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# The 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 deal 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 inception until 1 March 2022. An additional search of OpenGrey will be searched to identify grey literature. Randomized 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 complete 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 Risk of Bias Tool. Any disagreements will be referred to a third reviewer to reach a consensus. If appropriate, a meta-analyse 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**

- This will be the first systematic review to synthesise the effect of FCC interventions on parental mental health and parent-infant interaction of parents and their preterm infants.
- 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.
- Two independent reviewers will independently perform the study selection, data extraction and critical appraisal.
- The research team includes researchers and practitioners with methodological and clinical expertise.
- Various types of FCC interventions could be a source of heterogeneity between the studies, and language bias may be caused by only including English and Chinese articles.

## INTRODUCTION

Premature delivery, basically when a baby is 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, and the preterm birth rate is 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 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 need to be hospitalized and treated in the neonatal intensive care unit (NICU) immediately after birth for several weeks to several months depending on their illness condition, leading the early connection 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 the parental role establishment for the parents are inhibited[9]. Furthermore, the closed management of the NICU, changes in a infant's illness condition and prognosis will lead to mental instability of the parents and cause emotional problems such as anxiety and depression, among which severe cases can develop into acute stress disorder and posttraumatic stress disorder[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 continue 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 stress level and more severe 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, and 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.

More specifically, during hospitalization, 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 hospitalization 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 hospitalization[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 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 last 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 hospitalization[32 33]. Some mothers even suffer from posttraumatic stress symptoms related to the severity of the infant's illness condition[34].

In the past six decades, the concept of family-centred care (FCC) has been implemented to varying degrees in different medical institutions[35-37]. FCC is more of a nursing concept and approach, which emphasizes four principles: dignity and respect, information sharing, participation in nursing and decision-making[38 39] 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 prepare for taking care of their babies after their discharge from the hospital[40 41]. Compared with conventional interventions, FCC programs 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[42 43]. However, some researchers have found that experimental groups and control groups showed no significant differences in the mental health of the parents[44 45]. 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[46-48]. 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) program in one of the commonly-used interventions, which provides education and skills training activities for parents of preterm infants and encourages them to be involved in the care of their preterm infants in the NICU[49 50]. 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[51]. However, this systematic review has some limitations. More

specifically, the quality of the included studies was not considered, the components of the empowerment program were incomplete, and the effectiveness of the empowerment program 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[50]. However, this systematic review exceeds the requirement that Cochrane's systematic literature review database needs to be updated every two years.

Compared with standard care (SC), there is no sufficient robust evidence supporting the outcome of parents and infants in the NICU with FCC inventions. Although SC varies from country to country, it generally includes restrictions on parents visiting their newborns in the NICU or providing basic care for their babies. 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 reducing 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 interaction for parents and their preterm infants in randomized controlled trials (RCTs) published only in Chinese or English and to conduct a meta-analysis if possible. The following research question was defined: Does family-centred care improve parental mental health and parent-infant interactions for preterm infants in the NICU, and why were they effective (or not)?

## 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)[52]. The proposed review findings will be reported in accordance with guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[53]. The systematic review is registered at PROSPERO, and any important changes to the protocol will be updated.

### Eligibility criteria

*Types of studies*

All randomized controlled trials (RCTs) with at least two groups are eligible to be included. 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, fathers, or grandparents.

*Types of interventions*

Any FCC interventions involving the establishment of a collaborative partnership between the family and the health care 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)
- personalized care (needs and wishes)
- parent support (psychological and visiting access)
- information and communication

*Types of comparators/controls*

Trials will be included if the intervention group is compared with standard care or usual care, which was defined as care with no or limited support to parents, i.e., limitations in visiting or the involvement in care. Studies comparing one type of FCC with another type of FCC will also be included.

*Types of outcome measures*

The unexpected delivery of a preterm infant triggers anxiety, depression, stress and other negative psychological outcomes in the parents, and this psychological distress and the closed environment of the NICU will affect the establishment of the parent-child relationship. Studies employing any of the following outcome measurements will be included in this review but are not restricted to:

- The Beck Anxiety Inventory (BAI)
- The State-Trait Anxiety Inventory (STAI)
- The Beck Depressive Inventory (BDI)
- The Self-Rating Depression Scale (SDS)
- The Parental Stressor Scale (PSS)
- The Parenting Stress Index (PSI)
- The Depressive Anxiety Stress Scale (DASS)
- The records of mother-infant interactions

**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 standard deviation of the outcome indicators cannot be calculated.

## Search strategy

### *Electronic databases*

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 database inception to 1 March 2022. 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. No language or time restrictions were set for this search, but FCC has been described in the literature since 1960. 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 detailed PubMed search strategy)[54]. 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 (ICTRP), the Australian New Zealand Clinical Trials Registry and the Chinese Clinical Registry. We will retrieve the relevant SRs 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 better

data management and reference storage[55]. 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 all the titles and abstracts of the candidate studies at the same time 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, and their eligibility will be determined. 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[53].

*Data extraction*

The data will be extracted independently by two reviewers from all included studies using a standardized data extraction table, and the data extraction form will be developed based on the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions[56]. The TIDieR (Template for Intervention Description and Replication) checklist will also be incorporated into the data extraction form to summarize the list of intervention characteristics and assist in the replicability of interventions and comparability between the studies[57]. 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 assessment of the included studies will be carried out by two independent reviewers using the Cochrane Handbook for Systematic Reviews of Interventions[58]. Any discrepancies will be resolved by discussion with another reviewer. The evaluation items will include random sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other bias. According to the above criteria, each included literature will be evaluated item by item with "low risk of bias", "high risk of bias" or "unclear bias", and the quality of the included literature will be divided into three levels: A, B, and C. Among them, level A will indicate low bias, which means that the included literature fully meets the above quality standards, and its results were minimally affected by bias; level B will indicate moderately biased, which means that the included literature partially meets the above quality standards; and level C will indicate highly biased, which means that the included literature does not meet the above quality standards and should be excluded.

**Heterogeneity and reporting bias**

The heterogeneity between the included studies will be estimated by the $\chi^2$ 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[56], 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[59].

**Data synthesis and analysis**

A narrative synthesis of the included studies' results will be presented in a table. Studies will be narratively defined focusing on the intervention and outcomes, and the synthesis 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 (e.g., FCC interventions), which will enhance our understanding of the specific existing FCC intervention contents and the effectiveness of these interventions.

Statistical analysis of the power data will be performed using Reviewer Manager 5.4. A meta-analysis will be performed with the outcome measures if two or more studies present data that can be pooled. For continuous variables, the outcomes will be presented as the mean differences (MDs)/standardized mean differences (SMDs) with 95% confidence intervals (CIs)

unless otherwise stated. For dichotomous data, risk ratios (RRs) with 95% CIs will be calculated.

Whether a fixed-effects model (FEM) or a random-effects model (REM) is used will depend on the results of the $\chi^2$ test and $I^2$ test for heterogeneity[60]. If the studies are of substantial heterogeneity (that is, $P<0.1$, and $I^2>75\%$), only descriptive analysis will be conducted, and a fixed-effects model (FEM) will be adopted to conduct a meta-analysis if there is low heterogeneity (that is, $P \geq 0.1$, and $I^2 \leq 50\%$) between the studies. If the studies have moderate heterogeneity (that is, $P < 0.1$, $I^2 = 50\%\sim75\%$), the random effects model will be used for meta-analysis after excluding the influence of obvious clinical and methodological heterogeneity.

If there are sufficient studies, subgroup analyses 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. In addition, sensitivity analyses will be performed to identify studies at high risk of bias and understand how factors influence the effect sizes, which include the risk of bias of the included studies and large and long trials, to understand the extent to which they influence the results. Different effect size measurements, such as the risk ratio and odds ratio, along with various statistical models, such as fixed effects and random effects models, will be used to test the robustness of the results. Then, studies with a lower quality will be excluded considering their sample size, the evidence of their 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 GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach with the guidance of the Cochrane Handbook for Systematic Reviews of Interventions[56 61]. 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[62]. 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[63 64]. Prior studies have found that in the FCC programs, family members especially the parents of preterm infants feel more being valued when incorporating with nurses in taking care of their preterm infants, which will reduce the mental burden on caregivers[65 66]. Therefore, parents should be involved in care for preterm infants to improve their caring abilities while providing emotional, social, and physical developmental support for their preterm infants so as to enhance the infants' motor and neurobehavioral development[67 68]. The FCC model has attracted international institutions and the medical community. Although there have been some studies examining the impact of FCC 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 standardized FCC interventions in the NICU environments of different countries.

**Author contributions** The original version of the systematic protocol was conceived and drafted by QC under the supervision of XFX, and was revised by QC and XFX. HW, DQC and QC will perform the screening, study selection and collect data from all included studies. WLX, 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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**Competing interests** None declared.

# References

1. Frey HA, Klebanoff MA. The epidemiology, etiology, and costs of preterm birth. Semin Fetal Neonatal Med 2016; 21:68-73.

2. Mirzakhani H, Kelly RS, Yadama AP, et al. Stability of developmental status and risk of impairment at 24 and 36 months in late preterm infants. Infant Behav Dev 2020;60:101462.

