INPLASY PROTOCOL

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Conflicts of interest: **No.**

Effectiveness and safety of massage for knee osteoarthritis: A protocol for systematic review and meta-analysis

Qin, S[1]; Xiao, Y[2]; Jiao, L[3].

Review question / Objective: **This study comprehensively searched the literature to further systematically evaluate the efficacy and safety of massage for knee osteoarthritis, with a view to clinically treating patients with knee osteoarthritis, alleviating its related clinical symptoms and preventing its further development, and providing the latest evidence-based medical evidence.**

Condition being studied: **Knee osteoarthritis (KOA) is complex chronic arthritis, characterized by focal loss of articular cartilage, marginal and central new bone formation. Approximately 35% of women and men aged 60 years and above have KOA and nearly half of these people have symptoms, affecting 9 million individuals in the United States. Patients often face either surgical interventions or the burden of debilitating joint pain, weakness, and loss of function if symptoms cannot be effectively managed. While physicians generally recommend pharmacotherapy for osteoarthritis, concerns over its limited effectiveness and associations with adverse events are growing. Collectively, these concerns have reduced public confidence in use of pharmaceuticals for osteoarthritis and increased interest in therapies perceived to be safer. The need for additional safe and effective treatments for KOA is clear. Massage is a Chinese nursing intervention that can effectively relieve pain and stiffness in patients with osteoarthritis of the knee, but there is no objective systematic evaluation of the efficacy reported in different literatures. This study aims to evaluate the clinical efficacy of massage in treating osteoarthritis of the knee through meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 August 2020 and was last updated on 27 August 2020 (registration number INPLASY202080115).

INTRODUCTION

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METHODS

Search strategy: 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database. The retrieval time was from the time the database was built to August 1, 2020. The search uses the keyword search. Chinese search terms include Osteoarthritis of the Knee, Knee Osteoarthritis, Osteoarthritis of the Knee, Massage, tuina, random. English search terms include "Osteoarthritis, Knee" and "Massage or Massage Therapy ".This study does not limit the scope of language retrieval. In addition, we manually searched other literature, as well as unpublished research and conference materials. If the test report data is unknown or lacking, we will contact the author by email.

Participant or population: All cases included in the trial were patients with knee osteoarthritis and met the clinical diagnostic criteria of knee osteoarthritis, without age and race restrictions.

Intervention: The treatment group was mainly massage therapy. The comparison group consisted of those receiving routine care or any intervention other than massage therapy.

Comparator: All cases included in the trial were patients with knee osteoarthritis and met the clinical diagnostic criteria of knee osteoarthritis, without age and race restrictions.

Study designs to be included: A randomized controlled trial(RCT) study on massage for knee osteoarthritis, published in any language.

Eligibility criteria: Types of study:All randomized controlled trials (RCTs) study on massage for knee osteoarthritis. Others such as case reports, animal experiments, non-RCTs, or RCT protocol will be excluded.

Information sources: 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database.

Main outcome(s): The Western Ontario and McMaster Universities Osteoarthritis Index scale(WOMAC).

Additional outcome(s): Visual Analogue scale (VAS); Symptom score; Lysholm score; Adverse events.

Data management: Two reviewers independently screened the literature, extracted the data, and cross-checked. If there were differences, they would discuss or listen to a third party to resolve them. The extracted data mainly include: basic characteristics: author, year of publication, sample size, age, gender, intervention measures, course of treatment, outcome indicators, follow-up, etc. ? methodological characteristics: random allocation method, random scheme concealment, blind method, etc.

Quality assessment / Risk of bias analysis: Two reviewers performed rigorous methodological quality evaluation of the included studies with reference to the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features.

Strategy of data synthesis: Meta analysis was performed using RevMan5.3 provided by the Cochrane collaboration network. Relative risk (RR) was used for the two categorical variables, and mean difference (MD) was used for the continuous variables. Both were expressed with 95% confidence intervals (CI). The heterogeneity test between the results of the included studies was performed using the I^2 test. The I^2 value reflects the proportion of the total variation in the effect size due to the existence of heterogeneity. I^2 ? 50%, indicating that heterogeneity is more obvious. If there is no obvious heterogeneity between the research results (I^2 <50%), the fixed effect model is used to merge them; if there is significant heterogeneity (I^2?50%), the source of the heterogeneity is analyzed first, which may lead to heterogeneity Factors for subgroup analysis. If statistical heterogeneity exists in each subgroup without clinical heterogeneity, a random effects model is used for analysis. If the heterogeneity is too large and the results cannot be combined, a descriptive analysis is used and a sensitivity analysis is performed if necessary.

Subgroup analysis: Subgroup analysis will be handled according to the differences in massage methods, patient conditions, and control.

Sensibility analysis: Sensitivity analyses will be performed to verify the robustness of the review conclusions. The impacts of study design, methodological quality, and missing data will be evaluated. Sensitivity analyses were planned by studies considered being at low risk of bias.

Country(ies) involved: China.

Keywords: Massage, knee osteoarthritis, meta-analysis, systematic review.

Contributions of each author:
Author 1 - Siyu Qin - Author 1 drafted the manuscript.
Author 2 - Yuanyi Xiao - The author provided statistical expertise.
Author 3 - Lin Jiao - The author provided funding and guidance.