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[Intervention Protocol]

Parenting interventions for people with schizophrenia or related serious mental illness

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of parenting interventions for people with schizophrenia or related serious mental illness.

BACKGROUND

Description of the condition

Schizophrenia is a severe mental illness that can be characterised by the experience of negative symptoms, disorganised speech, diagnosed behaviour, and psychotic or positive symptoms that consist of hallucinations and delusions (APA 2013). One in 150 people will be diagnosed with schizophrenia or a related disorder, such as schizoaffective disorder, delusional disorder, or brief psychotic disorder, during their lifetime (Moreno-Küstner 2018). Schizophrenia typically develops in men between the ages of 15 and 25 years and in women between the ages of 20 and 29 years, although there has also been a second wave of onset in women documented around menopause (Häfner 1993). It is a long-term condition characterised by high levels of social adversity (Heinz 2013). Psychotic relapses are likely, especially after non-adherence to treatment (Emsley 2013; Haro 2006), and people diagnosed with schizophrenia have a recovery rate of one in seven (Jääskeläinen 2013).

Estimates of the proportion of people with schizophrenia who have children range between 38% and 44%, with women with schizophrenia being more likely to have children than men with schizophrenia (Campbell 2012; Schrank 2016), and in some parts of the world, the number of individuals with a diagnosis of schizophrenia who have parental responsibility is rising (Campbell 2012). This may be in part due to newer atypical antipsychotic medication no longer causing such a large increase in prolactin levels, which is known to reduce fertility (Howard 2002), as well as people experiencing shorter hospital stays, giving them the opportunity to integrate into their community more than was possible before (Vigod 2012).

People with schizophrenia are more likely to experience unemployment, housing problems, lower educational attainment, and a smaller social network (Boydell 2013; Kessler 1995; Topor 2016). As a result of this parental social adversity, the children are also more likely to experience social adversity, as well as have emotional and behavioural problems during their childhood (Dean 2010; Somers 2007), become carers (Grant 2008; O'Connell 2008), and develop their own mental health problems (Rasic 2014; Riches 2019).

Parenting has been reported as a positive aspect of the lives of people with schizophrenia, giving them pride, a sense of purpose, and motivation to maintain their own well-being for the benefit of their children (Ackerson 2003; Evenson 2008). However, psychotic symptoms may render a parent both emotionally unavailable through experiencing acute psychotic symptoms and practically unavailable due to hospitalisation (Snellen 1999; Somers 2007). The negative symptoms of schizophrenia and the adverse effects from antipsychotic medication can diminish empathy and emotional engagement with their child (Montag 2007), and may result in an overly permissive parenting style (Oyserman 2005). The presence of acute psychotic symptoms such as delusions may mean that the parent is unable to provide a safe environment for their child (Dipple 2002; Gearing 2012; Seeman 2015).

Description of the intervention

Parenting interventions are methods of supporting parents to improve their practices and manage their child's behaviour. An

example is the Triple P Positive Parenting Program (TPPPP), which uses social learning principles to teach parents behaviour management strategies and how to enhance positive interactions with their child (Sanders 1999). It has been shown to be effective in decreasing child disruptive behaviour (Sanders 2000), and improving parenting skills (Nowak 2008). TTPPP has been adapted for use with parents with mental health problems through the addition of modules on the impact of mental health on parenting and on promoting children's development (Phelan 2006; Sanders 2000). Some parenting interventions have been specifically designed with the purpose of meeting the needs of parents with mental health problems such as the Family Options Program, a long-term one-to-one personalised programme for parents with severe mental illness (Nicholson 2009).

Parenting interventions also exist in the form of video feedback programmes, where the aim is to enhance parental sensitivity through a process that involves recording parent-child interactions and subsequently reviewing these videos with the parent, while highlighting moments of positive interactions to them (Kennedy 2010). Video guidance has been used with mothers experiencing postpartum depression (Vik 2006), as well as parents with an eating disorder (Stein 2006), and this method may potentially help to mitigate the effect of cognitive distortions experienced by parents with schizophrenia that may be a barrier to them having an valid awareness of their parenting skills (Wan 2008).

