meta-regression

Intensive Case Management versus standard care	ICM	ICM	ICM	SC	SC	SC	Note
Study ID	Mean	SD	Total	Mean	SD	Total	
Audini-UK 1994	0.95	2.84*	33	0.93	2.03*	33	*SD imputed
Bjorkman-Sweden 2002	0.83	3.13	33	2.15	4.13	44	
Bond-Chicago1 1990	3.22	4.55	42	5.3	5.42	40	
Bond-Indiana1 (A)	1.28	3.17*	29	7.72	8.99*	32	*SD imputed
Bond-Indiana1 (B)	2.72	4.54*	34	3.62	5.24*	30	*SD imputed
Bond-Indiana1 (C)	0.05	1.89*	21	3.38	4.98*	21	*SD imputed
Chandler-California1 (A)	0.47	2.34*	102	0.78	1.84*	101	*SD imputed
Chandler-California1 (B)	0.67	2.55*	115	0.96	2.07*	114	*SD imputed
Curtis-New York 1992	1.77	1.79	146	1.02	1.18	143	
Ford-UK 1995	3.07	6.9	39	1.76	3.67	38	
Hampton-Illinois (A)	1.75	3.63*	48	4.83	6.49*	47	*SD imputed
Hampton-Illinois (B)	3.25	5.01*	34	3.42	5.02*	36	*SD imputed
Holloway-UK 1996	2.4	5.1	34	1.2	3	26	
Jerrell-SCarolina1 1991	0.53	2.40*	40	0.8	1.86*	40	*SD imputed
Lehman-Maryland1 1994	3.04	5.15	77	5.41	7	75	
Marshall-UK 1995	1.04	2.18	40	1.56	4.45	40	
Muijen-UK2 1994	2.53	5.55	41	2.45	5.83	41	
Muller-Clemm-Canada 1996	1.68	3.56*	61	1.63	2.93*	57	*SD imputed
OPUS-Denmark 1999	5.11	7.7	263	6.57	8.73	244	

Table 2. Average number of days in hospital per month - at about 24 months - entering meta-regression (Continued)

Quinlivan-California 1995	1.09	2.65	30	5.53	8.65	30	
Rosenheck-USA-GMS (A)	3.63	3.89	44	3.71	2.76	35	
Rosenheck-USA-GMS (B)	6.99	4.85	47	4.23	5.18	47	
Rosenheck-USA-NP (C)	18.52	11.16	50	19.16	12.19	43	
Rosenheck-USA-GMS (D)	2.8	3.31	49	3.26	3.98	53	
Rosenheck-USA-NP (E)	4.13	5.24	34	3.05	4.61	33	
Rosenheck-USA-GMS (F)	2.39	3.16	43	2.58	2.45	35	
Rosenheck-USA-NP (G)	7.68	7.72	40	12.2	10.65	31	
Rosenheck-USA-NP (H)	4.63	8.58	59	11.21	13.38	55	
Rosenheck-USA-GMS (I)	5.62	4.67	44	7.8	6.63	44	
Sytema-Netherlands 1999	3.4	5.4	58	4.3	7.3	57	
Test-Wisconsin 1985	0.42	2.29*	72	2.13	3.54*	41	*SD imputed
Intensive Case Management versus non-Intensive Case Management	ICM	ICM	ICM	Non-ICM	Non-ICM	Non-ICM	Note
Study ID	Mean	SD	Total	Mean	SD	Total	
Bush-Georgia 1990	1.58	3.46*	14	2.39	3.85*	14	*SD imputed
Drake-NHamp (A)	0.5	0.94	7	2.17	3.21	9	
Drake-NHamp (B)	0.85	1.43	16	1.41	2.06	14	
Drake-NHamp (C)	2.28	3.2	10	1.67	3.84	12	
Drake-NHamp (D)	1.04	2.44	13	0.63	0.91	11	
Drake-NHamp (E)	1.08	4.15	30	1.39	2.36	27	
Drake-NHamp (F)	1.66	4.49	10	0.84	2.33	13	

Table 2. Average number of days in hospital per month - at about 24 months - entering meta-regression (Continued)

Drake-NHamp 1998 G	2.05	3.06	9	0.87	0.92	8	
Essock-Connecticut1 1995	2.87	7.82	130	4.3	9.52	132	
Essock-Connecticut2 2006	0.64	1.9	99	0.72	1.3	99	
Harrison-Read-UK 2000	2.94	5.74	97	3.76	5.83	96	
Johnston-Australia 1998	4.0	5.75	35	3.08	4.3	33	
McDonel-Indiana (A)	3.15	7.1	61	1.43	2.91	64	
McDonel-Indiana (B)	1.22	3.66	14	0.58	1.29	17	
Quinlivan-California 1995	1.09	2.65	30	2.8	4.74	30	
REACT-UK 2002	9.0	8.9	124	8.0	7.8	119	
Salkever-SCarolina 1999	1.12	3.01*	91	1.3	2.51*	53	*SD imputed
UK700-UK (A)	3.08	5.77	94	2.64	3.49	95	
UK700-UK (B)	3.2	4.79	77	3.16	4.97	73	
UK700-UK (C)	3.29	5.41	76	2.48	4.71	75	
UK700-UK (D)	2.74	4.69	91	3.79	5.22	98	

ICM: Intensive Case Management
 SC: standard care
 SD: standard deviation
 Study ID: Study identification name

Table 3. Covariates entering meta-regression

Intensive Case Management versus standard care	Baseline hospital use	Baseline hospital use	IFACT	IFACT	IFACT	Note
Study ID	Mean	Total	Total score	Organisation sub-scale score	Staff sub-scale score	
Audini-UK 1994	1.08	66	6.7	3.5	3.2	
Bjorkman-Sweden 2002	5.63	77	7	4.5	2.5	
Bond-Chicago1 1990	7.83	88	6	4	2	
Bond-Indiana1 (A)	14.17	61	9.2	7	2.2	
Bond-Indiana1 (B)	4.95	64	2.2	1	1.2	
Bond-Indiana1 (C)	10.86	42	7.4	5	2.4	
Chandler-California1 (A)	0.5	203	8.5	5	3.5	
Chandler-California1 (B)	1.14	229	6.6	5	1.6	
Curtis-New York 1992	0.95*	289	5.8	3.5	2.3	*Mean imputed
Ford-UK 1995	2.61	77	4.8	2	2.8	
Hampton-Illinois (A)	5.6	95	6	4	2	
Hampton-Illinois (B)	5.2	70	5	3	2	
Holloway-UK 1996	7.37	70	9.3	6	3.3	
Jerrell-SCarolina1 1991	2.85	80	8.8	5.5	3.3	
Lehman-Maryland1 1994	4.94*	152	11	7	4	*Mean imputed
Marshall-UK 1995	3.31*	80	4.9	4	0.9	*Mean imputed
Muijen-UK2 1994	8.43*	82	5.4	3	2.4	*Mean imputed
Muller-Clemm-Canada 1996	4.07	123	6.2	4	2.2	
OPUS-Denmark 1999	NA	547	8	4	4	*Baseline hospital use: not applicable as first episode

