



BMJ Open Effectiveness of non-pharmacological treatments for postpartum depression: an umbrella review protocol

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ABSTRACT

Introduction Non-pharmacological treatments for postpartum depression have been investigated in various systematic reviews, and their efficacy has been evaluated. However, the quality of the evidence as a whole has not been quantified. The quality of this evidence may influence the choice of interventions and even cause misleading clinical decisions. This study aims to provide an objective presentation of the methodological bias and identify treatments supported by solid evidence.

Methods and analysis For the purpose of conducting systematic reviews and meta-analyses, a comprehensive search of the relevant published literature will be conducted in English databases such as PubMed, Embase, Cochrane Library, PsycINFO and Scopus, as well as in four Chinese databases: the Chinese Biomedical Databases (CBM), Wan fang database, China National Knowledge Infrastructure and VIP Database (VIP). The time of publication will be limited from their inception to 31 May 2022. We will extract the following data from the included literature: title, first author, journal type of included literature, number and sample size, intervention/control measures, outcome indicators and main study outcomes. The Assessment of Multiple Systematic Reviews-2 will be used to measure the quality of the methods. In addition, we will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement to evaluate the quality of the reporting, as well as the Grading of Recommendations Assessment, Development and Evaluation to evaluate the quality of the evidence.

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INTRODUCTION

Postpartum depression (PPD) is variably defined as occurring from 4 weeks to 12 months after childbirth in clinical practice.¹ The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, fifth edition, defines PPD as a major depressive episode 'with peripartum onset' and elaborates, 'if the onset of mood symptoms occurs during pregnancy or in the 4 weeks following delivery'.^{2 3} PPD has been linked to depressive symptoms, anhedonia, loss of sleep and appetite, inattention, dyskinesia, lethargy, feelings of worthlessness or

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The umbrella review evaluates the overall quality of systematic reviews and meta-analyses (SRs/MAs) of non-pharmacological for postpartum depression.
- ⇒ This review grades the reliability of the acquired evidence and visually displays the treatments with greater degrees of evidence.
- ⇒ Language constraints may lead to omitted included studies, resulting in selective bias.
- ⇒ Subjective variables may have an impact on the literature screening process.
- ⇒ Due to the fact that the umbrella review was based on SRs/MAs, risk factors not addressed in any of the original studies may be also excluded from this study.

guilt and an increased risk of suicidality.⁴ This disorder can have a tremendous impact on women experiencing it and their children and families.^{5 6}

Approximately 50% of women who have just given birth are susceptible to PPD.⁷ Recent estimates by the Centers for Disease Control and Prevention place the national prevalence of PPD at 13%, with a range of 9.7%–23.5% by state.⁸ And the overall prevalence of PPD in mainland China was 14.8%.⁹ Only 30.8% of women diagnosed with PPD are detected in clinical settings, 15.8% receive therapy, 6.3% obtain adequate treatment and 3.2% achieve remission.¹⁰

Antidepressant medication, evidence-based psychotherapy, neuromodulation therapy and hormone therapy are all used in the clinical treatment of PPD.^{11–13} Drug treatment mainly includes the following two types of drugs: preferred drugs are 5-hydroxytryptamine reuptake inhibitors, including sertraline hydrochloride and paroxetine hydrochloride, fluoxetine.¹⁴ These drugs have certain antidepressant effects, and side effects include digestive system disorders, sleep disorders, irregular heart rate, etc,¹⁵ which can be tolerated by most patients but should be used with