Previous parenting interventions for common mental health problems have often attempted to involve multiple members of the family in the intervention to improve their social networks, and have focused on making tailored goals for each family based on the parent's and child's strengths (Beardslee 2007; Falkov 2012; Nicholson 2009). Parenting interventions that target parents with psychosis may aim to improve parenting quality and parent-child interactions. Components of these interventions may include education about the child's development, child behaviour management techniques, advice on how to explain their diagnosis to their child (Reupert 2015), as well as more practical elements such as financial management and improving social networks (Nicholson 2009). If there is a peer-support element to the intervention, role modelling may play a part and the intervention could also involve the child (Coates 2017; Reupert 2011).

Parenting programmes can be delivered at any point in the participant's illness and can be in multiple forms such as by a trained professional, through peer-support from other parents, or in the form of self-help. They may be group-based, individual, or delivered online, and the intervention may contain one session or multiple sessions over any length of time (Wan 2008).

How the intervention might work

Given the additional challenges associated with being a parent with psychosis, more generalised parenting programmes may be less appropriate forms of support, and parents with severe mental illness have even expressed their desire for diagnosis-specific parenting groups (Venkataraman 2008). Standard parenting interventions typically aim to improve parenting quality and the strength of the parent-child relationship through educating the parent about their child's development, giving them advice about behaviour management, and promoting their coping mechanisms. Focusing on the parents' coping skills may also lead them to experience less stress during volatile situations, which may lead to

a reduction in expressed emotion within the family environment and a smaller chance of a psychotic relapse (Howes 2014). Increasing the parent's knowledge of their child's development and of parenting practises may increase their self-belief and empowerment, which in turn could influence self-efficacy during parenting (Vauth 2007).

By taking into account the social relationships of the parent and involving family members, the ongoing support of the intervention may also indirectly increase the stability of the parent's social relationships (Falkov 2012; Hosman 2009), which is known to be an important protective factor (Chang 2007; Somers 2007). The parenting intervention may also help parents develop skills and knowledge for planning in advance of relapse, and as a result give their children more stability.

Why it is important to do this review

Over a third of people with schizophrenia and related disorders have children (Campbell 2012; Schrank 2016), and there is currently a lack of evidence regarding the effects and effectiveness of different ways of helping them to parent. Public organisations have highlighted the lack of evidence for this population. The UK's Social Care Institute of Excellence (www.scie.org.uk/) produced their 'Think Family' guide in 2011 which recommended improvements in screening for children of adults with mental health problems as well as improvements in signposting and collaboration with this population (Diggins 2011). More recently, the 2019 UK NHS Long Term Plan (www.longtermplan.nhs.uk/) stressed the importance of increasing the evidence base for women with perinatal mental health difficulties and the necessity to put more emphasis on the relationship between mental health and the maternity experience (Alderwick 2019). This review will determine the extent of the available evidence and the effects of programmes for this group of parents. If we find sufficient studies, this review will also look at the differences in effect between parents of different marital status, gender, ethnicity, and sexual orientation.

OBJECTIVES

To assess the effects of parenting interventions for people with schizophrenia or related serious mental illness.

METHODS

Criteria for considering studies for this review

Types of studies

We will consider all relevant randomised controlled trials (RCTs). We will include RCTs meeting our inclusion criteria and reporting useable data. We will consider trials that are described as 'double blind' – in which randomisation is implied – and include or exclude once we have carried out a sensitivity analysis (see [Sensitivity analysis](#)). We will exclude quasi-randomised studies, such as those that allocate intervention by alternate days of the week. Where people are given additional treatments as well as a parenting intervention, we will only include data if the adjunct treatment is evenly distributed between groups and it is only the parenting intervention that is randomised.

Types of participants

Adults, however defined, with schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder, and

delusional disorder, by any means of diagnosis, who are a parent to a child between the ages of 0 and 18 years or an expectant parent. If a study includes participants with a variety of mental health diagnoses and the results for those with schizophrenia are not reported separately, it will only be included where at least 50% of the total sample are adults with schizophrenia or related disorders.

We are interested in making sure that information is as relevant as possible to the current care of people with schizophrenia, so aim to highlight the current clinical state clearly (acute, early postacute, partial remission, remission), as well as the stage (prodromal, first episode, early illness, persistent), and whether the studies primarily focused on people with particular problems (e.g. negative symptoms, treatment-resistant illnesses).

Types of interventions

1. Parenting interventions

We will include all parenting programmes whose primary aim is to improve the parenting skills or parent-child interaction (or both) of parents with schizophrenia or a related serious mental illness. Programmes may be any length, delivered in any type of setting, in any form including by a trained professional, through peer-support or in the form of self-help, and may be underpinned by any theoretical approach.

