INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results.

Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: The purpose of this study was to conduct a metaanalysis on the efficacy and safety of tuina therapy for frozen shoulder.

Efficacy and safety of Tuina for frozen shoulder

A protocol for systematic review and meta-analysis

Zheng, L1; Wang, J2; Mi, S3; Wang, K4; Qiao, Y5; Li, H6.

Review question / Objective: The purpose of this study was to conduct a meta-analysis on the efficacy and safety of tuina therapy for frozen shoulder.

Condition being studied: The databases of China National Knowledge Network (CNKI), China Biomedical Literature Database (CBM), VIP, Wanfang Digital Journal Group (WF), Cochrane Library, Web of Science, EMBASE, Springer, MEDLINE, China Knowledge Infrastructure, WHO International Clinical Trial Registry platform, and Chinese Science Journal database will be searched for RCT of tuina for frozen shoulder. If the full text could not be obtained, manual retrieval was carried out with the back issue database of Shandong University of Traditional Chinese Medicine library. The retrieval time limit was from the construction of each database to March 2022 for the randomized controlled trial of massage treatment frozen shoulder. The primary outcome included response rate, safety, visual analog scale (VAS), Constant-Murley shoulder function score, and the secondary outcome was MRI. Cochrane bias risk assessment tool was used to screen and evaluate the literature, and RevMan5.4 was used to collect data for statistical analysis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2022 and was last updated on 10 April 2022 (registration number INPLASY202230136).

Condition being studied: The databases of China National Knowledge Network (CNKI), China Biomedical Literature Database (CBM), VIP, Wanfang Digital Journal Group (WF), Cochrane Library, Web of Science, EMBASE, Springer, MEDLINE, China Knowledge Infrastructure, WHO International Clinical Trial Registry platform, and Chinese Science Journal database will be searched for RCT of tuina for frozen shoulder. If the full text could not be obtained, manual retrieval was carried out with the back issue database of **Shandong University of Traditional Chinese** Medicine library. The retrieval time limit was from the construction of each database to March 2022 for the randomized controlled trial of massage treatment frozen shoulder. The primary outcome included response rate, safety, visual analog scale (VAS), Constant-Murley shoulder function score, and the secondary outcome was MRI. Cochrane bias risk assessment tool was used to screen and evaluate the literature, and RevMan5.4 was used to collect data for statistical analysis.

METHODS

Participant or population: Patients diagnosed with frozen shoulder were confirmed, and the age, sex and source of the patients were not limited.

Intervention: Intervention can be any type of massage: acupoint massage, meridian massage, chiropractic massage, local point pressing, stretching, pulling, etc.

Comparator: Types of controlled interventions include: no treatment, placebo, and other interventions(e.g., acupuncture, cupping therapy, drug and physical interventions, moxibustion). However, if the intervention and comparison in this study included massage, it would be excluded. Massage interventions will be included only if combined massage therapy is compared with other therapies alone.

Study designs to be included: Randomized controlled trial (RCT) and blinded research will be included. Published clinical trials that reported the effificacy and safety on Tuina for FS will be included. RCTs that involve at least 1 Tuina related treatment to FS, and 1 control treatment (or blank treatment) will be included. As there is a risk of interference with the outcome, nonRCTs will be excluded. Studies of

animal experiment, review, case report, and meta-analysis poster presentations will be excluded.

Eligibility criteria: Inclusion criteria: (1)Research type Randomized controlled trial (RCTS) of Massage therapy for FS in Chinese and English. (2) Research object Patients diagnosed with frozen shoulder were confirmed, and the age, sex and source of the patients were not limited. (3) Intervention measures The experimental group was treated with massage or combined massage, while the control group was treated with non-massage.(4) Outcome Indicators (1) Main indicators: efficiency and safety. For example, VAS score, constant-Murley shoulder function assessment scale: 2 Secondary indicators: imaging findingsExclusion criteria:(1)Nonrandomized controlled trials, such as review literature, animal experiments, experience summary, etc.;(2)Repeatedly published and retrieved literatures;(3) There is no literature on clear diagnostic criteria and efficacy criteria;(4) Literatures with insufficient data support and obvious loopholes in experimental design; (5) Literature with inconsistent outcome indicators.

Information sources: Chinese and English databases were searched by computer. Chinese databases were CNKI, CBM, VIP, WF and Springer If the full text of the RCT literatures related to the treatment of frozen shoulder in the MEDLINE Database of Chinese Scientific journals (WHO International Clinical Trial Registration Platform) cannot be obtained, manual retrieval will be carried out with the back journal database of Shandong University of Traditional Chinese Medicine, and the retrieval time will be set up until March 2022. We will search manual related literature, such as replacing and supplementing some references, such as medical textbooks, clinical laboratory manuals, etc. We will also search the relevant reference lists to identify articles relevant to published journals, books, conference papers, and grey literature. For confusing literature, we will try to contact the author.

Main outcome(s): Efficiency and safety. For example, VAS score, constant-Murley shoulder function assessment scale.

Additional outcome(s): Imaging findings:MRI observation of frozen shoulder characteristics: coracohumeral ligament edema, swelling of inferior glenohumeral ligament, rotator cuff space edema volume, change of joint capsule thickness, etc.

Quality assessment / Risk of bias analysis:

All possible risk of bias in the included literature will be assessed independently by two authors according to the Cochrane Handbook(5.2.0) using The Review Manager(5.3.5) in the following areas: bias allocation by randomised processes hidden blinding (participant personnel results) Data outcome integrity bias Selection bias and other sources of bias reported results, such as baseline imbalance When two authors cannot reach a consensus, third party experts will be consulted to determine selection differences and make a final decision.

Strategy of data synthesis: The two authors independently selected clinical trials that met the inclusion criteria for screening, and excluded unrelated, repetitive, and non-standard studies. If complete literature was not available or the relevant data were incomplete, the corresponding author was contacted to determine selection differences by consulting third-party experts and the data was reviewed by another author.

Subgroup analysis: Subgroup analysis will be performed based on the results of data synthesis. If heterogeneity is found to be caused by specific characteristics of the included studies (such as interventions such as type time period, and measures used in clinical trials), subgroup analysis will be performed for these categories.

Sensitivity analysis: According to the recommendations of the Cochrane

Handbook, to conduct a sensitivity analysis, in order to test the stability and reliability of the results of this studyThe main analysis points included the impact of method quality, sample size, and missing data on the study. If there was no directional change after the sensitivity analysis, the results were stable.

Country(ies) involved: China.

Keywords: tuina; frozen shoulder; protocol; systematic review.

Contributions of each author:

Author 1 - Lijun Zheng - The author drafted the manuscript.

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Author 2 - Jianmin Wang - The author provided statistical expertise.

Author 3 - Shuaishuai Mi - Investigation.

Author 4 - Kai Wang - The author provided methodology Investigation.

Author 5 - Yingjie Qiao - The author provided methodology.

Author 6 - Huadong Li - The author read, provided feedback and approved the final manuscript.

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