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caution in patients with liver and kidney dysfunction.¹⁶ The other type of antidepressant is a tricyclic antidepressant, such as amitriptyline, which is effective for all types of depression but has more side effects and fewer therapeutic applications.¹⁷ However, among the most commonly used antidepressants, paroxetine and serotonin-noradrenaline reuptake inhibitors have been linked to an increased risk of reporting withdrawal syndrome.¹⁸ While additional evidence supports the safety of sertraline 44 and paroxetine during breastfeeding, the extent to which the concentration of the drug in breast milk and infant plasma affects its lactation safety profile is unknown.^{11 19 20} Because of the small number and size of randomised controlled trials (RCTs) and inconsistent findings, current information on the use of estradiol is limited. Few data exist on the treatment of synthetic progesterone.²¹ Psychological counselling, psychosocial interventions, physical therapy, kinesitherapies and Chinese medicine treatment are some of the current non-pharmacological treatments for PPD.^{2 22 23} Several systematic reviews and meta-analyses (SRs/MAs) have been conducted on the efficacy of non-pharmacological therapy for PPD. Cognitive-behavioural therapy (CBT) and interpersonal psychotherapy (IPT) therapies help lower depression symptoms, as supported by substantial data. However, the methodological quality of papers suitable for inclusion in the meta-analysis varied considerably.^{24 25} Numerous RCTs demonstrate that physical activity and acupuncture are risk-free methods for enhancing psychological health and reducing PPD. This drawback is inescapable due to the impracticality of blinding treatments, and the scoring of the included research was low.^{26–28} While some studies have observed small impact sizes of exercise-based therapies in lowering depressed symptoms, the quality of the evidence across the different trials has been inadequate.²⁹ Existing information on the efficacy of repetitive transcranial magnetic stimulation (rTMS) is limited, and uncertainties remain as to which stimulation parameters are most useful.³⁰ Only high-quality SRs/MAs can provide a therapeutic basis due to the absence of low-quality original research and methodology, as well as misleading clinical decisions.³¹ All of these challenges when analysing the efficacy of non-pharmacological treatments may limit the applicability of SRs/MAs techniques. It is possible that the evidence will have less credibility and will be of less utility for clinical treatment if the quality of the evidence drops as a result of research design faults and bias.³² There is still a lack of overall evaluation of non-pharmacological treatments for PPD. Clinicians and patients need up-to-date and evidence-based information to choose depression treatment. A preliminary search for existing umbrella reviews on the topic has been conducted, and there is no existing umbrella review or overview of systematic reviews available on the topic. The databases, include PubMed, Embase, Cochrane Library, PsycINFO, Scopus, PROSPERO, Chinese Biomedical Databases (CBM), Wanfang database, China National Knowledge Infrastructure (CNKI) and VIP Database (VIP).

METHODS AND ANALYSIS

Study design

For these above reasons, many clinical observations of non-pharmacological treatments for PPD have been conducted and many SRs/MAs have been published on their clinical efficacy and safety. Therefore, this study performed is an overview of SRs/MAs that aims to (1) evaluate the methodological quality of the included reviews using the Assessment of Multiple Systematic Reviews-2 (AMSTAR-2) tool^{33 34}; (2) rate the quality of evidence of essential outcomes from included reviews using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach^{35 36}; (3) use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement³⁷ to evaluate the reporting quality and (4) summarise the conclusions of the included reviews and meta-analyses.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research, because this research is based on published studies.

Inclusion and exclusion criteria of the studies

We will include the types of SRs and/or MAs of RCTs meeting our inclusion criteria, and the original study was on the effectiveness of non-pharmacological treatments for PPD. Languages are limited to Chinese and English. Duplicate publications, abstracts or posters from conferences, the protocol for SRs and/or MAs, and other summaries will be excluded. Reviews that incorporate theoretical studies or text and opinion as their primary source of evidence will be excluded. When numerous systematic reviews addressing the same subject are discovered, we will keep the one with the most RCTs.

Search key terms

Terms of study type—defining: systematic review(s), meta-analysis, meta analyses, data pooling(s).

Terms of disease—defining: postpartum depression, postnatal depression, puerperium depression, puerperal depression.

Terms of intervention—defining: cognitive-behavioral therapy, CBT, interpersonal psychotherapy, IPT, mindfulness therapy, physical therapies, repetitive transcranial magnetic stimulation, rTMS, light therapy, kinesitherapies, aerobic exercise, yoga, music therapy, Acupuncture, Acupuncture Therapy, acupuncture, acupressure, acupoint, needle, needling, electroacupuncture, electroacupuncture, pyonex, moxibustion.

The time frame of the review

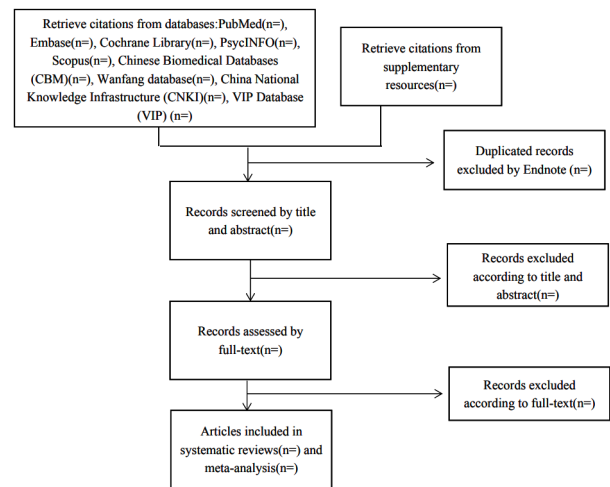
We expect to start the review on 1 October 2021, and the review is expected to be completed on 1 October 2023. The time of publication we included will be limited from their inception to 31 May 2022.

