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Parenting interventions for people with schizophrenia or related serious mental illness (Review)

Radley J, Grant C, Barlow J, Johns L

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[Intervention Review]

Parenting interventions for people with schizophrenia or related serious mental illness

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ABSTRACT

Background

Around a third of people with schizophrenia or related serious mental illness will be a parent. Both the parents and the children in this population are at increased risk of adverse outcomes due to parental mental illness. Parenting interventions are known to improve parenting skills and decrease child disruptive behaviour. This systematic review aimed to synthesise the evidence base for parenting interventions designed specifically for parents who have schizophrenia or related serious mental illness.

Objectives

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

Search methods

On 10 February 2021 we searched the Cochrane Schizophrenia Group's Study-Based Register of Trials, which is based on the following: Cochrane Central Register of Controlled Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), ClinicalTrials.Gov, Embase, International Standard Randomised Controlled Trial Number (ISRCTN), MEDLINE, PsycINFO, PubMed, and the World Health Organization International Clinical Trials Registry Platform.

Selection criteria

Eligible studies were randomised controlled trials (RCTs) that compared parenting interventions with a control condition for people with schizophrenia or related serious mental illness with a child between the ages of 0 and 18 years.

Data collection and analysis

We independently inspected citations, selected studies, extracted data and appraised study quality. We assessed risk of bias for included studies.

Main results

We only included one trial (n = 50), and it was not possible to extract any data because the authors did not provide any means and standard deviations for our outcomes of interest; they only reported whether outcomes were significant or not at the 0.05 level. Three domains of the trial were rated as having a high risk of bias.

Authors' conclusions

The only included trial provided inconclusive evidence. There is insufficient evidence to make recommendations to people with schizophrenia (or related serious mental illness) or clinicians, or for policy changes. Although there is no RCT evidence, parenting



interventions for people with schizophrenia or related serious mental illness have been developed. Future research should test these in RCTs in order to improve the evidence base for this population.

PLAIN LANGUAGE SUMMARY

Parenting programmes for parents with schizophrenia or related serious mental illness

Review question

How effective are parenting programmes for people with schizophrenia or related serious mental illness?

Background

Around one third of people with schizophrenia are a parent. Parenting programmes aim to provide support and training for parents to help manage their child's behaviour. Targeted parenting programmes for this group could have a positive effect for both the parents and their children. This review aimed to gather the current evidence for parenting programmes for people with schizophrenia or related mental illness to understand whether such support is effective at improving parenting skills or parent-child interaction.

Searching

We ran an electronic search in March 2020 and February 2021 for randomised controlled trials of parenting programmes aimed at people with schizophrenia or related serious mental illness. We found 36 studies and checked these to see if they were relevant to our research.

Available evidence

One trial met the review requirements but did not provide usable data. Therefore, there is not enough robust evidence to know anything about the effectiveness of parenting programmes for people with schizophrenia or related mental illness.

Conclusions

There is not enough evidence to make recommendations about parenting programmes for people with schizophrenia or related serious mental illness. Future research should conduct rigorous studies to test the effectiveness of parenting programmes that have already been designed.

SUMMARY OF FINDINGS

Cochrane Database of Systematic Reviews

Summary of findings 1. Parenting interventions compared to control conditions for parents with schizophrenia or related serious mental illness

Patient or population: parents with schizophrenia or related serious mental illness

Settings: any

Intervention: parenting intervention

Comparison: any active or inactive control

Outcomes	Illustrative com- parative risks	Relative effect	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
Parenting skills: clinically important change	Not estimable	Not estimable	0	-	The authors of the only included study did not provide any data in - terms of means and standard de-
Parenting skills: any change	Not estimable	Not estimable	0	-	viations, except on rehospitalisa- tions, and only reported whether
Adverse event: at least one adverse event	Not estimable	Not estimable	0	-	outcomes were significant or not at the 0.05 level (Cohler 1982). There-
Quality of relationship with child: clinical- ly important change	Not estimable	Not estimable	0	-	fore, we could not calculate the comparative risk or relative effect.
Quality of relationship with child: any change	Not estimable	Not estimable	0	-	
Behaviour of child: clinically important change in specific aspects of behaviour	Not estimable	Not estimable	0	-	_
Social services involvement: at least one child protection issue reported	Not estimable	Not estimable	0	-	-



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 (Jääskelänen 2013).

Estimates of the proportion of people with schizophrenia who have children range between 38% and 44%; women with schizophrenia are more likely to have children than men with schizophrenia are (Campbell 2012; Schrank 2015). 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, their 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 for their parents (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 the person's 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, 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). Triple P 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-toone 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 a 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 2015), 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 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; NHS 2019). This review aimed to determine the extent of the available evidence and the effects of programmes for this group of parents. If we had found sufficient studies, we also would have looked 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 considered all relevant randomised controlled trials (RCTs). We included RCTs meeting our inclusion criteria and reporting usable data. If a trial had been described as double-blind, but it was implied it had been randomised, we would have included these trials in a sensitivity analysis (see Sensitivity analysis). We excluded quasi-randomised studies, such as those that allocated intervention by alternate days of the week. Where people were given additional treatments as well as a parenting intervention, we only included data if the adjunct treatment was evenly distributed between groups and it was only the parenting intervention that was randomised.

