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Effect of family-centred care on parental mental health and parent–infant interactions for preterm infants: a systematic review protocol

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ABSTRACT

Introduction Unexpected premature delivery and separation from preterm infants are common problems that parents of preterm infants must handle with. Parents of preterm infants may suffer from severe psychological distress. Family-centred care (FCC) can effectively ease parents' psychological distress and strengthen connections between parents and their preterm infants. The purpose of this systematic review will be to systematically review and evaluate the impacts of FCC interventions on the mental health of parents of preterm infants and the parent–infant relationship.

Methods and analysis This protocol for this systematic review will be conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol. We will search databases including PubMed, Embase, The Cochrane Library, CINAHL, Web of Science, PsycINFO, Scopus and ProQuest, CNKI, SinoMed and Wanfang Data from 1 July 2012 to 1 July 2022. An additional search of OpenGrey will be conducted to identify grey literature. Randomised controlled trials related to FCC inventions for preterm infants≤37 weeks' gestational age and their parents will be included, and the outcome measures will be parental mental health and parent–infant interaction. Two reviewers will independently conduct title and abstract screening, full-text screening, data extraction and study quality assessment. Risk of bias for the studies will be evaluated using the Cochrane Collaboration Risk of Bias V.2.0. Any disagreements will be solved by a third reviewer to reach a consensus. If appropriate, a meta-analysis will be conducted to assess the effect of FCC on parental mental health and parent–infant relationship.

Ethics and dissemination Research ethics approval will not be required for this review since it will not involve the collection of primary data and will only use published literature. The results will be disseminated in a peer-reviewed journal through publication or by presentation at relevant academic conference.

PROSPERO registration number CRD42022299203.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The protocol for this review, together with PROSPERO registration, follows the Cochrane methodology and Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines.
⇒ Rigorous methods of review will be followed with at least two independent reviewers to conduct study selection, data extraction and critical appraisal.
⇒ The research team includes researchers and practitioners with methodological and clinical expertise.
⇒ Since different scales may be adopted in trials, the pooling of analysis of all included studies may not be possible; however, subgroup analyses will be conducted according to different outcomes.
⇒ Various types of FCC interventions could be a source of heterogeneity between the studies, and there could be number of studies of low quality affecting pooled estimates and our ability to conduct a meta-analysis.

INTRODUCTION

Premature delivery, referring to a baby born at fewer than 37 weeks' gestational age, has become a global problem.[1 2] Approximately 15 million preterm infants are born worldwide each year, with a preterm birth rate of 11.1%.[3] In China, approximately 1.2 million preterm infants are delivered each year, with a preterm birth rate of 7.0%, and this number has been increasing in these years.[4] With the rapid development of perinatal medicine and neonatal care, the survival rate of premature infants has continued to increase in recent years.[5 6] Premature infants are required to be hospitalised and treated in the neonatal intensive care unit (NICU) immediately after birth for several weeks to several months depending on their illness conditions, leading the early connection establishment between parents and their premature infants being postponed.[7 8] Since the parents cannot participate in the care of their preterm infants in the NICU, parent–child interactions cannot be carried out normally and their parental role establishment are inhibited.[9] Furthermore, the closed management of the NICU, fluctuation in the infant's illness condition and prognosis will cause mental instability and emotional problems such as anxiety

and depression, and some severe cases may develop into acute stress disorder and post-traumatic stress disorder (PTSD).[10 11]

Premature birth is a traumatic life event for a family. Unexpected premature delivery may make parents feel anxious, depressed and stressed.[12–15] If the parents of premature infants do not receive proper support and guidance for their psychological problems, the negative impacts may not cease until the infant is discharged from the NICU, which will not only harm the physical and mental health of the parents but also affect the subsequent development of the premature infant.[16–18] The more severe the psychological problems of the parents are, such as a higher level of stress or depression, the more behavioural problems their preterm infants will encounter.[19] Studies have shown that the long-term psychological health problems of parents of preterm infants are associated with the subsequent social and emotional problems, impaired language and neurite outgrowth of their children, as well as a bad parent–child relationship.[20 21] Therefore, it is of great necessity to pay attention to parents' mental health and develop interventions to help ease their physiological problems.