Table 1 Search strategy in PubMed

No	Search terms
1	postpartum depression [Mesh] OR postpartum depression (Title/Abstract) OR postnatal depression (Title/Abstract) OR puerperium depression (Title/Abstract) OR puerperal depression (Title/Abstract)
2	(postpartum (Title/Abstract) OR post-partum (Title/Abstract) OR postnatal (Title/Abstract)) AND (depress* (Title/Abstract) OR mood (Title/Abstract) OR mental health (Title/Abstract) OR depressive disorder* (Title/Abstract))
3	1 OR 2
4	“Meta-Analysis as Topic” [Mesh] OR “Meta-Analysis” [Publication Type] OR meta-analysis (Title/Abstract) OR meta analyses (Title / Abstract) OR meta-analysis (Title / Abstract) OR meta-an-alyse (Title/Abstract) OR metaanalysis (Title/ Abstract) OR metanalysis (Title/ Abstract) OR met-analysis (Title/Abstract) OR metaanalyses (Title/ Abstract) OR metanalyses (Title/ Abstract) OR met-analyses (Title/ Abstract) OR data pooling (Title/Abstract) OR data poolings (Title/ Abstract) OR clinical trial overview (Title/Abstract) OR clinical trial overviews (Title/Abstract)
5	systematic review (Title/Abstract) OR systematic reviews (Title/Abstract)
6	4 OR 5
7	cognitive-behavioral therapy (Title/Abstract) OR CBT (Title/Abstract) OR interpersonal psychotherapy (Title/Abstract) OR IPT (Title/ Abstract) OR mindfulness therapy OR physical therapies (Title/Abstract) OR repetitive transcranial magnetic stimulation (Title/Abstract) OR rTMS (Title/ Abstract) OR light therapy (Title/Abstract) OR kinesitherapies (Title/Abstract) OR aerobic exercise (Title/Abstract) OR yoga (Title/Abstract) OR music therapy (Title/Abstract) OR Acupuncture [Mesh] OR Acupuncture Therapy [Mesh] OR acupuncture (Title/Abstract) OR acupressure (Title/ Abstract) OR acupoint (Title/Abstract) OR needle (Title/Abstract) OR needling (Title/Abstract) OR electroacupuncture (Title/Abstract) OR electroacupuncture (Title/Abstract) OR pyonex (Title/ Abstract) OR moxibustion (Title/Abstract)
8	3 AND 6 AND 7

Search strategy

We will conduct a systematic search in five English databases, including PubMed, Embase, Cochrane Library, PsycINFO and Scopus, and four Chinese databases, including Chinese Biomedical Databases (CBM), Wanfang database, CNKI, and VIP Database (VIP), from their inception to 31 May 2022. To find the systematic reviews that we need, a combination of medical subject headings (MeSH) and keywords will be used in the search approach. And we will search grey reports in OpenGrey, OpenDoar and BASE databases. [Table 1](#) outlines the


Figure 1 Search flow diagram.

search strategy that will be used. [Figure 1](#) outlines the flow diagram that will be used to search.

Participants

Females are identified by clinical diagnosis or scoring system in the postpartum period with depression, regardless of gender, age, geography or duration of disease.

Interventions and comparisons

The intervention group includes individuals treated with non-pharmacological treatments. These treatments included psychological counselling, psychosocial interventions, physical therapy, kinesitherapies and Chinese medicine treatment. The above therapies, include CBT, interpersonal psychotherapy (IPT), mindfulness therapy, rTMS, light therapy, aerobic exercise, yoga, music therapy and acupuncture. Studies combining multiple non-pharmacological therapies will be included and in terms of course treatment, there are no restrictions. The control groups include individuals treated with medication, blank control, wait-list control, placebo therapy, etc. Studies that include both pharmacotherapy and non-pharmacotherapy will be disqualified.

Outcome measurements

The main outcome indicator will be the assessment of depressive symptoms measured by depression assessment tools, such as the HAMD (Hamilton Depression Rating Scale), BDI (Beck Depression Inventory), GAD-7 SDS (Generalized Anxiety Disorder-7 Self-Rating Depression Scale), CESD (Center for Epidemiologic Studies Depression Scale), EPDS (Edinburg Postpartum Depression Scale) and PHQ-9s (Patient Health Questionnaire-9). The long-term effects of non-pharmacological treatments will be investigated as a secondary outcome.

Data extraction

After the literature search, studies will be imported into the Endnote program. Using its check function, duplicate studies will be removed. Two trained investigators will

independently screen the titles and abstracts of selected studies that did not meet the standards we set, to eliminate and determine whether the studies are potentially qualified. After being screened and cross-checked, if they cannot decide if a systematic review should be included, disagreement between the investigators will be resolved by consulting a third investigator. Another two reviewers will independently read the full texts and use standardised sheets to collect data from the studies that are eligible. Extracts include general information like the literature title, first author, journal, country and year. And then, we will extract the names of the therapies and comparisons, quality assessment tools and conclusions, effect size and 95% CI, and the study limitations for every single study.