Table 3. Covariates entering meta-regression (Continued)

Quinlivan-California 1995	4.50*	60	6.4	4	2.4	*Mean imputed
Rosenheck-USA-GMS (A)	3.96	79	6	2	4	
Rosenheck-USA-GMS (B)	5.83	94	3.8	2	1.8	
Rosenheck-USA-NP (C)	19.8	93	7.7	5	2.7	
Rosenheck-USA-GMS (D)	4.19	102	7	3	4	
Rosenheck-USA-NP (E)	5.33	67	6.4	3.5	2.9	
Rosenheck-USA-GMS (F)	3.22	78	6.6	3	3.6	
Rosenheck-USA-NP (G)	11.42	71	8.4	5	3.4	
Rosenheck-USA-NP (H)	11.4	114	6.4	4	2.4	
Rosenheck-USA-GMS (I)	8.28	88	5.8	2	3.8	
Sytema-Netherlands 1999	12.17*	118	7.6*	5.1*	2.5*	*Mean and IFACT score imputed
Test-Wisconsin 1985	2.33	122	8.5	5.5	3	
Intensive Case Management versus non-Intensive Case Management	Baseline hospital use	Baseline hospital use	IFACT	IFACT	IFACT	Note
Study ID	Mean	Total	Total score	Organisa-tion sub-scale score	Staff sub-scale score	
Bush-Georgia 1990	3.99	28	3.1	2	1.1	
Drake-NHamp (A)	2.88	19	8	5	3	
Drake-NHamp (B)	1.72	33	3.8	3	0.8	
Drake-NHamp (C)	3.02	25	8.8	5.5	3.3	
Drake-NHamp (D)	1.78	26	7.8	4.5	3.3	
Drake-NHamp (E)	2.76	66	8.5	4.5	4	
Drake-NHamp (F)	2.34	22	3.5	3	0.5	
Drake-NHamp 1998 (G)	4.1	19	5	2	3	
Essock-Connecticut1 1995	2.81*	262	8.5	4.5	4	*Mean imputed
Essock-Connecticut2 2006	1.08*	198	10*	7*	3*	*Mean and IFACT score imputed

Table 3. Covariates entering meta-regression (Continued)

Harrison-Read-UK 2000	4.11	193	7.6	4	3.6	
Johnston-Australia 1998	3.66	71	7.3	3.5	3.8	
McDonel-Indiana (A)	4.2	152	4.2	3	1.2	
McDonel-Indiana (B)	1.16	39	4.4	3	1.4	
Quinlivan-California 1995	2.96*	60	6.4	4	2.4	*Mean imputed
REACT-UK 2002	7.3	251	10.3	6.5	3.8	
Salkever-SCarolina 1999	3.06	144	7	5	2	
UK700-UK (A)	4.55	196	8.8	5	3.8	
UK700-UK (B)	4.66	153	4.5	3	1.5	
UK700-UK (C)	4.33	158	4.2	2	2.2	
UK700-UK (D)	4.59	200	8.5	5	3.5	

Baseline hospital use: average number of days per month in hospital for all participants in the two years before the study began

IFACT: Index of Fidelity to Assertive Community Treatment

NA: not applicable

Study ID: Study identification name

Table 4. Interventions in Curtis-New York

1. ICM: "Intensive outreach case management" from a multidisciplinary team at Harlem Hospital Center. This team implemented a discharge treatment plan and monitored clinical and social problems. The team did not "assume direct responsibility for care but [...] help[ed] the patient enrol in a day hospital programme, adult mental health clinic, rehabilitation programme, or alcohol treatment programme". Caseload: 1:17. N = 147.
2. Standard care: routine aftercare, within the discharge treatment plan prescribed for each patient from Harlem Hospital Center; "most received at least initial treatment from various divisions of the departments of psychiatry within the Health and Hospitals Corporation". N = 145.

APPENDICES

Appendix 1. Previous searches

1 Search method Assertive Community Treatment Review

1.1 Electronic searches

1.1.1 CINAHL (January 1982 to May 1997)

It was searched using the CSG's terms for randomised controlled trials and the CSG's terms for schizophrenia combined with the phrase:

[and ((case or care) near management) or CPA or (Care near1 Programme near1 Approach) or (Assertive near1 Community near1 Treatment) or PACT or TCL or (Training near (community near1 living)) or (Madison near4 model)]

1.1.2 The Cochrane Schizophrenia Group's Register (1997)

It was searched using the phrase:

Intensive case management for severe mental illness (Review)

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[and ((case or care) and management) or CPA or (Care and Programme and Approach) or (Assertive and Community and Treatment) or PACT or TCL or (Training and (community and living)) or (Madison and model)]

1.1.3 EMBASE (January 1980 to May 1997)

It was searched using the CSG's terms for randomised controlled trials and the CSG's terms for schizophrenia combined with the phrase:

[and (((case or care) near management) or CPA or (Care near1 Programme near1 Approach) or (Assertive near1 Community near1 Treatment) or PACT or TCL or (Training near (community near1 living)) or (Madison near4 model)]

1.1.4 MEDLINE (January 1966 to May 1997)

It was searched using the CSG's terms for randomised controlled trials and the CSG's terms for schizophrenia combined with the phrase:

[and ((case or care) near management) or CPA or (Care near1 Programme near1 Approach) or (Assertive near1 Community near1 Treatment) or PACT or TCL or (Training near (community near1 living)) or (Madison near4 model)]

1.1.5 PsycLIT (January 1974 to May 1997)

It was searched using the CSG's terms for randomised controlled trials and the CSG's terms for schizophrenia combined with the phrase:

[and ((case or care) near management) or CPA or (Care near1 Programme near1 Approach) or (Assertive near1 Community near1 Treatment) or PACT or TCL or (Training near (community near1 living)) or (Madison near4 model)]

1.2. Searching other resources

1.2.1 Reference searching

Each of the randomised controlled trial identified was sought as a citation on the SCISEARCH database. Reports of articles that had cited these studies were inspected in order to identify further trials. Reference lists of all included trials and identified reviews were scanned for evidence of trials missed by the computerised search.

It should be noted that in electronic searches the phrase 'ACT' is not feasible as this common word generates a very large number of false positives.

2 Search method Case Management Review

2.1. Electronic searches

The Cochrane Schizophrenia Group's Register (1997), EMBASE (January 1980 to May 1995), MEDLINE (January 1966 to May 1995), PsycLIT (January 1974 to May 1995) and CINAHL were all searched for any text containing the following phrases:

[((case or care) and (management)) or CPA or (Care Programme Approach) or (Assertive Community Treatment) or (PACT) or (TCL) or (Training near2 community living) or (Madison near model)]

Each randomised controlled trial identified by the search was sought as a citation on the SCISEARCH database.

2.2. Searching other resources

2.2.1 Hand searching

Reports of articles that had cited these studies were inspected in order to identify further trials.

Citation lists of all included trials and identified reviews were scanned for evidence of trials missed by the computerised search.