3. March of Dimes, The Partnership for Maternal, Newborn & Child Health, Save the Children, the World Health Organization, et al. Born too soon: the global action report on preterm birth, 2012. Available: https://www.who.int/pmnch/knowledge/publications/preterm_birth_report/en/.

4. General Office of the National Health and Family Planning Commission, Interpretation of the normative policies for the health care work of premature infants, 2017. Available: http://www.nhc.gov.cn/fys/s3586/201703/0816ecd330c04c338c3fd468f1baf29f.shtml.

5. Glass HC, Costarino AT, Stayer SA, et al. Outcomes for extremely premature infants. Anesth Analg 2015;120:1337-51.

6. Mactier H, Bates SE, Johnston T, et al. Perinatal management of extreme preterm birth before 27 weeks of gestation: a framework for practice. Arch Dis Child Fetal Neonatal Ed 2020;105:232-9.

7. Ionio C, Colombo C, Brazzoduro V, et al. Mothers and Fathers in NICU: The Impact of Preterm Birth on Parental Distress. Eur J Psychol 2016;12:604-21.

8. Ionio C, Lista G, Mascheroni E, et al. Premature birth: complexities and difficulties in building the mother-child relationship. J Reprod Infant Psychol 2017;35:509-23.

9. Dickinson C, Vangaveti V, Browne A. Psychological impact of neonatal intensive care unit admissions on parents: A regional perspective. Aust J Rural Health 2022.

10. Boulais J, Vente T, Daley M, et al. Concern for mortality in the neonatal intensive care unit (NICU): parent and physician perspectives. J Perinatol 2018;38:718-27.

11. Trumello C, Candelori C, Cofini M, et al. Mothers' Depression, Anxiety, and Mental Representations After Preterm Birth: A Study During the Infant's Hospitalization in a Neonatal Intensive Care Unit. Front Public Health 2018;6:359.

12. Alexopoulou P, Evagelou E, Mpakoula-Tzoumaka C, et al. Assessing anxiety and depression in parents of preterm infants. J Neonatal Nurs 2018;24:273-6.

13. Cajiao-Nieto J, Torres-Giménez A, Merelles-Tormo A, et al. Paternal symptoms of anxiety and depression in the first month after childbirth: A comparison between fathers of full term and preterm infants. J Affect Disord 2021;282:517-26.

14. Pichler-Stachl E, Urlesberger P, Mattersberger C, et al. Parental Stress Experience and Age of Mothers and Fathers After Preterm Birth and Admission of Their Neonate to Neonatal Intensive Care Unit; A Prospective Observational Pilot Study. Front Pediatr 2019;7:439.

15. Malouf R, Harrison S, Burton HAL, et al. Prevalence of anxiety and post-traumatic stress (PTS) among the parents of babies admitted to neonatal units: A systematic review and meta-analysis. EClinicalMedicine 2021;43:101233.

16. Hoffman C, Dunn DM, Njoroge WFM. Impact of Postpartum Mental Illness Upon Infant Development. Curr Psychiatry Rep 2017;12:100.

17. Aoyagi SS, Tsuchiya KJ. Does maternal postpartum depression affect children's developmental outcomes? J Obstet Gynaecol Res 2019;45:1809-20.

18. Oyetunji A, Chandra P. Postpartum stress and infant outcome: A review of current literature. Psychiatry Res 2020;284:112769.

19. Neri E, Genova F, Monti F, et al. Developmental Dimensions in Preterm Infants During the 1st Year of Life: The Influence of Severity of Prematurity and Maternal Generalized Anxiety. Front Psychol 2020;11:455.

20. Nath S, Pearson RM, Moran P, et al. The association between prenatal maternal anxiety disorders and postpartum perceived and observed mother-infant relationship quality. J Anxiety Disord 2019;68:102148.

21. Cook N, Ayers S, Horsch A. Maternal posttraumatic stress disorder during the perinatal period and child outcomes: A systematic review. J Affect Disord 2018;225:18-31.

22. Nazari R, Moradi Koosha F, Rezaie S, et al. Experiences of the mothers of infants hospitalized in the neonatal intensive care unit (NICU). J Neonatal Perinatal Med 2020;13:571-9.

23. Hemle Jerntorp S, Sivberg B, Lundqvist P. Fathers' lived experiences of caring for their preterm infant at the neonatal unit and in neonatal home care after the introduction of a parental support programme: A phenomenological study. Scand J Caring Sci 2021;35:1143-51.

24. Bry A, Wigert H. Psychosocial support for parents of extremely preterm infants in neonatal intensive care: a qualitative interview study. BMC Psychol 2019;7:76.

25. Toly VB, Blanchette JE, Liu W, et al. Maternal stress and mental health prior to their technology-dependent infant's discharge home from the NICU. J Perinat Neonatal Nurs 2019;33:149-59.

26. Beck CT, Woynar J. Posttraumatic Stress in Mothers While Their Preterm Infants Are in the Newborn Intensive Care Unit: A Mixed Research Synthesis. ANS Adv Nurs Sci 2017;40:337-55.

27. Holditch-Davis D, Santos H, Levy J, et al. Patterns of psychological distress in mothers of preterm infants. Infant Behav Dev 2015;41:154-63.

28. Shaw RJ, Lilo EA, Storfer-Isser A, et al. Screening for symptoms of postpartum traumatic stress in a sample of mothers with preterm infants. Issues Ment Health Nurs 2014; 35:198–207.

29. Rogers CE, Kidokoro H, Wallendorf M, et al. Identifying mothers of very preterm infants atrisk for postpartum depression and anxiety before discharge. J Perinatol 2013; 33:171–6.

30. Holditch-Davis D, Miles MS, Weaver MA, et al. Patterns of distress in African-American mothers of preterm infants. J Dev Behav Pediatr 2009; 30:193–205.

31. Berns HM, Drake D. Postpartum Depression Screening for Mothers of Babies in the Neonatal Intensive Care Unit. MCN Am J Matern Child Nurs 2021;46:323-329.

32. Northrup TF, Evans PW, Stotts AL. Depression among mothers of high-risk infants discharged from a neonatal intensive care unit. MCN Am J Matern Child Nurs 2013;38:89-94.

33. Grundvig Nylund A, Gonzalez Lindh M, Ahlsson F, et al. Parents experiences of feeding their extremely preterm children during the first 2-3 years - A qualitative study. Acta Paediatr 2020;109:976-81.

34. Shaw RJ, Lilo EA, Storfer-Isser A, et al. Screening for symptoms of postpartum traumatic stress in a sample of mothers with preterm infants. Issues Ment Health Nurs 2014; 35:198–207.

35. Franck L S, Callery P. Re-thinking family-centred care across the continuum of children's healthcare. Child Care Health Dev 2004;30:265-77.

36. Mikkelsen G, Frederiksen K. Family-centred care of children in hospital-a concept analysis. J Adv Nurs 2011;67:1152-62.

37. Uniacke S, Browne TK, Shields L. How should we understand family-centred care?. J Child Health Care 2018;22:460-9.

38. Ramezani T, Shirazi ZH, Sarvestani RS, et al. Family-centered care in neonatal intensive care unit: a concept analysis. Int J Community Based Nurs Midwifery 2014;2:268-78.

39. Al-Motlaq MA, Shields L. Family-centered care as a Western-centric model in developing countries. Holist Nurs Pract 2017;31:343-7.

40. De Bernardo G, Svelto M, Giordano M, et al. Supporting parents in taking care of their infants admitted to a neonatal intensive care unit: a prospective cohort pilot study. Ital J Pediatr 2017;43:36.

41. Aydon L, Hauck Y, Murdoch J, et al. Transition from hospital to home: parents' perception of their preparation and readiness for discharge with their preterm infant. J Clin Nurs 2018;27:269-77.

42. Uhm JY, Kim HS. Impact of the mother–nurse partnership programme on mother and infant outcomes in paediatric cardiac intensive care unit. Intensive Crit Care Nurs 2019;50:79-87.

43. Givrad S, Hartzell G, Scala M. Promoting infant mental health in the neonatal intensive care unit (NICU): A review of nurturing factors and interventions for NICU infant-parent relationships. Early Hum Dev 2021;154:105281.

44. Melnyk BM, Feinstein NF, Alpert-Gillis L, et al. Reducing premature infants' length of stay and improving parents' mental health outcomes with the Creating Opportunities for Parent Empowerment (COPE) neonatal intensive care unit program: a randomized, controlled trial. Pediatrics 2006;118:e1414-27.

45. Villamizar-Carvajal B, Vargas-Porras C, García-Corzo JR. Decrease of premature mothers' stress levels in the intensive care unit. Enferm Intensiva (Engl Ed) 2018;29:113-20.

46. Heinemann AB, Hellström-Westas L, Hedberg Nyqvist K. Factors affecting parents' presence with their extremely preterm infants in a neonatal intensive care room. Acta Paediatr 2013;102:695-702.

47. Zhang X, Lee SY, Chen J, et al. Factors influencing implementation of developmental care among NICU nurses in China. Clin Nurs Res 2016;25:238-53.

48. Murray PD, Swanson JR. Visitation restrictions: is it right and how do we support families in the NICU during COVID-19?. J Perinatol 2020;40:1576-81.