Risk of bias(quality)assessment

The AMSTAR 2 scale⁹ will be used to evaluate the methodological quality of the included studies, which comprise 16 evaluation items, each of which has the following response options: yes, no, partial yes. Where checklist 2, 4, 7, 9, 11, 13 and 15 are the key lists. Instead of obtaining an overall score from the findings of each entry, AMSTAR 2's development team advocated focusing on the presence of methodological faults in significant entries and assigning a 'confidence' level to the entire evaluation. The quality scale has four levels: high, moderate, low and very low.

Quality of report assessment

The PRISMA statement evaluation tool will be used to evaluate the quality reports of the included kinds of literature. The PRISMA declaration list consists of 27 items, with the following score criteria: a complete report is worth 1 point, a partial report is worth 0.5 points, and an incomplete report is worth 0 points. The maximum score is 27. A final score of ≤ 15 is considered to indicate relatively serious information defects, a score of ~ 21 is considered to indicate have some defects in the report, and a score of ~ 27 is considered to indicate a relatively complete report.

Quality of evidence assessment

The GRADE system will be used to evaluate and grade the outcome indicators of the included literature, with each outcome indicator being treated as a separate piece of evidence. The outcome indicators of each study will be evaluated based on the following five factors: risk of bias, inconsistency, indirectness, imprecision and publication bias. The RCT studies will be preset as the highest grade of evidence in the evaluation. The quality of evidence will be divided into four categories: high, moderate, low and very low quality. Very low evidence suggests that the true value is significantly different from the estimated value; low evidence suggests that the true value may be significantly different from the estimated value; moderate evidence suggests that the true value is likely to be close to the estimated value but still substantially different, and strong evidence suggests that the true effect value is close to the effect estimate.

Data synthesis

To convey our study findings and analytic summaries of subsets of data, we will use texts, figures and/or tables. Tabular data will be presented in a way that is clear, accurate and comprehensive. It is expected that all evidence and calculations will be presented with precision.³⁸ Since the data were retrieved and entered by two individuals, the intraclass correlation coefficient will be used to evaluate the consistency of the evaluation results. Heterogeneity will be determined using I^2 and p value. The relative risk and 95% CI indicate the effect size. If $I^2 \leq 50\%$ and $p \geq 0.1$ indicate no heterogeneity, and in such cases a fixed-effects model will be used; when $I^2 > 50\%$ or < 0.1 indicate heterogeneity, and in such cases a random-effects model will be used. When conducting an investigation into the possibility of publication bias, we plan to make use of funnel plots, as well as Begg's and Egger's tests. SPSS (V.26.0) program and RevMan (V.5.4) program will be used to perform data analysis.

DISCUSSION

With the introduction of evidence-based medicine and its development, medical practitioners are paying increasing attention to the quality of evidence in clinical studies, and many SRs/MAs have emerged in recent years. However, there is a lack of evaluation of the methodological quality and quality of evidence for these SRs/MAs.³⁹ Umbrella review is a strategy for collecting and conducting exhaustive research on relevant systematic evaluations of the therapy or genesis, diagnosis and prognosis of the same condition.^{40 41} It is more favourable to evidence pooling and can supply users of evidence with high-quality evidence.⁴² This study collected SRs/MAs texts on non-pharmacological treatments for PPD for evaluation studies and evaluate the methodological (using the AMSTAR-2) and the quality of evidence (using GRADE) for each outcome index. This review is proposed due to the fact that the quality of reporting and the level of evidence are uneven, which may influence the clinical decision to provide a reliable reference for evidence users.

Strengths and limitations

This umbrella evaluation will conduct a wide range of search for SRs/MAs of non-pharmacological treatments for PPD and assess the methodological quality and level of evidence of the included studies in order to provide a more reliable basis for the clinical management of patients with PPD.

However, only SRs/MAs based on RCTs were included in this study, which may introduce some bias to the findings. In addition, the majority of the study results were derived from the most recently published systematic review, and their stability may be influenced by new publications or literature updates. Additionally, if there are new therapies for this condition that have not yet been reviewed, they cannot be included in this study. Other limitations of this research include: Language limitations

may result in the omission of included studies, leading to a selective bias. Subjective variables may have an impact on the literature screening process. Due to the fact that the umbrella review was based on SRs/MAs, risk factors not addressed in any of the original studies may be also excluded from this study.

Ethics and dissemination

This overview intends to evaluate the SRs/MAs of non-pharmacological treatments for PPD to provide quality evidence of the methodological and reporting quality. And this study will be published in a peer-reviewed journal. Ethical approval is not required for this study because the data for this study will be extracted from existing research.

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Contributors XL and LF contributed equally to this paper. XL and LF designed the study, and LF submitted the registration to PROSPERO. YX and YaZ developed the search strategies. HX, M-QG and ZY revised the language. XL and YuZ are the study guarantor. All authors approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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