3 Search method 2009, 2012 versions ICM Review

3.1. Cochrane Schizophrenia Group Trials Register (February 2009)

The register was searched using the phrase:

(*ca?e management* OR *cpa* OR *community treatment* OR *community team* OR *community cent* OR *community care approach* OR *madison model* OR *outreach* OR *hostel* OR *aftercare* OR *residential* OR *housing* OR *transitional* OR *posthospital* OR *partial hospitali?ation* OR *Foster* OR *Guardianship* OR *daily living programme* OR *crisis intervention* OR *early intervention* OR *Ambulatory treatment* OR *Ambulatory care* OR *community living* OR *social support* OR *patient care team* OR *community mental health* OR *patient participation* OR *assertive outreach* OR *drop-in hospital* OR *drop-in care* OR *drop-in treatment* OR *drop-in cent* OR *drop-in unit* OR *drop in hospital* OR *drop in care* OR *drop in treatment* OR *drop in cent* OR *drop in unit* OR *day hospital* OR *day care* OR *day treatment* OR *day cent* OR *day unit* OR *Intensive care* OR *Intensive interven* OR *Intensive treat* OR *Intensive therap* OR *Intensive management* OR *Intensive model* OR *Intensive programm* OR *Intensive team* OR *Intensive service* OR *mobile care* OR *mobile interven* OR *mobile treat* OR *mobile therap* OR *mobile management* OR *mobile model* OR *mobile programm* OR *mobile team* OR *mobile service* OR *outreach care* OR *outreach interven* OR *outreach treat* OR

outreach therap OR *outreach management* OR *outreach model* OR *outreach programm* OR *outreach team* OR *outreach service* OR *community care* OR *community interven* OR *community treat* OR *community therap* OR *community management* OR *community model* OR *community programm* OR *community team* OR *community service* OR *community base* OR *home care* OR *home interven* OR *home treat* OR *home therap* OR *home management* OR *home model* OR *home programm* OR *home team* OR *home service* OR *home base* OR *aggressive outreach* OR *broker* OR *programme* OR *care programme approach* OR *care programme* in title, abstract, index terms of REFERENCE and in interventions of STUDY) OR (*Pact* OR *tcl* In title) OR(Pact* OR tcl* in abstract and index terms of REFERENCE and in interventions of STUDY)

This register is compiled by systematic searches of major databases, hand searches and conference proceedings (see [Group's Module - Specialised Register](#)).

3.2. Cochrane Schizophrenia Group Trials Register (August) 2012

The Trials Search Co-ordinator searched the Cochrane Schizophrenia Group's Trials Register (August 2012)

(*ca?e management* OR *cpa* OR *community treatment* OR *community team* OR *community cent* OR *community care approach* OR *madison model* OR *outreach* OR *hostel* OR *aftercare* OR *residential* OR *housing* OR *transitional* OR *posthospital* OR *partial hospitali?ation* OR *Foster* OR *Guardianship* OR *daily living programme* OR *crisis intervention* OR *early intervention* OR *Ambulatory treatment* OR *Ambulatory care* OR *community living* OR *social support* OR *patient care team* OR *community mental health* OR *patient participation* OR *assertive outreach* OR *drop-in hospital* OR *drop-in care* OR *drop-in treatment* OR *drop-in cent* OR *drop-in unit* OR *drop in hospital* OR *drop in care* OR *drop in treatment* OR *drop in cent* OR *drop in unit* OR *day hospital* OR *day care* OR *day treatment* OR *day cent* OR *day unit* OR *Intensive care* OR *Intensive interven* OR *Intensive treat* OR *Intensive therap* OR *Intensive management* OR *Intensive model* OR *Intensive programm* OR *Intensive team* OR *Intensive service* OR *mobile care* OR *mobile interven* OR *mobile treat* OR *mobile therap* OR *mobile management* OR *mobile model* OR *mobile programm* OR *mobile team* OR *mobile service* OR *outreach care* OR *outreach interven* OR *outreach treat* OR *outreach therap* OR *outreach management* OR *outreach model* OR *outreach programm* OR *outreach team* OR *outreach service* OR *community care* OR *community interven* OR *community treat* OR *community therap* OR *community management* OR *community model* OR *community programm* OR *community team* OR *community service* OR *community base* OR *home care* OR *home interven* OR *home treat* OR *home therap* OR *home management* OR *home model* OR *home programm* OR *home team* OR *home service* OR *home base* OR *aggressive outreach* OR *broker* OR *programme* OR *care programme approach* OR *care programme* or *Pact* OR *tcl* iin title, abstract, index terms of REFERENCE)

The Cochrane Schizophrenia Group's Trials Register is compiled by systematic searches of major databases, handsearches and conference proceedings (see [Group's Module](#)). Incoming trials are assigned to existing or new review titles.

Appendix 2. Previous data collection and analyses methods

Selection of studies

The principal reviewer (MD) inspected all abstracts of studies identified as above and identified potentially relevant reports. In addition, to ensure reliability, CBI inspected a random sample of these abstracts, comprising 10% of the total. Where disagreement occurred this was resolved by discussion, or where there was still doubt, the full article was acquired for further inspection. The full articles of relevant reports were acquired for reassessment and carefully inspected for a final decision on inclusion (see [Criteria for considering studies for this review](#)). Once the full articles were obtained, in turn MD and CBI inspected all full reports and independently decided whether they met inclusion criteria. MD and CBI were not blinded to the names of the authors, institutions or journal of publication. Where difficulties or disputes arose, we asked author MM for help and if it was impossible to decide, these studies were added to those awaiting assessment and the authors of the papers contacted for clarification.

Data extraction and management

1. Extraction

1.1 Data regarding criteria and outcomes

The principal reviewer (MD) extracted data from all included studies. In addition, to ensure reliability, CBI independently extracted data from a random sample of these studies, comprising 10% of the total. Again, any disagreement was discussed, decisions documented and, if necessary, authors of studies were contacted for clarification. With remaining problems MM helped clarify issues and those final decisions were documented. Data presented only in graphs and figures were extracted whenever possible, but were included only if two reviewers independently had the same result. Attempts were made to contact authors through an open-ended request in order to obtain missing information or for clarification whenever necessary. Where possible, we extracted data relevant to each component centre of multi-centre studies separately.

1.2 Additional data

1.2.1 Fidelity

This rating related to the Intensive Case Management intervention. This rated fidelity of the intervention to assertive community treatment on the 'team membership' and 'team structure and organisation' sub-scales of the Index of Fidelity to Assertive Community Treatment (IFACT) ([McGrew 1994](#)).

This index was derived from a survey of 20 clinical experts in assertive community treatment and validated in a survey of 18 programmes.

a. The 'team membership' sub-scale comprises four items:

- ratio of patients to staff
- total size of team
- extent of psychiatric input
- extent of nursing input to the team

b. The 'structure and organisation' sub-scale comprises seven items, whether the team is:

- the primary source of care for its patients
- is situated away from the hospital
- meets daily
- shares responsibility for caseloads
- is available 24 hours a day
- has a team leader who is also a case manager
- offers unlimited time for its services

We chose IFACT because the sub-scales are brief and are possible to be completed from published or unpublished text. For each item on the index, a score of one indicates high fidelity to the model. Score ranges from 0 to 11, where the maximum score available on 'team membership' sub-scale is 4, and on 'structure and organisation' sub-scale is 7, with higher scores indicating higher fidelity to the model.

