INPLASY PROTOCOL

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None declared.

The effect of acupuncture on Condition being studied emotional disorders in patients with postpartum: A protocol for systemic review and meta-analysis

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Review question / Objective: **To comprehensively explore the effectiveness and safety of acupuncture in the treatment of emotional disorders in patients with postpartum.**
Condition being studied: **Postpartum emotional disorders (PEDs) are psychological disorders that occur specifically during the period of postpartum, including postpartum depression, postpartum anxiety, and post-traumatic disorder, etc. Worryingly, approximately 27% of the postpartum women suffer from PEDs, nevertheless it often had been overlooked. Hence, the both of physical and mental health of the maternal and infant can also be affected significantly. Besides, the relationships of parent-child and family were influenced as well. The most frequently prescribed drug for PEDs remains to be anti-depressants, anxiolytics, psychostimulants, and antipsychotics, given that the significant intolerable side effects will be occurred, mainly including dizzy, poor concentration and ataxia. Besides, the psychological interventions for patients were also limited by the lack of providers and financial resources. Robust evidences demonstrated that the effectiveness of acupuncture in treating anxiety and depression. However, the effectiveness of acupuncture for PEDs is still remain largely uncertain and the relevant evidence is deficiency. Accordingly, the first systematic review and meta-analysis will be conducted to investigate the efficacy and safety of acupuncture in the treatment of PEDs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 December 2021 and was last updated on 21 December 2021 (registration number INPLASY2021120091).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with postpartum emotional disorder will be included.

Intervention: The interventions under consideration must involve needle insertion at acupuncture points, pain points or trigger points, and had to be described as acupuncture. Studies evaluating the following treatments, including body acupuncture (MA or EA), auricular acupuncture, scalp acupuncture, warm needle acupuncture, plum blossom needling and fire needling, will be considered.

Comparator: The inclusion of the comparator mainly included sham or placebo acupuncture intervention such as non-penetrating, sham needle or superficial needling at non-acupuncture points, waiting list control, western medicine, moxibustion, massage and psychological intervention will also be taken into account.

Study designs to be included: Only randomized controlled trials (RCTs) comparing acupuncture to either placebo or sham, no treatment, conventional therapies or Chinese herbal medicine for patients with postpartum emotional disorders will be involved.

Eligibility criteria: Inclusion criteria: (1) RCTs involving acupuncture against another treatment or placebo/sham in patients with postpartum emotional disorders; or studies that in the term of 'randomization' was mentioned. (2) Participants must be diagnosed with postpartum emotional disorders. No restrictions on age, nationally, and race. (3) The intervention was acupuncture, electro-acupuncture or warm acupuncture and was compared with the control group. Exclusion criteria: (1) Incorrect randomization methods and other designs (such as in vivo, in vitro, case report and non-RCTs). (2) Studies comparing between different types of acupuncture therapies, such as only compared different manipulation forms or acupoint-selection methods of acupuncture, will be excluded. (3) Duplicate literature and incomplete data will not be considered.

Information sources: The 8 databases including the PubMed, Web of Science (WoS), EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wanfang Database, and Technology Periodical Database (VIP) will be searched by two researchers independently.

Main outcome(s): The Edinburgh Postpartum Depression Scale (EPDS).

Quality assessment / Risk of bias analysis: Two authors will assess the risk of bias independently by using Cochrane Collaboration's tool for all included studies. We will evaluate the risk of bias in the following domains: sequence generation, allocation sequence concealment, blinding of participants and personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. In addition, we will grade the quality of the evidence-based on the Grades Profiler as the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system. The assessments will be classified into three levels: low risk, high risk, and unclear risk.

Strategy of data synthesis: We will use the Review Manager software V.5.3 to carry out statistical analysis. Mean difference (MD) or standardized means difference (SMD) will be used for continuous data. Risk ratio (RR) or risk difference (RD) will be used for the analysis of dichotomous data. If the I^2 test is less than 50%, the fixed effect model will be used for data synthesis. If the I^2 test is between 50% to 75%, the random-effects model will be conducted for data synthesis. And if the I^2 test is higher than 75%, we will find the possible reasons from both clinical and methodological perspectives and provide an explanation or conduct subgroup analysis.

Subgroup analysis: Subgroup analysis will be executed if data is available. To detect possible heterogeneity of the results, subgroups analysis will be performed about the following four aspects: (1) Chinese studies vs other countries studies; (2) Acupuncture vs controls or different type of sham acupuncture; (3) Length of treatment differences. In addition, subgroup analysis will also be conducted if any significant covariates contributing to the heterogeneity.

Sensitivity analysis: To test the robustness of the review conclusions, a sensitivity analysis will be performed for the primary outcomes. The results of the sensitivity analysis will be presented in summary tables. The risk of bias in the review process as indicated by the results of the sensitivity analysis will be discussed.

Country(ies) involved: China.

Keywords: Emotional disorders, Postpartum, Perinatal women, Acupuncture, Meta-analysis.

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