Types of participants

We included 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 included participants with a variety of mental health diagnoses and the results for those with schizophrenia were not reported separately, we would only have included it if at least 50% of the participants were adults with schizophrenia or related disorders.

We were interested in making sure that information is as relevant as possible to the current care of people with schizophrenia, so aimed 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 included all parenting programmes whose primary aim was to improve the parenting skills or parent-child interaction (or both) of parents with schizophrenia or a related serious mental illness. Programmes may have been 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 have been underpinned by any theoretical approach.

We excluded 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 considered any control intervention whether active or inactive.

Types of outcome measures

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

We endeavoured 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 listed other binary outcomes and then those that are continuous.

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

For valid scales see Data extraction and management.

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

Primary outcomes

- 1. Parenting outcomes
 - a. Parenting behaviours, skills, attitudes, or knowledge
 - i. Clinically important change in parenting behaviours, skills, attitudes, or knowledge
 - ii. Any change in parenting behaviours, skills, attitudes, or knowledge



- 2. Adverse events involving child or parent
 - a. General adverse events (i.e. parenting stress, deterioration of parent's mental state)
 - i. At least one adverse event

Secondary outcomes

- 1. Parenting outcomes
 - a. Parenting behaviours, skills, attitudes, or knowledge
 - i. Average endpoint or change score on a parenting behaviours, skills, attitudes, or knowledge scale
 - b. Quality of relationship with child (i.e. attachment, parental reflectivity, parental sensitivity)
 - i. Clinically important change in quality of relationship with child
 - ii. Any change in quality of relationship with child
 - iii. Average endpoint or change score on a quality of relationship with child scale
- 2. Adverse events involving child or parent
 - a. General adverse events (i.e. parenting stress, deterioration of parent's mental state)
 - i. Clinically important adverse event
 - ii. Average endpoint or change score on an adverse-event/ effect scale
 - b. Death
 - i. Any cause except suicide, homicide, and filicide (death of child caused by parent)
 - ii. Suicide
 - iii. Homicide
 - iv. Filicide
- 3. Behaviour of child
- a. General
 - i. Clinically important change in general behaviour
 - ii. Any change in general behaviour
 - iii. Average endpoint or change score on a general behaviour scale
- b. Specific
 - i. Clinically important change in specific aspects of behaviour (e.g. aggression, socioemotional adjustment)
 - ii. Any change in specific aspects of behaviour (e.g. aggression, socioemotional adjustment)
 - iii. Average endpoint or change on specific aspects of behaviour scale
- 4. Social services involvement
 - a. At least one child protection issue reported
 - b. Child referred to social services for an assessment/ investigation
 - c. Child taken into care

- 5. General functioning of parent or child
 - a. Overall
 - i. Clinically important change in general functioning, including working ability
 - ii. Any change in general functioning, including working ability
 - iii. Average endpoint or change score on a general functioning scale
 - b. Specific
 - i. Clinically important change in specific aspects of functioning, such as life skills
 - ii. Any change in specific aspects of functioning, such as life skills
 - iii. Any change in educational status
 - iv. Any change in employment status
 - v. Average endpoint or change score on specific aspects of functioning scale
- 6. Social functioning of parent or child
 - a. Clinically important change in social functioning
 - b. Any change in social functioning
 - c. Average endpoint or change score on a social functioning scale
- 7. Global state of parent
 - a. Clinically important change in global state (e.g. global impression of much improved, or more than 50% improvement on a rating scale)
 - b. Relapse
 - c. Any change in global state
 - d. Average endpoint or change score on a global state scale
 - e. Use of other medications
- 8. Mental state of parent
 - a. General
 - i. Clinically important change in general mental state
 - ii. Any change in general mental state
 - iii. Average endpoint or change score on a general mental state scale
 - b. Specific
 - Clinically important change in specific symptoms (e.g. positive, negative, affective, cognitive symptoms of schizophrenia)
 - ii. Any change in specific symptoms (e.g. positive, negative, affective, cognitive symptoms of schizophrenia)
 - iii. Average endpoint or change score on a specific symptom scale
- 9. Quality of life of parent or child
 - a. Overall
 - i. Clinically important change in quality of life
 - ii. Any change in quality of life
 - iii. Average endpoint or change score on a quality-of-life scale
 - b. Specific
 - i. Clinically important change in specific aspects of quality of life
 - ii. Any change in specific aspects of quality of life
 - iii. Average endpoint or change score on specific aspects of quality-of-life scale



- 10.Service use of parent
 - a. Clinically important engagement with services
 - b. Any engagement with services
 - c. Average endpoint or change score on engagement scale
 - d. Compliance with medication or other treatment, or both
 - e. Number of hospitalisations
 - f. Number of days in hospital
 - g. Inability to be discharged from hospital
- 11.Leaving the study early
 - a. 11.1. For any reason
 - b. Due to inefficacy
 - c. Due to adverse effect
- 12.Economic costs
 - a. Costs due to treatment, as defined by each study
 - b. Savings due to treatment, as defined by each study

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Group's Study-Based Register of Trials

On 30 March 2020 and 10 February 2021, the Information Specialist searched 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 because all the studies have already been organised based on their interventions and linked to the relevant topics (Shokraneh 2017; Shokraneh 2021; Roberts 2021). 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), this register is compiled by systematic searches of major resources (Cochrane Central Register of Controlled Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), ClinicalTrials.Gov, Embase, International Standard Randomised Controlled Trial Number (ISRCTN), MEDLINE, PsycINFO, PubMed, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and their monthly updates, ProQuest Dissertations and Theses A&I and its quarterly update, handsearches, grey literature, and conference proceedings (Shokraneh 2020; see Group's website). There are no language, date, document type, or publication status limitations for inclusion of records into the register.