49. Mendelson T, Cluxton-Keller F, Vullo GC, et al. NICU-based Interventions To Reduce Maternal Depressive and Anxiety Symptoms: A Meta-analysis. Pediatrics 2017;139:e20161870.

50. 50 Ding X, Zhu L, Zhang R, et al. Effects of family-centred care interventions on preterm infants and parents in neonatal intensive care units: a systematic review and meta-analysis of randomised controlled trials. Aust Crit Care 2019;32:63-75.

51. Mirghafourvand M, Ouladsahebmadarek E, Hosseini MB, et al. The effect of creating opportunities for parent empowerment program on parent's mental health: A systematic review. Iran J Pediatr 2017;27:e5704.

52. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015;4:1.

53. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 2009;339:b2535.

54. Bramer WM, de Jonge GB, Rethlefsen ML, et al. A systematic approach to searching: an efficient and complete method to develop literature searches. J Med Libr Assoc 2018;106:531–41.

55. Clarivate. Endnote X9, 2019. Available: https://endnote.com/

56. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. Version 5.1.0. The Cochrane collaboration, 2011. www. handbook.cochrane.org

57. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687.

58. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.

59. Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629–34.

60. Higgins JPT, Thompson SG, Deeks JJ, et al. Measuring inconsistency in meta-analyses. BMJ 2003;327:557–60.

61. Balshem H, Helfand M, Schünemann HJ, et al. Grade guidelines: 3. rating the quality of evidence. J Clin Epidemiol 2011;64:401–6.

62. Guyatt GH, Oxman AD, Vist GE, et al. Grade: an emerging consensus on rating quality of evidence

and strength of recommendations. BMJ 2008;336:924–6.

63. Lakshmanan A, Agni M, Lieu T, et al. The impact of preterm birth <37 weeks on parents and families: a cross-sectional study in the 2 years after discharge from the neonatal intensive care unit. Health Qual Life Outcomes 2017;15:38.

64. Pravia CI, Benny M. Long-term consequences of prematurity. Cleve Clin J Med 2020;87:759-67.

65. Treyvaud K, Spittle A, Anderson PJ, et al. A multilayered approach is needed in the NICU to support parents after the preterm birth of their infant. Early Hum Dev 2019;139:104838.

66. Sivanandan S, Bethou A, Ramanujam SS, et al. Implementing Family-Centered Care in the Neonatal Intensive Care Unit - A Quality Improvement Initiative. Indian J Pediatr 2021;88:872-8.

67. Craig JW, Glick C, Phillips R, Hall SL, Smith J, Browne J. Recommendations for involving the family in developmental care of the NICU baby. J Perinatol 2015;35 Suppl 1:S5-S8.

68. Yu Y T, Hsieh W S, Hsu C H, et al. Family-centered care improved neonatal medical and neurobehavioral outcomes in preterm infants: randomized controlled trial. Physical therapy 2017; 97:1158-68.

## Supplementary file 1: PRISMA –P checklist

**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol***

| Section and topic | Item No | Checklist item | Page |
|---|---|---|---|
| **ADMINISTRATIVE INFORMATION** | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | 1 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | N/A |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | 2 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | 1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | 11 |
| Amendments | 4 | If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments | N/A |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | 11 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | 11 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | 11 |
| **INTRODUCTION** | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | 3-5 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | 5 |
| **METHODS** | | | |
| Eligibility criteria | 8 | Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review | 5-7 |
| Information sources | 9 | Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage | 7 |
| Search strategy | 10 | Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it | 7 supplementary file 2 |

| | | | |
|---|---|---|---|
| | | could be repeated | |
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | 8 |
| Selection process | 11b | State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) | 8 |
| Data collection process | 11c | Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators | 8 |
| Data items | 12 | List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications | 8-9 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | 8-9 |
| Risk of bias in individual studies | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | 9 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | 9-10 |
| | 15b | If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$, Kendall's $\tau$) | 10 |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | 10 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | 9 |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | 9 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | 10 |

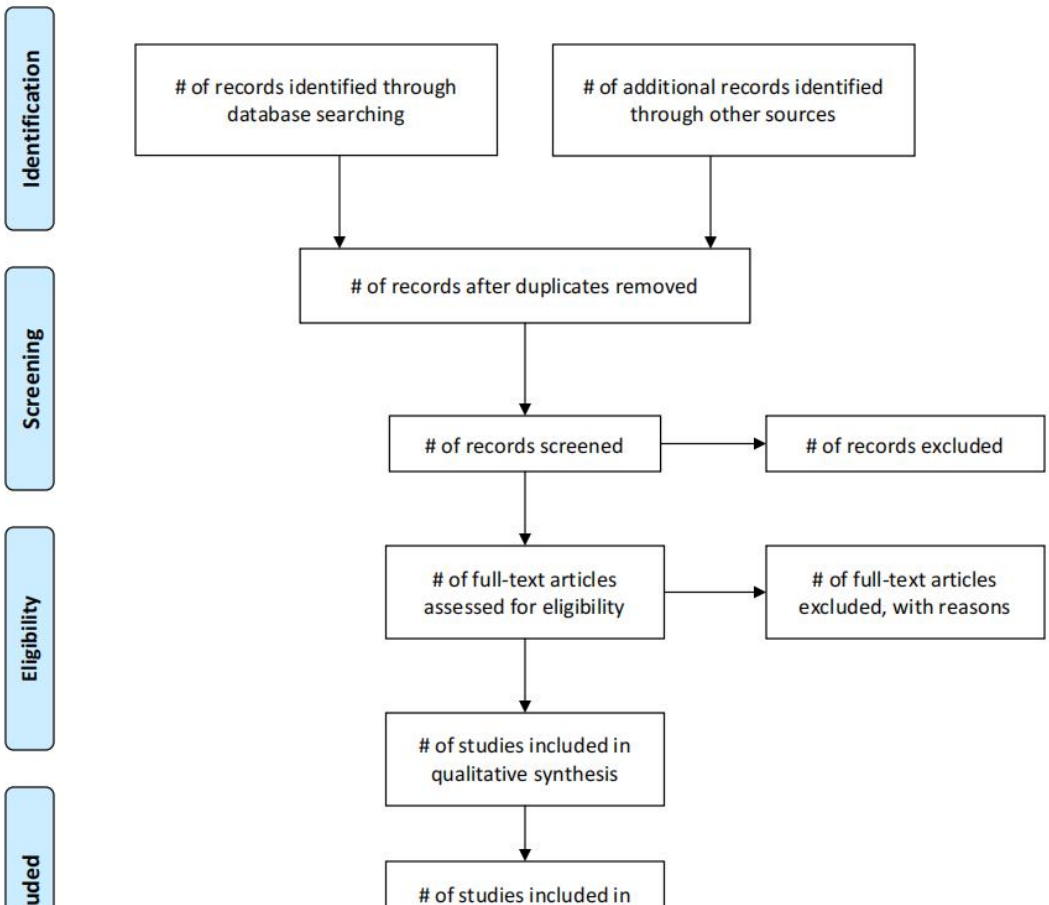
**N/A = Not applicable**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

## Supplementary file 2: PubMed search strategy

| Search | Query |
|---|---|
| #1 | "Intensive Care, Neonatal"[Mesh] OR "Intensive Care Units, Neonatal"[Mesh] OR "Premature Birth"[Mesh] OR "Infant, Newborn"[Mesh] OR "Infant, Premature"[Mesh] OR "Infant, Extremely Premature"[Mesh] OR "Infant, Low Birth Weight"[Mesh] OR premat*[Title/Abstract] OR preterm*[Title/Abstract] OR premie*[Title/Abstract] OR neonat*[Title/Abstract] OR infant*[Title/Abstract] OR newborn*[Title/Abstract] OR "low birth weight"[Title/Abstract] OR LBW[Title/Abstract] OR NICU[Title/Abstract] |
| #2 | "Parents"[Mesh] OR "Parenting"[Mesh] OR "Mothers"[Mesh] OR "Fathers"[Mesh] OR "Caregivers"[Mesh] OR "Family"[Mesh] OR parent*[Title/Abstract] OR mother*[Title/Abstract] OR father*[Title/Abstract] OR mater*[Title/Abstract] OR pater*[Title/Abstract] OR caregiver*[Title/Abstract] OR care giver*[Title/Abstract] OR family[Title/Abstract] OR families[Title/Abstract] |
| #3 | "Family Nursing"[Mesh] OR "Professional-Family Relations"[Mesh] OR “family nursing”[Title/Abstract] OR “family-cent*”[Title/Abstract] OR FCC[Title/Abstract] OR “family-integrated care”[Title/Abstract] OR FIC[Title/Abstract] OR “decision making”[Title/Abstract] OR empowerment[Title/Abstract] OR collaboration[Title/Abstract] OR involvement[Title/Abstract] OR participation[Title/Abstract] |
| #4 | Psychology[Mesh] OR Anxiety[Mesh] OR "Anxiety Disorders"[Mesh] OR Depression[Mesh] OR "Depressive Disorder"[Mesh] OR Emotions[Mesh] OR Stress, Psychological[Mesh] OR "Psychological Distress"[Mesh] OR "Mental Health"[Mesh] OR "Mental Disorders"[Mesh] OR "Mood Disorders"[Mesh] OR "Stress Disorders, Traumatic"[Mesh] OR "Stress Disorders, Post-Traumatic"[Mesh] OR "Parent-Child Relations"[Mesh] OR "Father-Child Relations"[Mesh] OR "Mother-Child Relations"[Mesh] OR psycholog*[Title/Abstract] OR anxi*[Title/Abstract] OR depress*[Title/Abstract] OR emotion*[Title/Abstract] OR stress*[Title/Abstract] OR distress*[Title/Abstract] OR “mental health”[Title/Abstract] OR “mental illness”[Title/Abstract] OR “mental disorder”[Title/Abstract] OR “mood disorder”[Title/Abstract] OR “post-traumatic stress disorder”[Title/Abstract] OR PTSD[Title/Abstract] OR “post-traumatic symptom*”[Title/Abstract] OR “infant interaction”[Title/Abstract] OR “infant relationship*”[Title/Abstract] OR “infant attachment”[Title/Abstract] OR “infant bonding”[Title/Abstract] OR “infant closeness”[Title/Abstract] |
| #5 | "Randomized Controlled Trial"[Publication Type] OR "Controlled Clinical Trial" [Publication Type] OR randomized[Title/Abstract] OR randomised[Title/Abstract] OR randomly[Title/Abstract] OR RCT[Title/Abstract] |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**Supplementary file 3: Flow Diagram of the study selection process**



