Published in final edited form as:
Cochrane Database Syst Rev. ; 5: CD001087. doi:10.1002/14651858.CD001087.pub4.

Crisis intervention for people with severe mental illnesses

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Abstract

Background—A particularly difficult challenge for community treatment of people with serious mental illnesses is the delivery of an acceptable level of care during the acute phases of severe mental illness. Crisis intervention models of care were developed as a possible solution.

Objectives—To review the effects of crisis intervention models for anyone with serious mental illness experiencing an acute episode, compared with 'standard care'.

Search methods—We updated the 1998, 2003 and 2006 searches with a search of the Cochrane Schizophrenia Group's Register of trials (2010) which is based on regular searches of CINAHL, EMBASE, MEDLINE, and PsycINFO.

Selection criteria—We included all randomised controlled trials of crisis intervention models versus standard care for people with severe mental illnesses.

Data collection and analysis—We independently extracted data from these trials and we estimated risk ratios (RR) or mean differences (MD), with 95% confidence intervals (CI). We assumed that people who left early from a trial had no improvement.

Main results—Three new studies have been found since the last review in 2006 to add to the five studies already included in this review. None of the previously included studies investigated crisis intervention alone; all used a form of home care for acutely ill people, which included elements of crisis intervention. However, one of the new studies focuses purely on crisis intervention as provided by Crisis Resolution Home Teams within the UK; the two other new studies investigated crisis houses i.e. residential alternatives to hospitalisation providing home-like environments.

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CONTRIBUTIONS OF AUTHORS Suzanne Murphy - trial selection, data extraction, completion of 2010 update.
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Clive Adams - acquisition of funding, protocol writing, help and supervision of data extraction, completion of report completion of 2003, 2006 and 2010 updates.
Editorial group: Cochrane Schizophrenia Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 5, 2012.
Review content assessed as up-to-date: 12 February 2012.

DECLARATIONS OF INTEREST There was no potential conflict of interest.

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Crisis intervention appears to reduce repeat admissions to hospital after the initial ‘index’ crises investigated in the included studies, this was particularly so for mobile crisis teams supporting patients in their own homes.

Crisis intervention reduces the number of people leaving the study early, reduces family burden, is a more satisfactory form of care for both patients and families and at three months after crisis, mental state is superior to standard care. We found no differences in death outcomes. Some studies found crisis interventions to be more cost effective than hospital care but all numerical data were either skewed or unusable. No data on staff satisfaction, carer input, complications with medication or number of relapses were available.

Authors’ conclusions—Care based on crisis intervention principles, with or without an ongoing home care package, appears to be a viable and acceptable way of treating people with serious mental illnesses. If this approach is to be widely implemented it would seem that more evaluative studies are still needed.

Medical Subject Headings (MeSH)

Caregivers [psychology]; Crisis Intervention [*methods]; Mental Disorders [psychology; *therapy]; Randomized Controlled Trials as Topic

MeSH check words

Humans

BACKGROUND

Description of the condition

Severe psychiatric illnesses are phasic. After initial treatment, people with schizophrenia or other similar disorders usually experience long periods of relative stability (Bleuler 1974). Relapses can, however, occur for reasons such as exposure to environmental stressors or difficulties with medication concordance. During a psychotic relapse sufferers experience a sudden exacerbation of acute symptoms such as delusions and hallucinations and consequently will have disturbed and difficult behaviour. Some people become aggressive, threatening harm to themselves or others. Intervention at this stage is crucial as it brings much needed relief for both the sufferer and their carers and can help prevent further deterioration (Weisman 1989).

During the last 40 years large-scale closure of psychiatric hospitals and reduction in the availability of bed spaces has facilitated a sharp rise in the number of people with serious mental illnesses being treated in the community. After an initial reduction in admissions however, there was a rise in the number of people requiring hospital readmission, suggesting that this policy of community care was perhaps failing some vulnerable people (Ellison 1974). Although research suggested there were many benefits to community care (Pasamanick 1967; Langsley 1968), in practice it was proving difficult to implement. A particularly difficult area was the delivery of an acceptable level of care during the acute phases of severe mental illness (Audit Comm 1986; WHO 1987). A major problem with

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early community care was that although it could care for people during their relatively stable periods, it was unable to cope with acute phases or relapses. This created a cyclic pattern whereby people were hospitalised for short periods during a crisis, then discharged into the community until a further crisis arose (Hoult 1986).

