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Clinical efficacy and safety of Traditional Chinese Medicine Fumigation for knee osteoarthritis

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ADMINISTRATIVE INFORMATION

Support - Shidong Hospital Affiliated to University of Shanghai for Science and Technology.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 June 2025 and was last updated on 7 June 2025.

INTRODUCTION

Review question / Objective P:patients diagnosed with knee osteoarthritis; I:Traditional Chinese Medicine Fumigation; C:Western medicine(e.g.,Diclofenac Diethylamine); O:curative effect(VAS score,stiffniss,the activity of daily living score,etc); S:randomized controlled trials.

Condition being studied Knee osteoarthritis is a chronic osteoarthropathy caused by knee cartilage degeneration and secondary hyperosteogeny. Clinically, most manifestations are knee swelling, pain and limited activity, which seriously affect the function of daily life.

METHODS

Search strategy Fumigation and washing,Knee osteoarthritis,Traditional Chinese medicine treatment

Pubmed, EMBASE, Cochrane Library, CNKI ,WANFANG, and VIP (from January 2010 to December 2024)
The search is limited to articles published in the Chinese and English languages.

Participant or population Patients diagnosed with knee osteoarthritis who met the following inclusion criteria:(1) American College of Rheumatology of KOA, (2) Chinese Society of Orthopedics confirmed of KOA.

Intervention Traditional Chinese Medicine Fumigation.Treatment duration of at least 2 weeks, and the detailed operation process during the treatment exactly recorded, such as time, temperature, frequency.

Comparator Western medicine(including all kinds of anti-inflammatory and analgesic drugs ,oral or external application).

Study designs to be included Randomized controlled trials（RCTs).

Eligibility criteria Inclusion criteria: (1) American College of Rheumatology of KOA, (2) Chinese Society of Orthopedics confirmed of KOA. (3) Being a randomized controlled trial with either a parallel or cross-over design, (4) Trials were required to report at least one of the following outcomes: Visual Analog Scale (VAS) of pain or the Western Ontario and McMaster Universities (WOMAC) arthritis index, or Hospital for Special Surgery knee score (HSS),or American Knee Society knee score(KSS),Lysholm.(5)Treatment duration of at least 2 weeks, and the detailed operation process during the treatment exactly recorded,such as time,temperature,frequency.
Exclusion criteria： (1) non-interventional trials, (2) Because we were interested in evaluating single therapy,so combination therapy were excluded,(3) observational studies with case–control, cross-sectional or cohort design, and (4) lack of sufficient information to analyse.

Information sources Pubmed, EMBASE, Cochrane Library, CNKI ,WANFANG, and VIP (from January 2010 to December 2024).

Main outcome(s) Efficiency, Visual Analog Scale (VAS) of pain or the Western Ontario and McMaster Universities (WOMAC) arthritis index, or Hospital for Special Surgery knee score (HSS),or American Knee Society knee score(KSS),Lysholm.

Quality assessment / Risk of bias analysis RCTs:Cochrane risk of bias 2.0, conducted independently by two reviewers,disagreements were resolved by third reviewer.

Strategy of data synthesis Review Manager Software for windows(Version 5.2.Copenhagen:The Nordic Cochrane Centre, The Cochrane Collaboration) to perform the meta-analysis.

Subgroup analysis Subgroups are defined in terms of judgements for different details of treatment options.
Subgroup analysis is performed through RevMan(Cochrane tool)to explore the source of heterogeneity when heterogeneity existed.

Sensitivity analysis Between-trial heterogeneity is assessed using the I^2 statistic; values higher than 50% are considered to indicate substantial heterogeneity. While I^20.1, we use a fixed-effects model to evaluate, otherwise, a random-effects is used.

Language restriction Chinese and English.

Country(ies) involved China.

Keywords Fumigation and washing;Knee osteoarthritis;Traditional Chinese medicine treatment;Meta analysis;Non steroidal anti-inflammatory drugs.

Contributions of each author
Author 1 - HuiPing Lu - Drafted the manuscript. also conceptualization and data curation.
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