INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Acupuncture plus rehabilitation for post-stroke insomnia A protocol for systematic review and meta analysis

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Review question / Objective: **This meta-analysis aims to assess the effectiveness of acupuncture combined with rehabilitation in treating PSI, which could allow may provide alternative non-drug treatment options for PSI.**
Condition being studied: **Stroke is a major fatal disease in the world, and it is also a leading cause of disability in adults, with a high risk of relapse. Post-stroke insomnia (PSI) is a common complication after stroke. A related meta-analysis shows that the incidence is as high as 38.2%. The main manifestations of PSI are difficulty falling asleep and maintaining sleep, early morning awakening, and nonrestorative sleep. PSI not only affects quality of life and sroke recovery, but also increases the risk of stroke recurrence and mental disorders such as anxiety, depression and cognitive decline. In addition, insomnia is also one of the factors of suicide after stroke patients. Therefore, it is important to determine the appropriate PSI treatment for lowering the associated disability and mortality rate.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 August 2022 and was last updated on 01 August 2022 (registration number INPLASY202280002).

INTRODUCTION

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METHODS

Search strategy: The following electronic databases will be searched: Embase, PubMed, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang, China Biology Medicine Database (CBM). We will consider articles published between the database initiation and July 2022. Table 1 presents the details of the search strategy for PubMed. Similar search strategies will be used for all electronic databases.

Participant or population: We will consider patients with a clinical diagnosis of PSI irrespective of their age, gender, country, severity, and disease duration. Both the patient and the family informed the study and signed a consent form.

Intervention: The experimental group will comprise of individuals who received individuals who received individual treatment with filiform needle acupuncture together with rehabilitation treatment. Studies assessing combined filiform needle acupuncture treatments with rehabilitation should use the same rehabilitation treatment protocol for the control and experimental groups.

Comparator: The control group should receive selective western medicine combined with rehabilitation treatment.

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

Eligibility criteria: This review will include randomized controlled trials (RCTs) on acupuncture for PSI published in Chinese and English. We will exclude non-RCTs, review studies, animal experiments, and case reports. The experimental group will comprise of individuals who received individuals who received individual treatment with filiform needle acupuncture together with rehabilitation treatment. Studies assessing combined filiform needle acupuncture treatments with rehabilitation should use the same rehabilitation treatment protocol for the control and experimental groups. The control group should receive selective western medicine combined with rehabilitation treatment.

Information sources: The following electronic databases will be searched: Embase, PubMed, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang, China Biology Medicine Database (CBM). We will consider articles published between the database initiation and July 2022.

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: The data will be independently extracted by 2 reviewers using a uniform data form. The following information will be extracted according to the CONSORT statement format: the journal title, first author, year of publication, study design, patient characteristics, control intervention, experimental intervention, outcomes, duration of intervention, etc. 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.

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 studies are adequately homogeneous in design and comparison, we will conduct data synthesis using Review Manager Software 5.3. The fixed-effects or random-effects model will be chosen depending on the I2 value. A 95% confidence interval will be the effective size for data synthesis. We will perform qualitative analysis if the data is not fit for quantitative analysis.

Subgroup analysis: We will perform subgroup analysis among patient conditions, treatment methods, and outcome measurements if feasible.

Sensitivity analysis: If the result shows high heterogeneity (the I2 test is>75%), we will perform sensitivity analysis to examine the robustness and reliability of merged outcome results with the exclusion of small and low-quality studies. Then we will acquire a stable result of our study.

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

Country(ies) involved: China.

Keywords: post-stroke insomnia, acupuncture, rehabilitation, meta-analysis, protocol.

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