Searching other resources

1. Reference searching

We inspected references of the included studies for further relevant studies.

2. Personal contact

We contacted the first author of the included study for information regarding unpublished trials. We noted the outcome of this contact in the Characteristics of included studies table.

Data collection and analysis

Selection of studies

Two review authors (JR and CG) independently inspected citations from the searches and identified relevant abstracts; one review author (JB) independently re-inspected a random 20% sample of these abstracts to ensure reliability of selection. Where disputes arose, we acquired the full report for more detailed scrutiny. Two review authors (JR and CG) then obtained and inspected full reports of the abstracts or reports meeting the review criteria. Where it was not possible to resolve disagreement by discussion, we attempted to contact the authors of the study concerned for clarification. We listed studies excluded at this stage in the Characteristics of excluded studies table.

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

Data extraction and management

1. Extraction

Two review authors (JR and CG) extracted data from the included study and presented in the Characteristics of included studies table. We attempted to extract data presented only in graphs and figures whenever possible, but only included the data if two review authors independently obtained the same result. If studies were multicentre, we extracted data relevant to each where possible. We discussed any disagreements and documented our decisions. If necessary, we attempted to contact authors through an open-ended request to obtain missing information or for clarification. One review author (JB) helped clarify issues regarding any remaining problems and we documented these final decisions.

2. Management

2.1. Forms

We extracted data onto standard, predesigned, simple forms.

2.2. Scale-derived data

We planned to include continuous data from rating scales only if:

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

Ideally, the measuring instrument should either have been a selfreport or completed by an independent rater or relative (not the therapist). We realise that this is not often reported clearly; we noted if this was 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 decided primarily to use endpoint data, and only use change data if the former were not available. If necessary, we would have combined endpoint and change data in the analysis, as we would have preferred 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 would have applied the following standards to relevant continuous data before inclusion.

We planned the following approach for endpoint data from studies including fewer than 200 participants.

- For scales starting from the finite number zero, we would have subtracted the lowest possible value from the mean, and divided this by the standard deviation (SD). If this value had been lower than one, it would have strongly suggested that the data were skewed, and we would have excluded these data. If this ratio had been higher than one but less than two, there would have been some suggestion that the data were skewed: we would have entered these data and tested whether their inclusion or exclusion changed the results substantially. If such data changed results, we would have entered them as 'other data'. Finally, if the ratio had been larger than two, we would have included these data because it would have been less likely that they were skewed (Altman 1996).
- 2. For a scale starting from a positive value (such as the Positive and Negative Syndrome Scale (PANSS), which can have values from 30 to 210 (Kay 1986)), we would have modified the calculation described above to take the scale starting point into account. In these cases, skewed data would have been present if 2 SD > (S S_{min}), where S is the mean score and S_{min} is the minimum score.

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

2.5. Common measurement

To facilitate comparison between trials (where relevant), we would have 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 would have attempted 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 were not available, we planned to use the primary cut-off presented by the study authors.

2.7. Direction of graphs

Where possible, we planned to enter data in such a way that the area to the left of the line of no effect indicated a favourable outcome for the parenting intervention. Where keeping to this would have made it impossible to avoid outcome titles with clumsy double-negatives (e.g. 'not unimproved'), we would have reported data where the left of the line indicated an unfavourable outcome and noted this in the relevant graphs.

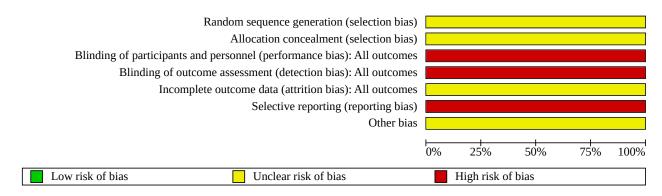
Assessment of risk of bias in included studies

Two review authors (JR and CG) independently assessed 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 disagreed, we made the final rating by consensus. Where inadequate details of randomisation and other characteristics of trials are provided, we attempted to contact authors of the studies to obtain further information. We reported non-concurrence in quality assessment, but if disputes arose regarding the category to which a trial is to be allocated, we resolved this by discussion. We noted the level of risk of bias in the text of the review, risk of bias graph (Figure 1), and risk of bias summary (Figure 2).



Figure 1. review authors' judgements about each risk of bias item presented as percentages across all included studies.





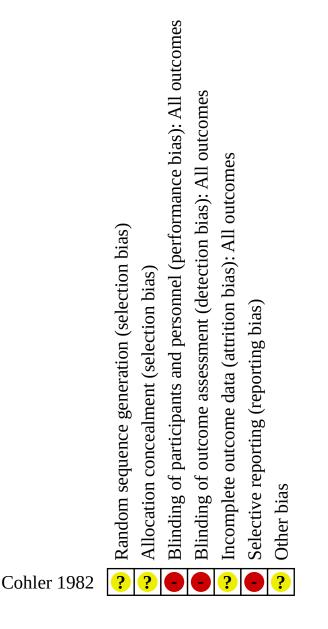


Figure 2. review authors' judgements about each risk of bias item for each included study.

