

INPLASY PROTOCOL

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None declared.

Protocol for systematic review and meta-analysis of efficacy and safety of acupuncture combined with rehabilitation therapy for upper limb spasticity after stroke

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Review question / Objective: The study aims to assess the efficacy and safety of acupuncture combined with rehabilitation therapy for upper limb spasticity after stroke.

Information sources: The following databases will be searched electronically: PubMed, Embase, Medicine, and Cochrane Library, China National Knowledge Infrastructure, China Biomedical Literature Database, China Science Journal Database and Wan-Fang Database. In addition, we will retrieve unpublished protocols and summarize the results by searching the clinical trial registry at <https://ClinicalTrials.gov>. We will also manually retrieve relevant conference reports and contact experts in the field and corresponding authors to obtain important information that cannot be obtained by the above retrieval.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 May 2021 and was last updated on 19 May 2021 (registration number INPLASY202150076).

Condition being studied: Stroke, with high incidence and disability rates, has become the third most common cause of disability in the world, and it is the number one killer in China. Studies have shown that within three weeks after a stroke, 90% of patients will have spastic paralysis, and more than

INTRODUCTION

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half of them will have upper limb spasm. The upper limb is an important carrier for us to complete information communication and emotional communication, which undertakes more than 80% of our daily activities. Therefore, if upper limb is in spasm and cannot be recovered, it will have great impact on the quality of life and psychological state of patients of post-stroke. Rehabilitation training is a common non drug therapy for post-stroke spasticity, which mainly includes physical therapy (PT) and occupational therapy (OT). Acupuncture is a traditional medical method of Traditional Chinese Medicine, which has been used for thousands of years in China. In view of this upper limb spasm after stroke, it can achieve the effect of relieving muscle spasm and recovering the motor function of patients through stimulating the specific acupoints of patients based on the meridian theory of Traditional Chinese Medicine. In recent years, more and more clinical studies tend to use comprehensive therapy to intervene the disease; in which the treatment of acupuncture combined with rehabilitation therapy is a popular choice. Although many clinical studies have reported its positive effect for upper limb spasticity after stroke, there is no scientific evidence. Therefore, the systematic review aims to assess the efficacy and safety of acupuncture combined with rehabilitation therapy for upper limb spasticity after stroke to provide a guide for clinical decision-making.

METHODS

Search strategy: We will collect relevant articles by searching following databases: Pubmed, Web of Science, Medicine, EMBASE, Cochrane Library, China National Knowledge Infrastructure, China Biomedical Literature Database, China Science Journal Database and Wan-Fang Database. All databases will be searched from creating to 1 May 2021 by the following words: Stroke, Post-stroke, Spastic paralysis, Spastic hemiplegia, Upper limb spasticity, Upper spastic paraparesis, Upper muscl, Acupuncture, Acupoint, Rehabilitation, Habilitation, RCT,

etc. In addition, we will search the reference list of included studies and existing systematic review related to our topic. We will also search retrieve other literature resource including Chinese Clinical Trial Register, conference papers and other related gay literature to make our search as complete as possible.

Participant or population: All patients should be diagnosed with a stroke and show symptoms of upper limb muscle spasm, and they should be older than 18 years old. While their race, gender, education status will not be limited. The diagnosis of stroke should meet the criteria of WHO.

Intervention: The intervention of test group should be acupuncture combined with rehabilitation training. The methods of acupuncture should include Filiform Needle Acupuncture, Fire-Needle Acupuncture, Scalp Acupuncture Abdominal Acupuncture and Electroacupuncture, while the methods of rehabilitation training are not limited (including all kinds of rehabilitation training methods for upper limb spasticity after stroke as Bobath Technology, Bood Technology, Brunnstrom Therapy, Excercise Relearning Therapy, Proprioceptive Neuromuscular Facilitation and so on). If there are other adjuvant treatments, it should be consistent with the control group.

Comparator: Exercise Relearning Therapy, Proprioceptive Neuromuscular Facilitation and so on). If there are other adjuvant treatments, it should be consistent with the experiment group.

