INPLASY PROTOCOL

To cite: Ji et al. Tuina combined with physical therapy for spasticity of poststroke: A protocol for systematic review and meta analysis. Inplasy protocol 2021110064. doi: 10.37766/inplasy2021.11.0064

Received: 17 November 2021

Published: 17 November 2021

Corresponding author:
Yuanyuan Ji

2211842943@qq.com

Author Affiliation:
Changchun Traditional Chinese Medicine.

Support: **2018YFC1706006; 2018YFC1706002.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Tuina combined with physical therapy for spasticity of poststroke: A protocol for systematic review and meta analysis

Ji, Y[1]; Lou, H[2]; Pang, T[3]; Li, Z[4]; Yang, K[5]; Wang, Y[6]; Hu, G[7]; Cong, D[8].

Review question / Objective: **The purpose of this study was to evaluate the effectiveness and safety of Tuina combined with physical therapy for spasticity of poststroke.**
Condition being studied: **To collect relevant literature, we will research following databases: Medicine, PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, Wan-Fang Database, Chongqing VIP Chinese Science and Technology Periodicaols Database and China Biomedical Database; the time is from its creation to May 2021, and the language is limited to Chinese and English. In addition, we will retrieve other literature resources, including the Chinese Clinical Trial Register and conference papers. Two reviewers will independently complete the literature screen and data extraction, and quality assessment of the included studies will be independently completed by two other researchers. The primary outcomes included the Modified Ashworth scale (MAS) and the simplified Fugl-Meyer Assessment scale (SFMA). The Modified Barthel Index (MBI), the China Stroke Scale (CSS), and adverse reactions as secondary outcomes were assessed. RevMan V.5.4.1 software will be used for meta-analysis, and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be used to assess the quality of evidence.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2021 and was last updated on 17 November 2021 (registration number INPLASY2021110064).

INTRODUCTION

Review question / Objective: **The purpose of this study was to evaluate the effectiveness and safety of Tuina combined with physical therapy for spasticity of poststroke.**

Condition being studied: To collect relevant literature, we will research following databases: Medicine, PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, Wan-Fang Database, Chongqing VIP Chinese Science and Technology Periodicaols Database and China Biomedical Database; the time is from its creation to May 2021, and the language is limited to Chinese and English. In addition, we will retrieve other literature resources, including the Chinese Clinical Trial Register and conference papers. Two reviewers will independently complete the literature screen and data extraction, and quality assessment of the included studies will be independently completed by two other researchers. The primary outcomes included the Modified Ashworth scale (MAS) and the simplified Fugl-Meyer Assessment scale (SFMA). The Modified Barthel Index (MBI), the China Stroke Scale (CSS), and adverse reactions as secondary outcomes were assessed. RevMan V.5.4.1 software will be used for meta-analysis, and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be used to assess the quality of evidence.

METHODS

Participant or population: Patients suffering postacute phase of post- stroke spasticity (>18 years old) will be included.

Intervention: Tuina combined with physical therapy.

Comparator: oral medication, acupuncture, Chinese herbal medication, physical therapy, surgery, botox injections and so on or even with no treatment.

Study designs to be included: We will include randomised controlled trials (RCTs) (not included quasi- RCTs) of tuina combined with physical therapy for poststroke spasticity in the treatment groups. If multiarm RCTs comes, we will select the group which used tuina and another without tuina for analysis. We will select the first stage of cross over RCTs, in which tuina was first used in one group. RCTs' language of English, Chinese will be included.Patients suffering postacute phase of post- stroke spasticity (>18 years old) will be included.

Eligibility criteria: Stroke (cerebral infarction or cerebral haemorrhage) is diagnosed according to WHO criteria.

Information sources: Medicine, PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, Wan-Fang Database, Chongqing VIP Chinese Science and Technology Periodicaols Database and China Biomedical Database.

Main outcome(s): We will include the Modified Ashworth Scale (MAS) and Simplified Fugl-Meyer Assessment scale (SFMA) as the main outcomes.

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 were rated as low-risk, high-risk, or uncertain risk. In the process, if there is disagreement, a third reviewer will be invited to make a decision.

Strategy of data synthesis: The meta-analysis of data from included outcomes will be performed using the RevMan 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^2 < 50%, the fixed-effects model was used for data synthesis. If there is high heterogeneity (I^2 > 50%), the random-effects 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, course, sample size, different methods of tuina or phisicalphysical therapy, 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; Spasticity; Tuina; physical therapy; Systematic review; Meta-analysis.

Contributions of each author:
Author 1 - Yuanyuan Ji.
Author 2 - Huijuan Lou.
Author 3 - Tingting Pang.
Author 4 - Zhanxin Li.
Author 5 - Kang Yang.
Author 6 - Yufeng Wang.
Author 7 - Guanyu Hu.
Author 8 - Deyu Cong.