Description of the intervention

Breaking this cycle required the development of some form of community care that could adequately treat psychiatric crises in the home environment. Psychiatric services in Amsterdam were at the forefront of such treatment introducing a 24-hour 'first-aid' emergency home service just after the Second World War (Querido 1968). In the 1970's more specific crisis intervention models were introduced. Like Amsterdam's first-aid service, crisis intervention models aimed to treat psychiatric crises in the community and if possible avoid hospitalisation or, if this was unavoidable, reduce time spent in hospital (Weisman 1989). Crisis intervention models for people with serious mental illnesses were based on models originally developed to treat normally healthy individuals in psychological crisis. A crisis can be defined as a situation where a person experiencing overwhelming stress due to a life event such as bereavement, rape or major illness finds that their usual coping mechanisms for everyday life break down (Caplan 1964; Lindemann 1944). People with severe psychiatric illnesses may have fragile coping mechanisms. If exposed to excessive stress, these coping mechanisms can breakdown, leading to an exacerbation of their acute symptoms for which crisis intervention techniques may be used (Weisman 1989).

In keeping with the original ethos of earlier crisis intervention models, the models used for people with serious mental illnesses usually, but not always, require a multidisciplinary team of specifically trained staff. These teams may be available 24 hours a day. They advocate prompt detection of exacerbation of serious mental illness followed by swift, time-limited, intense treatment delivered in a community setting. There is immediate assessment and identification of problems followed by initial implementation of treatment. Treatment usually involves a combination of medication, counselling/therapy plus practical help with living skills and support for close family members. After the crisis has been stabilised, sufferers are carefully introduced to other models of care more suited for the chronic phases of psychiatric illnesses. The aim of crisis intervention models is to prevent, where possible, hospitalisation, further deterioration of symptoms and stress experienced by relatives/others involved in the crisis situation (Thomas 1970). Since their initial introduction several 'crisis' programmes have emerged, all designed to offer intensive crisis-oriented treatment to severely disturbed mentally ill people in a variety of community settings. These include programmes such as mobile crisis teams, crisis units in hospitals, crisis day treatment centres and crisis residential programs. This expansion of crisis intervention programs has been dramatic. In countries such as Australia and in North America it is now the central method of treatment used in community mental health programmes (Finch 1991; Weisman 1989). In the UK, government policy mandated that crisis resolution home teams (CRHTs) be established throughout England (Department of Health 2000).

How the intervention might work

The rapid dissemination of crisis intervention models suggests they have been successful methods of treatment for psychiatric crises. Supporting this is much research suggesting that crisis intervention models are beneficial in that they reduce hospital admissions by up to 50%, are more cost-effective, and reduce the stigma of institutionalisation for both the sufferer and their family (Hoult 1984a; Hoult 1984b; Hoult 1986; Lamb 1979; Schoenfeld 1986; Stein 1978; Test 1978). In addition, early intervention with immediate reduction of psychotic symptoms is said to be beneficial for the long-term prognoses of these illnesses (McGorry 1996). A survey, however, has suggested that the original claims for the efficacy of mobile crisis teams were not based on enough empirical evidence and it calls for more research into the effects of this intervention (Geller 1995).

Why it is important to do this review

The review was last updated in 2006, and after this update, the data relating to readmission, length of stay, general functioning and mental state remained inconclusive. The 2006 review is now somewhat out-of-date, and more recent studies have been published. This is a subject that has also been covered by other reviews within The Cochrane Collaboration. Crisis interventions for people with borderline personality as well as alternatives to inpatient mental health care for children and young people have been reviewed (see Table 1).

OBJECTIVES

To review the effects of crisis intervention models for anyone with serious mental illness experiencing an acute episode compared to the standard care they would normally receive. If possible, to compare the effects of mobile crisis teams visiting patients' homes with crisis units based in home-like residential houses.

METHODS

Criteria for considering studies for this review

Types of studies—Randomised controlled trials. If a trial had been described was 'double-blind' but only implied randomisation, we would have included it in a sensitivity analysis of all such trials. If there was no substantive difference within primary outcomes (see Types of outcome measures) when these 'implied randomisation' studies were added, then we would have included them in the final analysis. If there was a substantive difference, we would have only included clearly randomised trials and described the results of the sensitivity analysis in the text. We excluded quasi-randomised studies, such as those allocating by using alternate days of the week.