Measures of treatment effect

1. Binary data

For binary outcomes, we would have calculated 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 Summary of findings 1, we had planned to calculate illustrative comparative risks.

2. Continuous data

For continuous outcomes, we would have estimated MD between groups. We would have preferred not to calculate effect size measures (SMD). However, if scales of very considerable similarity had been used, we would have presumed there was a small difference in measurement, calculated the effect size and

transformed the effect back into the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster-randomised 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 cluster-randomised 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 had been incorporated into the analysis of primary studies, we had planned to present these data as if from a non-cluster-randomised study, but adjusted for the clustering effect.

Where clustering had not been accounted for in primary studies, we had planned to present data in a table, with a (*) symbol to indicate the presence of a probable unit-of-analysis error. We would have sought 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 sought statistical advice and were advised that the binary data from cluster-randomised 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 = $1 + (m - 1) \times ICC$ (Donner 2002). If the ICC is not reported, it is assumed to be 0.1 (Ukoumunne 1999).

If cluster studies had been appropriately analysed and taken ICCs and relevant data documented in the report into account, 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. 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 planned to use only 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, we planned to present the additional treatment arms in comparisons. If data were binary, we would simply have added these and combined them within the two-by-two table. If data were continuous, we planned to combine data following the formula in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). Where additional treatment arms were not relevant, we would not have reproduced these data and would have listed them in the Characteristics of included studies table.

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Dealing with missing data

1. Overall loss of credibility

At some degree of loss to follow-up, data must lose credibility (Xia 2009). We chose that, for any particular outcome, should more than 50% of data have been unaccounted for, we would not have reproduced these data or used 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 would have addressed this within Summary of findings 1 by downgrading certainty. Finally, we also planned to downgrade certainty within Summary of findings 1 should the loss have been 25% to 50% in total.

2. Binary

In the case where attrition for a binary outcome was between 0% and 50% and where these data were not clearly described, we would have presented data on a 'once-randomised-alwaysanalyse' basis (an intention-to-treat (ITT) analysis). We would have assumed that those leaving the study early had the same rates of negative outcome as those who completed. We planned to use the rate of those who stayed in the study – in that particular arm of the trial – and apply this also to those who did not. We planned to undertake a sensitivity analysis testing how prone the primary outcomes were to change when we only used data from people who completed the study to that point, compared to the ITT analysis using the above assumptions.

3. Continuous

3.1. Attrition

We planned to use data where attrition for a continuous outcome was between 0% and 50%, and would only have reported data from people who completed the study to that point.

3.2. Standard deviations

If a study did not report SDs, we would have tried to obtain the missing values from the study authors. If these were not available, where there were missing measures of variance for continuous data, but an exact standard error (SE) and CIs were available for group means, and either a P value or t value available for differences in mean, we would have calculated SDs according to the rules described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011b). When only the SE is reported, SDs can be calculated by the formula SD = SE × $\sqrt{(n)}$, 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 did not apply, we planned to 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 have been to exclude a given study's outcome and thus to lose information. Nevertheless, we planned to examine the validity of the imputations in a sensitivity analysis that excluded 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 did not exclude studies based on the statistical approach used. However, by preference we planned to use the more sophisticated approaches, that is, we would have preferred to use MMRM or multiple-imputation to LOCF, and we would only have presented completer analyses if some type of ITT data were not available. Moreover, we would have addressed this issue in the item 'Incomplete outcome data' of the risk of bias tool.

Assessment of heterogeneity

1. Clinical heterogeneity

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

2. Methodological heterogeneity

We had planned to judge methodological heterogeneity by considering all included studies before seeing comparison data. We would have reviewed all studies for clearly outlying methods that we had not predicted would arise, and would have discussed any such methodological outliers.

3. Statistical heterogeneity

3.1. Visual inspection

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

3.2. Employing the I² statistic

We planned to investigate heterogeneity between studies by considering the I² statistic alongside the Chi² P value. The I² 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 I² statistic depends on the magnitude and direction of effects as well as the strength of evidence for heterogeneity (e.g. P value from Chi² test, or a CI for the I² statistic). We would have interpreted an I² estimate of 50% or more, when accompanied by a statistically significant Chi² statistic, as evidence of substantial heterogeneity (Chapter 9. *Cochrane Handbook for Systematic Reviews of Interventions*; Deeks 2011). When there were substantial levels of heterogeneity for the primary outcomes, we planned to 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 Systemic reviews of Interventions* (Sterne 2011).

1. Protocol versus full study

We tried to locate protocols of included randomised trials. If the protocol was available, we planned to compare outcomes in the protocol with those in the published report. If the protocol was not available, we planned to compare outcomes listed in the methods section of the trial report with the results actually reported.

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 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 would have sought 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 planned to use a random-effects model for analyses.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We did not expect there to be sufficient power to report subgroup analyses. However, if data were available, we would have looked 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 would have reported if inconsistency was high. First, we would have investigated whether data had been entered correctly. Second, if data were correct, we would have inspected the graph visually and removed outlying studies successively to see if homogeneity was restored. For this review, we decided that should this occur with data contributing to the summary finding of no more than 10% of the total weighting, we would have presented data. If not, we would not have pooled these data and instead would have discussed 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 was obvious, we would have simply stated hypotheses regarding these for future reviews or versions of this review. We did not anticipate undertaking analyses relating to these.

