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ADMINISTRATIVE INFORMATION**Support** - N/A.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202470051**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 July 2024 and was last updated on 12 July 2024.**INTRODUCTION**

Review question / Objective The objective of this study was to systematically assess the effectiveness of the combined therapy for KOA and to furnish clinical evidence supporting its use in treatment.

Condition being studied Needle-knife therapy (NKT) directly alleviates knee joint pain and stiffness, while Chinese herbal medicine (CHM) aids in the regulation of systemic functions and the mitigation of various symptoms. This integrated approach is theoretically appropriate for the treatment of knee osteoarthritis (KOA).

METHODS

Participant or population Subjects: Patients suffering from KOA are eligible, with no restrictions on age or duration of the disease course.

Intervention Intervention: The intervention group received treatment combining needle knife therapy

with Chinese herbal medicine, whereas the control group only received needle knife therapy.

Comparator Nine randomized controlled trials, involving 880 patients, reported on the clinical efficacy of needle knife therapy combined with Chinese herbal medicine in treating knee osteoarthritis (KOA).

Study designs to be included Research Type: Randomized Controlled Clinical Trial.

Eligibility criteria**2.2 Eligibility criteria**

The literature inclusion criteria were as follows:

(1) Research Type: Randomized Controlled Clinical Trial.

(2) Subjects: Patients suffering from KOA are eligible, with no restrictions on age or duration of the disease course.

(3) Intervention: The intervention group received treatment combining needle knife therapy with Chinese herbal medicine, whereas the control group only received needle knife therapy.

The literature exclusion criteria were as follows:

- (1) Studies that were duplicates or had incomplete data.
- (2) Animal experiments, conference proceedings, abstracts, reviews, or case reports.

Information sources We accessed pertinent articles from PubMed, Medline, Embase, Wanfang, and the China National Knowledge Network (CNKI) from their inception up to February 18, 2023. Our search strategy involved a combination of subject headings and free-text terms, using keywords such as 'Needle Knife,' 'Small Needle Knife,' 'Therapy,' 'Treatment,' 'Chinese Herbal Medicine,' 'Osteoarthritis of Knee,' 'KOA,' and 'Knee Osteoarthritis.'

Main outcome(s) Clinical efficacy and VAS score.

Quality assessment / Risk of bias analysis The screening process was conducted by two authors independently, who applied the predefined inclusion and exclusion criteria. They subsequently cross-verified their findings to ensure accuracy. In instances of discrepancies, a third researcher was consulted to resolve and harmonize the differences. Data extraction entailed recording information such as author names, publication years, sample sizes, participants' ages, interventions, treatment durations, and outcome measures. The methodological quality of the included studies was evaluated using the Cochrane Handbook quality assessment tool.

Strategy of data synthesis RevMan version 5.3 was utilized to perform this meta-analysis. Mean differences (MD) with their 95% confidence intervals (CIs) were employed as effect sizes for representing continuous variable data. Relative risk ratios (RR) along with their 95% CIs were used to illustrate dichotomous variables. Heterogeneity across study outcomes was assessed via the χ^2 and I² tests. A significance level of $P < 0.05$ was criterion for establishing statistical significance between the intervention and control groups.

Subgroup analysis Subgroup analysis is a statistical method used to examine the effects of a particular treatment, intervention, or phenomenon within specific subgroups of a larger population. In other words, it involves breaking down the data into smaller, more defined groups based on certain characteristics or criteria to see if there are any differences in the results or impacts on these subsets of the population.

Sensitivity analysis Sensitivity analysis is a statistical technique used to understand how the

results of a model or study respond to changes in its assumptions or inputs. It is commonly used in a variety of fields, including economics, engineering, environmental science, and medicine, to assess the robustness of results and to identify which inputs or assumptions have the most significant impact on the outcome.

The basic idea behind sensitivity analysis is to vary one or more input variables within a specified range and observe how this affects the output or results of the model. By doing this, researchers can determine which variables have the most influence on the outcome and thereby gain a better understanding of the model's reliability and the potential for error.

Country(ies) involved China.

Keywords Needle-knife therapy; Chinese herbal medicine; Knee osteoarthritis; efficacy; Meta-analysis.

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