INPLASY PROTOCOL

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Electroacupuncture for patients with spasticity after stroke: a protocol for systematic review and meta analysis

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Review question / Objective: Stroke is the third most common cause of disability in the world and the number one killer in China. Spasticity after stroke is a common dysfunction, causing pain, joint contractures and affecting the free movement of limbs. AHA/ASA adult stroke rehabilitation treatment guidelines recommended the treatment including oral drugs, normal limb position placement, and botulinum toxin injections. However, oral antispasmodic drugs can't selectively target the spasm site. At the same time, it is not widely used the intrathecal injection of baclofen due to the small sample size of the study and the high technical requirements. Therefore, an increasing number of patients have sought alternative treatments. Acupuncture therapy is widely used in the treatment of spasticity after stroke due to confirmed efficacy and few adverse effects. Electro-acupuncture, derived from the integration of traditional acupuncture and modern electrical stimulation, is another kind of acupuncture. Compared with traditional manual acupuncture, electroacupuncture can provide a constant stimulation, whose intensity, frequency and duration are quantifiable. Nowadays, there have been more and more studies on electroacupuncture in the treatment of spasticity after stroke.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 November 2020 and was last updated on 22 November 2020 (registration number INPLASY2020110098).

INTRODUCTION

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movement of limbs. AHA/ASA adult stroke rehabilitation treatment guidelines recommended the treatment including oral drugs, normal limb position placement, and botulinum toxin injections. However, oral antispasmodic drugs can't selectively target the spasm site. At the same time, it is not widely used the intrathecal injection of baclofen due to the small sample size of the study and the high technical requirements. Therefore, an increasing number of patients have sought alternative treatments. Acupuncture therapy is widely used in the treatment of spasticity after stroke due to confirmed efficacy and few adverse effects. Electroacupuncture, derived from the integration of traditional acupuncture and modern electrical stimulation, is another kind of acupuncture. Compared with traditional manual acupuncture, electroacupuncture can provide a constant stimulation, whose intensity, frequency and duration are quantifiable. Nowadays, there have been more and more studies on electro-acupuncture in the treatment of spasticity after stroke.

Condition being studied: So far, as we all know, there is only one systematic review (SR) about electroacupuncture for patients with spasticity after stroke. Because the quality of reporting is low, and the author concluded that the clinical result was tentative because of a lack of high-quality evidence. Therefore, according to a rigorous review method, we intend to perform a SR to evaluate the effectiveness and safety of electroacupuncture for patients with spasticity after stroke.

METHODS

Participant or population: Patients with diagnosed spasticity after stroke will be included, regardless of gender, age, race, education status, and cases of the source. All participants included in the SR must comply with the diagnostic criteria of stroke and symptoms of increased limb muscle tension.

Intervention: Intervention measures should be electroacupuncture alone or combined with other methods to treat spasticity after stroke. If combined with other methods, only the control group with the same intervention measures as the experimental group will be included.

Comparator: Study designs to be included: his review will only include RCTs of traditional Chinese mind-body exercises for insomnia. Case reports, observational studies, and cross-sectional design studies will be excluded. The study protocol and conference abstract of RCTs will also be excluded, if the corresponding author could not provide detailed information.

Study designs to be included: Randomized controlled clinical trials and quasi-randomized controlled trials will be included. We will exclude any other types of literature including literature on electroacupuncture as non-major interventions, retrospective research literature, repeated publication literature, conference abstracts, literature that data cannot be extracted, case reports, and bibliometrics research.

Eligibility criteria: Our SR is designed in strict compliance with the preferred reporting items for systematic reviews and meta-analysis protocol (PRISMA-P) . The PRISMA guidelines and the Cochrane Handbook will be used for us to evaluate the included studies. Besides, our SR will carry out bias risk analysis, heterogeneity analysis. If necessary, subgroup analysis and sensitivity analysis will be conducted.

Information sources: This study will use computer search Medline, Embase, Pubmed, Web of science and the Cochrane Central Register of Controlled Trials. In addition, we will also collect 4 databases of China: China National Knowledge Infrastructure, China Biomedical Literature Database, China Science Journal Database, and Wan-fang Database. All databases will be searched from the date of creation to June 2020. The following search terms will be used: spastic paralysis, spastic hemiplegia, spastic paraparesis, stroke, post-stroke, apoplex,

acupuncture, meridian, electro-acupuncture, electro acupuncture, electro-stimulation, etc. The example search strategy will be used for Pubmed. This search strategy will be slightly modified and used in several other databases.

Main outcome(s): The primary outcomes will be the modified Ashworth scale (MAS). The MAS will be used to evaluate muscle tone. The degree of spasm is divided into 0, I, I+, II, III, and IV levels according to the resistance felt by the evaluators during passive movement of the elbow and knee joints of hemiplegic patients in the resting state. The higher the score, the higher the degree of spasm. The secondary outcomes will include the following measures: (1) Simplified Fugl–Meyer assessment scale (FMA); (2) Stroke specific quality of life scale (SS-QOL); (3) Adverse events.

Quality assessment / Risk of bias analysis: We will use the Risk of bias tool in Cochrane Manual V.5.1.0 to evaluate the bias risk of each included studies. The contents include: random sequence generation, allocation sequence concealment, blinding of participants and personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. The assessment results will be divided into 3 levels: low risk, high risk, and uncertain risk.

Strategy of data synthesis: Data synthesis will use the risk ratio and the standardized or weighted average difference of continuous data to represent the results.

Subgroup analysis: In the case of high heterogeneity, we will conduct a subgroup analysis to identify the sources of heterogeneity. Besides, according to different course time, or other factors affecting the results, we will also make subgroup analysis.

Sensibility analysis: In order to test the robustness of the main decisions in the review process, we will conduct a sensitivity analysis. The main analysis points include the impact of method quality, sample size, and missing data on the study. The meta-analysis will be reused, and more inferior quality studies will be excluded. The results will be compared and discussed according to the results.

Country(ies) involved: China.

Keywords: Electroacupuncture, Spasticity after stroke, Protocol, Systematic review.

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