Sensitivity analysis

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



1. Implication of randomisation

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

2. Assumptions for lost binary data

Where assumptions had to be made regarding people lost to followup (see Dealing with missing data), we planned to compare the findings of the primary outcomes when we used our assumption compared with completer data only. If there had been a substantial difference, we planned to report results and discuss them, but would have continued to employ our assumption.

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

3. Risk of bias

We planned to analyse the effects of excluding trials that were at high risk of bias across one or more of the domains for the metaanalysis of the primary outcome (see Assessment of risk of bias in included studies).

4. Imputed values

We planned to undertake a sensitivity analysis to assess the effects of including data from trials with imputed values for ICC in calculating the design effect in cluster-randomised trials.

5. Fixed-effect and random-effects

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

We aimed to carry out these sensitivity analyses for primary outcomes only. If there had been substantial differences in the direction or precision of effect estimates in any of the sensitivity analyses listed above, we would not have added data from the lower-quality studies to the results of the higher-quality trials, but instead presented these data within a subcategory. If their inclusion had not resulted in a substantive difference, they would have remained in the analyses.

Summary of findings and assessment of the certainty of the evidence

We used the GRADE approach to interpret findings (Schünemann 2011); and created a summary of findings table using RevMan Web. Summary of findings tables provide outcome-specific information concerning the overall certainty of evidence from each included study in a comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes that are important to patient care and decision making. We aimed 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 were not available for these prespecified outcomes but were available for ones that are similar, we planned to present the closest outcome to the prespecified one in the table and take this into account when grading the finding.

Methods of the present review were based on the published protocol (see Radley 2020).

RESULTS

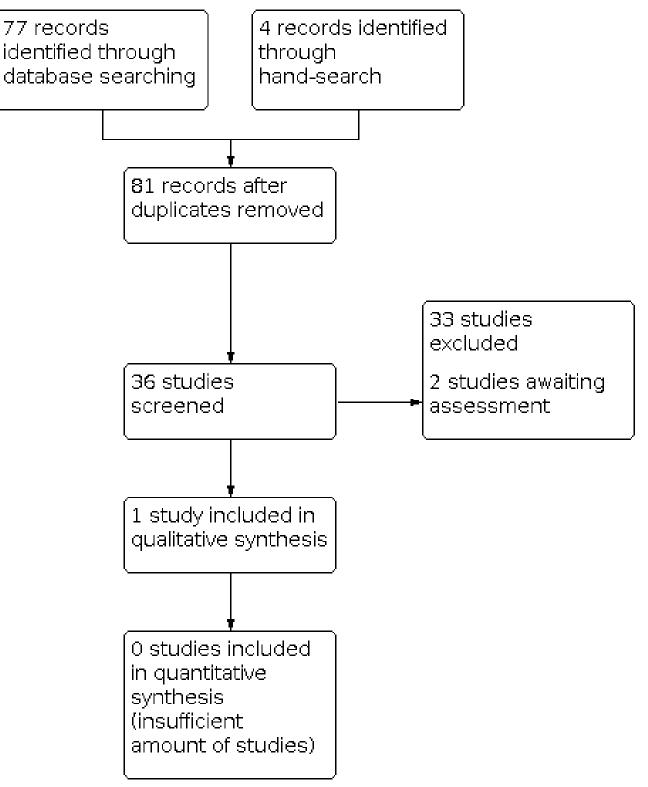
Description of studies

The systematic search returned 77 reports and we obtained four more reports by handsearching. In total, 81 reports summarising the results of 36 studies were screened. Where it was unclear whether a study was eligible or not, e.g. due to only having obtained the trial protocol, we contacted the authors to confirm eligibility status. This was the case for four studies.

See Figure 3.



Figure 3. Study flow diagram



Results of the search

Authors JR and CG independently screened and assessed the eligibility of 81 full-text records with any disagreements discussed and resolved between the two authors. JB independently checked

eligibility of 20% of records. After reviewing all reports, we only included one study (Cohler 1982).

Parenting interventions for people with schizophrenia or related serious mental illness (Review) Copyright © 2021 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.



Included studies

1. Design and duration

Cohler 1982 described a parallel randomised control trial which took place over one to two years.

2. Participants

The study included mothers with psychosis who had previously been hospitalised and had at least one child below the age of six.

3. Size

There were 50 mothers, with 25 assigned to the intervention and 25 assigned to the control condition.

4. Setting

Participants were recruited from public and private hospitals around Boston, USA. The intervention was offered in the participants' own homes.

5. Intervention

5.1 Intervention

The intervention comprised long-term aftercare home visits delivered by specially trained psychiatric nurses in addition to treatment as usual. Nurses visited the participants weekly over one to two years. Each visit lasted between 60 and 90 minutes. The nurse observed the mother's interactions with her youngest child and discussed these with the mother. Other factors, such as unresolved issues in the mother's life, were also incorporated into the intervention. The intervention group received 1384 visits in total.

5.2 Control

The control group received treatment as usual and were described to have minimal contact with fewer visits from the specialist aftercare nurses. The control group received 130 visits in total.

