INPLASY PROTOCOL

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Conflicts of interest:
None.

Non-pharmacological interventions for Post stroke depression: a protocol for systematic review and network meta-analysis

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Review question / Objective: **All Participants were diagnosed with PSD through systematic clinical interviews or a validated depression score system. The age, sex, education and economic status of the patients were not restricted. Type of intervention and control. Interventions: our study will include RCTs to evaluate the effectiveness of non-pharmacological therapy for PSD. Psychological / psychosocial interventions including cognitive behavioral therapy, including CBT and IPT, physiotherapy (including rTMS and light therapy), exercise therapy, music therapy, acupuncture (traditional acupuncture or electroacupuncture, auricular point therapy), moxibustion will participate in our study. Control group: the control group includes drug treatment group (SSRIs), blank group, routine treatment group, pseudo-stimulation group, or any one of the intervention measures can be compared with each other. There is no limit to the method of administration and the duration of treatment. Studies that exclude a combination of non-pharmacological therapy and drug therapy will be excluded.Outcome measures The primary outcome will be the changes of Hamilton Depression scale (HAMD), The additional outcomes will include Geriatric Depression scale (GDS), Baker Depression scale (BDI), self-rating Depression scale (SDS). In order to examine the possible maintenance effect of non-pharmacological therapy, the effect at the end of follow-up will also be evaluated as a additional outcome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 December 2020 and was last updated on 09 December 2020 (registration number INPLASY2020120051).

INTRODUCTION

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Condition being studied: Post-stroke depression (PSD) is one of the common mental disorders after stroke, and the prevalence rate is high in the world. Both drug therapy and non-pharmacological intervention are effective for PSD. As the side effects of drug therapy have been revealed, non-pharmacological therapy is more favored by doctors and patients because of its safety and effectiveness. Prescriptions for these non-pharmacological methods should be guided by high-quality evidence

METHODS

Participant or population: Patients with post-stroke depression identified by systematic clinical interviews or validated depression scoring system.

Intervention: All types of non-pharmacological treatment will be included, such as psychological/ psychosocial intervention, physical therapy, kinesitherapy, music therapy, acupuncture, and so on. There are no limitations on the administration methods and duration of treatments. Studies combining non-pharmacological treatments and pharmacological treatments will be excluded, while studies with concomitant use of different non-pharmacological interventions will be included.

Comparator: Waiting-list control, non-treatment control, usual care, and placebo.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: The study included all RCT, associated with non-pharmacological interventions for the treatment of PSD, regardless of blindness and concealment. However, The written language is limited in English or Chinese.

Information sources: Our study will search the following electronic bibliographic databases: PubMed, EMBASE, The Cochrane Library, Scopus, Web of Science, China National knowledge Infrastructure (CNKI), Chongqing VIP Database , Wanfang Database and Chinese Biomedical Literature Database to find non-pharmacological interventions for related randomized controlled trials (RCT) for PSD.

Main outcome(s): The primary outcome will be the changes of Hamilton Depression scale (HAMD), The additional outcomes will include Geriatric Depression scale (GDS), Baker Depression scale (BDI), self-rating Depression scale (SDS).

Quality assessment / Risk of bias analysis: According to the Cochrane Handbook, two independent reviewers(CW and YJ) will evaluate the risk of bias in the study, including the generation of random sequences, the concealment of assignments, the blindness of participants, personnel and outcome evaluators, incomplete outcome data, selective

reports, and other sources of bias. We divide each area into three levels: high risk of bias, unclear or low. Differences of opinion among reviewers will be resolved through discussion or negotiation with the third reviewer(CY).

Strategy of data synthesis: We will conduct a traditional meta-analysis for direct comparison. The influence of continuous variable data will be calculated by standardized mean difference (SMD), while the impact of binary variable data will be calculated by risk ratio (RR). The 95% confidence interval (CI) of SMD and RR will also be calculated (95%CI). For indirect comparisons, reticular meta analysis is needed to mix the results to improve statistical efficiency. The network meta-analysis will be carried out using the "netmeta" package of the R software. the results of direct and indirect comparisons will be presented in the form of a network diagram.

Subgroup analysis: We will conduct a subgroup analysis to search for potential inconsistencies and heterogeneity, such as PSD level, gender, ethnicity, etc.

Sensibility analysis: We will conduct a sensitivity analysis to verify the robustness of the results. Studies with uncertain or high-risk bias risks will be excluded to check whether the results will change.

Language: The written language is limited in English or Chinese.

Country(ies) involved: China.

Keywords: network meta-analysis, non-pharmacological intervention, post-stroke depression, protocol.

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Author 2 - Yuan Jie.
Author 3 - Cao Wei.
Author 4 - Wen ChuanBiao.