INPLASY PROTOCOL

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None declared.

Scalp acupuncture for Post-stroke depression: A protocol for a systematic review and meta-analysis of randomized controlled clinical trials

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Review question / Objective: **To evaluate the efficacy and safety of scalp acupuncture for poststroke depression for the first time, and the results of this systematic review will be helpful for clinicians to use scalp acupuncture in the treatment of PSD.**
Condition being studied: **Post-stroke depression (PSD) is one of the most common psychological sequelae of stroke, which is a state characterized by low mood and aversion to activity. It is one of the main obstacles in the process of stroke rehabilitation, which has a detrimental impact on functional recovery and quality of life and even increases mortality. Although the pathogenic factors of PSD are complex and diverse, it is now widely believed to involve complex interactions between neurobiological dysfunctions, psychosocial distress and biological factors. Despite increasing awareness and clinically based research on PSD, drugs to relieve and treat symptoms have made only limited gains. The use of antidepressants is accompanied by various unavoidable adverse effects, including headache, nausea, restlessness, and sexual dysfunction. A previous meta-analysis demonstrated that acupuncture can be safe and effective for the treatment of post-stroke depression. However, there is a lack of systematic reviews to evaluate the efficacy and safety of scalp acupuncture, which is a commonly used acupuncture modality in the treatment of PSD. Consequently, this study will assess the efficacy and safety of scalp acupuncture therapy for PSD compared to other treatments.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 April 2022 and was last updated on 10 April 2022 (registration number INPLASY202240059).

INTRODUCTION

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clinicians to use scalp acupuncture in the treatment of PSD.

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METHODS

Participant or population: Participants who were diagnosed with PSD according to at least one clinical definition will be included. There are no race, gender, or age restrictions.

Intervention: Scalp acupuncture therapy is the alone intervention, that involves insertion of needles into points or lines on the scalp. There are no requirements for needle selection, puncture, or course of treatment during needle operation.

Comparator: The control group include drugs, body acupuncture therapy, physical exercise.

Study designs to be included: This study will only include all published randomized controlled trials. The language will be limited to Chinese and English and there will be no regional restrictions. Case reports, literature reviews, retrospective studies, animal studies, and studies with unbelievable or unavailable data will be excluded.

Eligibility criteria: Type of studies This study will only include all published randomized controlled trials. The language will be limited to Chinese and English and there will be no regional restrictions. Case reports, literature reviews, retrospective studies, animal studies, and studies with unbelievable or unavailable data will be excluded.Type of participants Participants who were diagnosed with PSD according to at least one clinical definition will be included. There are no race, gender, or age restrictions.Type of intervention and types of comparisons The treatment group is mainly treated with scalp acupuncture (no restriction on needle material, operation method, duration of needle retention, or course of treatment), while the control group include drugs, body acupuncture therapy, physical exercise.Primary outcomes The degree of depression plays a critical role in PSD assessment; therefore, improvement in depression, as measured by the Hamilton Depression Scale, is the primary outcome. Secondary outcomes Other validated sca.

Information sources: The following eight electronic databases will be searched: Embase, Cochrane Library, Web of Science, PubMed, Wanfang Database, Chinese Biomedical Database, China National Knowledge Infrastructure, and the Chinese Scientific Journal database.

Main outcome(s): The degree of depression plays a critical role in PSD assessment; therefore, improvement in depression, as measured by the Hamilton Depression Scale, is the primary outcome.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk bias of RCT using Cochrane Handbook 5.1.0. These items will be evaluated in three categories: low, unclear or high risk of bias. The following characteristics will be evaluated: selection (including random sequence generation and allocation concealment), implementation (including blinding of researchers and participants), measurement (blind evaluation of study outcomes), follow-up (integrity of outcome data), reporting (selective reporting of research results), and other (other sources of bias). In case of disagreement, a third researcher will be consulted.

Strategy of data synthesis: We will perform different measurements according to different data types and outcome variables. The index types of the data results included in the literature are dichotomous variables, and the relative risk (RR) will be used as a statistic and expressed by a 95% confidence interval (CI). The weighted mean difference (WMD) or standard mean difference (SMD) will be analysed for continuous outcomes. Heterogeneity will be assessed using RevMan 5.4 software. It will measure the χ2 test and the forest plot and the inconsistencies among the included studies will be quantified using the I2 statistic. When P< 0.1 and I2> 50%, there is significant heterogeneity among the included studies. The random-effect model will be used to analyze the existence of heterogeneity, whereas in the case of no heterogeneity, the fixed-effects model will be used for analysis. If the group data cannot be synthesized and subgroup analysis is not available, descriptive analysis will be used.

Subgroup analysis: When the relevant data are sufficient and available, we will investigate heterogeneity by performing the following subgroup analyses: 1. types of stroke (hemorrhagic stroke or ischemic stroke); 2. phases of stroke (acute, subacute or recovery phases following stroke); 3. types of control (drug treatment, conventional therapy, no acupuncture treatment, body acupuncture, and sham acupuncture treatment).

Sensitivity analysis: Sensitivity analysis will be conducted to ensure the robustness of the results; the lower the sensitivity, the more robust and credible the results. Sensitivity analysis will be used to test the robustness of major decisions made during the review process, including the effect of method quality, sample size, and related questions.

Country(ies) involved: China.

Keywords: Scalp acupuncture, Post-stroke depression, Systematic review, Meta-analysis.

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