We obtained fidelity data from published and unpublished trial reports, direct contact with trialists, and data previously obtained directly from trialists by previous reviews (Burns 2001, Catty 2002, Burns 2007). Two raters (MD and CBI) independently combined these data into a single fidelity score. Multicentre trials of Intensive Case Management often struggle to implement a uniform approach, with centres operating at different degrees of fidelity. Where possible, we rated each component centre separately.

1.2.2 Baseline hospital use

The average number of days per month in hospital for all participants in the two years before the study began.

We obtained this data from published and unpublished trial reports and from direct contact with trialists.

1.2.3 Service use: hospitalisation

We obtained the primary outcome mean number of days per month in hospital for the included studies from published and unpublished trial reports, direct contact with trialists and data previously obtained directly from trialists reported by a previous review (Burns 2007).

2. Management

2.1 Forms

Data were extracted onto standard, simple forms.

2.2 Data from multi-centre trials

Where possible MD and CBI verified independently calculated centre data against original trial reports.

3. Scale-derived data

We included continuous data from rating scales only if:

- a. the psychometric properties of the measuring instrument had been described in a peer-reviewed journal (Marshall 2000); and
- b. the measuring instrument was not written or modified by one of the trialists for that particular trial; and
- c. the measuring instrument is either i. a self-report or ii. completed by an independent rater or relative (not the therapist).

4. Endpoint versus change data

We preferred to use scale endpoint data, which typically cannot have negative values and is easier to interpret from a clinical point of view. Change data are often not ordinal and are very problematic to interpret. If endpoint data were unavailable, we used change data.

5. Skewed data

5.1 General

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aim to apply the following standards to all data before inclusion: a) standard deviations and means are reported in the paper or obtainable from the authors; b) when a scale starts from the finite number zero, the standard deviation, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution, (Altman 1996); c) if a scale started from a positive value (such as PANSS which can have values from 30 to 210) the calculation described above was modified to take the scale starting point into account. In these cases skew is present if $2SD > (S - S_{min})$, where S is the mean score and S min is the minimum score. Endpoint scores on scales often have a finite start and end point and these rules can be applied. When continuous data are presented on a scale which includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed

or not. Skewed data from studies of less than 200 participants were entered in additional tables rather than into an analysis. Skewed data pose less of a problem when looking at means if the sample size is large and were entered into syntheses.

5.2 Specific - mean number of days in hospital

We implemented one exception to the above rule (5.1) in order to present more data, recognising that this is a 'post hoc' decision, but also that the rules as regards management of skewed data and how robust skewed data are within meta-analysis is unclear ([Higgins 2011](#)). Where mean number of days in hospital data were skewed, and they were provided by studies of less than 200 participants, we nevertheless entered those data into a sub-group of the overall analysis. We also presented the overall effect from all data pooled.

6. Common measure

To facilitate comparison between trials, we intended to convert variables that can be reported in different metrics, such as days in hospital (mean days per year, per week or per month) to a common metric (e.g. mean days per month).

7. Conversion of continuous to binary

Where possible, efforts were made to convert outcome measures to dichotomous data. This could be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It was generally assumed that if there had been a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, [Overall 1962](#)) or the Positive and Negative Syndrome Scale (PANSS, [Kay 1986](#)), this could be considered as a clinically significant response ([Leucht 2005a](#), [Leucht 2005b](#)). If data based on these thresholds were not available, we used the primary cut-off point presented by the original authors.

8. Direction of graphs

Where possible, we entered data in such a way that the area to the left of the line of no effect indicates a favourable outcome for Intensive Case Management.

Assessment of risk of bias in included studies

Again working independently, the principal reviewer (MD) assessed risk of bias of all included studies and the second reviewer (CBI) assessed risk of bias from a random sample of these studies, comprising 10% of the total. MD and CBI assessed risk of bias using the tool described in the Cochrane Collaboration Handbook ([Higgins 2011](#)). This tool encourages consideration of how the sequence was generated, how allocation was concealed, the integrity of blinding at outcome, the completeness of outcome data, selective reporting and other biases. We would have excluded studies where allocation was clearly not concealed.

Trials with high risk of bias (defined as at least three out of five domains categorised as 'No') were not included in the meta-analysis. If the raters disagreed, the final rating was made by consensus with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials are provided, authors of the studies were contacted in order to obtain further information. Non-concurrence in quality assessment was reported.

Measures of treatment effect

1. Binary data

For binary outcomes we calculated a standard estimation of the random-effects risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive ([Boissel 1999](#)) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians ([Deeks 2000](#)). For statistically significant results we had planned to calculate the number needed to treat to provide benefit /to induce harm statistic (NNTB/H), and its 95% confidence interval (CI) using Visual Rx (<http://www.nntonline.net/>) taking account of the event rate in the control group. This, however, was superseded by Summary of findings table 1 and the calculations therein.

2. Continuous data

2.1 Summary statistic

For continuous outcomes we estimated a random-effects mean difference (MD) between groups. We preferred not to calculate effect size measures (standardised mean difference SMD). However, in the case of where scales were of such similarity to allow presuming there was a small difference in measurement, we calculated it and, whenever possible, we transformed the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems. Firstly, authors often fail to account for intra-class correlation in clustered studies, leading to a 'unit of analysis' error ([Divine 1992](#)) whereby p values are spuriously low, confidence intervals unduly narrow and statistical significance overestimated. This causes type I errors ([Bland 1997](#), [Gulliford 1999](#)).

Where clustering is not accounted for in primary studies, we presented data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. In subsequent versions of this review we will seek to contact first authors of studies to obtain intra-class correlation coefficients for their clustered data and to adjust for this by using accepted methods ([Gulliford 1999](#)). Where clustering had

been incorporated into the analysis of primary studies, we present these data as if from a non-cluster randomised study, but adjusted for the clustering effect.

We have sought statistical advice and have been advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the intra-class correlation coefficient (ICC) [Design effect = $1+(m-1)*ICC$] (Donner 2002). If the ICC was not reported it was assumed to be 0.1 (Ukoumunne 1999).

If cluster studies has been appropriately analysed taking into account intra-class correlation coefficients and relevant data documented in the report, synthesis with other studies would have been possible using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. It occurs if an effect (e.g. pharmacological, physiological or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we only used data of the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, if relevant, the additional treatment arms were presented in comparisons. Where the additional treatment arms were not relevant, these data were not reproduced.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2007). For any particular outcome should more than 50% of data be unaccounted for, we did not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we marked such data with (*) to indicate that such a result may well be prone to bias.

2. Binary

In the case where attrition for a binary outcome is between 0 and 50% and where these data were not clearly described, data were presented on a 'once-randomised-always-analyse' basis (an intention to treat analysis). Those leaving the study early were all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death. A sensitivity analysis was undertaken testing how prone the primary outcomes were to change when data from only those who completed the study were compared with intention to treat data using the assumption outlined above.

In the case where number of death was more than 10% of the sample overall, the above statement was applied but attrition due to death was not imputed.