6. Outcomes

Mothers completed self-rated measures on 1) social-role performance, 2) improvement in one's capacity to care for one's own child, 3) interpersonal relationships, 4) self-efficacy, 5) psychological distress, and 6) rehospitalisation. Partners rated their wives on social functioning.

Nurses rated participants on 1) capacity for closeness as a friend, 2) capacity for closeness with husband, 3) adaptive functioning in housewife role, 4) psychological symptoms, 5) intrafamily conflicts. They rated children on 1) behaviour, 2) mental health and 3) social interactions.

The study used the Minnesota Multiphasic Personality Interview (MMPI) for mothers to self-rate psychological distress. However, it is not clear whether the study measured the other outcomes above using validated measures, or assessed them using rating scales that were developed for the purpose of this research.

Excluded studies

Excluded studies

We excluded the majority of studies because they were either 1) an intervention for the parents of people who had a psychotic

disorder or 2) an intervention for the children of parents with a psychotic disorder. In the latter case, these interventions may have also measured parenting, but we could not include them because their primary goal was not to improve parenting quality or the parent-child relationship, rather they were focused primarily on the outcome for the child (see Characteristics of excluded studies).

We also excluded four studies because they described a parenting intervention for parents with mental health difficulties, and less than 50% of participants had a psychotic disorder. We contacted these authors, asking if it was possible to provide data for participants with psychosis separately. Two authors replied saying it was not possible, so we excluded these (DRKS00017398; Wittkowski 2018). The other two studies' authors did not reply, so these are awaiting classification (ACTRN12616000460404; Kaplan 2013).

Ongoing studies

We are unaware of any ongoing studies.

Awaiting classification

There are two studies awaiting classification (ACTRN12616000460404; Kaplan 2013). ACTRN12616000460404 is a trial of the intervention Let's Talk about Children, for parents with any kind of mental health diagnosis. Kaplan 2013 describes an online parenting education course for parents with severe mental illness.

Risk of bias in included studies

See also Figure 1 and Figure 2.

Allocation

It was unclear what the risk of allocation bias was since although Cohler 1982 stated participants were assigned 'randomly', no further details were given. It was also unclear whether participants or personnel were aware of the allocation sequence.

Blinding

There was a high risk of performance bias since it was stated that nurses were aware of which group participants

were allocated to. Due to the difference in contact time between the intervention and control group, it is likely

that participants also knew which arm they were in. This may have biased the assessment of outcome.

Incomplete outcome data

It was unclear what the risk of attrition bias due to missing data was because very few details were provided in terms of the numbers of participants as malating the study.

terms of the numbers of participants completing the study.

Selective reporting

There was a high risk of reporting bias due to the fact that parenting skills were measured in multiple ways

without a pre-specified analysis plan detailed in the methodology. Towards the end of the results section, the

authors investigate a subgroup of patients who were rated as 'changing more' in psychological and social

functioning, and provided details on outcome measures for these patients that were not previously mentioned,



such as 'encouraging mother-child reciprocity' and 'fostering appropriate mother-child closeness'. It is not made

clear how the intervention and control group differed on these measures. Outcomes measures for the children

are also mentioned, but the results of these are not reported.

Other potential sources of bias

The methodology was lacking significant detail, providing little insight into the analysis plan. Additionally, there

was no information given on any conflict of interest between the researchers and the trial.

Effects of interventions

See: Summary of findings 1 Parenting interventions compared to control conditions for parents with schizophrenia or related serious mental illness

The authors did not provide any data in terms of means and standard deviations, except for rehospitalisations. They only reported whether outcomes were significant or not at the 0.05 level.

Therefore, it was not possible to include this study in the analysis.

DISCUSSION

Summary of main results

This review aimed to assess the effectiveness of parenting interventions for parents with schizophrenia or related mental illness. The results of the search suggest that there is a lack of studies evaluating such interventions, with only one study out of 36 meeting the criteria after full-text inspection. This study was published almost 40 years ago, with inconclusive results on whether parenting interventions change parenting quality or the parent-child relationship, and 3 domains of this study were rated as high risk of bias. We excluded studies because they either sought to measure the child's outcomes, rather than a change in parenting quality or the parent-child relationship, or because less than 50% of the participants had schizophrenia or related serious mental illness.

Overall completeness and applicability of evidence

It cannot be said that this evidence is complete or applicable. We only found one study, from which we could not extract any data, and its results were inconclusive. The intervention itself was also not well described and, therefore, could not be repeated. Furthermore, this study was almost 40 years old so it could not be said to be applicable to any current parents with psychosis.

Quality of the evidence

A high risk of bias was judged in three domains (performance, detecting, and reporting bias). The main source of bias was the poor reporting of measures, analyses and results. It was also clear that both the participants and the nurses delivering the intervention and assessments were aware of the group allocation. The study only reported significance levels and did not provide any usable data.

Potential biases in the review process

The search conducted by Cochrane Schizophrenia was thorough, and the review authors followed the protocol strictly. However,

there is always the possibility of unpublished trials that were not identified and therefore not reported here. Although only one study was included, two more had the potential to be included (ACTRN12616000460404; Kaplan 2013). However, the review authors were not able to contact the study authors to clarify their eligibility criteria.

