

**Efficacy and safety of Tuina for knee osteoarthritis:
A protocol for systematic review and meta-analysis**

INPLASY2024100054

doi: 10.37766/inplasy2024.10.0054

Received: 12 October 2024

Published: 12 October 2024

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Hospital.**ADMINISTRATIVE INFORMATION****Support** - This paper is funded by National Natural Science Foundation of China(No. 81760899, 8226150627).**Review Stage at time of this submission** - The review has not yet started.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2024100054**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 October 2024 and was last updated on 12 October 2024.**INTRODUCTION**

Review question / Objective Is Tuina safe and effective in the treatment of knee osteoarthritis?

Condition being studied Knee osteoarthritis (KOA) is the most common chronic osteoarthritis disease. Cartilage damage is the main tissue affected by KOA and may lead to subsequent symptoms including joint pain, joint swelling, stiffness, and reduced range of motion. It is the most common cause of chronic pain and fall disability in middle-aged and older adults.

METHODS

Participant or population Patients with a definite diagnosis of KOA, regardless of age, sex, or geography.

Intervention Tuina as the only study of experimental intervention. It also includes other similar Tuina interventions such as Massage, Chinese Tuina, Chinese Massage, Traditional Chinese medicine massage, etc.

Comparator Drug therapy, physiotherapy, behavioral therapy and no treatment, acupuncture or placebo will be included.

Study designs to be included All randomized controlled trials (RCTs) will be included on Tuina in the treatment of KOA, with no language restrictions. Observational studies, case-control studies, laboratory studies, literature presentations, cohort studies, and case series will be excluded.

Eligibility criteria Observational studies; laboratory studies; case studies; literature presentations; and cohort studies; secondary knee OA, such as trauma and rheumatism; It is not possible to extract relevant data from published

results; The original data is not available after the authors are contacted.

Information sources We will search articles in the following electronic databases: PubMed, Embase, Wan-fang Database, and the Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Web of Science, the Cochrane Library, Chinese Scientific Journal Database (VIP), and 1 clinical trials register platform: WHO International Clinical Trials Registry Platform.

Main outcome(s) Clinical effectiveness, Visual analogue scale, Incidence of any adverse events.

Additional outcome(s) Western Ontario and McMaster Universities Osteoarthritis Index.

Quality assessment / Risk of bias analysis The bias risk of the included studies will be assessed by two independent reviewers (Yujie Su and Qidong Tian) using the assessment tool of Cochrane Reviewer Handbook 5.0.24. The assessment included risk of bias in the following domains: blinding of personnel and outcome assessors, allocation sequence generation, incomplete information, allocation sequence concealment, outcome selective reporting, outcome data, and other sources of data bias. It is assessed on 3 levels: low risk, high risk, and unclear risk. We will contact the appropriate author to query for unclear items and get the details. Dissenting data will be resolved through experts (Jian Ai and Chunlin Wang) consultation or inter-investigator discussions.

Strategy of data synthesis Measures of treatment effect.

Data statistics will be performed using RevManV.5.3.0 software for data analysis and quantification. For dichotomous data, we will use a risk ratio analysis with 95% confidence intervals (95% CI). We will use mean difference or standardized mean difference with 95% CI to analysis continuous data, and for fewer than 2 studies, we will describe the results with descriptive analysis.

Heterogeneity analysis.

We will test heterogeneity with the χ^2 test. Assess the data with a fixed-effect analysis model if the heterogeneity of the studies was smaller ($P > .05$, $I^2 < 50\%$), and assess with random-effects model analysis if heterogeneity was high ($P \leq .05$, $I^2 \geq 50\%$). Publication bias will be assessed using funnel plots and Begger test.

Subgroup analysis If the data are reliable and sufficient, the following subjects will be analyzed in subgroups: age, study quality, duration of treatment, intervention in the study group, control group, etc.

Sensitivity analysis To verify the robustness of the assay results, we will perform a sensitivity analysis. Sensitivity analyses will be performed for the following decision points: missing data results, sample size, and methodological quality. Duplicate analyses will be performed after low-quality studies were excluded.

Language restriction No language restriction.

Country(ies) involved China.

Keywords randomized controlled trial, KOA, Tuina, protocol, meta-analysis.

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