3. Continuous

3.1 Attrition

In the case where attrition for a continuous outcome is between 0 and 50% and data from only those who completed the study are reported, we have reproduced these.

3.2 Standard deviations

3.2.1 General

Where there are missing measures of variance for continuous data, but exact standard errors or confidence intervals for group means, or either 'p' or 't' values for differences in means, we calculated standard deviation value according to method described in Section 7.7.3 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). If standard deviations were not reported and could not be calculated from available data, we asked authors to supply the data. In the absence of data from authors, we used the mean standard deviation from other studies.

3.2.2 Standard deviation mean number of days per month in hospital

For the primary outcome, mean number of days per month in hospital, if standard deviations were not reported and could not be calculated from available data, we asked authors for additional information. In the absence of data from authors, we imputed the missing standard deviations using a regression analysis of SD against mean from those trials that provided both. We documented in Table 2 in what studies we imputed SDs according to the above technique.

3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results. Therefore, where LOCF data has been used in the trial, if less than 50% of the data had been assumed, we reproduced these data and indicated that they are the product of LOCF assumptions.

3.4 Incomplete data for meta-regression

In some cases we anticipated that IFACT score variables would not all be available. If IFACT score could not be calculated from available data, we imputed it by multiple imputation using the *mi* library in R (R 2008). As explained above, we only made these assumptions if we were able to directly rate over 50% of the data. We documented in Table 3 in what studies we calculated IFACT score according to the above technique.

In some cases we anticipated that baseline hospital use data would not all be available. Missing data was imputed as for the IFACT scores. As explained above, we only make these assumptions if we were able to directly rate over 50% of the data. We documented for which studies we calculated baseline hospital use data according to the above technique (Table 3).

A sensitivity analysis was undertaken testing how prone the results from meta-regression were to change when data from only those who completed the studies were compared with the imputed data using the assumption outlined above.

Assessment of heterogeneity

1. Clinical heterogeneity

We considered all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We simply inspected all studies for clearly outlying situations or people, which we had not predicted would arise. When such situations or participant groups arose, these were fully discussed.

In addition two potential sources of heterogeneity were specified a priori (fidelity and baseline level of hospital use (Data extraction and management)). These data were extracted as described above.

2. Methodological heterogeneity

We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods which we had not predicted would arise. Should such methodological outliers arise these will be fully discussed.

3. Statistical heterogeneity

3.1 Visual inspection

We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I^2 statistic

Heterogeneity between studies was investigated by considering the I^2 method alongside the χ^2 'p' value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance (Higgins 2003). The importance of the observed value of I^2 depends on i. magnitude and direction of effects and ii. strength of evidence for heterogeneity (e.g. 'p' value from χ^2 test, or a confidence interval for I^2). I^2 estimate greater than or equal to 50% accompanied by a statistically significant χ^2 statistic, was interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2011). When substantial levels of heterogeneity were found in the primary outcome, we explored reasons for heterogeneity (Subgroup analysis and investigation of heterogeneity).

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results (Egger 1997). These are described in Section 10 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We did not use funnel plots for outcomes where there were ten or fewer studies, or where all studies were of similar sizes. In other cases, where funnel plots were possible, we sought statistical advice in their interpretation.

Data synthesis

Where possible we employed a random-effects model for analyses. We understand that there is no closed argument for preference for use of fixed or random-effects models. The random-effects method incorporates an assumption that different studies are estimating different, yet related, intervention effects. According to our hypothesis of an existing variation across studies, to be explored further in the meta-regression analysis despite being cautious that random-effects methods does put added weight onto the smaller of the studies - we favoured using random-effects model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We anticipate two sub-group analyses. For the first version of the protocol for this review we did not anticipate any sub-group analyses. On further consideration we now realise that analysis at separate time periods could be thought of as sub-groups. The second sub-group is within the primary outcome and relates to skewed and non-skewed data. This has been introduced late into this protocol and could be considered post hoc. However, we are also conscious that our original rule for management of these data could be considered overly cautious and result in some important data not being presented (Higgins 2011).

2. Investigation of heterogeneity

2.1 Anticipated heterogeneity - outcome of mean days per month in hospital

Investigation of heterogeneity formed part of the secondary objectives of the review. We hypothesised that the effect of Intensive Case Management on one of our primary outcomes (mean number of days per month in hospital) differs according to fidelity of intervention to the assertive community treatment model and the baseline level of hospital use.

The association of the IFACT score and the baseline number of days in hospital with the treatment effect was examined by performing random-effects meta-regression analysis in R ([R 2008](#)). The script we used to perform meta-regression analyses is reported in [Appendix 3](#). Meta-regression was also carried out using both variables within the same model. The relationship between the treatment effect and the two variables was also examined using a thin plate spline. If possible data from multi-centre studies were to be entered in the meta-regression disaggregated into the component centre with outcome and fidelity data for each.

Meta-regression was performed:

- a) only if at least ten studies per comparison are available ([Higgins 2011](#))
- b) all included studies were entered into the meta-regression. Comparison type was also tested as an additional regressor in the model.

2.2 Unanticipated heterogeneity - other outcomes

2.2.1 For outcomes other than the second primary outcome (not remaining in contact with psychiatric services)

If inconsistency was high this was reported and no exploration undertaken.

2.2.2 For outcome 'not remaining in contact with psychiatric services'

If inconsistency was high this was reported. First we investigated whether data had been entered correctly. Second, if data had been correct, the graph was visually inspected and studies outside of the company of the rest were successively removed to see if heterogeneity was restored. Should this occur with no more than 10% of the data being excluded, data were presented. If not, data were not pooled.

Should unanticipated clinical or methodological heterogeneity be obvious we simply stated hypotheses regarding these for future reviews or versions of this review. We did not anticipate undertaking analyses relating to these.

Sensitivity analysis

1. Implication of randomisation

We aimed to include trials in a sensitivity analysis if they are described in some way as to imply randomisation. For the primary outcomes we included these studies and if there was no substantive difference when the implied randomised studies were added to those with better description of randomisation, then all data were employed from these studies.

2. Standard care caseload

If data were available, a sensitivity analysis was undertaken testing how prone the primary outcomes were to change when trials comparing Intensive Case Management to standard community care caseload ≤ 20 were compared with trials comparing Intensive Case Management to standard community care caseload >20 . If there was a substantial difference, we reported results and discussed them but continued to pool the data.