Types of participants

1. For previous versions: Adults, however defined, with schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, again, by any means of diagnosis. We are interested in making sure that information is as relevant to the current care of people with schizophrenia as possible so propose to clearly highlight the current clinical state (acute, early post-acute, partial remission, remission) as well as the

stage (prodromal, first episode, early illness, persistent) and as to whether the studies primarily focused on people with particular problems (for example, negative symptoms, treatment-resistant illnesses).

2. For 2010 update: In previous versions of this review we included studies such as Stein 1975 which did not describe clearly the illness from which people suffered. This, we feel was correct to do as it was in keeping with the title of this review and the desired focus of this work. However, on consideration, the definition regarding types of participants used in the older versions is not correct and we now wish to be clearer.

Adults, however defined, with either (a) severe mental illness as defined for the previous version of the review or (b) adults with severe mental health conditions *except* where the focus of the trial is one particular group of people only with a particular condition. For example, a study that includes adults with severe depression only would be excluded, but a mixed study including severe depression and other severe mental illnesses would be included.

Types of interventions

1. Crisis intervention: Any type of crisis-orientated treatment of an acute psychiatric episode by staff with a specific remit to deal with such situations, in and beyond ‘office hours’. This can include mobile teams caring for patients within their own homes, or non-mobile residential programmes based in a home-like houses within the community.

2. Standard care: The normal care given to those suffering from acute psychiatric episodes in the area concerned.

3. Different forms of crisis interventions: If data were available we would have assessed one delivery setting for crisis care with another (mobile versus non-mobile) in separate comparisons.

Types of outcome measures—We divided outcomes into very short-term (less than three months), short term (less than six months), medium term (seven to 12 months) and long term (over one year).

Primary outcomes

1. Service utilisation

Secondary outcomes

1. Satisfaction with treatment

2. Clinical outcome

3. Social outcome

4. Cost of treatment

4.3 Carer input - change in lifestyle/no change in lifestyle/loss of income: We have selected outcome measures that provide global estimations of functioning. We did not report highly specific outcomes, such as, ‘sense of safety’. Such specific outcomes are rarely

reported in more than one study and it is difficult to assess their relevance to the effectiveness of the treatment.

Search methods for identification of studies

Electronic searches—For previous electronic search terms please see Appendix 1

1.1 Update search (2010): We searched the Cochrane Schizophrenia Group Trials Register (March 2010)

The register was searched using the phrase: [(acute* or cris?s* or emergenc* or intensiv* or mobile* or outreach* or (time* and limit*) or commun* or home*) and (* care* or interven* or treat* or therap* or managem* or model* or programm* or team* or service* or base*) * or hospital* and (diversion* or alternative*) in title and *acute* or *cris?s* or *emergenc* or *intensiv* or *mobile* or *outreach* or * (time and limit*) or *commun* or *home*) and (*care* or *interven* or *treat* or *therap* or *managem* or *model* or *programm* or *team* or *service* or *base*) * or *hospital* and (diversion* or *alternative*) in title, abstract or Index terms of REFERENCE) or (brief Hosp* OR community mental health service, I* OR community resid* OR crisis* OR critical time int* OR district psychiatric c* OR *brief intensive* in interventions of STUDY field)]

This register is compiled by systematic searches of major databases, handsearches and conference proceedings (see Group Module)

Searching other resources

1. Reference searching: We inspected references of all identified studies for further relevant studies.

2. Personal contact: We contacted the first author of each included study for information regarding unpublished trials.

Data collection and analysis

Selection of studies—Review author SM independently inspected citations from the searches and identified relevant abstracts. The protocol planned that a random 20% sample should be independently re-inspected by RD to ensure reliability, however, as only seven studies met the review criteria, all of these were checked by RD. Where disputes arose, the full report was acquired for more detailed scrutiny. Full reports of the abstracts meeting the review criteria were obtained and inspected by SM. Where it was not possible to resolve disagreement by discussion, we attempted to contact the authors of the study for clarification.

Data extraction and management

1. Extraction—Review author SM extracted data from all included studies. The protocol stated that, to ensure reliability, RD would independently extract data from a random sample of these studies, comprising 10% of the total, however, there were actually only three new studies so all were checked. Disagreement on the data extracted were discussed, decisions

documented and, if necessary, we contacted authors of studies for clarification. With remaining problems CI and CA helped clarify issues and these final decisions were documented. Data presented only in graphs and figures were extracted whenever possible, but included only if the two review authors 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. If studies were multi-centre, where possible, we extracted data relevant to each component centre separately.