Study designs to be included: All randomized control trial (RCTs) of acupuncture combined with rehabilitation therapy for upper limb spasticity after stroke will be included in the study.

Eligibility criteria: We will include only the literature of randomized controlled clinical trials (RCTs) of acupuncture combining with rehabilitation therapy for upper limb spasticity after stroke. We will exclude any

other literature including non randomized clinical controlled trials, retrospective research literature, conference abstracts, case reports, repeated published literature and literature of inform without data.

Information sources: The following databases will be searched electronically: PubMed, Embase, Medicine, and Cochrane Library, China National Knowledge Infrastructure, China Biomedical Literature Database, China Science Journal Database and Wan-Fang Database. In addition, we will retrieve unpublished protocols and summarize the results by searching the clinical trial registry at <https://ClinicalTrials.gov>. We will also manually retrieve relevant conference reports and contact experts in the field and corresponding authors to obtain important information that cannot be obtained by the above retrieval.

Main outcome(s): We will include Modified Ashworth scale (MAS) and Simplified Fugl-Meyer Assessment scale (SFMA) as main outcomes. The MAS will be used to evaluate muscle tone of the patient's upper limbs and divide into five grades according to the severity. The SFMA, 100 points in total, can assess movement function of patient's limbs (including upper and lower limbs), yet only the part of SFMA about upper limbs was used (66 points) in this study.

Additional outcome(s): Second outcomes will be include: (1)Modified Barthel Index (MBI) used to evaluate daily living ability of stroke patients, adverse reactions.

Data management: Data extraction will be done by two reviewers (who and who) independently, and the results will be cross-matched. When the differences and opinions are inconsistent, they should be settled through discussion. If the differences encountered cannot be resolved through discussion, a third researcher will be invited to resolve them. We will make an Excel to extract data, which includes the first author, country, year of publication, patient characteristics, number of participants, interventions, outcome, results, main conclusions,

conflicts of interest, ethical approval and other information. If necessary, we will contact the correspondence author by E-mail for more accurate data.

Quality assessment / Risk of bias analysis: Two researchers will independently evaluate the bias risk included studies using the assessment tool of risk bias in Cochrane Handbook V.5.1.0. The contents include: random sequence generation, allocation sequence concealment, blinding of participants and personnel, outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias. The assessment results will be rated in low risk, high risk and uncertain risk. In the process, if there is disagreement, a third reviewer will invited to make a decision.

Strategy of data synthesis: The meta-analysis of data from included outcomes will be performed by using the RevMan V.5.4.1, and we will choose randomized or fixed effect model for data statistics according to the results of heterogeneity test. The enumeration data are expressed as relative risk (RR), and the weight mean difference (WMD) will be used as the measurement data; each effect amount are expressed in 95% confidence interval (CI). The specific methods are as follows: If the heterogeneity is low ($I^2 < 50\%$), the fixed-effects model will be used for data synthesis. If there is high heterogeneity ($I^2 > 50\%$), the random-effects model will be conducted for data synthesis after excluding possible heterogeneity sources. The investigation methods include subgroup analysis and sensitive analysis If data cannot be synthesized, we will provide a descriptive analysis to solve this problem.

Subgroup analysis: If there is high heterogeneity ($I^2 > 50\%$) among the included studies, we will conduct a subgroup analysis to analysis the sources of heterogeneity according to the following factors: age, sex, race, courses, sample sizes, different methods of acupuncture or rehabilitation and other possible reasons affecting the results.

Sensitivity analysis: In order to test the stability and reliability of results of this study, we will conduct sensitivity analysis according to following points: method quality, size of sample and missing data. After that, we will do a data analysis again and compare the results. If there is no directional change after sensitivity analysis, the results are stable.

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Language: English.

Country(ies) involved: China.

Other relevant information: As a part of project, the study will complete a task of systematic review for the rehabilitation of post-stroke.

Keywords: Stroke; Rehabilitation; Acupuncture; Systematic review; Meta-analysis.

Dissemination plans: To producing a report for the funder of this review, which will be made available free of charge on their website; an article will be submitted to a leading journal in this field.

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