We will exclude mother and baby units as these are considered crisis programmes for mothers experiencing acute psychotic symptoms after the birth of their child, where the focus is primarily to treat the mother's symptoms while not separating the mother and baby.

2. Control

We will consider any control intervention whether active or inactive.

Types of outcome measures

We aim to divide all outcomes into short term (less than six months), medium term (six to 12 months), and long term (over 12 months).

We will endeavour to report binary outcomes recording clear and clinically meaningful degrees of change (e.g. global impression of much improved, or more than 50% improvement on a rating scale – as defined within the trials) before any others. Thereafter, we will list other binary outcomes and then those that are continuous.

For outcomes such as 'clinically important change', 'any change', and 'relapse', we will use the definition used by each of the trials.

For valid scales. see [Data extraction and management](#).

Outcomes of interest will not form part of the eligibility criteria for this review.

Primary outcomes

1. Parenting outcomes

1.1. Parenting behaviours, skills, attitudes, or knowledge

1.1.1. Clinically important change in parenting behaviours, skills, attitudes, or knowledge

1.1.2. Any change in parenting behaviours, skills, attitudes, or knowledge

2. Adverse events involving child or parent

2.1. General adverse events (i.e. parenting stress, deterioration of parent's mental state)

2.1.1. At least one adverse event

Secondary outcomes

1. Parenting outcomes

1.1. Parenting behaviours, skills, attitudes, or knowledge

1.1.1. Average endpoint or change score on a parenting behaviours, skills, attitudes, or knowledge scale

1.2. Quality of relationship with child (i.e. attachment, parental reflectivity, parental sensitivity)

1.2.1. Clinically important change in quality of relationship with child

1.2.2. Any change in quality of relationship with child

1.2.3. Average endpoint or change score on a quality of relationship with child scale

2. Adverse events involving child or parent

2.1. General adverse events (i.e. parenting stress, deterioration of parent's mental state)

2.1.1. Clinically important adverse event

2.1.2. Average endpoint or change score on an adverse-event/effect scale

2.2. Death

2.2.1. Any cause except suicide, homicide, and filicide

2.2.2. Suicide

2.2.3. Homicide

2.2.4. Filicide (death of child caused by parent)

3. Behaviour of child

3.1. General

3.1.1. Clinically important change in general behaviour

3.1.2. Any change in general behaviour

3.1.3. Average endpoint or change score on a general behaviour scale

3.2. Specific

3.2.1. Clinically important change in specific aspects of behaviour (e.g. aggression, socioemotional adjustment)

3.2.2. Any change in specific aspects of behaviour (e.g. aggression, socioemotional adjustment)

3.2.3. Average endpoint or change on a specific aspects of behaviour scale

4. Social services involvement

4.1. At least one child protection issue reported

4.2. Child referred to social services for an assessment/investigation

4.3. Child taken into care

5. General functioning of parent or child

5.1. Overall

5.1.1. Clinically important change in general functioning, including working ability

5.1.2. Any change in general functioning, including working ability

5.1.3. Average endpoint or change score on a general functioning scale

5.2. Specific

5.2.1. Clinically important change in specific aspects of functioning, such as life skills

5.2.2. Any change in specific aspects of functioning, such as life skills

5.2.3. Any change in educational status

5.2.4. Any change in employment status

5.2.5. Average endpoint or change score on a specific aspects of functioning scale

6. Social functioning of parent or child

6.1. Clinically important change in social functioning

6.2. Any change in social functioning

6.3. Average endpoint or change score on a social functioning scale

7. Global state of parent

7.1. Clinically important change in global state (e.g. global impression of much improved, or more than 50% improvement on a rating scale).