Moreover, during hospitalisation, parents of preterm infants are worried that their baby may not survive and feel sad for the baby's immaturity and frequent health crises.[22 23] The loss of the expected parental role due to the unwanted separation from their preterm infants during hospitalisation is also a major source of stress.[7 24] Almost 50% of the mothers of premature infants suffer from high levels of anxiety and/or depression during the infant's hospitalisation.[25 26] The severity of psychological distress may be related to the severity of the infant's disease,[27] although the results are inconsistent.[28 29] In addition, other factors in daily life may exacerbate these psychological symptoms, such as daily stressors or postpartum depression.[30 31] The psychological distress of the parents of the preterm infants may be sustained for months or even years after the infants are discharged from the NICU, and the severity of psychological distress is significantly related to the severity of psychological distress during the infant's hospitalisation.[32 33] Some mothers even suffer from post-traumatic stress symptoms in accordance with the severity of the infant's illness condition.[28]

In the past six decades, the concept of family-centred care (FCC) has been implemented to varying degrees in different medical institutions.[34–36] FCC is more of a nursing concept and approach, which emphasises four principles: dignity and respect, information sharing, participation in nursing and decision-making[37 38] and encourage parents to be involved in the care of their preterm infants. Studies have shown that parents want to participate in the care of their newborns in the NICU to get prepared for taking care of their babies after they are discharged from the hospitals.[39 40] Compared with conventional interventions, FCC programmes have been shown to be effective in reducing parents' negative emotions and have also produced many benefits in terms of the parent–child relationship, self-efficacy and caring behaviours.[41 42] However, some researchers have found that experimental groups and control groups showed no significant differences in the mental health of the parents.[43 44] Although some developed countries have studied the impact of FCC on preterm infants and their parents, the reality is that in many countries, the opportunities for parents to participate in the care of their preterm infants in the NICU are very limited.[45–47] China is still in the beginning stage of implementing and testing this innovative care model and the parents of preterm infants are even restricted from visiting the NICU.

Different interventions based on the FCC philosophy are developed up to now. Creating Opportunities for Parents Empowerment (COPE) programme in one of the commonly used interventions, during which education and skills training activities for parents of preterm infants are provided and the parents are encouraged to be involved in the care of their preterm infants in the NICU.[48 49] Mirghafourvand *et al* conducted a systematic review on the COPE program from 2000 to 2015, which proved that COPE has a beneficial effect on maternal stress and anxiety, but its effect on depression is unclear.[50] However, this systematic review has some limitations: the quality of the included studies was not considered; the components of the empowerment programme were incomplete; and the effectiveness of the empowerment programme for fathers was not evaluated. Ding *et al* evaluated the effects of FCC on preterm infants and their parents and proved that FCC is effective in relieving the anxiety, depression and stress of parents of preterm infants.[49] However, this systematic review exceeds the requirement that Cochrane's systematic literature review database needs to be updated every 2 years.

Compared with routine care, there is no sufficient robust evidence supporting the outcome of parents and infants in the NICU with FCC inventions. Although routine care varies from country to country, it generally includes no or limited support to parents, that is, restrictions on parents visiting their newborns in the NICU in China. To the best of our knowledge, there is no systematic review or meta-analysis that comprehensively involves FCC practices in reducing parents' psychological distress and enhancing the parent–child relationship. For the above reasons, it is necessary to construct a systematic review by a systematic search and literature review to explore the effectiveness of FCC interventions in easing the mental health problems of parents of preterm infants and improving the parent–child relationship.

OBJECTIVES

The purposes of this study are to systematically review the effects of FCC interventions on parental mental health and parent–infant interactions for parents and their preterm infants in randomised controlled trials (RCTs) published only in Chinese or English and to conduct a meta-analysis if possible. The following research question was defined: Does FCC improve parental mental health and parent–infant interactions for preterm infants in the NICU?

METHODS AND ANALYSIS

This systematic review protocol follows the Preferred Reporting Items of Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines (see online supplemental file 1).[51] The proposed review findings will be reported in accordance with guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[52] The systematic review is registered at PROSPERO, and any important changes to the protocol will be updated.