BMJ Open

# The effect of family-centred care on parental mental health and parent-infant interactions for preterm infants: A systematic review protocol



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# The effect of family-centred care on parental mental health and parent-infant interactions for preterm infants: A systematic review protocol

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**Key words:** family-centred care, mental health, parent-infant interactions, preterm infants, systematic review protocol

**Word Count:** 3611

## 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. Randomized 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 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 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 hospitalized 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 posttraumatic stress disorder[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 hospitalization, 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 hospitalization 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 hospitalization[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 hospitalization[32 33]. Some mothers even suffer from posttraumatic stress symptoms in accordance with the severity of the infant's illness condition[34].

In the past six decades, the concept of family-centred care (FCC) has been implemented to varying degrees in different medical institutions[35-37]. FCC is more of a nursing concept and approach, which emphasizes four principles: dignity and respect, information sharing, participation in nursing and decision-making[38 39] 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[40 41]. Compared with conventional interventions, FCC programs 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[42 43]. However, some researchers have found that experimental groups and control groups showed no significant differences in the mental health of the parents[44 45]. 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[46-48]. 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) program 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[49 50]. 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[51]. However, this systematic review has some limitations: the quality of the included studies was not considered; the components of the empowerment program were incomplete; and the effectiveness of the empowerment program 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[50]. However, this systematic review exceeds the requirement that Cochrane's systematic literature review database needs to be updated every two 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, i.e., 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 randomized controlled trials (RCTs) published only in Chinese or English and to conduct a meta-analysis if possible. The following research question was defined: Does family-centred care 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)[52]. The proposed review findings will be reported in accordance with guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[53]. The systematic review is registered at PROSPERO, and any important changes to the protocol will be updated.

### Eligibility criteria

*Types of studies*

Randomized controlled trials (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 health care 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)
- personalized 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, i.e., limitations in visiting or involvement of care.

*Types of outcome*

➢ Primary outcome

Parental health

- Validated measures of anxiety, such as The Beck Anxiety Inventory (BAI) and The State-Trait Anxiety Inventory (STAI).
- Validated measures of depression, such as The Beck Depressive Inventory (BDI) and The Self-Rating Depression Scale (SDS).
- Validated measures of stress, such as The Parental Stressor Scale (PSS), and The Parenting Stress Index (PSI).

Parent-infant interactions

- Infant interactive behaviors, such as activity (e.g., movements, vocalizations, or expressive language) and engagement (e.g., facial expressions or eye contact).

- Parental interactive behaviors, such as sensitivity, vigilance, intrusiveness, and emotional involvement (e.g., proximal stimulation and smiling).
- Dyadic interactive patterns, such as synchrony, reciprocity, and coregulation (e.g., timing and rhythmicity).

➢ Secondary outcomes

- Other indicators of parental mental health, such as posttraumatic stress disorder (PTSD).
- Parent satisfaction.
- Neonatal behavioral 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 standard deviation 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)[54]. 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 (ICTRP), the Australian New Zealand Clinical Trials Registry and the Chinese Clinical Registry. We will retrieve the relevant SRs 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[55]. 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[53].

*Data extraction*

The data will be extracted independently by two reviewers from all included studies using a standardized data extraction table, and the data extraction form will be developed based on the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions[56]. The TIDieR (Template for Intervention Description and Replication) checklist will also be incorporated into the data extraction form to summarize the list of intervention characteristics and assist in the replicability of interventions and comparability

between the studies[57]. 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 2.0)[58]. 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 randomization 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 $\chi^2$ 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[56], 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[59].

**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 (e.g., 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 utilizing Reviewer Manager 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)/standardized mean differences (SMDs) with 95% confidence intervals (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 $\chi^2$ test and $I^2$ test for heterogeneity[60]. If the studies are of substantial heterogeneity (that is, $P<0.1$, and $I^2 >75\%$), only descriptive analysis will be conducted, and a fixed-effects model (FEM) will be adopted to conduct a meta-analysis if there is low heterogeneity (that is, $P \geq 0.1$, and $I^2 \leq 50\%$) 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 risk ratio and odds ratio, along with various statistical models, such as fixed effects and random effects models, will be utilized 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 GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach with the guidance of the Cochrane Handbook for Systematic Reviews of Interventions[56 61]. 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[62]. 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[63 64]. Prior studies have found that in the FCC programs, 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[65 66]. 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[67 68]. 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 standardized FCC interventions in the NICU environments of different countries.

**Author contributions** The original version of the systematic protocol was conceived and drafted by QC under the supervision of XFX, and was revised by QC and XFX. HW, DQC and QC will perform the screening, study selection and collect data from all included studies. WLX, 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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**Competing interests** None declared.

# References

1. Frey HA, Klebanoff MA. The epidemiology, etiology, and costs of preterm birth. Semin Fetal Neonatal Med 2016; 21:68-73.
2. Mirzakhani H, Kelly RS, Yadama AP, et al. Stability of developmental status and risk of impairment at 24 and 36 months in late preterm infants. Infant Behav Dev 2020;60:101462.
3. March of Dimes, The Partnership for Maternal, Newborn & Child Health, Save the Children, the World Health Organization, et al. Born too soon: the global action report on preterm birth, 2012. Available: https://www.who.int/pmnch/knowledge/publications/preterm_birth_report/en/.
4. General Office of the National Health and Family Planning Commission, Interpretation of the normative policies for the health care work of premature infants, 2017. Available: http://www.nhc.gov.cn/fys/s3586/201703/0816ecd330c04c338c3fd468f1baf29f.shtml.
5. Glass HC, Costarino AT, Stayer SA, et al. Outcomes for extremely premature infants. Anesth Analg 2015;120:1337-51.
6. Mactier H, Bates SE, Johnston T, et al. Perinatal management of extreme preterm birth before 27 weeks of gestation: a framework for practice. Arch Dis Child Fetal Neonatal Ed 2020;105:232-9.
7. Ionio C, Colombo C, Brazzoduro V, et al. Mothers and Fathers in NICU: The Impact of Preterm Birth on Parental Distress. Eur J Psychol 2016;12:604-21.
8. Ionio C, Lista G, Mascheroni E, et al. Premature birth: complexities and difficulties in building the mother-child relationship. J Reprod Infant Psychol 2017;35:509-23.
9. Dickinson C, Vangaveti V, Browne A. Psychological impact of neonatal intensive care unit admissions on parents: A regional perspective. Aust J Rural Health 2022.
10. Boulais J, Vente T, Daley M, et al. Concern for mortality in the neonatal intensive care unit (NICU): parent and physician perspectives. J Perinatol 2018;38:718-27.

11. Trumello C, Candelori C, Cofini M, et al. Mothers' Depression, Anxiety, and Mental Representations After Preterm Birth: A Study During the Infant's Hospitalization in a Neonatal Intensive Care Unit. Front Public Health 2018;6:359.

12. Alexopoulou P, Evagelou E, Mpakoula-Tzoumaka C, et al. Assessing anxiety and depression in parents of preterm infants. J Neonatal Nurs 2018;24:273-6.

13. Cajiao-Nieto J, Torres-Giménez A, Merelles-Tormo A, et al. Paternal symptoms of anxiety and depression in the first month after childbirth: A comparison between fathers of full term and preterm infants. J Affect Disord 2021;282:517-26.

14. Pichler-Stachl E, Urlesberger P, Mattersberger C, et al. Parental Stress Experience and Age of Mothers and Fathers After Preterm Birth and Admission of Their Neonate to Neonatal Intensive Care Unit; A Prospective Observational Pilot Study. Front Pediatr 2019;7:439.

