

INPLASY PROTOCOL

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The authors declare no conflicts of interest.

Efficacy and safety of thunder-fire moxibustion for patients with Knee Osteoarthritis: protocol of a systematic review and meta-analysis

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Review question / Objective: To evaluate the efficacy and safety of thunder-fire moxibustion for Knee Osteoarthritis.
Condition being studied: Knee Osteoarthritis is a progressive joint disease characterized by cartilage degeneration, subchondral bone remodeling, and secondary inflammation of the synovial membrane. The clinical presentation combines pain and joint stiffness responsible for functional impairment. It is the most prevalent chronic joint disease, Osteoarthritis of the knee increases in prevalence with age, with about 10% of individuals older than 60 years being affected worldwide and is more common in women than in men. Risk factors include obesity, knee injury, previous knee surgery, and occupational bending and lifting.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 October 2020 and was last updated on 05 October 2020 (registration number INPLASY2020100012).

INTRODUCTION

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Condition being studied: Knee Osteoarthritis is a progressive joint disease characterized by cartilage degeneration, subchondral bone remodeling, and secondary inflammation of the synovial membrane. The clinical presentation

combines pain and joint stiffness responsible for functional impairment. It is the most prevalent chronic joint disease, Osteoarthritis of the knee increases in prevalence with age, with about 10% of individuals older than 60 years being affected worldwide and is more common in women than in men. Risk factors include obesity, knee injury, previous knee surgery, and occupational bending and lifting.

METHODS

Participant or population: Patients with osteoarthritis of the knee.

Intervention: Thunder-fire moxibustion, or thunder-fire moxibustion with other traditional Chinese medicine treatments.

Comparator: Routine acupuncture, Western medicine, placebo, sham acupuncture, no treatment, or any combination of these.

Study designs to be included: Randomized controlled trials (RCTs) which assessed the efficacy and safety of thunder-fire moxibustion for knee osteoarthritis will be included.

Eligibility criteria: Subjects: patients with osteoarthritis of the knee, age and sex were not restricted. Intervention measures: Thunder-fire moxibustion, or thunder-fire moxibustion combined with other traditional Chinese medicine treatments were used as the intervention measures in the treatment group, while conventional were used other therapy like routine acupuncture, western medicine, placebo, sham acupuncture, or any combination of these as the intervention measures in the control group Outcome measures: the visual analogue scale (VAS), WOMAC scores, Numerical Rating Scale, Lysholm knee scoring scale.

Information sources: Pubmed, EMBASE, Cochrane Library, Chinese Biomedical Literatures Database (CBM), China National Knowledge Infrastructure (CNKI),

WangFang Database (WF), Chinese Scientific Journal Database (VIP).

Main outcome(s): The Visual Analogue Scale (VAS), WOMAC scores.

Additional outcome(s): Numerical Rating Scale, Lysholm knee scoring scale.

Quality assessment / Risk of bias analysis: Quality assessment: According to the improved Jadad scoring scale, the quality of the included literature was evaluated. 1-3 were classified as low quality and 4-7 as high quality. Risk of bias (quality) assessment: Included randomized studies will be assessed for risk of bias by two independent raters (HQT/JYF) using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Any disagreements will be resolved through discussion or consultation with a third reviewer (XJ).

Strategy of data synthesis: RevMan 5.4 software (Cochrane Collaboration) was used for the meta-analysis. Dichotomous data were reported as risk ratio (RR) with 95% confidence intervals (CI), while continuous data were reported as standardized mean difference (SMD) with 95% CIs. The Higgins I^2 test was used to test heterogeneity with a significance level set at 50%. If heterogeneity was not significant ($I^2 \leq 50\%$), the fixed effects model was used for meta-analysis. Otherwise, the random effects model was used ($I^2 \geq 50\%$). If possible, we investigated the potential explanations for heterogeneity and conducted subgroup analysis.

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows: 1. Control interventions (eg, sham/placebo acupuncture, massage, no treatment, or non-TCM treatment). 2. Outcome indicators (eg, Numerical Rating Scale, Lysholm knee scoring scale).

Sensibility analysis: Sensibility analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one

study at a time to confirm that the findings were not influenced by any single study.

Country(ies) involved: China.

Keywords: Knee Osteoarthritis, Thunder-fire moxibustion, protocol, systematic review, Meta-analysis.

Contributions of each author:

Author 1 - Qiaotong Huang - The author drafted and improved the manuscript.

Author 2 - Yunfeng Jiang - The author provided statistical expertise.