7.2. Relapse

7.3. Any change in global state

7.4. Average endpoint or change score on a global state scale

7.5. Use of other medications

8. Mental state of parent

8.1. General

8.1.1. Clinically important change in general mental state

8.1.2. Any change in general mental state

8.1.3. Average endpoint or change score on a general mental state scale

8.2. Specific

8.2.1. Clinically important change in specific symptoms (e.g. positive, negative, affective, cognitive symptoms of schizophrenia)

8.2.2. Any change in specific symptoms (e.g. positive, negative, affective, cognitive symptoms of schizophrenia)

8.2.3. Average endpoint or change score on a specific symptom scale

9. Quality of life of parent or child

9.1. Overall

9.1.1. Clinically important change in quality of life

9.1.2. Any change in quality of life

9.1.3. Average endpoint or change score on a quality-of-life scale

9.2. Specific

- 9.2.1. Clinically important change in specific aspects of quality of life
- 9.2.2. Any change in specific aspects of quality of life
- 9.2.3. Average endpoint or change score on a specific aspects of quality-of-life scale

10. Service use of parent

- 10.1. Clinically important engagement with services
- 10.2. Any engagement with services
- 10.3. Average endpoint or change score on engagement scale
- 10.4. Compliance with medication or other treatment, or both
- 10.5. Number of hospitalisations
- 10.6. Number of days in hospital
- 10.7. Inability to be discharged from hospital
- 11. Leaving the study early
 - 11.1. For any reason
 - 11.2. Due to inefficacy
 - 11.3. Due to adverse effect
- 12. Economic costs
 - 12.1. Costs due to treatment, as defined by each study.
 - 12.2. Savings due to treatment, as defined by each study.

'Summary of findings' table(s)

We will use the GRADE approach to interpret findings (Schünemann 2011); and will use GRADEpro GDT to export data from our review (Review Manager 2014) to create a 'Summary of findings' table. These tables provide outcome-specific information concerning the overall certainty 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 rate as important to patient care and decision making. We aim to select the following main outcomes for inclusion in the 'Summary of findings' table.

1. Parenting skills: clinically important change
2. Parenting skills: any change
3. Adverse event: at least one adverse event
4. Quality of relationship with child: clinically important change
5. Quality of relationship with child: any change
6. Behaviour of child: clinically important change in specific aspects of behaviour
7. Social services involvement: at least one child protection issue reported

If data are not available for these prespecified outcomes but are available for ones that are similar, we will present the closest outcome to the prespecified one in the table but take this into account when grading the finding.

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Group's Study-Based Register of Trials

The Information Specialist will search the register using the following search strategy:

Parenting in Intervention Field of STUDY

In such a study-based register, searching the major concept retrieves all the synonyms and relevant studies. This is because the studies have already been organised, based on their interventions, and linked to the relevant topics (Shokraneh 2017). This allows rapid and accurate searches that reduce waste in the next steps of systematic reviewing (Shokraneh 2019).

Following the methods from Cochrane (Lefebvre 2019), the Information Specialist compiles this register from systematic searches of major resources and their monthly updates (unless otherwise specified):

1. Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
2. MEDLINE;
3. Embase;
4. Allied and Complementary Medicine (AMED);
5. BIOSIS;
6. Cumulative Index to Nursing and Allied Health Literature (CINAHL);
7. PsycINFO;
8. PubMed;
9. US National Institute of Health Ongoing Trials Register (ClinicalTrials.gov);
10. World Health Organization International Clinical Trials Registry Platform (www.who.int/ictrp);
11. ProQuest Dissertations and Theses A&I and its quarterly update;
12. Chinese databases (Chinese Biomedical Literature Database, China Knowledge Resource Integrated Database, and Wanfang) and their annual updates.

The register also includes handsearches and conference proceedings (see Group's website; schizophrenia.cochrane.org/register-trials). It places no limitations on language, date, document type, or publication status.

Searching other resources

1. Reference searching

We will inspect references of all included studies for further relevant studies.

2. Personal contact

We will contact the first author of each included study for information regarding unpublished trials. We will note the outcome of this contact in the 'Characteristics of included studies' or 'Characteristics of studies awaiting classification' tables.

Data collection and analysis

Selection of studies

Two review authors (JR and CG) will independently inspect citations from the searches and identify relevant abstracts; one review author (JB or LJ) will independently reinspect a random 20% sample of these abstracts to ensure reliability of selection. Where disputes arise, we will acquire the full report for more detailed scrutiny. One review author (JB or LJ) will then obtain and inspect full reports of the abstracts or reports meeting the review criteria.

One review author (JB or LJ) will reinspect a random 20% of these full reports in order to ensure reliability of selection. Where it is not possible to resolve disagreement by discussion, we will attempt to contact the authors of the study concerned for clarification. We will list studies excluded at this stage in the 'Characteristics of excluded studies' table.

Where studies have multiple publications, we will collate the reports of the same study so that each study, rather than each report, is the unit of interest for the review, and such studies have a single identifier with multiple references.