15. Malouf R, Harrison S, Burton HAL, et al. Prevalence of anxiety and post-traumatic stress (PTS) among the parents of babies admitted to neonatal units: A systematic review and meta-analysis. EClinicalMedicine 2021;43:101233.

16. Hoffman C, Dunn DM, Njoroge WFM. Impact of Postpartum Mental Illness Upon Infant Development. Curr Psychiatry Rep 2017;12:100.

17. Aoyagi SS, Tsuchiya KJ. Does maternal postpartum depression affect children's developmental outcomes? J Obstet Gynaecol Res 2019;45:1809-20.

18. Oyetunji A, Chandra P. Postpartum stress and infant outcome: A review of current literature. Psychiatry Res 2020;284:112769.

19. Neri E, Genova F, Monti F, et al. Developmental Dimensions in Preterm Infants During the 1st Year of Life: The Influence of Severity of Prematurity and Maternal Generalized Anxiety. Front Psychol 2020;11:455.

20. Nath S, Pearson RM, Moran P, et al. The association between prenatal maternal anxiety disorders and postpartum perceived and observed mother-infant relationship quality. J Anxiety Disord 2019;68:102148.

21. Cook N, Ayers S, Horsch A. Maternal posttraumatic stress disorder during the perinatal period and child outcomes: A systematic review. J Affect Disord 2018;225:18-31.

22. Nazari R, Moradi Koosha F, Rezaie S, et al. Experiences of the mothers of infants hospitalized in the neonatal intensive care unit (NICU). J Neonatal Perinatal Med 2020;13:571-9.

23. Hemle Jerntorp S, Sivberg B, Lundqvist P. Fathers' lived experiences of caring for their preterm infant at the neonatal unit and in neonatal home care after the introduction of a parental support programme: A phenomenological study. Scand J Caring Sci 2021;35:1143-51.

24. Bry A, Wigert H. Psychosocial support for parents of extremely preterm infants in neonatal intensive care: a qualitative interview study. BMC Psychol 2019;7:76.

25. Toly VB, Blanchette JE, Liu W, et al. Maternal stress and mental health prior to their technology-dependent infant's discharge home from the NICU. J Perinat Neonatal Nurs 2019;33:149-59.

26. Beck CT, Woynar J. Posttraumatic Stress in Mothers While Their Preterm Infants Are in the Newborn Intensive Care Unit: A Mixed Research Synthesis. ANS Adv Nurs Sci 2017;40:337-55.

27. Holditch-Davis D, Santos H, Levy J, et al. Patterns of psychological distress in mothers of preterm infants. Infant Behav Dev 2015;41:154-63.

28. Shaw RJ, Lilo EA, Storfer-Isser A, et al. Screening for symptoms of postpartum traumatic stress in a sample of mothers with preterm infants. Issues Ment Health Nurs 2014; 35:198–207.

29. Rogers CE, Kidokoro H, Wallendorf M, et al. Identifying mothers of very preterm infants atrisk for postpartum depression and anxiety before discharge. J Perinatol 2013; 33:171–6.

30. Holditch-Davis D, Miles MS, Weaver MA, et al. Patterns of distress in African-American mothers of preterm infants. J Dev Behav Pediatr 2009; 30:193–205.

31. Berns HM, Drake D. Postpartum Depression Screening for Mothers of Babies in the Neonatal Intensive Care Unit. MCN Am J Matern Child Nurs 2021;46:323-329.

32. Northrup TF, Evans PW, Stotts AL. Depression among mothers of high-risk infants discharged from a neonatal intensive care unit. MCN Am J Matern Child Nurs 2013;38:89-94.

33. Grundvig Nylund A, Gonzalez Lindh M, Ahlsson F, et al. Parents experiences of feeding their extremely preterm children during the first 2-3 years - A qualitative study. Acta Paediatr 2020;109:976-81.

34. Shaw RJ, Lilo EA, Storfer-Isser A, et al. Screening for symptoms of postpartum traumatic stress in a sample of mothers with preterm infants. Issues Ment Health Nurs 2014; 35:198–207.

35. Franck L S, Callery P. Re-thinking family-centred care across the continuum of children's healthcare. Child Care Health Dev 2004;30:265-77.

36. Mikkelsen G, Frederiksen K. Family-centred care of children in hospital-a concept analysis. J Adv Nurs 2011;67:1152-62.

37. Uniacke S, Browne TK, Shields L. How should we understand family-centred care?. J Child Health Care 2018;22:460-9.

38. Ramezani T, Shirazi ZH, Sarvestani RS, et al. Family-centered care in neonatal intensive care unit: a concept analysis. Int J Community Based Nurs Midwifery 2014;2:268-78.

39. Al-Motlaq MA, Shields L. Family-centered care as a Western-centric model in developing countries. Holist Nurs Pract 2017;31:343-7.

40. De Bernardo G, Svelto M, Giordano M, et al. Supporting parents in taking care of their infants admitted to a neonatal intensive care unit: a prospective cohort pilot study. Ital J Pediatr 2017;43:36.

41. Aydon L, Hauck Y, Murdoch J, et al. Transition from hospital to home: parents' perception of their preparation and readiness for discharge with their preterm infant. J Clin Nurs 2018;27:269-77.

42. Uhm JY, Kim HS. Impact of the mother–nurse partnership programme on mother and infant outcomes in paediatric cardiac intensive care unit. Intensive Crit Care Nurs 2019;50:79-87.

43. Givrad S, Hartzell G, Scala M. Promoting infant mental health in the neonatal intensive care unit (NICU): A review of nurturing factors and interventions for NICU infant-parent relationships. Early Hum Dev 2021;154:105281.

44. Melnyk BM, Feinstein NF, Alpert-Gillis L, et al. Reducing premature infants' length of stay and improving parents' mental health outcomes with the Creating Opportunities for Parent Empowerment (COPE) neonatal intensive care unit program: a randomized, controlled trial. Pediatrics 2006;118:e1414-27.

45. Villamizar-Carvajal B, Vargas-Porras C, García-Corzo JR. Decrease of premature mothers' stress levels in the intensive care unit. Enferm Intensiva (Engl Ed) 2018;29:113-20.

46. Heinemann AB, Hellström-Westas L, Hedberg Nyqvist K. Factors affecting parents' presence with their extremely preterm infants in a neonatal intensive care room. Acta Paediatr 2013;102:695-702.

47. Zhang X, Lee SY, Chen J, et al. Factors influencing implementation of developmental care among NICU nurses in China. Clin Nurs Res 2016;25:238-53.

48. Murray PD, Swanson JR. Visitation restrictions: is it right and how do we support families in the NICU during COVID-19?. J Perinatol 2020;40:1576-81.

49. Mendelson T, Cluxton-Keller F, Vullo GC, et al. NICU-based Interventions To Reduce Maternal Depressive and Anxiety Symptoms: A Meta-analysis. Pediatrics 2017;139:e20161870.

50. 50 Ding X, Zhu L, Zhang R, et al. Effects of family-centred care interventions on preterm infants and parents in neonatal intensive care units: a systematic review and meta-analysis of randomised controlled trials. Aust Crit Care 2019;32:63-75.

51. Mirghafourvand M, Ouladsahebmadarek E, Hosseini MB, et al. The effect of creating opportunities for parent empowerment program on parent's mental health: A systematic review. Iran J Pediatr 2017;27:e5704.

52. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015;4:1.

53. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and

meta-analyses: the PRISMA statement. BMJ 2009;339:b2535.

54. Bramer WM, de Jonge GB, Rethlefsen ML, et al. A systematic approach to searching: an efficient and complete method to develop literature searches. J Med Libr Assoc 2018;106:531–41.

55. Clarivate. Endnote X9, 2019. Available: https://endnote.com/.

56. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. Version 5.1.0. The Cochrane collaboration, 2011. www. handbook.cochrane.org.

57. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687.

58. Higgins JPT, SavovićJ, Page MJ, et al. A revised tool to assess risk or bias in randomized trials (RoB 2.0), 2016. Available: https://sites.google.com/site/riskofbiastool/welcome/rob-2-0-tool.

59. Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629–34.

60. Higgins JPT, Thompson SG, Deeks JJ, et al. Measuring inconsistency in meta-analyses. BMJ 2003;327:557–60.

61. Balshem H, Helfand M, Schünemann HJ, et al. Grade guidelines: 3. rating the quality of evidence. J Clin Epidemiol 2011;64:401–6.

62. Guyatt GH, Oxman AD, Vist GE, et al. Grade: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924–6.

63. Lakshmanan A, Agni M, Lieu T, et al. The impact of preterm birth <37 weeks on parents and families: a cross-sectional study in the 2 years after discharge from the neonatal intensive care unit. Health Qual Life Outcomes 2017;15:38.

64. Pravia CI, Benny M. Long-term consequences of prematurity. Cleve Clin J Med 2020;87:759-67.

65. Treyvaud K, Spittle A, Anderson PJ, et al. A multilayered approach is needed in the NICU to support parents after the preterm birth of their infant. Early Hum Dev 2019;139:104838.

66. Sivanandan S, Bethou A, Ramanujam SS, et al. Implementing Family-Centered Care in the Neonatal Intensive Care Unit - A Quality Improvement Initiative. Indian J Pediatr 2021;88:872-8.

