INPLASY PROTOCOL

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Conflicts of interest: None declared.

The effects on pain and quality of life of traditional Chinese manual therapy for knee osteoarthritis: a protocol for systematic review and meta-analysis

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Review question / Objective: The current systematic review and meta-analysis will be conducted to assess the effects on pain and quality of life of traditional Chinese manual therapy for KOA.

Condition being studied: Knee osteoarthritis (KOA) is a common disease with the high occurrence in the world. The symptom of pain and dysfunction decrease quality of life in KOA patients. Some studies reported traditional Chinese manual therapy show beneficial effects improving pain and dysfunction of patient with KOA, but the effect of traditional Chinese manual therapy for KOA remain controversial. Most previous reviews did not focus on the effect on quality life of traditional Chinese manual therapy for KOA. However, better quality of life is important for patients suffering chronic pain due to KOA.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2021 and was last updated on 08 December 2021 (registration number INPLASY2021120043).

INTRODUCTION

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METHODS

Participant or population: Patients with KOA will be included in this study regardless of sex, age, race or severity and duration of disease. chinesespeaker.

Intervention: Studies applied traditional Chinese manual therapy in the experimental group will be included.

Comparator: The control group will include pharmacological, physical, behavioral, joint injections, assistive devices, joint replacement surgery or acupuncture therapy.

Study designs to be included: Randomized controlled trials (RCTs) of traditional Chinese manual therapy for KOA will be include in this review, whether or not the expression "randomization" is mentioned with the randomization methods. Other study such as case report, theoretical or basic research, retrospective studies will be excluded. Language will be restricted to Chinese and English.

Eligibility criteria: Studies applied traditional Chinese manual therapy in the experimental group will be included. The control group will include pharmacological, physical, behavioral, joint injections, assistive devices, joint replacement surgery or acupuncture therapy.

Information sources: We will search the following databases, include PubMed, Embase, the Cochrane Library, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), WanFang Data (Wan fang), Chinese Scientific Journal Database (VIP). We will search above electronic databases from the beginning to January 2021.Once any disagreement occurs during the screening process, it will be resolved through discussion and consensus between the 2 researchers or by consulting a third party arbitrator.

Main outcome(s): Primary outcome. The quality of life will be measured by The 36item Short Form Health Survey (SF-36).The symptom will be measured by Visual Analog Scale (VAS).

Additional outcome(s): Secondary outcomes. The functional outcomes will be measured by the he Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Quality assessment / Risk of bias analysis: The quality assessment for each RCT will be assessed independently by 2 reviewers using the Cochrane Collaboration Risk of Bias Tool checklist. The tool assesses the methodological quality from seven aspects: random sequence generation, allocation sequence concealment, blinding of personnel and outcome assessors, blinding of outcome assessment, incomplete outcome data, selective reporting of outcomes, and other sources of data bias. Considering these areas, each trial will be divided into 3 levels: low risk, high risk and unclear risk. Any disagreement will be discussed with the third author to achieve consensus.

Strategy of data synthesis: Meta analysis will be performed using Rev Man5.3.0 software. For continuous data, the mean difference (MD) and the corresponding 95% confidence interval (CIs) will be used. In addition, we will use standardized mean differences (SMDs) if necessary. For dichotomous data (eg, number of patients during trial follow-up and adverse events), we will use the risk ratio (RR)and the corresponding 95% CIs. Other dichotomous data will be converted to RR values.

Subgroup analysis: Subgroup analysis will be performed to assess the heterogeneity of the research: (1) degree of disease. (2) different acupuncture points for Traditional Chinese manual therapy. (3) different types of manipulation.

Sensitivity analysis: Sensitivity analysis is an important method primarily used to assess the robustness and reliability of the combined results of meta-analysis. This evaluation refers to sensitivity analyses.

Language: English.

Country(ies) involved: China.

Keywords: KOA, meta-analysis, protocol, traditional Chinese manual therapy, quality of life.

Contributions of each author:

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