Eligibility criteria

Types of studies

RCTs with a parallel or crossover design will be included, but crossover trials are eligible only if data before the crossover are extractable to avoid the potential for a carryover phenomenon. We will select studies published only in Chinese or English.

Types of participants

The participants will include preterm infants born at less than 37 weeks of gestation and their primary caregivers. Primary caregivers can be either mothers or fathers.

Types of interventions

Any FCC interventions involving the establishment of a collaborative partnership between the family and the healthcare term will be eligible. The setting, frequency, timing and duration of the interventions will not be limited.

The following interventions related to one or more components of FCC will be included:

- Educational support (skills and knowledge of care).
- Partnership in care (empowerment and involvement in care).
- Personalised care (needs and wishes).
- Parent support (psychological and visiting access).
- Information and communication.

Types of comparators/controls

There is no limitation for comparators. Trials will be included if the intervention group is compared with routine care or active comparator, and studies comparing one type of FCC with another type of FCC will also be included. Routine care in this review was defined care with no or limited support to parents, that is, limitations in visiting or involvement of care.

Types of outcome

Primary outcome

Parental health

- Validated measures of anxiety, such as The Beck Anxiety Inventory and The State-Trait Anxiety Inventory.
- Validated measures of depression, such as The Beck Depressive Inventory and The Self-Rating Depression Scale.
- Validated measures of stress, such as The Parental Stressor Scale, and The Parenting Stress Index.

Parent–infant interactions

- Infant interactive behaviours, such as activity (eg, movements, vocalisations, or expressive language) and engagement (eg, facial expressions or eye contact).
- Parental interactive behaviours, such as sensitivity, vigilance, intrusiveness and emotional involvement (eg, proximal stimulation and smiling).
- Dyadic interactive patterns, such as synchrony, reciprocity and coregulation (eg, timing and rhythmicity).

Secondary outcomes

- Other indicators of parental mental health, such as PTSD.
- Parent satisfaction.
- Neonatal behavioural neurological assessment.

Exclusion criteria

Studies with the following will be excluded: (1) duplicate publications; (2) literature on preterm infants suffering from other life-threatening diseases (such as congenital heart disease), infants with abnormalities in the digestive tract and gastrointestinal tract, or infants with mothers with a history of mental illness; (3) literature whose data report is incomplete and the request for a complete data report is unsuccessful; (4) literature that only include abstracts and the request for a full text is unsuccessful; (5) literature from which available statistical data cannot be extracted; and (6) literature for which the mean and SD of the outcome indicators cannot be calculated.

Search strategy

Electronic databases

FCC practices have evolved and changed over the past years and older studies may not be representative of modern literature. Therefore, our search is limited to the last decade. The PubMed, EMBASE (Ovid interface), CINAHL (EBSCO interface), PyschINFO (Ovid interface), Web of Science (Clarivate Analytics interface), Cochrane Library, Scopus, ProQuest, China National Knowledge Infrastructure (CNKI, for Chinese literature), SinoMed (for Chinese literature) and WANFANG DATA (for Chinese literature) electronic databases will be searched from 1 July 2012 to 1 July 2022. The literature review will be updated less than 6 months before publication of results. The search strategies will be developed after discussion among reviewers using guidance from the Cochrane Handbook, and the first author and an academic librarian will be responsible for the development of the strategies. Medical Subject Heading/Emtree terms, keywords, and free words such as '早产儿', '父母', '以家庭为中心', '**焦虑**', '抑郁' and '亲子关系' were used to identify potential studies. The main body of the search strategy will be consistent across the databases; however, specific search terms will be adjusted for each database to reflect syntax differences (see online supplemental file 2 for the literature search strategy of all databases).[53] We will use equivalent search words in the Chinese

databases. Two reviewers will conduct the search process independently.

Other sources

The following clinical trial registries will be used to retrieve ongoing or unpublished trials: the NIH clinical registry ClinicalTrials.gov, the EU Clinical Trials Registry, the US National Institutes of Health Ongoing Trails Register, the WHO International Clinical Trials Registry Platform, the Australian New Zealand Clinical Trials Registry and the Chinese Clinical Registry. We will retrieve the relevant systematic reviews and meta-analyses manually and review them to identify additional studies. Useful but incomplete information will be acquired from the contact trial personnel. Grey literature sources, including OpenGrey, will be searched. Additionally, we will manually search the reference lists from the included articles to prevent omitting any related study.