67. Craig JW, Glick C, Phillips R, Hall SL, Smith J, Browne J. Recommendations for involving the family in developmental care of the NICU baby. J Perinatol 2015;35 Suppl 1:S5-S8.

68. Yu Y T, Hsieh W S, Hsu C H, et al. Family-centered care improved neonatal medical and neurobehavioral outcomes in preterm infants: randomized controlled trial. Physical therapy 2017; 97:1158-68.

## Supplementary file 1: PRISMA –P checklist

**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol***

| Section and topic | Item No | Checklist item | Page |
|---|---|---|---|
| **ADMINISTRATIVE INFORMATION** | | | |
| Title: | | | |
| Identification | 1a | Identify the report as a protocol of a systematic review | 1 |
| Update | 1b | If the protocol is for an update of a previous systematic review, identify as such | N/A |
| Registration | 2 | If registered, provide the name of the registry (such as PROSPERO) and registration number | 2 |
| Authors: | | | |
| Contact | 3a | Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author | 1 |
| Contributions | 3b | Describe contributions of protocol authors and identify the guarantor of the review | 12 |
| Amendments | 4 | If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments | N/A |
| Support: | | | |
| Sources | 5a | Indicate sources of financial or other support for the review | 12 |
| Sponsor | 5b | Provide name for the review funder and/or sponsor | 12 |
| Role of sponsor or funder | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | 12 |
| **INTRODUCTION** | | | |
| Rationale | 6 | Describe the rationale for the review in the context of what is already known | 3-5 |
| Objectives | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | 5 |
| **METHODS** | | | |
| Eligibility criteria | 8 | Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review | 5-7 |
| Information sources | 9 | Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage | 7-8 |
| Search strategy | 10 | Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it | 7 supplementary file 2 |

| | | | |
|---|---|---|---|
| | | could be repeated | |
| Study records: | | | |
| Data management | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | 8 |
| Selection process | 11b | State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) | 8 |
| Data collection process | 11c | Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators | 8-9 |
| Data items | 12 | List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications | 9 |
| Outcomes and prioritization | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | 8-9 |
| Risk of bias in individual studies | 14 | Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis | 9 |
| Data synthesis | 15a | Describe criteria under which study data will be quantitatively synthesised | 9-10 |
| | 15b | If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$, Kendall's $\tau$) | 10 |
| | 15c | Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) | 10 |
| | 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | 9-10 |
| Meta-bias(es) | 16 | Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) | 9 |
| Confidence in cumulative evidence | 17 | Describe how the strength of the body of evidence will be assessed (such as GRADE) | 10-11 |

**N/A = Not applicable**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

## Supplementary file 2: Literature search strategy

### PubMed

| Search | Query |
|---|---|
| #1 | "Intensive Care, Neonatal"[Mesh] OR "Intensive Care Units, Neonatal"[Mesh] OR "Premature Birth"[Mesh] OR "Infant, Newborn"[Mesh] OR "Infant, Premature"[Mesh] OR "Infant, Extremely Premature"[Mesh] OR "Infant, Low Birth Weight"[Mesh] OR premat*[Title/Abstract] OR preterm*[Title/Abstract] OR premie*[Title/Abstract] OR neonat*[Title/Abstract] OR infant*[Title/Abstract] OR newborn*[Title/Abstract] OR "low birth weight"[Title/Abstract] OR LBW[Title/Abstract] OR NICU[Title/Abstract] |
| #2 | "Parents"[Mesh] OR "Parenting"[Mesh] OR "Mothers"[Mesh] OR "Fathers"[Mesh] OR "Caregivers"[Mesh] OR "Family"[Mesh] OR parent*[Title/Abstract] OR mother*[Title/Abstract] OR father*[Title/Abstract] OR mater*[Title/Abstract] OR pater*[Title/Abstract] OR caregiver*[Title/Abstract] OR care giver*[Title/Abstract] OR family[Title/Abstract] OR families[Title/Abstract] |
| #3 | "Family Nursing"[Mesh] OR "Professional-Family Relations"[Mesh] OR “family nursing”[Title/Abstract] OR “family-cent*”[Title/Abstract] OR FCC[Title/Abstract] OR “family-integrated care”[Title/Abstract] OR FIC[Title/Abstract] OR “decision making”[Title/Abstract] OR empowerment[Title/Abstract] OR collaboration[Title/Abstract] OR involvement[Title/Abstract] OR participation[Title/Abstract] |
| #4 | Psychology[Mesh] OR Anxiety[Mesh] OR "Anxiety Disorders"[Mesh] OR Depression[Mesh] OR "Depressive Disorder"[Mesh] OR Emotions[Mesh] OR Stress, Psychological[Mesh] OR "Psychological Distress"[Mesh] OR "Mental Health"[Mesh] OR "Mental Disorders"[Mesh] OR "Mood Disorders"[Mesh] OR "Stress Disorders, Traumatic"[Mesh] OR "Stress Disorders, Post-Traumatic"[Mesh] OR "Parent-Child Relations"[Mesh] OR "Father-Child Relations"[Mesh] OR "Mother-Child Relations"[Mesh] OR psycholog*[Title/Abstract] OR anxi*[Title/Abstract] OR depress*[Title/Abstract] OR emotion*[Title/Abstract] OR stress*[Title/Abstract] OR distress*[Title/Abstract] OR “mental health”[Title/Abstract] OR “mental illness”[Title/Abstract] OR “mental disorder”[Title/Abstract] OR “mood disorder”[Title/Abstract] OR “post-traumatic stress disorder”[Title/Abstract] OR PTSD[Title/Abstract] OR “post-traumatic symptom*”[Title/Abstract] OR “infant interaction”[Title/Abstract] OR “infant relationship*”[Title/Abstract] OR “infant attachment”[Title/Abstract] OR “infant bonding”[Title/Abstract] OR “infant closeness”[Title/Abstract] |
| #5 | "Randomized Controlled Trial"[Publication Type] OR "Controlled Clinical Trial" [Publication Type] OR randomized[Title/Abstract] OR randomised[Title/Abstract] OR randomly[Title/Abstract] OR RCT[Title/Abstract] |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**Embase**

| Search | Query |
|---|---|
| #1 | 'newborn intensive care'/exp OR 'neonatal intensive care unit'/exp OR 'prematurity'/exp OR 'newborn'/exp OR 'low birth weight'/exp OR 'prematur*':ti,ab,kw OR 'preterm*':ti,ab,kw OR 'premie*':ti,ab,kw OR 'neonat*':ti,ab,kw OR ' infant*':ti,ab,kw OR 'newborn*':ti,ab,kw OR 'low birth weight':ti,ab,kw OR 'lbw':ti,ab,kw OR 'nicu':ti,ab,kw |
| #2 | 'parent'/exp OR 'mother'/exp OR 'father'/exp OR 'caregiver'/exp OR 'family'/exp OR 'families'/exp OR 'parent*':ti,ab,kw OR 'mother*':ti,ab,kw OR 'father*':ti,ab,kw OR 'mater*':ti,ab,kw OR 'pater*':ti,ab,kw OR 'caregiver*':ti,ab,kw OR 'care giver*':ti,ab,kw OR 'family':ti,ab,kw OR 'families':ti,ab,kw |
| #3 | 'family nursing'/exp OR 'family centered care'/exp OR 'family nursing':ti,ab,kw OR 'family cent*':ti,ab,kw OR 'fic':ti,ab,kw OR 'family-integrated care':ti,ab,kw OR 'fic':ti,ab,kw OR 'decision making':ti,ab,kw OR 'empowerment':ti,ab,kw OR 'collaboration':ti,ab,kw OR 'involvement':ti,ab,kw OR 'participation':ti,ab,kw |
| #4 | 'psychology'/exp OR 'anxiety'/exp OR 'anxiety disorder'/exp OR 'depression'/exp OR 'emotion'/exp OR 'mental stress'/exp OR 'distress syndrome'/exp OR 'mental health'/exp OR 'mental disease'/exp OR 'mood disorder'/exp OR 'posttraumatic stress disorder'/exp OR 'negative emotion'/exp OR 'physiological stress'/exp OR 'child parent relation'/exp OR 'father child relation'/exp OR 'mother child relation'/exp OR 'psycholog*':ti,ab,kw OR 'anxi*':ti,ab,kw OR 'depress*':ti,ab,kw OR 'emotion*':ti,ab,kw OR 'stress*':ti,ab,kw OR 'distress*':ti,ab,kw OR 'mental health':ti,ab,kw OR 'mental illness':ti,ab,kw OR 'mental disorder':ti,ab,kw OR 'mood disorder':ti,ab,kw OR 'post-traumatic stress disorder':ti,ab,kw OR 'ptsd':ti,ab,kw OR 'post-traumatic symptom*':ti,ab,kw OR 'infant interaction':ti,ab,kw OR 'infant relationship*':ti,ab,kw OR 'infant attachment':ti,ab,kw OR 'infant bonding':ti,ab,kw OR 'infant closeness':ti,ab,kw |
| #5 | 'randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'randomized':ti,ab,kw OR 'randomised':ti,ab,kw OR 'randomly':ti,ab,kw OR 'rct':ti,ab,kw |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**CINAHL**

