INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Acupuncture on treating Insomnia after stroke: A protocol for systematic review and meta analysis

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Review question / Objective: **To investigate the clinical effectiveness and safety of acupuncture on treating insomnia after stroke.**
Condition being studied: **Insomnia is a symptom that often occurs after stroke. With the progress and aggravation of insomnia symptoms, stroke patients can further develop depression, anxiety and other negative emotions, which can affect the recovery of stroke patients, and even aggravate the condition of stroke. It affects the ability of daily life and increases the burden on the family and society. Insomnia after stroke has been paid more and more attention by clinicians, patients and their families. In many clinical trials, it has been confirmed that acupuncture has a very good effect on insomnia after stroke, and there is room for further research. Therefore this work aims at investigating the clinical effectiveness and safety of acupuncture on treating insomnia after stroke.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2022 and was last updated on 24 March 2022 (registration number INPLASY202230135).

INTRODUCTION

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attention by clinicians, patients and their families. In many clinical trials, it has been confirmed that acupuncture has a very good effect on insomnia after stroke, and there is room for further research. Therefore this work aims at investigating the clinical effectiveness and safety of acupuncture on treating insomnia after stroke.

METHODS

Search strategy: Published RCTs will be retrieved by search Embase, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang database, China Biology Medicine Database (CBM).We will use the following search terms: randomized controlled trial, acupuncture, needle, stroke, insomnia, insomnia after stroke, post-stroke Insomnia.No language and publication status restrictions will be applied.

Participant or population: Patients who were diagnosed with insomnia after stroke will be included, regardless of age, gender, educational status or racial restrictions.

Intervention: Patients in the experimental group should be treated with acupuncture alone, or combined with other kinds of therapies.Studies which combine ACU treatments with other kinds of therapies are required to use the same therapy in both the experimental and the control groups.

Comparator: Patients in the control group will receive other treatment without acupuncture.

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

Eligibility criteria: This review will include clinical randomised controlled trials (RCTs) of insomnia after stroke with acupuncture. There is no language and publications limitation. Non-RCT, observational study, reviews,experimental study, clinical case reports, and animal research literature will be excluded.Patients in the treatment group should be treated with acupuncture alone,or combined with other kinds of therapies. Studies which combine ACU treatments with other kinds of therapies are required to use the same therapy in both the experimental and the control groups.Patients in the control group will receive other treatment without acupuncture.The language of the publication is limited to Chinese or English.

Information sources: Published RCTs will be retrieved by search Embase, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang database, China Biology Medicine Database (CBM), which will be searched from establishment of the database to March 10, 2022. We will use the following search terms: randomized controlled trial, acupuncture, needle, stroke, insomnia, insomnia after stroke, post-stroke Insomnia.

Main outcome(s): The Primary outcomes of interest will be The Pittsburgh sleep quality index(PSQI).This scale is mainly used to evaluate the sleep quality, with a total score ranging from 0 to 21 points. A higher score indicates poorer sleep quality.

Additional outcome(s): The secondary outcomes of interest will include the following 3 aspects. 1. Clinical efficacy which was measured by the efficacy standards of Chinese medicine (cured, markedly effective, effective, not effective). 2. Quality of life which was measured by a validated instrument questionnaire (e.g.,the World Health Organization QoL, the 36-Item Short Form Health Survey). 3. Safety evaluation (e.g., [TESS], adverse events).

Data management: Two reviewers will use the data extraction form to extract the participants. The following information will be extracted according to the CONSORT statement format: the basic information, the characteristics of subjects, the details of interventions, outcomes, methodological section, and adverse events. If there is any disagreement, it will be resolved through discussion between two reviewers. If it can't be agreed, a third-party reviewer will

decide. We will enter the data into Review Manager (RevMan V.5.3).

Quality assessment / Risk of bias analysis: Two reviewers will access the risk of bias employing the Cochrane Deviation Risk Collaborative Tool for Systematic Reviews of Interventions, which comprises 7 items: sequence generation, allocation hiding, blindness, incomplete data evaluation, selective results reporting, and other sources of bias.The assessment of risks of bias will be classified into three levels: low risk of bias, high risk of bias and unclear risk of bias.

Strategy of data synthesis: If a meta-analysis is possible, RevMan V.5.3 will be used to express results as risk ratios(RR) for binary data and mean difference(MD) for continuous data.If I2 test results are <50%, the data will be synthesized using a fixed-effects model. If they are between 50% and 75%, the data will be synthesized using a random-effects model. If they exceed 75%, we will investigate possible causes from a clinical and methodological perspective and perform subgroup analysis.

Subgroup analysis: If there are adequate studies and available data, we will plan to conduct subgroup analysis for age, racial, gender, duration and acupuncture stimulus gradient and frequency of treatment.

Sensitivity analysis: Sensitivity analysis refers to an analysis method that analyzes some factors that may affect the results of the analysis, excludes the results that may cause heterogeneity, and conducts the meta-analysis again, so as to make the stability of the meta-analysis results and the strength of the argument better. When conducting sensitivity analysis, it is important to consider whether there are differences in subject characteristics, intervention characteristics, control characteristics, outcome index characteristics, and research design. We will compare the results before and after excluding the studies, and discuss if the results vary significantly.

Language: The language of the publication is limited to Chinese or English.

Country(ies) involved: China.

Keywords: insomnia after stroke, meta-analysis, acupuncture, systematic review, protocol.

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