Study records

Data management

The results of the literature search will be imported into EndNote V.X9 software for data management and reference storage.[54] Any duplicates will be removed prior to the selection process. The reference, abstract and full text for all potentially eligible studies will be stored to allow effective screening.

Selection process

Two reviewers will independently screen the titles and abstracts of all the candidate studies to determine inclusion according to the predetermined eligibility criteria. The eligibility criterion of inclusion/exclusion/unclear will be used to assess the potential articles. Studies will be excluded if the objectives are clear from the title and abstract, but the content is not relevant. When a study cannot be excluded based on the information provided in the title and abstract, it will be graded as 'unclear'. After title and abstract screening, full-text copies of the 'include' and 'unclear' studies will be obtained to determine their eligibility. Studies will also be removed if the available information is insufficient for assessment and synthesis, such as full-text copies not being available. A third reviewer will arbitrate if any disagreement occurs.

The study selection process will be reported visually in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart (see online supplemental file 3), and excluded full-text papers will be tabulated with the reasons for exclusion.[52]

Data extraction

The data will be extracted independently by two reviewers from all included studies using a standardised data extraction table, and the data extraction form will be developed based on the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions.[55] The Template for Intervention Description and Replication checklist will also be incorporated into the data extraction form to summarise the list of intervention characteristics and assist in the replicability of interventions and comparability between the studies.[56] Prior to use in the main study, piloting on several studies will ensure completeness and suitability of the form. If insufficient information is reported to determine eligibility (including the intervention methods and intervention characteristics), the authors will contact the authors of that study no more than three times to gain further information. Any discrepancies between the two reviewers during abstract screening or full-text screening will be discussed until a consensus is reached. A third reviewer will be consulted if necessary.

The following information will be extracted from the included studies:

1. General information: first author, year of publication and country of origin.
2. Participants: characteristics (preterm infants≤37 weeks' gestational age and parents) and enrolment number (intervention/control).
3. FCC intervention: intervention components, timing, duration, frequency, setting, measurement point and control group.
4. Outcome measures: anxiety, depression, stress, other psychosocial findings and the parent–infant interaction.

Risk-of-bias assessment

Risk of bias of the included studies will be evaluated by two reviewers independently using the Cochrane Collaboration Risk of Bias (ROB V.2.0).[57] In accordance with this tool, each relevant outcome in the included studies will be assessed for bias risks with the following five domains: bias arising from the randomisation process; bias as a result of deviations from the intended interventions; bias as a result of missing outcome data; bias in the measurement of the outcome; and bias in the selection of the reported results. For each bias group, it is possible to assign a value of 'high', 'low' or 'some concerns'. Any discrepancies or disagreements in the evaluation process will be resolved by a third reviewer.

Heterogeneity and reporting bias

The heterogeneity between the included studies will be estimated by the χ^2 test (considering a value of $p<0.1$ to indicate heterogeneity) and I^2 statistic. As recommended by the Cochrane Handbook for Systematic Reviews of Interventions,[55] the I^2 value will be divided into four levels: low heterogeneity (≤25%), moderate heterogeneity (26%–50%), substantial heterogeneity (51%–75%) and considerable heterogeneity (76%–100%). Sensitivity analysis or subgroup analysis will be used to explore potential sources of heterogeneity.

As stated in the reporting biases, we will draw a funnel plot when more than 10 studies are included, and potential reporting biases will be further assessed with Egger's test when there are fewer than 10 studies.[58]

Data synthesis and analysis

In case that outcomes could not be quantitatively synthesis due to insufficient studies, unavailable data, or high

heterogeneity of effect measures, a narrative approach will be adopted for data analysis. A narrative synthesis of the included studies' results will be presented in a table, which will give a comprehensive and detailed description after comparing differences and similarities among the study results and extracted data. Given the nature of this review, we anticipate that substantial differences exist between studies (eg, FCC interventions), and this will enhance our understanding of the specific existing FCC intervention contents and the effectiveness of these interventions.

