INPLASY PROTOCOL

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Conflicts of interest: **None.**

Lateral Wedge Insoles for Reducing Biomechanical Risk Factors for Medial Knee Osteoarthritis after a period of time: a meta-analysis of controlled randomized trials

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ABSTRACT

Review question: **What are the biomechanical effects of lateral wedge insoles in people with knee osteoarthritis after a period of time?**
Condition being studied: **Knee osteoarthritis.**
Information sources: **Randomized control studies investigating the use of lateral wedge insoles in reducing the biomechanical risk factors among patients with knee OA were searched from databases including PubMed, Embase, Web of Science, Cochrane library and MEDLINE. In addition, we also manually examined the reference lists of previously published systematic reviews on the subject of wedge insole for the treatment of KOA for pertinent studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2020 and was last updated on 29 March 2020 (registration number INPLASY202030014.

INTRODUCTION

Objectives / Review question: **What are the biomechanical effects of lateral wedge insoles in people with knee osteoarthritis after a period of time?**

Condition being studied:
Knee osteoarthritis.

METHODS

Participant or population: Patients with knee osteoarthritis.

Intervention: Inclusion: All types of lateral wedge insoles; Exclusions: Combination of interventions (e.g. taping, knee brace, and other types of insole).

Comparator: Without lateral-wedge insole treatment.

Study designs to be included: RCT's.

Eligibility criteria: (1) randomized controlled trial with a lateral-wedge insole treatment group and control (without lateral-wedge insole treatment) group; (2) participants must be diagnosed with KOA based on X-ray examination; (3) outcomes should include the first peak EKAM, and the KAAI. As this review was focuses on the biomechanical effects after continuous wearing of LWI, those articles that have not undergone this process will be excluded.

Information sources: Randomized control studies investigating the use of lateral wedge insoles in reducing the biomechanical risk factors among patients with knee OA were searched from databases including PubMed, Embase, Web of Science, Cochrane library and MEDLINE. In addition, we also manually examined the reference lists of previously published systematic reviews on the subject of wedge insole for the treatment of KOA for pertinent studies.

Main outcome(s): EKAM and KAAI. The difference in mean changes of EKAM and KAAI from baseline to follow up between patients receiving lateral-wedge therapy and control treatment.

Quality assessment / Risk of bias analysis: Two authors (HXM, YZX) extracted data independently and then cross-checked the data. Authors extracted the following data using a predefined information sheet: the first author's name, year of publication, country, population characteristics, intervention, and the time point. We contacted the authors of the original study to obtain more data when necessary. In this review, we use the Cochrane risk bias tool to assess the risk of bias in randomized controlled trials following key criteria: sequence generation, allocation concealment, blinding, incomplete outcome data addressed, selective outcome reporting, and other bias. The judgment of the bias risk of this item was completed by judging as "low", "high ", and "unclear ". Two authors independently assessed risk of bias of the included studies. The review authors discussed or referred to the opinion of a third independent review author to resolve any disagreements.

Strategy of data synthesis: Meta-analysis used Review Manager (RevMan) software (version 5.3, Cochrane Collaboration) to combine data from the eligible studies. The contribution of the effect sizes depended on the sample size and their accuracy of the estimates.

Sensibility analysis: If sensitivity analysis is necessary we will do it.

Subgroup analysis: Subgroup analysis was stratified by the treatments of control groups in the studies to explore the source of heterogeneity.

Language: English.

Keywords: OA; LWI; EKAM; KAAI.

Contributions of each author:

Author 1 - Literature Search; Data Collection and Quality assessment ; Statistical Analysis; Write the article.

Author 2 - Literature Search; Data Collection and Quality assessment ; Statistical Analysis; Write the article.

Author 3 - Literature Search; Data Collection and Quality assessment.