3. Assumptions for lost binary data

Where assumptions had to be made regarding people lost to follow-up (see [Dealing with missing data](#)) we compared the findings of the primary outcomes when we used our assumption compared with completer data only. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

4. Assumptions for incomplete data for meta-regression

Where assumptions had to be made regarding missing SDs data in studies entering meta-regression (see [Dealing with missing data](#)), we compared the findings of the meta-regression on our primary outcome when we used our assumption compared with data taken from only those who completed the studies. A sensitivity analysis was undertaken testing how prone results from meta-regression were to change when data from those who completed were compared with imputed data using the assumption outlined above. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

Appendix 3. R script used to impute data and perform meta-regression analysis

```
AOIP <- read.csv('META-REG_2010_fmi.csv')
AOIP <- AOIP[1:52,]
names(AOIP)
AOIPM <- AOIP
# initially replace missing SD's by simple regression model on means
exp <- lm(AOIP$Exp_SD ~ poly(AOIP$Exp_MEAN,2))
exp2 <- predict(exp, as.data.frame(AOIP$Exp_MEAN), type = 'response')
# plot(AOIP$Exp_SD, AOIP$Exp_MEAN, xlim = c(0,15))
# points(exp2, AOIP$Exp_MEAN, col = 'red')
exp3 <- AOIP$Exp_SD
```



```
exp3[is.na(exp3)] <- exp2[is.na(exp3)]
AOIP$Exp_SD <- exp3

exp <- lm(AOIP$Con_SD ~ poly(AOIP$Con_MEAN,2))
exp2 <- predict(exp, as.data.frame(AOIP$Con_MEAN), type = 'response')
# plot(AOIP$Con_SD, AOIP$Con_MEAN, xlim = c(0,15))
# points(exp2, AOIP$Con_MEAN, col = 'red')
exp3 <- AOIP$Con_SD
exp3[is.na(exp3)] <- exp2[is.na(exp3)]
AOIP$Con_SD <- exp3

library(mi)

AOIP2 <- cbind(AOIP[,18], AOIP[,5:11], AOIP[,13], AOIP[,16:17])
names(AOIP2)[1] <- names(AOIP)[18]
names(AOIP2)[9] <- names(AOIP)[13]

info.aoip <- mi.info(AOIP2)

# info.aoip <- update(info.aoip, "include",
# list(trial_no="FALSE",cent.no="FALSE",trial_id="FALSE",centre_id="FALSE" ))

imp.aoip <- mi(AOIP2, info.aoip, n.iter = 30)
AOIP2 <- mi.data.frame(imp.aoip)
AOIP2 <- cbind(AOIP[,1:4],AOIP2)
# recreate Fideltot
Fideltot <- AOIP2$Fid.Org + AOIP2$Fidstaff
AOIP2 <- cbind(AOIP2, Fideltot)

# set OPUS baseline mean to missing
is.na(AOIP2[,13]) <- 19
AOIP2.mi <- AOIP2
AOIP <- AOIPM

# write.csv(AOIP2, 'metaregdataset_imputed2010.csv')
# meta analysis

library(meta)

AO1 <- metacont(AOIP$Exp_N, AOIP$Exp_MEAN, AOIP$Exp_SD, AOIP$Con_N, AOIP$Con_MEAN,
AOIP$Con_SD, AOIP$centre_id)

AO2 <- metacont(AOIP2$Exp_N, AOIP2$Exp_MEAN, AOIP2$Exp_SD, AOIP2$Con_N, AOIP2$Con_MEAN,
AOIP2$Con_SD, AOIP2$centre_id)
AO3 <- metacont(AOIP2$Exp_N, AOIP2$Exp_MEAN, AOIP2$Exp_SD, AOIP2$Con_N, AOIP2$Con_MEAN,
AOIP2$Con_SD, AOIP2$centre_id, subset = (AOIP2$SCvsLICM == 1))
AO4 <- metacont(AOIP2$Exp_N, AOIP2$Exp_MEAN, AOIP2$Exp_SD, AOIP2$Con_N, AOIP2$Con_MEAN,
AOIP2$Con_SD, AOIP2$centre_id, subset = (AOIP2$SCvsLICM == 2))

summary(AO1)
summary(AO2)

# metaregression

# Control type
AO2rct <- lm(AO2$TE ~ AOIP2$SCvsLICM, weights = AO2$w.random)
summary(AO2rct)

# Total fidelity score
AO2r1 <- lm(AO2$TE ~ AOIP2$Fideltot, weights = AO2$w.random)
summary(AO2r1)
plot(AO2$TE ~ AOIP2$Fideltot)
```



```
abline(lm(AO2$TE ~ AOIP2$Fideltot, weights = AO2$w.random))

# Interaction
AO2rint <- lm(AO2$TE ~ AOIP2$Fideltot * AOIP2$SCvsLICM, weights = AO2$w.random)
summary(AO2rint)
plot(AO2$TE ~ AOIP2$Fideltot)
abline(lm(AO2$TE ~ AOIP2$Fideltot, weights = AO2$w.random))

# Organizational fidelity score
AO2r2 <- lm(AO2$TE ~ AOIP2$Fid.Org, weights = AO2$w.random)
summary(AO2r2)
plot(AO2$TE ~ AOIP2$Fid.Org)
abline(lm(AO2$TE ~ AOIP2$Fid.Org, weights = AO2$w.random))
# more fancy plot
plot(AO1$TE ~ AOIP$Fid.Org, pch = 21, bg = 'blue', cex = AO1$w.random*6,
ylab = 'Treatment Effect (Days)', xlab = 'Organizational Fidelity Score')
abline(lm(AO2$TE ~ AOIP2$Fid.Org, weights = AO2$w.random))

# against baseline
AO2r4 <- lm(AO2$TE ~ AOIP2$Baseline_Mean, weights = AO2$w.random)
summary(AO2r4)
plot(AO2$TE ~ AOIP2$Baseline_Mean)
abline(lm(AO2$TE ~ AOIP2$Baseline_Mean, weights = AO2$w.random))
# fancy plot
plot(AO1$TE ~ AOIP$Baseline_Mean, pch = 21, bg = 'blue', cex = AO1$w.random*6,
ylab = 'Treatment Effect (Days)', xlab = 'Baseline Days in Hospital')
abline(lm(AO2$TE ~ AOIP2$Baseline_Mean, weights = AO2$w.random))

# multivariate model
AO2r5 <- lm(AO2$TE ~ AOIP2$Baseline_Mean + AOIP2$SCvsLICM + AOIP2$Fid.Org, weights = AO2$w.random)
summary(AO2r5)

# Thin plate spline

library(fields)

x <- cbind(AOIP2$Baseline_Mean[-19], AOIP2$Fid.Org[-19])
fit <- Tps(x, AO2$TE[-19], weights = AO2$w.random[-19], df = 10)
par(mfrow=c(2,1))
surface(fit)
plot(x, pch = 21, bg = 'red', cex = AO2$w.random[-19]*4)
```

Appendix 4. Results of searches from previous versions of this review

1. Selection of studies (see [Selection of studies](#)).

When CBI inspected a random sample of study abstracts identified as above (see [Search methods for identification of studies](#)) comprising 10% of total abstracts the principal reviewer (MD) had inspected, disagreement did occur. Full articles were therefore acquired for further inspection. At this next stage MD and CBI had full agreement on the total sample of reports selected for further inspection.

When MD and CBI in turn inspected all full articles of relevant reports and independently decided whether they met inclusion criteria (see [Criteria for considering studies for this review](#)), they fully agreed and no difficulties or disputes arose on any report. It was not necessary contact third reviewer (MM) for clarifying issues.

2. Data extraction (see [Data extraction and management](#))

When CBI independently extracted data from a random sample of included studies (10% of total) disagreements were discussed. MD and CBI reached full agreement on final decisions.