Data extraction and management

1. Extraction

Two review authors (JR and CG) will extract data from all included studies and present them in the 'Characteristics of included studies' table. In addition, to ensure reliability, one review author (JB or LJ) will independently extract data from a random sample of these studies, comprising 10% of the total. We will attempt to extract data presented only in graphs and figures whenever possible, but will include only if two review authors independently obtained the same result. If studies are multicentre, then where possible we will extract data relevant to each. We will discuss any disagreement and document our decisions. If necessary, we will attempt to contact authors through an open-ended request to obtain missing information or for clarification. One review author (JB or LJ) will help clarify issues regarding any remaining problems and we will document these final decisions.

2. Management

2.1. Forms

We will extract data onto standard, predesigned, simple forms.

2.2. Scale-derived data

We will include continuous data from rating scales only if:

1. the psychometric properties of the measuring instrument have been described in a peer-reviewed journal ([Marshall 2000](#));
2. the measuring instrument has not been written or modified by one of the trialists for that particular trial; and
3. the instrument is a global assessment of an area of functioning and not subscores which are not, in themselves, validated or shown to be reliable. However there are exceptions, we will include subscores from mental state scales measuring positive and negative symptoms of schizophrenia.

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

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; however, calculation of change needs two assessments (baseline and endpoint) that can be difficult to obtain in unstable and difficult-to-measure conditions such as schizophrenia. We have decided primarily to use endpoint data, and only use change data if the former are not available. If necessary, we will combine endpoint and change data in the

analysis, as we prefer to use mean differences (MDs) rather than standardised mean differences (SMDs) throughout ([Deeks 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 will apply the following standards to relevant continuous data before inclusion.

For endpoint data from studies including fewer than 200 participants.

1. When a scale starts from the finite number zero, we will subtract the lowest possible value from the mean, and divide this by the standard deviation (SD). If this value is lower than one, it strongly suggests that the data are skewed and we will exclude these data. If this ratio is higher than one but less than two, there is suggestion that the data are skewed: we will enter these data and test whether their inclusion or exclusion would change the results substantially. If such data change results, we will enter them as 'other data'. Finally, if the ratio is larger than two we will include these data, because it is less likely that they are skewed ([Altman 1996](#)).
2. 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 will modify the calculation described above to take the scale starting point into account. In these cases, skewed data are present if $2\text{SD} > (S - S_{\min})$, where S is the mean score and ' S_{\min} ' is the minimum score.

Please note: we will enter all relevant data from studies of more than 200 participants in the analysis irrespective of the above rules, because skewed data pose less of a problem in large studies. We will also enter 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 or not data are skewed.

2.5. Common measurement

To facilitate comparison between trials we aim, where relevant, 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).

2.6. Conversion of continuous to binary

Where possible, we will attempt 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 the PANSS ([Kay 1986](#)), this could be considered as a clinically significant response ([Leucht 2005a](#); [Leucht 2005b](#)). If data based on these thresholds are not available, we will use the primary cut-off presented by the study authors.

2.7. Direction of graphs

Where possible, we will enter data in such a way that the area to the left of the line of no effect indicates a favourable outcome for the parenting intervention. Where keeping to this makes it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'not

unimproved') we will report data where the left of the line indicates an unfavourable outcome and note this in the relevant graphs.

Assessment of risk of bias in included studies

Two review authors (JR and CG) will independently assess risk of bias by using criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* to assess trial quality (Higgins 2011a). This set of criteria is based on evidence of associations between potential overestimation of effect and the level of risk of bias of the article that may be due to aspects of sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting, or the way in which these 'domains' are reported.

If the raters disagree, we will make the final rating by consensus. Where inadequate details of randomisation and other characteristics of trials are provided, we will attempt to contact authors of the studies to obtain further information. We will report non-concurrence in quality assessment, but if disputes arise regarding the category to which a trial is to be allocated, we will resolve this by discussion.

We will note the level of risk of bias in the text of the review, 'Risk of bias' graph, 'Risk of bias' summary, and the 'Summary of findings' table.

Measures of treatment effect

1. Binary data

For binary outcomes, we will calculate a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI), as it has been shown that RR is more intuitive than odds ratios (Boissel 1999); and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). Although the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH), with their 95% CIs, are intuitively attractive to clinicians, they are problematic to calculate and interpret in meta-analyses (Hutton 2009). For binary data presented in the 'Summary of findings' table, we will, where possible, calculate illustrative comparative risks.