2. Management

2.1 Forms: We extracted data onto standard, simple forms.

2.2 Scale-derived data: We included continuous data from rating scales only if: a. the psychometric properties of the measuring instrument have been described in a peer-reviewed journal (Marshall 2000); and b. the measuring instrument has not been written or modified by one of the trialists for that particular trial.

Ideally the measuring instrument should either be i. a self-report or ii. completed by an independent rater or relative (not the therapist). We realise that this is not often reported clearly, in Description of studies we noted if this was the case or not.

2.3 Endpoint versus change data: There are advantages of both endpoint and change data. 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 primarily to use endpoint data, and only use change data if the former were not available. Endpoint and change data were combined in the analysis as we used mean differences (MD) rather than standardised mean differences (SMD) throughout (Higgins 2011, Chapter 9.4.5.2).

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 aimed to apply the following standards to all data before inclusion: a) standard deviations (SDs) and means are reported in the paper or obtainable from the authors; b) when a scale starts from the finite number zero, the SD, 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 the Positive and Negative Syndrome Scale (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 2 SD > (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 that included a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. We entered skewed data from studies of less than 200 participants in additional tables and marked the data as skewed rather than into an analysis. Skewed data pose less of a problem

when looking at means if the sample size is large (over 200) and we entered such data into the syntheses.

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, efforts were made to convert outcome measures to dichotomous data. This can be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It is generally assumed that if there is a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, Overall 1962) or PANSS (Kay 1986), this could be considered as a clinically significant response (Leucht 2005; Leucht 2005a). 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 indicates a favourable outcome for crisis intervention. Where keeping to this makes it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'Not improved'), we reported data where the left of the line indicates an unfavourable outcome. This was noted in the relevant graphs.

2.8 Summary of findings table: We used the GRADE approach to interpret findings (Schünemann 2008) and used GRADE profiler (GRADE Profiler) to import data from RevMan 5 (RevMan) 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 for the main comparison. Outcomes were selected using the following criteria, in priority order: endpoint versus change data, data where loss was below 30%, largest sample size for a particular outcome, the longest follow-up time available for a particular outcome.

1. Service utilisation outcomes:

- Hospital use

2. Quality of Life:

- As measured by the Manchester Short Assessment of quality of life (MANSA)

3. Clinical response in global state:

- As measured by the Global Assessment Scale (GAS)

4. Clinical response in general mental state:

- As Measured by the Brief Psychiatric Rating Scale (BPRS)

5. Burden on family:

- Overall burden on family by six months

Assessment of risk of bias in included studies—Again, SM and RD worked independently to assess risk of bias by using criteria described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011 to assess trial quality. 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.

Where 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 were provided, we contacted authors of the studies in order to obtain further information. Non-concurrence in quality assessment was reported.

The level of risk of bias was noted in both the text of the review and in the Summary of findings for the main comparison.

Measures of treatment effect

1. Binary data: For binary outcomes, we calculated a standard estimation of the 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).

2. Continuous data: For continuous outcomes, we estimated the mean difference (MD) between groups. We preferred not to calculate effect size measures (standardised mean difference SMD). However, if scales of very considerable similarity were used, we would have presumed there was a small difference in measurement, and we would have calculated effect size and 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 was not accounted for in primary studies, we would have 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 has been incorporated into the analysis

of primary studies, we will 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 intra-class correlation coefficient (ICC) [Design effect = 1+ (m-1) *ICC] (Donner 2002). If the ICC is not reported it will be assumed to be 0.1 (Ukoumunne 1999).

If cluster studies have 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 from 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. If data were binary, we simply added and combined the data within the two-by-two table. If data were continuous, we combined data following the formula in section 7.7.3.8 (Combining groups) of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). 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 2009). We chose that, for any particular outcome, should more than 50% of data be unaccounted for, we would 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 was 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 and adverse effects. For these outcomes the rate of those who stayed in the study - in that particular arm of the trial - were used for those who did not. A sensitivity analysis was undertaken testing how prone the primary outcomes are to change when 'completer' data only were compared to the intention-to-treat analysis using the above assumptions.