Agreements and disagreements with other studies or reviews

Two recent reviews on similar topics have been conducted, one of which investigated the effectiveness of interventions for mothers with schizophrenia (Gearing 2012), and the other of which examined the effectiveness of interventions for a group of participants, of whom at least 20% had a severe mental illness (Schrank 2015). In Gearing 2012, the majority of included studies were looking at the effects of mother and baby units where the primary aim is to improve the mother's mental health without foregoing infant attachment, rather than specifically to improve parenting quality, and none of the included studies were RCTs. The systematic review by Schrank 2015 included the only study found in this review (Cohler 1982); the other RCTs in the Schrank 2015 review were aimed at parents with major depression so would have been excluded by the eligibility criteria for this Cochrane Review.

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with schizophrenia

While there is a well-developed evidence base for parenting interventions in the general population and for people with other mental health conditions, such as depression, this review found that there is currently no rigorous evidence evaluating their effectiveness in improving parenting outcomes for parents with schizophrenia or related mental illness. There are, as such, no implications of this review for this population of parents.

2. For clinicians

This review shows that there is currently no randomised controlled trial (RCT) evidence regarding the effectiveness of parenting programmes for parents with schizophrenia or related serious mental illness, and thereby no implications in terms of clinical practice.

3. For policy makers

There is insufficient evidence from this review to support a policy change.

Implications for research

1. General

This systematic review demonstrated a lack of evidence to support the use of parenting interventions for parents with schizophrenia or related serious mental illness. We excluded studies for three main reasons: 1) the intervention was targeting the parents of someone with schizophrenia or related serious mental illness; 2) the intervention was a parenting intervention but for parents with mental health problems more generally, and less than 50% of its participants had a diagnosis of any kind of psychosis; and 3) the intervention was targeting parents with psychosis, however it was focused on improving child outcomes rather than parenting quality

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or the parent-child relationship. In terms of supporting parents with psychosis, the literature is typically focused solely on outcomes for the child (Reupert 2017). Having a focus on improving parenting quality can also result in improved outcomes for the child, such as reduced behavioural difficulties (Nowak 2008), and decreased levels of neglect (Cummins 2012). Therefore, future research in this field should broaden its focus to include benefits for parents with psychosis, as well as for their children.

2. Specific

Other reviews describe interventions which have been devised but have not been tested in an RCT (Schrank 2015 Suarez 2016). Examples of some such interventions are Family Options (Nicholson 2009), Family Model (Falkov 2012), and the Mental Health Positive Parenting Program (Phelan 2006). Therefore, this lack of an evidence base is not due to a lack of conceptualisations of what a parenting intervention could look like but rather a lack of RCTs testing these interventions. Research must now focus on conducting RCTs in order to develop this evidence base. One of the main reasons we excluded studies was also because they included participants with any mental health condition and the proportion of their participants with psychosis was too low (e.g. DRKS00017398; Wittkowski 2018). Researchers have recommended diagnosis-specific groups, and parents have also asked for these (Campbell 2012 Suarez 2016 Venkataraman 2008). Efforts should now be made to tailor interventions towards the specific needs of parents with psychosis.

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Cochrane Schizophrenia's Editorial Base, situated across the University of Melbourne, Australia; the Technical University of Munich, Germany; and the University of Nottingham, UK, produces and maintains standard text for use in the Methods sections of their reviews. We have used this text as the basis of what appears here, and adapted it as required.

We would also like to thank and acknowledge Giovanni Croatto and Daisy Zamora for peer reviewing this Cochrane Review, and editor Javier Ortiz-Orendain.

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CHARACTERISTICS OF STUDIES

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* Indicates the major publication for the study

Study characterist	tics
Methods	Allocation: randomised.
	Blinding: nurses aware of allocation groups
	Duration: 1 to 2 years



Cohler 1982 (Continued)

	Design: parallel groups
	Country: USA
Participants	Diagnosis: psychosis
	History: previous hospitalisation
	N = 50
	Sex: 0 men, 50 women
	Age of children: under 6 years
	Setting: participants' own home
Interventions	 Intensive long-term nursing aftercare, visits by a nurse weekly for 60 to 90 minutes, consisting of 1384 visits in total: N = 25
	2. Minimal contact, consisting of 130 visits in total: N = 25
Outcomes	1. Social-role performance
	2. Improvement in one's capacity to care for one's own child
	3. Interpersonal relationships
	4. Self-efficacy
	5. Psychological distress
	6. Rehospitalisation
	No usable data were provided for any of the outcomes.
Notes	There is a lack of reporting about which outcome measures were used and what kind of analyses were conducted. Both authors are deceased so it was not possible to contact them for further information.

Risk of bias

Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	Quote: 'Two groups of 25 were formed by random assignment of the psychotic mothers'.	
		Comment: No more details are given in the process of randomisation so this remains unclear.	
Allocation concealment (selection bias)	Unclear risk	Comment: No detail on what the allocation sequence was or whether it was concealed.	
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Quote: 'The fact that the psychiatric nurses knew the study hypotheses and were aware of the treatment group to which their patients belonged leads to the possibility that their ratings may have been biased in the direction of the more intensively treated patients'.	
		Comment: Interventions were either 'intensive long-term nursing aftercare' or 'minimal contact'. Therefore both participants and nurses delivering intervention were aware.	
Blinding of outcome as-	High risk	Quote: see above quote.	
sessment (detection bias) All outcomes		Comment: patients rated their own parenting skills change.	