2. Continuous data

For continuous outcomes, we will estimate MD between groups. We prefer not to calculate effect size measures (SMD). However, if scales of very considerable similarity are used, we will presume there is a small difference in measurement, and we 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 poses problems. Authors often fail to account for intraclass correlation in clustered studies, leading to a unit-of-analysis error whereby P values are spuriously low, CIs unduly narrow, and statistical significance overestimated (Divine 1992). This causes type I errors (Bland 1997; 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.

Where clustering is not accounted for in primary studies, we will present data in a table, with a (*) symbol to indicate the presence of a probable unit-of-analysis error. We will seek to contact first authors of studies to obtain intraclass correlation coefficients (ICC) for their clustered data and to adjust for this by using accepted methods (Gulliford 1999).

We have sought statistical advice and have been advised that the binary data from cluster trials 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 ICC: thus design effect = $1 + (m - 1) \times \text{ICC}$ (Donner 2002). If the ICC is not reported, we will assume it to be 0.1 (Ukoumunne 1999).

If cluster studies have been appropriately analysed and taken ICCs and relevant data documented in the report into account, synthesis with other studies will be possible using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. This 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, participants can differ significantly from their initial state at entry to the second phase, despite a washout phase. For the same reason, cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both carry-over and unstable conditions are very likely in severe mental illness, we will only use data from the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involves more than two treatment arms, if relevant, we will present the additional treatment arms in comparisons. If data are binary, we will simply add these and combine within the two-by-two table. If data are continuous, we will combine data following the formula in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). Where additional treatment arms are not relevant, we will not reproduce these data but will list them in the 'Characteristics of included studies' table.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2009). We choose that, for any particular outcome, should more than 50% of data be unaccounted for, we will not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study are lost, but the total loss is less than 50%, we will address this within the 'Summary of findings' table by downgrading certainty. Finally, we will also downgrade certainty within the 'Summary of findings' table should the loss be 25% to 50% in total.

2. Binary

In the case where attrition for a binary outcome is between 0% and 50% and where these data are not clearly described, we

will present data on a 'once-randomised-always-analyse' basis (an intention-to-treat (ITT) analysis). Those leaving the study early are all assumed to have the same rates of negative outcome as those who completed. We will use the rate of those who stay in the study – in that particular arm of the trial – and apply this also to those who did not. We will undertake a sensitivity analysis testing how prone the primary outcomes are to change when data only from people who complete the study to that point are compared to the ITT analysis using the above assumptions.

3. Continuous

3.1. Attrition

We will use data where attrition for a continuous outcome is between 0% and 50%, and data only from people who complete the study to that point are reported.

3.2. Standard deviations

If SDs are not reported, we will try to obtain the missing values from the study authors. If these are not available, where there are missing measures of variance for continuous data, but an exact standard error (SE) and CIs available for group means, and either P value or t value available for differences in mean, we can calculate SDs according to the rules described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). When only the SE is reported, SDs are calculated by the formula $SD = SE \times \sqrt{n}$, where n is the number of participants. The *Cochrane Handbook for Systematic Reviews of Interventions* presents detailed formulae for estimating SDs from P, t, or F values; CIs; ranges; or other statistics (Higgins 2011b). If these formulae do not apply, we will calculate 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. Nevertheless, we will examine the validity of the imputations in a sensitivity analysis that excludes imputed values.

3.3. Assumptions about participants who left the trials early or were lost to follow-up

Various methods are available to account for participants who left the trials early or were lost to follow-up. Some trials just present the results of study completers; others use the method of last observation carried forward (LOCF); while more recently, methods such as multiple imputation or mixed-effects models for repeated measurements (MMRM) have become more of a standard. While the latter methods seem to be somewhat better than LOCF (Leon 2006), we feel that the high percentage of participants leaving the studies early and differences between groups in their reasons for doing so is often the core problem in randomised schizophrenia trials. Therefore, we will not exclude studies based on the statistical approach used. However, by preference we will use the more sophisticated approaches, that is, we will prefer to use MMRM or multiple-imputation to LOCF, and we will only present completer analyses if some type of ITT data are not available. Moreover, we will address this issue in the item 'Incomplete outcome data' of the 'Risk of bias' tool.