| Search | Query |
|---|---|
| #1 | (MH "Intensive Care, Neonatal+") OR (MH "Intensive Care Units, Neonatal") OR (MH "Infant, Premature") OR (MH "Childbirth, Premature") OR (MH "Infant, Low Birth Weight+") OR (MH "Infant, Very Low Birth Weight") OR (MH "Infant, Newborn+") OR TI prematur* OR TI preterm* OR TI premie* OR TI neonat* OR TI infant* OR TI newborn* OR TI "low birth weight" OR TI LBW OR TI NICU OR AB prematur* OR AB preterm* OR AB premie* OR AB neonat* OR AB infant* OR AB newborn* OR AB "low birth weigh"t OR AB LBW OR AB NICU |
| #2 | (MH "Parents+") OR (MH "Parenting") OR (MH "Mothers+") OR (MH "Fathers+") OR (MH "Caregivers") OR (MH "Family+") OR TI parent* OR TI mother* OR TI father* OR TI mater* OR TI pater* OR TI caregiver* OR TI "care giver*" OR TI family OR TI families OR AB parent* OR AB mother* OR AB father* OR AB mater* OR AB pater* OR AB caregiver* OR AB "care giver*" OR AB family OR AB families |
| #3 | (MH "Family Nursing") OR (MH "Professional-Family Relations") OR (MH "Family Centered Care+") OR TI family nursing" OR TI "family cent*" OR TI FCC OR TI "family-integrated care" OR TI FIC OR TI "decision making" OR TI empowerment OR TI collaboration OR TI involvement OR TI participation OR AB "family nursing" OR AB "family cent*" OR AB FCC OR AB "family-integrated care" OR AB FIC OR AB "decision making" OR AB empowerment OR AB collaboration OR AB involvement OR AB participation |
| #4 | (MH "Psychology+") OR (MH "Anxiety+") OR (MH "Anxiety Disorders+") OR (MH "Depression+") OR (MH "Emotions+") OR (MH "Stress, Psychological+") OR (MH "Psychological Distress") OR (MH "Mental Health") OR (MH "Mental Disorders+") OR (MH "Affective Disorders+") OR (MH "Stress Disorders, Post-Traumatic+") OR (MH "Parent-Child Relations+") OR (MH "Father-Child Relations") OR (MH "Mother-Child Relations") OR TI psycholog* OR TI anxi* OR TI depress* OR TI emotion* OR TI stress* OR TI distress* OR TI "mental health" OR TI "mental illness" OR TI "mental disorder" OR TI "mood disorder" OR TI "post-traumatic stress disorder" OR TI PTSD OR TI "post-traumatic symptom*" OR TI "infant interaction" OR TI "infant relationship*" OR TI "infant attachment" OR TI "infant bonding" OR TI "infant closeness" OR AB psycholog* OR AB anxi* OR AB depress* OR AB emotion* OR AB stress* OR AB distress* OR AB "mental health" OR AB "mental illness" OR AB "mental disorder" OR AB "mood disorder" OR AB "post-traumatic stress disorder" OR AB PTSD OR AB "post-traumatic symptom*" OR AB "infant interaction" OR AB "infant relationship*" OR AB "infant attachment" OR AB "infant bonding" OR AB "infant closeness" |
| #5 | (MH "Randomized Controlled Trials+") OR (MH "Clinical Trials+") OR TI randomized OR TI randomised OR TI randomly OR TI RCT OR AB randomized OR AB randomised OR AB randomly OR AB RCT |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

## Cochrane Library

| Search | Query |
|---|---|
| #1 | MeSH descriptor: [Intensive Care, Neonatal] explode all trees OR MeSH descriptor: [Intensive Care Units, Neonatal] explode all trees OR MeSH descriptor: [Premature Birth] explode all trees OR MeSH descriptor: [Infant, Newborn] explode all trees OR MeSH descriptor: [Infant, Premature] explode all trees OR MeSH descriptor: [Infant, Extremely Premature] explode all trees OR MeSH descriptor: [Infant, Low Birth Weight] explode all trees OR (prematur*):ti,ab,kw OR (preterm*):ti,ab,kw OR (premie*):ti,ab,kw OR (neonat*):ti,ab,kw OR (infant*):ti,ab,kw OR (newborn*):ti,ab,kw OR ("low birth weight"):ti,ab,kw OR (LBW):ti,ab,kw OR (NICU):ti,ab,kw |
| #2 | "Parents"[Mesh] OR "Parenting"[Mesh] OR "Mothers"[Mesh] OR "Fathers"[Mesh] OR "Caregivers"[Mesh] OR "Family"[Mesh] OR parent*[Title/Abstract] OR mother*[Title/Abstract] OR father*[Title/Abstract] OR mater*[Title/Abstract] OR patter*[Title/Abstract] OR caregiver*[Title/Abstract] OR care giver*[Title/Abstract] OR family[Title/Abstract] OR families[Title/Abstract] |
| #3 | "Family Nursing"[Mesh] OR "Professional-Family Relations"[Mesh] OR “family nursing”[Title/Abstract] OR “family-cent*”[Title/Abstract] OR FCC[Title/Abstract] OR “family-integrated care”[Title/Abstract] OR FIC[Title/Abstract] OR “decision making”[Title/Abstract] OR empowerment[Title/Abstract] OR collaboration[Title/Abstract] OR involvement[Title/Abstract] OR participation[Title/Abstract] |
| #4 | Psychology[Mesh]) OR Anxiety[Mesh] OR "Anxiety Disorders"[Mesh] OR Depression[Mesh] OR "Depressive Disorder"[Mesh] OR Emotions[Mesh] OR Stress, Psychological[Mesh] OR "Psychological Distress"[Mesh] OR "Mental Health"[Mesh]) OR "Mental Disorders"[Mesh]) OR "Mood Disorders"[Mesh] OR "Stress Disorders, Traumatic"[Mesh] OR "Stress Disorders, Post-Traumatic"[Mesh] OR "Parent-Child Relations"[Mesh] OR "Father-Child Relations"[Mesh] OR "Mother-Child Relations"[Mesh] OR psycholog*[Title/Abstract] OR anxi*[Title/Abstract] OR depress*[Title/Abstract] OR emotion*[Title/Abstract] OR stress*[Title/Abstract] OR distress*[Title/Abstract] OR “mental health”[Title/Abstract] OR “mental illness”[Title/Abstract] OR “mental disorder”[Title/Abstract] OR “mood disorder”[Title/Abstract] OR “post-traumatic stress disorder”[Title/Abstract] OR PTSD[Title/Abstract] OR “post-traumatic symptom*”[Title/Abstract] OR “infant interaction”[Title/Abstract] OR “infant relationship*”[Title/Abstract] OR “infant attachment”[Title/Abstract] OR “infant bonding”[Title/Abstract] OR “infant closeness”[Title/Abstract] |
| #5 | "Randomized Controlled Trial"[Publication Type] OR "Controlled Clinical Trial" [Publication Type] OR randomized[Title/Abstract] OR randomised[Title/Abstract] OR randomly[Title/Abstract] OR RCT[Title/Abstract] |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**PsycINFO**

| Search | Query |
|---|---|
| #1 | DE "Neonatal Intensive Care" OR DE "Premature Birth" OR DE "Birth Weight" OR TI prematur* OR TI preterm* OR TI premie* OR TI neonat* OR TI infant* OR TI newborn* OR TI "low birth weight" OR TI LBW OR TI NICU OR AB prematur* OR AB preterm* OR AB premie* OR AB neonat* OR AB infant* OR AB newborn* OR AB "low birth weight" OR AB LBW OR AB NICU |
| #2 | DE "Parents" OR DE "Parenting" OR DE "Mothers" OR DE "Fathers" OR DE "Caregivers" OR DE "Family" OR TI parent* OR TI mother* OR TI father* OR TI mater* OR TI pater* OR TI caregiver* OR TI "care giver*" OR TI family OR TI families OR AB parent* OR AB mother* OR AB father* OR AB mater* OR AB pater* OR AB caregiver* OR AB "care giver*" OR AB family OR AB families |
| #3 | TI "family nursing" OR TI "family cent*" OR TI FCC OR TI "family-integrated care" OR TI FIC OR TI "decision making" OR TI empowerment OR TI collaboration OR TI involvement OR TI participation OR AB "family nursing" OR AB "family cent*" OR AB FCC OR AB "family-integrated care" OR AB FIC OR AB "decision making" OR AB empowerment OR AB collaboration OR AB involvement OR AB participation |
| #4 | DE "Psychology" OR DE "Anxiety" OR DE "Anxiety Disorders" OR DE "Depression (Emotion)" OR DE "Postpartum Depression" OR DE "Emotions" OR DE "Negative Emotions" OR DE "Psychological Stress" OR DE "Perceived Stress" OR DE "Stress" OR DE "Distress" OR DE "Mental Health" OR DE "Mental Disorders" OR DE "Affective Disorders" OR DE "Posttraumatic Stress" OR DE "Posttraumatic Stress Disorder" OR DE "Parent Child Relations" OR DE "Father Child Relations" OR DE "Mother Child Relations" OR TI psycholog* OR TI anxi* OR TI depress* OR TI emotion* OR TI stress* OR TI distress* OR TI "mental health" OR TI "mental illness" OR TI "mental disorder" OR TI "mood disorder" OR TI "post-traumatic stress disorder" OR TI PTSD OR TI "post-traumatic symptom*" OR TI "infant interaction" OR TI "infant relationship*" OR TI "infant attachment" OR TI "infant bonding" OR TI "infant closeness" OR AB psycholog* OR AB anxi* OR AB depress* OR AB emotion* OR AB stress* OR AB distress* OR AB "mental health" OR AB "mental illness" OR AB "mental disorder" OR AB "mood disorder" OR AB "post-traumatic stress disorder" OR AB PTSD OR AB "post-traumatic symptom*" OR AB "infant interaction" OR AB "infant relationship*" OR AB "infant attachment" OR AB "infant bonding" OR AB "infant closeness" |
| #5 | DE "Randomized Controlled Trials" OR DE "Randomized Clinical Trials" OR DE "Random Sampling" OR DE "Clinical Trials" OR TI randomized OR TI randomised OR TI randomly OR TI RCT OR AB randomized OR AB randomised OR AB randomly OR AB RCT |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**Scopus**