Cohler 1982 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information on the extent of missing data, what kind of analyses were used, and what measures they used to measure their desired outcomes.
Selective reporting (re- porting bias)	High risk	Comment: Authors have measured parenting skills in multiple ways without a pre-specified analysis plan. They mention that they measured nurse-rated 'encouraging mother-child reciprocity' and 'fostering appropriate mother-child closeness' but they do not report the difference between the control group and intervention group on these measures.
Other bias	Unclear risk	Comment: lack of a detailed methodology to assess other sources of bias.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion	
ACTRN12619000335190	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.	
Canning 1997	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.	
DRKS00017398	Ineligible participants: less than 50% with schizophrenia. Authors were contacted, asking if they could provide data for those with schizophrenia or related disorders separately, and they replied saying this was not possible.	
Falloon 1982	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.	
Fraser 2008	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.	
Gellatly 2018	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.	
Greene 1999	Ineligible participants: intervention is aimed at children with mental health problems.	
Harrington 1996	Ineligible participants: intervention does not involve parents.	
Jones 2016	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related s rious mental illness rather than parents with schizophrenia or related serious mental illness.	
Kucuk 2020	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.	
Lenior 1999	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se rious mental illness rather than parents with schizophrenia or related serious mental illness.	
Linszen 1994	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.	



Study	Reason for exclusion
Linszen 1996	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
Linszen 2007	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
Liu 2016	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
NCT02114593	Ineligible participants: the parents in this study do not have mental health problems.
NCT02313493	Ineligible participants: the parents in this study do not have mental health problems.
NCT02329431	Ineligible participants: the parents in this study do not have mental health problems.
NCT02723357	Ineligible participants: the parents in this study do not have mental health problems.
NCT04018521	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
NCT04369625	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.
NCT04412590	Ineligible participants: the parents in this study do not have mental health problems.
Qian 2005	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
Schwenck 2016	Ineligible participants: intervention is aimed at children with mental health problems.
Smeerdijk 2009	Ineligible participants intervention is aimed at parents of people with schizophrenia or related seri- ous mental illness rather than parents with schizophrenia or related serious mental illness.
Terja 2016	Ineligible participants: intervention is aimed at children with behavioural difficulties.
Thorup 2018	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.
Washington 2018	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.
Wittkowski 2018	Ineligible participants: less than 50% with schizophrenia. Authors were contacted, asking if they could provide data for those with schizophrenia or related disorders separately, and they replied saying this was not possible.
Woolderink 2015	Ineligible intervention: intervention is aimed at the children of parents with mental illness rather than being a parenting intervention.
Zhan 2003	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
Zhang 2005a	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.
Zhang 2005b	Ineligible participants: intervention is aimed at parents of people with schizophrenia or related se- rious mental illness rather than parents with schizophrenia or related serious mental illness.



Characteristics of studies awaiting classification [ordered by study ID]

Methods	Allocation: randomised.		
	Blindness: researchers collecting the outcome measures will be blind to the participants' alloca- tion		
	Duration: 2 to 3 weeks		
	Design: parallel groups		
	Country: Australia		
Participants	Diagnosis: any mental illness		
	N = 192 (target)		
	Setting: outpatient		
Interventions	1. Let's Talk about Children. 2 to 3 sessions with parents with mental illness, and their families. Ses- sions are once a week for 60 minutes, and the practitioner decides whether families will have two or three sessions		
	2. Treatment as usual, and offered intervention after 6 months		
Outcomes	Recovery		
	Parenting stress		
	Family functioning		
	Engagement with children about parental mental illness		
	Working alliance		
	Quality of life		
Notes	Authors were contacted, twice, to determine how many participants had a diagnosis of schizophre nia or related disorders, and if fewer than 50%, whether their outcome data were available sepa- rately. No answer was received.		

Kaplan 2013	
Methods	Allocation: randomised
	Blindness: not documented
	Duration: 3 months
	Design: parallel groups
	Country: USA
Participants	Diagnosis: mood disorder or schizophrenia spectrum disorder
	N = 60
	Sex: 100% women



Kaplan 2013 (Continued)	Setting: online
Interventions	1. Parenting Education, which consisted of 12 30-minute modules, accessed online, and peer sup- port through e-mail: N = 31
	2. Healthy Lifestyles Education, accessed online: N = 29
Outcomes	Parental efficacy
	Parenting skills
	Coping skills
	Social support
	Parental stress
Notes	Authors were contacted, twice, to determine whether their outcome data for the parents who had a diagnosis of schizophrenia or a related disorder were available separately. No answer was re- ceived.

WHAT'S NEW

Date	Event	Description
10 February 2021	Amended	Search found 77 reports (containing 36 studies). All added to Studies awaiting classification section of this review.

HISTORY

Protocol first published: Issue 2, 2020

CONTRIBUTIONS OF AUTHORS

Conceived the review: JR and LJ.

Wrote the protocol and review: JR.

Reviewed and drafted parts of the protocol and review: CG, JB, LJ.

DECLARATIONS OF INTEREST

JR: none

CG: none

JB: none

LJ: none

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Internal sources

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• Mental Health Research UK, UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We assigned tasks to different authors than those stated in the protocol, due to changes in availability.

As we only found one study that did not provide data usable for the meta-analysis, we carried out a narrative summary and could not perform the methods described under Data synthesis.

We produced the summary of findings table using RevMan Web rather than GRADE Pro GDT.