3. Original Cochrane reviews ([Marshall 2000a](#), [Marshall 2000b](#))

3.1 ACT ([Marshall 2000b](#))

Fourteen trials had met inclusion for the ACT versus standard care comparison. The trials included were [Aberg-Wistedt-Sweden 1995](#), [Audini-UK 1994](#), [Bond-Chicago1 1990](#), [Bond-Indiana1 1988](#), [Chandler-California1 1991](#), [Hampton-Illinois 1992](#), [Herinckx-Oregon 1996](#), [Jerrell-SCarolina1 1991](#), [Lehman-Maryland1 1994](#), [Morse-Missouri1 1992](#), [Quinlivan-California 1995](#), [Rosenheck-USA 1993](#), [Solomon-Pennsylvania 1994](#) and [Test-Wisconsin 1985](#). All trials were included in the current review in the comparison ICM versus standard care.

For the ACT versus hospital-based rehabilitation comparison, three trials had been eligible for inclusion ([De Cangas-Canada 1994](#), [Lafave-Canada 1996](#), [Marx-Wisconsin 1973](#)). All three have been excluded from the current update as they did not meet inclusion criteria.

Six trials were included in the ACT versus case management comparison ([Bush-Georgia 1990](#), [Essock-Connecticut1 1995](#), [Jerrell-SCarolina1 1991](#), [Morse-Missouri2 1997](#), [Quinlivan-California 1995](#), [Solomon-Pennsylvania 1994](#)). Of the original six studies described above, two were included in the ICM versus standard care comparison as both are three arm studies comparing ICM (in two arms) versus standard care ([Jerrell-SCarolina1 1991](#), [Solomon-Pennsylvania 1994](#)). Three trials were included in the ICM versus non-ICM comparison ([Bush-Georgia 1990](#), [Essock-Connecticut1 1995](#), [Quinlivan-California 1995](#)). [Quinlivan-California 1995](#) was included in both comparisons ICM versus standard care and ICM versus non-ICM, as it had three arms comparing three differentiated interventions (ICM, non-ICM and standard care). The sixth trial, [Morse-Missouri2 1997](#), although previously included, was excluded from the current update because it contained no usable data, as number for treatment groups were not presented.

3.2 Case Management ([Marshall 2000a](#))

Ten randomised controlled trials were included in the comparison of case management versus standard care ([Curtis-New York 1992](#), [Ford-UK 1995](#), [Franklin-Texas 1987](#), [Jerrell-SCarolina1 1991](#), [Macias-Utah 1994](#), [Marshall-UK 1995](#), [Muijen-UK2 1994](#), [Quinlivan-California 1995](#), [Solomon-Pennsylvania 1994](#), [Tyrer-UK 1995](#)). Of these eight are now included ([Curtis-New York 1992](#), [Ford-UK 1995](#), [Jerrell-SCarolina1 1991](#), [Macias-Utah 1994](#), [Marshall-UK 1995](#), [Muijen-UK2 1994](#), [Quinlivan-California 1995](#), [Solomon-Pennsylvania 1994](#)). [Franklin-Texas 1987](#) and [Tyrer-UK 1995](#) had to be excluded as they did not meet inclusion criteria on type of intervention.

4. 2009 update

The February 2009 update search of Cochrane Schizophrenia Group's Register of trials yielded 2565 references. We selected 55 for further inspection. Of these 14 trials met the inclusion criteria and were included ([Bjorkman-Sweden 2002](#), [Drake-NHamp 1998](#), [Essock-Connecticut2 2006](#), [Harrison-Read-UK 2000](#), [Johnston-Australia 1998](#), [Morse-Missouri3 2005](#), [Muller-Clemm-Canada 1996](#), [Okpaku-Tennessee 1997](#), [OPUS-Denmark 1999](#), [Pique-California 1999](#), [REACT-UK 2002](#), [Sytema-Netherlands 1999](#), [Salkever-SCarolina 1999](#), [UK700-UK 1999](#)). Thirty one trials were excluded.

We added ten English language trials and five Chinese trials to those awaiting assessment and sought further information. Three trials which had been previously been awaiting assessment were able to be included as more reports had become available ([Fekete 1998](#) now included as [McDonel-Indiana 1997](#), [Holloway-UK 1996](#), [Shern-USA1 2000](#)).

Appendix 5. Dealing with missing data - standard deviation mean number of days per month in hospital (Intensive Case Management Protocol)

3.2.2 Standard deviation mean number of days per month in hospital

For the primary outcome, mean number of days per month in hospital, if standard deviations were not reported and could not be calculated from available data, we asked authors for additional information. In the absence of data from authors, we calculated missing standard deviations using a regression analysis of standard deviation against mean, based on data from studies which did report these data. If the standard deviations calculated according to the above technique were available from a previous review (published and unpublished data) ([Burns 2007](#)), we used these data.

Appendix 6. Dealing with missing data - incomplete data for meta-regression (Intensive Case Management Protocol)

3.4 Incomplete data for meta-regression

In some cases we anticipate that IFACT score variables will not all be available. Where these missing data are from multi-centre studies from which we do have relevant data we assumed the missing variable score to be the mode of the available data from the other centres that we used as a reference. Where there was no clear reference centres, we tried to match the study to another we felt to be closest and used those scores. As explained above, we will only make these assumptions if we are able to directly rate over 50% of the data within each multi-centre study and overall.

In some cases we anticipate that baseline hospital use data will not all be available. Where these missing data are from multi-centre studies from which we do have relevant data we assumed the missing information to be the mean of the available data from the other centres that we used as a reference. Where there was no clear reference centres, we tried to match the study to another we felt to be closest and used those means. As explained above, we will only make these assumptions if we are able to directly rate over 50% of the data within each multi-centre study and overall.

WHAT'S NEW

Date	Event	Description
23 August 2016	New search has been performed	Results of 2012 and 2015 update searches added to the review. Two new studies added to included studies.

Date	Event	Description
23 August 2016	New citation required but conclusions have not changed	Data from two new studies did not substantially alter results or change overall conclusions.
10 April 2015	Amended	Search updated, and 299 possibly related references were added to 'Classification pending references' of the review.

HISTORY

Protocol first published: Issue 3, 2009

Review first published: Issue 10, 2010

Date	Event	Description
12 August 2012	Amended	Update search of Cochrane Schizophrenia Group's Trial Register (see Search methods for identification of studies), 81 studies added to awaiting classification.
6 October 2010	Amended	Contact details updated.

CONTRIBUTIONS OF AUTHORS

Marina Dieterich: developed and wrote protocol, participated in literature searches, selected studies and extracted data, wrote report for both versions.

Claire Irving: developed and wrote protocol, participated in studies selection and data extraction for original version.

Hanna Bergman: carried out trial selection and data extraction for 2015 update.

Mariam Khokhar: carried out trial selection and data extraction for 2015 update.

Bert Park: carried out meta-regression analysis, helped in writing the report for original version.

Max Marshall: developed and wrote protocol, helped in studies selection, final draft for original version.

DECLARATIONS OF INTEREST

Marina Dieterich: none known.

Claire Irving: none known.

Hanna Bergman: none known.

Mariam Khokhar: none known.

