## INPLASY PROTOCOL

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# Acupuncture and massage combined with rehabilitation therapy for hemiplegia after stroke: A protocol for systematic review and meta analysis

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Review question / Objective: Population: hemiplegia after stroke; Intervention: acupuncture and massage combined with rehabilitation therapy; Comparison: rehabilitation therapy; Outcome: the Modified Ashworth Scale (MAS) and Simplified Fugl-Meyer Assessment scale (SFMA).

Eligibility criteria: We will include only randomized controlled clinical trials (RCTs) of Acupuncture and massage combined with rehabilitation therapy for hemiplegia 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 information without data. We will include only the literature of randomized controlled trials (RCTs) of aromatherapy massage for KOA. Nonrandomized controlled studies case reports, case series and reviews will not be included in this study.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 January 2022 and was last updated on 06 January 2022 (registration number INPLASY202210026).

#### INTRODUCTION

Review question / Objective: Population: hemiplegia after stroke; Intervention: acupuncture and massage combined with rehabilitation therapy; Comparison: rehabilitation therapy; Outcome: the Modified Ashworth Scale (MAS) and

Simplified Fugl-Meyer Assessment scale (SFMA).

Condition being studied: Stroke is a syndrome of limited or generalized cerebral deficits due to acute cerebral circulatory disorders. It is one of the common cranial lesions with long latency period, rapid

onset, high disability rate and high mortality rate and the incidence of stroke in China is increasing year by year with the accelerated aging of the population and the change of people's lifestyle, of which about 80% are ischemic strokes. Local cerebrovascular lesions in patients with ischemic stroke affect the neurological function of the body, such as hemiplegia and according to statistics, 50% of patients have reduced mobility due to hemiplegia. which not only seriously affects the quality of life of patients, but also brings a huge burden to families and society. Currently, there is no specific treatment for stroke hemiplegia, but rehabilitation training is the main treatment, combined with certain drugs, physiotherapy and surgery to promote functional recovery, but the treatment period is often long and the results are not satisfactory in some patients. Studies have pointed out that effective rehabilitation training at an early stage can promote the recovery of neurological function to a certain extent and is beneficial to the recovery of limb function in stroke patients. With the application of acupuncture and massage techniques in patients with ischemic stroke, their effectiveness and safety have been recognized and affirmed. In recent years, an increasing number of clinical studies have used integrative therapies to intervene in the disease, with acupuncture and massage combined with modern rehabilitation therapy being a popular choice. Although many clinical studies have reported its positive effects on poststroke hemiplegia, there is no scientific evidence. Therefore, this systematic review aims to evaluate the effectiveness and safety of acupuncture and massage combined with rehabilitation for poststroke hemiplegia and to provide a better basis for clinical decision making.

#### **METHODS**

Participant or population: All patients should be diagnosed with stroke and show symptoms of hemiplegia, and should be older than 18 years of age. However, race, gender, and educational status are not limited. The diagnosis of stroke should

meet WHO criteria. Participants with unstable vital signs or inability to cooperate with rehabilitation treatment should be excluded, such as patients with impaired hearing, visual and cognitive or severe infection, organ dysfunction, and so on.

Intervention: The intervention in the experimental group should be acupuncture and massage combined with rehabilitation therapy.

Comparator: Interventions of the control group should only be rehabilitation therapy.

Study designs to be included: Only randomized controlled trials (RCTs) will be included in this study.

Eligibility criteria: We will include only randomized controlled clinical trials (RCTs) of Acupuncture and massage combined with rehabilitation therapy for hemiplegia 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 information without data.We will include only the literature of randomized controlled trials (RCTs) of aromatherapy massage for KOA. Nonrandomized controlled studies case reports, case series and reviews will not be included in this study.

Information sources: We will collect relevant articles by searching the 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.

Main outcome(s): We will include the Modified Ashworth Scale (MAS) and Simplified Fugl-Meyer Assessment scale (SFMA) as the main outcomes. The MAS will be used to evaluate the muscle tone of the patient's upper limbs and divided into five grades according to 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 the upper limbs was used (66 points) in this study.

Additional outcome(s): (1)Modified Barthel Index (MBI) used to evaluate the daily living ability of patients with stroke. (2)China Stroke Scale (CSS) used to assess the neurological deficit of stroke patients. (3)adverse reactions.

### Quality assessment / Risk of bias analysis:

Two researchers will independently evaluate the bias risk, including studies using the assessment tool of risk bias in the Cochrane Handbook V.5.1.0. The contents included 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 as low-risk, high-risk, and uncertain risk. In the process, if there is disagreement, a third reviewer will be invited to make a decision.

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

Subgroup analysis: If there was high heterogeneity (I2>50%) among the included studies, we conducted a subgroup analysis

to analyze the sources of heterogeneity according to the following factors: age, sex, race, courses, sample sizes, different methods of aromatherapy massage, and other possible factors affecting the results.

Sensitivity analysis: To test the stability and reliability of the results of this study, we conducted a sensitivity analysis according to the following points: method quality, sample size, and missing data. After that, we will perform a data analysis again and compare the results. If there was no directional change after the sensitivity analysis, the results were stable.

Country(ies) involved: China.

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

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