We will perform a meta-analysis using Reviewer Manager V.5.4 when there are sufficient studies (two or more studies) with available data investigating the same outcome by similar effect measures that can be pooled. For continuous variables, the outcomes will be presented as the mean differences (MDs)/standardised mean differences with 95% CIs unless otherwise stated. For dichotomous data, risk ratios (RRs) with 95% CIs will be calculated. Subgroup analysis of factors, such as the characteristics of participants, countries, the mode of intervention and outcome measures (or different time points), can be selectively performed to explore the interaction between them.

Whether a fixed effects model (FEM) or a random effects model (REM) is used will depend on the results of the χ^2 test and I^2 test for heterogeneity.[59] If the studies are of substantial heterogeneity (that is, p<0.1, and I^2 >75%), only descriptive analysis will be conducted, and an FEM will be adopted to conduct a meta-analysis if there is low heterogeneity (that is, p≥0.1, and I^2≤50%) between the studies. If the studies have moderate heterogeneity (that is, p<0.1, I^2=50%–75%), the random effects model will be used for meta-analysis after excluding the influence of obvious clinical and methodological heterogeneity.

In addition, sensitivity analyses will be performed to identify studies at a high risk of bias and to understand how factors influence the effect sizes so as to understand the extent to which they influence the results. Different effect size measurements, such as the RR and OR, along with various statistical models, such as fixed effects and random effects models, will be utilised to test the robustness of the results. Then, studies with a lower quality will be excluded considering their sample size, the evidence strength and the impact of the size grounded effect.

Grading the quality of evidence

The quality of the evidence for each study outcome will be assessed using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach with the guidance of the Cochrane Handbook for Systematic Reviews of Interventions.[55 60] The GRADE approach, which is appropriate for use in this systematic review as it has been widely adopted to grade the quality of evidence, involves the consideration of within-study risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias.[61] In accordance with the GRADE definitions, the quality of evidence will be reported as high, moderate, low, or very low quality based on the GRADE certainty ratings. A high rating would conclude that further research is unlikely to greatly impact the confidence of the findings, and a low rating would suggest an uncertainty of the effect and the need for further research.

Patient and public involvement

Since publicly available data will be involved in our research, neither patients nor the public will be involved in the design, conduct, reporting or dissemination plans of the study.

Ethics and dissemination

This study does not require ethics committee approval, as it will only involve the data collection of previously published literature, and individual patients will not be included. There are no ethical concerns or informed consent required. All included studies will be in accordance with the Declaration of Helsinki and current ethical requirements. The final findings will be disseminated through peer-reviewed publications, academic presentations at conferences and the doctoral thesis of the first author. In addition, we will use innovative dissemination strategies, including virtual seminars and social media.

DISCUSSION

The impact of preterm birth is not limited to the preterm infant but rather the entire family.[62 63] Prior studies have found that in the FCC programmes, family members especially the parents of preterm infants feel more being valued when incorporating with nurses in taking care of their preterm infants, which reduces the mental burden on caregivers.[64 65] Therefore, parents should be involved in the care of their preterm infants in order to improve their caring abilities while providing emotional, social, and physical developmental support for their preterm infants to enhance the infants' motor and neurobehavioral development.[66 67] International institutions and the medical community have been attracted by the FCC model. Although there have been some studies examining the impact of FCC intervention on premature babies and their parents in developed countries, China is still in the initial stages of implementing and testing this innovative care approach.

In the system review, we aim to provide a comprehensive and detailed overview of the existing literature on this topic and lay the foundation for future research, intending to fill the gaps in the understanding of FCC. Our protocol is advantageous in its extensive search and inclusion criteria, which enables us to fully describe FCC interventions, highlight their benefits to the mental health of preterm infants' parents and the parent–child relationship, and assist policy-makers and health professionals in adopting appropriate evidence-based decisions and FCC practices. This systematic review also has certain guiding significance for the development of standardised

FCC interventions in the NICU environments of different countries.

Contributors The original version of the systematic protocol was conceived and drafted by QC under the supervision of XX, and was revised by QC and XX. HW, DC and QC will perform the screening, study selection and collect data from all included studies. WX, RY and QC will be responsible for reviewing the included studies. All authors have approved and contributed to the final manuscript.

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