Bert Park: none known.

Max Marshall: was involved in one included study and has written extensively in this area.

SOURCES OF SUPPORT

Internal sources

- University of Verona, Italy.

Department of Medicine and Public Health, Section of Psychiatry and Clinical Psychology

External sources

- NIHR, UK.

Cochrane Incentive Award 15/81/30 - Intensive case management for severe mental illness

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following section follows the numbering system of the methods of the review.

1.) Types of outcome measures (see [Types of outcome measures](#))

The time grouping of outcomes has been slightly amended in the review, introducing a different timing for follow-up assessed once the active intervention was stopped. We have reported the protocol version below.

Outcomes were grouped by time into short term (up to and including 6 months), medium term (7 months to up to and including 12 months) and long term (over 12 months). Where available, 24 months was the preferred follow-up point for calculating mean days per months in hospital. If more than one follow-up point within the same period were available, we reported the latest one.

2.) Some social functioning and costs outcomes have been slightly amended in the review (see [Secondary outcomes](#)). We have reported the protocol version below.

4. Social functioning

4.1 Imprisonment (i.e. police contacts & arrests)

9. Economic

9.1 Costs of psychiatric hospital care

9.2 Costs of health care

9.3 Costs of all care

3.) Compliance with medication (see [Secondary outcomes](#))

This secondary outcome was listed twice in the protocol due to inattention (both as global state and behaviour). We have amended it, listing 'compliance with medication' just under 'global state' outcome.

4.) Data regarding criteria and outcomes (see [Data extraction and management](#))

We further clarified this section in the review. We have reported the protocol version below.

1. Extraction

1.1 Data regarding criteria and outcomes

Authors MD and CBI independently extracted data from included studies. Again, any disagreement was discussed, decisions documented and, if necessary, authors of studies were contacted for clarification. With remaining problems MM helped clarify issues and those final decisions were documented. Data presented only in graphs and figures were extracted whenever possible, but were included only if two reviewers independently had the same result. Attempts were made to contact authors through an open-ended request in order to obtain missing information or for clarification whenever necessary. Where possible, we extracted data relevant to each component centre of multi-centre studies separately.

5.) Skewed data (see [Data extraction and management](#))

We had not anticipated the following clarification in the protocol, but added it in the review.

We implemented one exception to the above rules in order to present more data, recognising that this is a post hoc decision, but also that the rules with regards to management of skewed data and how robust skewed data are within meta-analysis are unclear ([Higgins 2011](#)). Where mean number of days in hospital data were skewed, and they were provided by studies of fewer than 200 participants, we entered those data into a subgroup of the overall analysis. We also presented the overall effect from all data pooled.

6.) 'Summary of findings' table (see [Data extraction and management](#))

The way the outcomes included in the 'Summary of findings' table were listed and presented were slightly rearranged, but not substantially modified. We have reported the protocol version below. Besides, we decided not to apply the low and high control risk calculation as stated in the protocol, and reported below.

Summary of findings table

We anticipate including the following long term main outcomes in a summary of findings table.

1. Global state

1.1 Hospitalisation: mean number of days per month in hospital

1.2 Relapse

1.3 Leaving the study early (lost to follow up)

2. Service use

2.1 Hospital admission across time

3. Adverse effect

3.1 Death - suicide

4. Social functioning

4.1 Employment - unemployed at end of study

5. Mental state: general symptoms

5.1. Not improved to a clinically meaningful extent (as defined in trial)

Within the Summary of findings table we assumed for calculation of the low risk groups that the lowest control risk applied to all data. We did the same for the assumption of the highest risk groups.

7.) Assessment of risk of bias in included studies (see [Assessment of risk of bias in included studies](#))

We further clarified this section in the review. We have reported the protocol version below.

Again working independently, MD and CBI assessed risk of bias using the tool described in the Cochrane Collaboration Handbook ([Higgins 2011](#)). This tool encourages consideration of how the sequence was generated, how allocation was concealed, the integrity of blinding at outcome, the completeness of outcome data, selective reporting and other biases. We would have excluded studies where allocation was clearly not concealed.

8.) Binary (see [Dealing with missing data](#), 2.)

We have further clarified this paragraph in the review. We have reported the protocol version below.

In the case where attrition for a binary outcome is between 0 and 50% and where these data were not clearly described, data were presented on a 'once-randomised-always-analyse' basis (an intention to treat analysis). Those leaving the study early were all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death. A sensitivity analysis was undertaken testing how prone the primary outcomes were to change when data from only those who completed the study were compared with intention to treat data using the assumption outlined above.

9.) Standard deviation mean number of days per month in hospital (see [Dealing with missing data](#), 3.2.2)

Substantially amended. For original protocol version, please see [Appendix 5](#).

10.) Incomplete data for meta-regression (see [Dealing with missing data](#), 3.4)

Substantially amended. For original protocol version, please see [Appendix 6](#).

11.) Statistical heterogeneity (see [Assessment of heterogeneity](#), 3.2)

We further clarified the last paragraph in the review. We have reported the protocol version below.

3.2 Employing the I^2 statistic

Heterogeneity between studies was investigated by considering the I^2 method alongside the Chi^2 'p' value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance ([Higgins 2003](#)). The importance of the observed value of I^2 depends on i. magnitude and direction of effects and ii. strength of evidence for heterogeneity (e.g. 'p' value from Chi^2 test, or a confidence interval for I^2). I^2 estimate greater than or equal to 50% accompanied by a statistically significant Chi^2 statistic, was interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - [Higgins 2011](#)) and reasons for heterogeneity were explored. If the inconsistency was high and the clear reasons were found, data were presented separately.

12.) Subgroup analyses (see [Subgroup analysis and investigation of heterogeneity](#), 1.)

No subgroup analyses had been anticipated in the protocol.

13. Subgroup analyses (see [Subgroup analysis and investigation of heterogeneity](#), 2.)

We further clarified this section in the review. We have reported the protocol version below.

2. Investigation of heterogeneity

2.1 Unanticipated heterogeneity

Should unanticipated clinical or methodological heterogeneity be obvious we will simply state hypotheses regarding these for future reviews or versions of this review. We do not anticipate undertaking analyses relating to these.

14.) Sensitivity analysis (see [Sensitivity analysis](#), 4.)

Substantially amended. We have reported the protocol version below.

4. Assumptions for incomplete data for meta-regression

Where assumptions had to be made regarding missing trial data for meta-regression (see [Dealing with missing data](#)) we compared the findings of the meta-regression on primary outcome when we used our assumption compared with complete data only. A sensitivity

analysis was undertaken testing how prone result from meta-regression were to change when 'completed' data only were compared to the imputed data using the above assumption. If there was a substantial difference, then only completed data were employed.

INDEX TERMS

Medical Subject Headings (MeSH)

*Case Management; Community Mental Health Services [*methods]; Employment [statistics & numerical data]; Hospitalization [statistics & numerical data]; Mental Disorders [*therapy]; Outcome and Process Assessment, Health Care [*methods]; Randomized Controlled Trials as Topic; Regression Analysis; Suicide [statistics & numerical data]

MeSH check words

Humans