Assessment of heterogeneity

1. Clinical heterogeneity

We will consider all included studies initially, without seeing comparison data, to judge clinical heterogeneity. We will simply inspect all studies for participants who are clearly outliers or situations that we had not predicted would arise and, where found, discuss such situations or participant groups.

2. Methodological heterogeneity

We will consider all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We will simply inspect all studies for clearly outlying methods which we had not predicted would arise and discuss any such methodological outliers.

3. Statistical heterogeneity

3.1. Visual inspection

We will inspect graphs visually to investigate the possibility of statistical heterogeneity.

3.2. Employing the I^2 statistic

We will investigate heterogeneity between studies by considering the I^2 statistic alongside the χ^2 P value. The I^2 statistic provides an estimate of the percentage of inconsistency thought to be due to chance (Higgins 2003). The importance of the observed value of the I^2 statistic depends on the magnitude and direction of effects as well as the strength of evidence for heterogeneity (e.g. P value from χ^2 test, or a CI for the I^2 statistic). We will interpret an I^2 estimate greater than or equal to 50% and accompanied by a statistically significant χ^2 statistic as evidence of substantial heterogeneity (Chapter 9. *Cochrane Handbook for Systematic Reviews of Interventions*; Deeks 2011). When there are substantial levels of heterogeneity, for the primary outcomes, we will explore 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 10.1 of the *Cochrane Handbook for Systematic reviews of Interventions* (Sterne 2011).

1. Protocol versus full study

We will try to locate protocols of included randomised trials. If the protocol is available, we will compare outcomes in the protocol and in the published report. If the protocol is not available, we will compare outcomes listed in the methods section of the trial report with actually reported results.

2. Funnel plot

We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We will not use funnel plots for outcomes where there are 10 or fewer studies, or where all studies are of similar size. 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 choose to use a random-effects model for analyses.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We do not expect there to be sufficient power to report subgroup analyses. However, if data are available, we will look at the effects of gender of the parent, ethnicity of the parent, marital status of the parent, sexual orientation of the parent, and the type of parenting intervention being investigated (e.g. Mental Health Positive Parenting Program (Phelan 2006) versus Falkov's Family Model (Falkov 2012)).

2. Investigation of heterogeneity

We will report if inconsistency is high. First, we will investigate whether data have been entered correctly. Second, if data are correct, we will inspect the graph visually and remove outlying studies successively to see if homogeneity is restored. For this review, we have decided that should this occur with data contributing to the summary finding of no more than 10% of the total weighting, we will present data. If not, we will not pool these data and will discuss any issues. We know of no supporting research for this 10% cut-off but are investigating use of prediction intervals as an alternative to this unsatisfactory state.

When unanticipated clinical or methodological heterogeneity is 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.

Sensitivity analysis

Where possible, we will perform sensitivity analyses to explore the influence of the following factors on effect size.

1. Implication of randomisation

If trials are described in some way as to imply randomisation, for the primary outcomes, we will pool data from the implied trials with trials that are randomised.

2. Assumptions for lost binary data

Where assumptions have to be made regarding people lost to follow-up (see [Dealing with missing data](#)), we will compare the findings of the primary outcomes when we use our assumption compared with completer data only. If there is a substantial difference, we will report results and discuss them but continue to employ our assumption.

Where assumptions have to be made regarding missing SDs (see [Dealing with missing data](#)), we will compare the findings on primary outcomes when we use our assumption compared with completer data only. We will undertake a sensitivity analysis testing how prone results are to change when 'completer' data only are compared to the imputed data using the above assumption. If there is a substantial difference, we will report results and discuss them but continue to employ our assumption.

3. Risk of bias

We will analyse the effects of excluding trials that are at high risk of bias across one or more of the domains for the meta-analysis of the primary outcome (see [Assessment of risk of bias in included studies](#)).

4. Imputed values

We will undertake a sensitivity analysis to assess the effects of including data from trials where we use imputed values for ICC in calculating the design effect in cluster randomised trials.

5. Fixed- and random-effects

We will synthesise data using a random-effects model; however, we will also synthesise data for the primary outcome using a fixed-effect model to evaluate whether this alters the significance of the results.

We aim to carry out these sensitivity analyses for primary outcomes only. If there are substantial differences in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we will not add data from the lower-quality studies to the results of the higher-quality trials, but will present these data within a subcategory. If their inclusion does not result in a substantive difference, they will remain in the analyses.

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Conceived the review: JR and LJ.

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