

INPLASY PROTOCOL

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None declared.

Thermotherapy for knee osteoarthritis: a systematic review protocol

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Chen, D⁸; Shao, Z⁹; Ren, C¹⁰; Xu, J¹¹.

Review question / Objective: Osteoarthritis of the knee is one of the leading causes of pain and disability among adults. Thermotherapy has been widely used to treat KOA. But its efficiency has not been scientifically and methodically evaluated. The aim of this study is to assess the benefits of thermotherapy for people with osteoarthritis of the knee, in terms of pain, stiffness, and physical dysfunction.

Condition being studied: Thermotherapy is the application of heat to the body resulting in increased tissue temperature. Techniques for thermotherapy include the application of Moxibustion, hot packs, superficial heat, and via diathermy (application of electromagnetic energy). Thermotherapy is used in rehabilitation to reduce pain and stiffness, and to increase mobility. Thermotherapy helps to relax muscles and increase circulation to the affected area, thus reducing pain and stiffness, although there is some concern that this may, in turn, worsen inflammation and edema. Thermotherapy can be selfapplied easily by the patient at home (such as the use of heat packs), and may also be combined with other rehabilitation interventions. There is only one review paper of thermotherapy in the treatment of knee osteoarthritis nearly 10 years ago. Since only 3 articles with more than 20 years have been included, there have been reports in recent years that different forms of thermotherapy have been widely used in clinical practice. It has been used to treat knee osteoarthritis and has achieved significant results, especially a kind of thermotherapy called moxibustion, which is commonly used in Chinese hospitals.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2021 and was last updated on 07 April 2021 (registration number INPLASY202140038).

INTRODUCTION

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METHODS

Search strategy: Eight databases will be searched from their inception to September 2020. They are as follows: PubMed, Embase, Cochrane Library, ClinicalTrials.gov, China Knowledge Resource Integrated Database (CNKI), Weipu Database for Chinese Technical Periodicals (VIP), Chinese Biomedical Literature Database (CBM), and Wanfang Database. There will be no limitation to study publication status or language. The search terms include KOA, gonarthrosis, osteoarthrosis, osteoarthropathy, arthralgia, thermotherapy, diathermy, heat therapy, Moxibustion, and RCTs. The equivalent search words will be used in the Chinese databases.

Participant or population: We will include participants with osteoarthritis of the knee (as defined by the study). There will also be no limitations related to age, sex, disease duration, and disease severity.

Intervention: Interventions using thermotherapy only were included in this review.

Comparator: Trials that compared thermotherapy with standard treatment and/or placebo were included. Thermotherapy with another active therapy versus the same therapy alone will also be investigated. Trials comparing head to head therapies, such as two different types of diathermy, were not included in this review.

Study designs to be included: All RCTs of thermotherapy for KOA without publication status restriction or writing language. Non-RCTs, quasi-RCTs, uncontrolled trials, reviews, case-controlled studies, animal trials, and laboratory studies will be excluded.

Eligibility criteria: For continuous data, a mean difference or standardized mean difference with 95% confidence intervals will be applied. For dichotomous outcome data, the risk ratio with 95% confidence intervals will be used to evaluate the treatment effect.

Information sources: Before data extraction, a standard form will be prepared for data collection. Two researchers will independently extract data of the included studies and write on the form. Any disagreement will be solved by consensus. The following data will be extracted: the first author, publication year, participants characteristics, interventions, duration of treatment, follow-up, outcome assessment, research results, adverse events, and other detail information. We will contact the original author for complete information when necessary.

Main outcome(s): The primary outcome is Western Ontario and McMaster Universities osteoarthritis index (WOMAC). WOMAC is a

self-report questionnaire for OA of the hip or knee, with higher scores indicating more serious pain, poorer physical function, and increased stiffness. It has been widely used as a tool by clinical investigators to assess patients with KOA.

Additional outcome(s): Lequesne index and Medical Outcomes Study Short Form 36 health survey will be accepted as the secondary outcomes.

Quality assessment / Risk of bias analysis: Assessment of risk of bias. Two researchers will assess the risk of bias of included studies independently according to the Cochrane collaboration's tool. The tool comprise 7 aspects which are random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete outcome data, and selective reports. Every risk of bias will be classified as low, unclear, and high.

Strategy of data synthesis: We plan to pool outcomes from trials with similar characteristics (participants, interventions and common comparators, outcome measures and timing of outcome measurement) to provide estimates of benefit and harm. We plan to synthesize effect estimates using a random-effects meta-analysis model based on the assumption that clinical diversity is likely to exist, and that different studies are estimating different intervention effects. Where we cannot pool data, we plan to present effect estimates and 95% CIs of each trial in tables, and summarize the results in text.

Subgroup analysis: If there is a significant heterogeneity in the included studies, subgroup analysis will be performed to detect the substantial heterogeneity based on the severity of KOA and types of thermotherapy.

Sensitivity analysis: Sensitivity analysis. When there are sufficient studies, sensitivity analysis will be performed to assess the robustness of studies according

to methodological quality, sample size, and missing data.

Country(ies) involved: China.

Keywords: Thermotherapy, knee osteoarthritis, protocol, systematic review.

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