INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
No.

Efficacy of transcranial magnetic stimulation and fluoxetine in the treatment of postpartum depression: a protocol for systematic review and meta-analysis

Guo, Y[1]; Shan, Y[2]; Wang, Z[3]; Shen, Z[4].

Review question / Objective: **Does transcranial magnetic stimulation (TMS) combined fluoxetine effectively treat postpartum depression (PPD)?**
Condition being studied: **Postpartum depression; fluoxetine; and transcranial magnetic stimulation.**
Information sources: **Electronic searches We will identify relevant RCTs involving the combination of TMS and fluoxetine on patients with PPD in the electronic databases from the inception to the April 1, 2020: Cochrane Library, EMBASE, MEDILINE, CINAHL, AMED, WANGFANG, VIP, and CNKI databases. We will not utilize any language and publication time restrictions to any literature search. The detailed search strategy of Cochrane Library is created as an example. We will also adapt similar search strategies for other electronic databases. Search for other resources Besides the above electronic databases, we will also search any relevant proceedings of conference/ meeting/symposium, websites of clinical trial registry, and reference lists of related reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 April 2020 and was last updated on 03 April 2020 (registration number INPLASY202040017.

INTRODUCTION

Review question / Objectives: **Does transcranial magnetic stimulation (TMS) combined fluoxetine effectively treat postpartum depression (PPD)?**

Condition being studied: **Postpartum depression; fluoxetine; and transcranial magnetic stimulation.**

METHODS

Participant or population: **All adult female participants (over 18 years old) who were diagnosed as PPD will be included**

regardless their country, race, educational background and economic status. However, we will exclude subjects if they had depression before the birth.

Intervention: In the experimental group, all patients must receive any types of TMS combined fluoxetine as their solely treatment.

Comparator: In the control group, all participants could undergo any therapies to manage their PPD condition. However, any combinations of TMS and fluoxetine with other treatments will be excluded.

Study designs to be included: This study will include randomized controlled trials (RCTs) that comparing the combination of TMS and fluoxetine with other conservative treatments.

Eligibility criteria: This study will include RCTs that comparing the efficacy of TMS and fluoxetine with other conservative treatments for patients with PPD.

Information sources: Electronic searches We will identify relevant RCTs involving the combination of TMS and fluoxetine on patients with PPD in the electronic databases from the inception to the April 1, 2020: Cochrane Library, EMBASE, MEDILINE, CINAHL, AMED, WANGFANG, VIP, and CNKI databases. We will not utilize any language and publication time restrictions to any literature search. The detailed search strategy of Cochrane Library is created as an example. We will also adapt similar search strategies for other electronic databases. Search for other resources Besides the above electronic databases, we will also search any relevant proceedings of conference/ meeting/symposium, websites of clinical trial registry, and reference lists of related reviews.

Main outcome(s): The primary outcome is depression, which is measured by Hamilton Depression Scale, or Edinburgh Postpartum Depression Scale, or any other relevant scales.

Quality assessment / Risk of bias analysis: Two authors will appraise study quality of each included trial using Cochrane risk of bias tool independently. It covers 7 items, and each one is rated as 'high risk of bias', 'unclear risk of bias', and 'low risk of bias'. Any controversy between two authors will be worked out with the help of a third author.

Additional outcome(s): The secondary outcomes are anxiety (as assessed by Hamilton Depression Scale or other associated scales); overall clinical efficacy (as reported in the trials); levels of estradiol, serotonin, adrenocorticotropic hormone, adrenocorticotropic hormone and cortisol in serum (as measured by radioimmunoassay), and adverse events.

Data management: Two authors will independently extract the associated data from each eligible trial using previously designed data collection sheet. It is comprises of title, first author, publication time, location, patient characteristics, diagnostic criteria, eligibility criteria, study design, study methods, sample size, specifics of intervention and control, following up information, outcome measurements, safety, results, findings, and funding information. Any uncertainty will be solved by a third author through discussion.

Strategy of data synthesis: RevMan 5.3 software will be established for statistical analysis. If sufficient trials are included and homogeneity is identified across these trials, we will conduct a meta-analysis in according with the minor variations in study characteristics, similar interventions and comparators, and outcome measurements. If considerable heterogeneity is found among trials, we will carry out subgroup analysis to identify the sources of the obvious heterogeneity. If there is still substantial heterogeneity after subgroup analysis, a meta-analysis is deemed not be performed, and we will synthesize the outcome data using a narrative summary.

Subgroup analysis: If necessary, subgroup analysis will be performed to explore the sources of considerable heterogeneity in according with the variations in study characteristics, different types of interventions, comparators, and outcome measurements.

Sensibility analysis: Where appropriate, we will carry out sensitivity analysis to investigate the robustness of the study findings by excluding low quality studies.

Coutries involved: China.

Keywords: Postpartum depression; fluoxetine; transcranial magnetic stimulation; efficacy; safety.