3. Continuous

3.1 Attrition: In the case where attrition for a continuous outcome was between 0% and 50% and completer-only data were reported, we reproduced these.

3.2 Standard deviations: If standard deviations (SDs) were not reported, we first tried to obtain the missing values from the authors. If not available, where there were missing measures of variance for continuous data, but an exact standard error (SE) and confidence intervals (CIs) available for group means, and either a 'P' value or 't' value available for differences in mean, we calculated them according to the rules described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011): When only the SEwas reported, SDs were calculated by the formula SD = SE * square root (n). Chapters 7.7.3 and 16.1.3 (Higgins 2011) present detailed formula for estimating SDs from P values, t or F values, CIs, ranges or other statistics. If these formula did not apply, we calculated the SDs according to a validated imputation method which is based on the SDs of the other included studies (Furukawa 2006). Although some of these imputation strategies can introduce error, the alternative would be to exclude a given study' s outcome and thus to lose information. We nevertheless examined the validity of the imputations in a sensitivity analysis excluding imputed values.

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 (Leucht 2007). 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.

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 people or situations which we had not predicted would arise. When such situations or participant groups arose, these were fully discussed.

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. When such methodological outliers arose, these were fully discussed.

3. Statistical heterogeneity

3.1 Visual inspection: We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I2 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). An I^2 estimate greater than or equal to around 50% accompanied by a statistically significant Chi^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 as there were less than 10 included studies. For future updates of this review, we will use the same methodology and not use funnel plots for outcomes where there are 10 or fewer studies, or where all studies are of similar sizes. In other cases, where funnel plots are possible, we will seek statistical advice in their interpretation.

Data synthesis—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 the different studies are estimating different, yet related, intervention effects. This often seems to be true to us and the random-effects model takes into account differences between studies even if there is no statistically significant heterogeneity. There is, however, a disadvantage to the random-effects model. It puts added weight onto small studies which often are the most biased ones. Depending on the direction of effect, these studies can either inflate or deflate the effect size. We chose random-effects model for all analyses. The reader is, however, able to choose to inspect the data using the fixed-effect model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses - only primary outcomes: We anticipated subgroup analyses investigating mobile crisis teams versus non-mobile residential home-like programmes. In the event however, such analyses were not possible due to lack of data comparing these conditions directly against each other.

1.2 Clinical state, stage or problem: We proposed to undertake this review and provide an overview of the effects of crisis intervention for people with severe mental illnesses. In addition, however, we tried to report data on subgroups of people in the same clinical state, stage and with similar problems.

2. Investigation of heterogeneity: If inconsistency was high, this was reported. First, we investigated whether data had been entered correctly. Second, if data were correct, we visually inspected the graph and successively removed outlying studies to see if heterogeneity was restored. For this review, we decided that should this occur with data contributing to the summary finding of no more than around 10% of the total weighting, data would be presented. If not, data would not be pooled and issues would be discussed.

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We know of no supporting research for this 10% cut-off but are investigating the use of prediction intervals as an alternative to this unsatisfactory state.

When unanticipated clinical or methodological heterogeneity were 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 better description of randomisation, then all data were employed from these studies.

2. 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 the results and discussed them but continued to employ our assumption.

Where assumptions have to be made regarding missing SDs data (see Dealing with missing data), we compared the findings on primary outcomes when we used our assumption compared with completer data only. A sensitivity analysis was undertaken testing how prone results changed when ‘completer’ data only were compared to the imputed data using the above assumption. If there was a substantial difference, we reported results and discussed them but continued to employ our assumption.

3. Risk of bias: We analysed the effects of excluding trials that were judged to be at high risk of bias across one or more of the domains of randomisation (implied as randomised with no further details available), allocation concealment, blinding and outcome reporting for the meta-analysis of the primary outcome. If the exclusion of trials at high risk of bias did not substantially alter the direction of effect or the precision of the effect estimates, then we included data from these trials in the analysis

4. Imputed values: We also undertook a sensitivity analysis to assess the effects of including data from trials where we used imputed values for ICC in calculating the design effect in cluster randomised trials.

If substantial differences were noted in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we did not pool data from the excluded trials with the other trials contributing to the outcome, but presented them separately

5. Fixed and random effects: All data were synthesised using a random-effects model, however, we also synthesised data for the primary outcome using a fixed-effect model to evaluate whether the greater weights assigned to larger trials with greater event rates, altered

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* *Indicates the major publication for the study*

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