| Search | Query |
|---|---|
| #1 | prematur* OR preterm* OR premie* OR neonat* OR infant* OR newborn* OR "low birth weight" OR LBW OR NICU |
| #2 | parent* OR mother* OR father* OR mater* OR pater* OR caregiver* OR "care giver*" OR family OR families |
| #3 | "family nursing" OR "family cent*" OR FCC OR "family-integrated care" OR FIC OR "decision making" OR empowerment OR collaboration OR involvement OR participation |
| #4 | psycholog* OR anxi* OR depress* OR emotion* OR stress* OR distress* OR "mental health" OR "mental illness" OR "mental disorder" OR "mood disorder" OR "post-traumatic stress disorder" OR PTSD OR "post-traumatic symptom*" OR "infant interaction" OR "infant relationship*" OR "infant attachment" OR "infant bonding" OR "infant closeness" |
| #5 | randomized OR randomised OR randomly OR RCT |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**Web of science**

| Search | Query |
|---|---|
| #1 | TS=(prematur* OR preterm* OR premie* OR neonat* OR infant* OR newborn* OR "low birth weight" OR LBW OR NICU) |
| #2 | TS=(parent* OR mother* OR father* OR mater* OR pater* OR caregiver* OR "care giver*" OR family OR families) |
| #3 | TS=("family nursing" OR "family cent*" OR FCC OR "family-integrated care" OR FIC OR "decision making" OR empowerment OR collaboration OR involvement OR participation) |
| #4 | TS=(psycholog* OR anxi* OR depress* OR emotion* OR stress* OR distress* OR "mental health" OR "mental illness" OR "mental disorder" OR "mood disorder" OR "post-traumatic stress disorder" OR PTSD OR "post-traumatic symptom*" OR "infant interaction" OR "infant relationship*" OR "infant attachment" OR "infant bonding" OR "infant closeness") |
| #5 | TS=(randomized OR randomised OR randomly OR RCT) |
| #6 | #1 AND #2 AND #3 AND #4 AND #5 |

**CNKI**

| Search | Query |
|---|---|
| #1 | TKA=(早产儿+新生儿重症监护室)*(父母+父亲+母亲+照顾者+家庭+家长+家属)*(以家庭为中心+家庭参与式+家长参与式+家属参与式+家庭式护理+家庭护理干预+家庭支持参与)*(心理+焦虑+抑郁+压力+情绪+母婴关系+亲子关系+依恋关系) |

**WAN FANG**

| Search | Query |
|---|---|
| #1 | 主题:(早产儿 or 新生儿重症监护室) and 主题:(父母 or 父亲 or 母亲 or 照顾者 or 家庭 or 家长 or 家属) and 主题:(以家庭为中心 or 家庭参与式 or 家长参与式 or 家属参与式 or 家庭式护理 or 家庭护理干预 or 家庭支持参与) and 主题:(心理 or 焦虑 or 抑郁 or 压力 or 情绪 or 母婴关系 or 亲子关系 or 依恋关系) |

**VIP**

| Search | Query |
|---|---|
| #1 | (M=(早产儿 OR 新生儿重症监护室) OR R=(早产儿 OR 新生儿重症监护室)) AND (M=(父母 OR 父亲 OR 母亲 OR 照顾者 OR 家庭 OR 家长 OR 家属) OR R=(父母 OR 父亲 OR 母亲 OR 照顾者 OR 家庭 OR 家长 OR 家属)) AND (M=(以家庭为中心 OR 家庭参与式 OR 家长参与式 OR 家属参与式 OR 家庭式护理 OR 家庭护理干预 OR 家庭支持参与) OR R=(以家庭为中心 OR 家庭参与式 OR 家长参与式 OR 家属参与式 OR 家庭式护理 OR 家庭护理干预 OR 家庭支持参与)) AND (M=(心理 OR 焦虑 OR 抑郁 OR 压力 OR 情绪 OR 母婴关系 OR 亲子关系 OR 依恋关系) OR R=(心理 OR 焦虑 OR 抑郁 OR 压力 OR 情绪 OR 母婴关系 OR 亲子关系 OR 依恋关系)) |

## Supplementary file 3: Flow Diagram of the study selection process

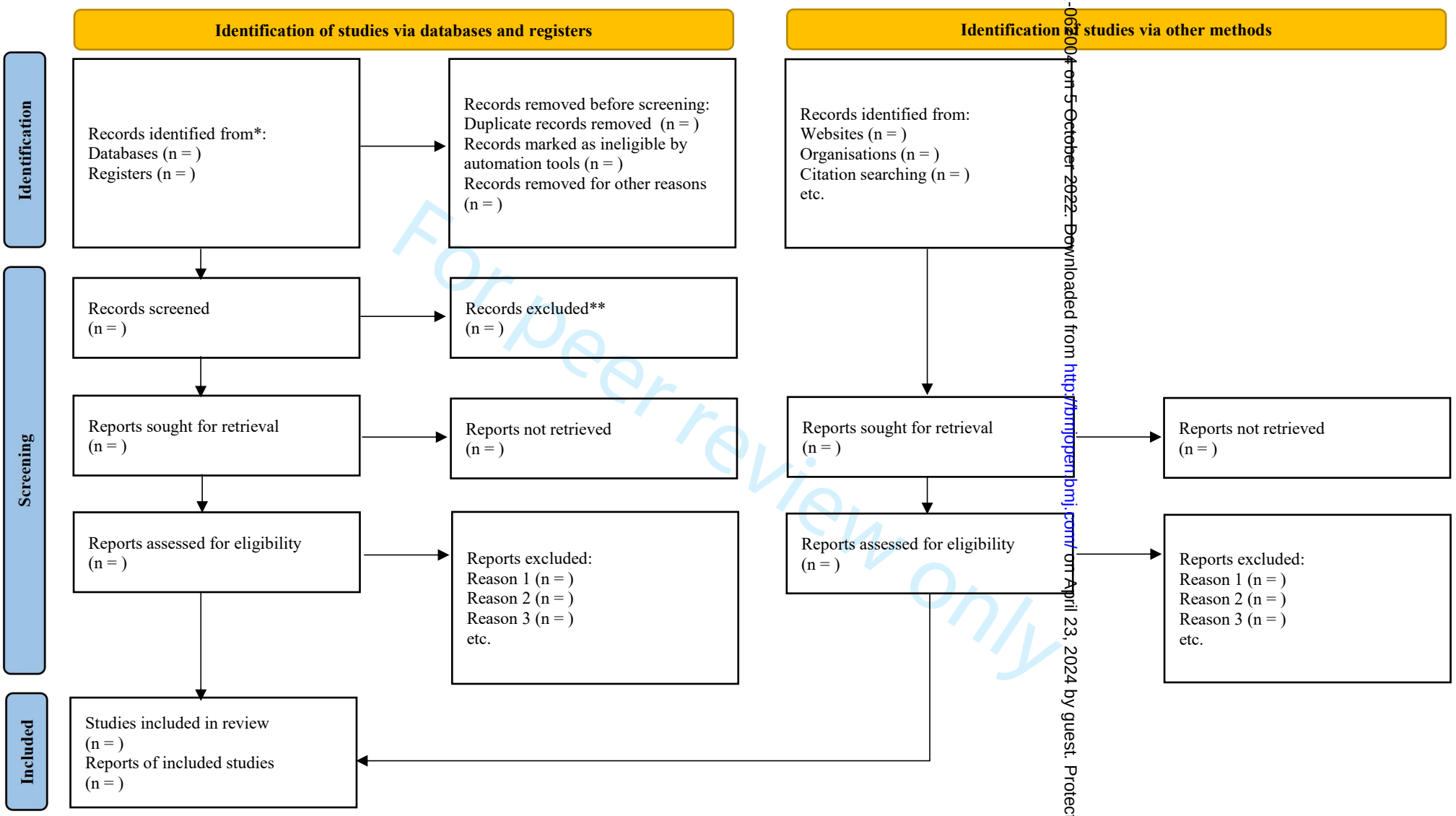


Figure 1. PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

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