

INPLASY PROTOCOL

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Rehabilitation training combined acupuncture for limb hemiplegia caused by cerebral infarction: a protocol for a systematic review of randomized controlled trial

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Review question / Objective: Previous studies have reported that rehabilitation training combined acupuncture (RTA) can be used for the treatment of limb hemiplegia (LH) caused by cerebral infarction (CI). However, its effectiveness is still unclear. In this systematic review study, we aim to evaluate the effectiveness and safety of RTA for LH following CI.

Condition being studied: Previous studies have reported that rehabilitation training combined acupuncture (RTA) can be used for the treatment of limb hemiplegia (LH) caused by cerebral infarction (CI). However, its effectiveness is still unclear. In this systematic review study, we aim to evaluate the effectiveness and safety of RTA for LH following CI.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 July 2020 and was last updated on 26 July 2020 (registration number INPLASY202070114).

INTRODUCTION

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METHODS

Participant or population: Patients with LH following CI, regarding sex, age, and race will all be included. However, patients are diagnosed with LH before the CI, or result from other disorders, except the CI will be excluded.

Intervention: The patients in the treatment group received rehabilitation training and acupuncture (no restriction on the methods of operation and course of treatment) and guideline-recommended conventional treatment.

Comparator: The control group could gain guideline-recommended conventional treatment and a placebo or no treatment.

Study designs to be included: Original studies of randomized controlled trials (RCTs) of RTA for the treatment of LH.

Eligibility criteria: Original studies of randomized controlled trials (RCTs) of RTA for the treatment of LH following CI will be included without publication status restriction or writing language. Letters to editors, review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded.

Information sources: Electronic databases including English databases (PubMed, MEDLINE, EMBASE, Web of Science, Cochrane Library) and Chinese databases (China National Knowledge Infrastructure, China Biology Medicine Database, Wanfang Database, VIP Database) will be searched from their inception to July 2020 with no language restrictions to recognize related studies. The RCTs that evaluate the

effectiveness and safety of RTA for LH caused by CI will be included. The search strategy that will be run in the PubMed and tailored to the other database when necessary is presented in Table 1. Besides, the reference lists of review articles will be searched for any possible titles matching the inclusion criteria. Similar strategies will be applied to the other electronic databases in this study.

Main outcome(s): The primary outcome includes limbs function, as measured by the WMFT Assessment scale, or other associated scales.

Quality assessment / Risk of bias analysis: The risk of bias will be independently assessed by two reviewers and any differences will be resolved through consultation or the participation of a third reviewer. The RCTs will be evaluated using the Cochrane "risk of bias assessment" tool. The tool assesses the risk of bias mainly in the following 7 aspects: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, and selective reports. As recommended by the Cochrane manual, the risk of bias in each of these areas will be assessed as low or high depending on whether the criteria were met or not met, and the lack of information will be recorded as unclear. In most cases, disagreements will be settled by discussion between the 2 reviewers. If disagreement remained after discussion, a third reviewer will be consulted before taking the final decision on the disagreements.

Strategy of data synthesis: We will use RevMan 5.3 software to carry out the data synthesis and meta-analysis. If heterogeneity is acceptable ($I^2 \leq 50\%$), a fixed-effect model will be utilized to synthesize the data, and meta-analysis will be performed. On the other hand, if heterogeneity is significant ($I^2 > 50\%$), a random-effect model will be used to pool the data and to operate the meta-analysis. In such a situation, subgroup analysis will be conducted to identify the factors that

may cause the significant heterogeneity. If there is still substantial heterogeneity after the subgroup analysis, then data will not be pooled, and meta-analysis will not be conducted. Instead, a narrative summary will be described.

Subgroup analysis: If significant heterogeneity will be detected, subgroup analysis will be carried out in accordance with the different treatments, control interventions, and outcome measurements.

Sensibility analysis: A sensitivity analysis will be performed to test the robustness of the review result and to detect the source of heterogeneity. This can be done by excluding trials with a high risk of bias or eliminating each study individually. And, the impact of methodological quality, sample size, and missing data will be assessed. Then the analysis will be repeated after the exclusion of low methodological quality studies and the results compared with the previous meta-analysis.

Country(ies) involved: China.

Keywords: acupuncture, cerebral infarction; effectiveness; limb hemiplegia; rehabilitation training; safety; systematic review.

Contributions of each author:

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