

INPLASY PROTOCOL

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None declared.

Which of the Acupuncture Treatment Regimen for Lumbar Disc Herniation is more Effective and Safer: A protocol for systematic review and network meta-analysis

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Review question / Objective: As the most common cause of lower back pain, lumbar disc herniation (LDH) seriously affects people's lives and work. Although many clinical trials and medical reports from ancient and modern times have shown that acupuncture treatments are effective for LDH, the comparative effectiveness of these different forms of acupuncture therapies is still unclear. This study will provide a protocol of network meta-analysis (NMA) to compare the effects and safety of acupuncture treatment regimen on LDH, using both direct and indirect evidence.

Condition being studied: Lumbar disc herniation.

Information sources: PubMed, Embase, the Cochrane Library, Web of Science, the Chinese Biomedical Literature Database(CBM), Chinese National Knowledge Infrastructure (CNKI), Wan Fang, and VIP. Trial registry platforms: ClinicalTrials.gov and the Chinese Clinical Trial Registry.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 February 2021 and was last updated on 24 February 2021 (registration number INPLASY202120077).

INTRODUCTION

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ancient and modern times have shown that acupuncture treatments are effective for LDH, the comparative effectiveness of these different forms of acupuncture therapies is still unclear. This study will provide a protocol of network meta-analysis (NMA) to compare the effects and

safety of acupuncture treatment regimen on LDH, using both direct and indirect evidence.

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METHODS

Search strategy: PubMed, Embase, the Cochrane Library, Web of Science, the Chinese Biomedical Literature Database(CBM), Chinese National Knowledge Infrastructure (CNKI), Wan Fang, and VIP. Trial registry platforms: ClinicalTrials.gov and the Chinese Clinical Trial Registry. The timeframe for searching literature covers the period from the establishment of the database to 1 December 2020. Publication in Chinese and English only.

Participant or population: The study will enroll adults who have been diagnosed with LDH by computed tomography CT or magnetic resonance imaging (MRI). Trials with unclear diagnostic criteria will be excluded.

Intervention: Acupuncture therapies for LDH, which includes manual acupuncture, appoint catgut embedding, acupoint herb application, warm acupuncture and moxibustion, fire needle, and so on.

Comparator: Medications, surgery, and exercise therapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Randomized controlled trials published in Chinese or English will be included. Less than 30 experimental cases in a single group. Literature review and duplicate studies will be excluded.

Information sources: PubMed, Embase, the Cochrane Library, Web of Science, the Chinese Biomedical Literature Database(CBM), Chinese National Knowledge Infrastructure (CNKI), Wan Fang, and VIP. Trial registry platforms:

ClinicalTrials.gov and the Chinese Clinical Trial Registry.

Main outcome(s): Verbal rating scale (mm) and functional disability.

Data management: Two reviewers will independently extract parameters from the applicable study, including identifying information (the first author and year of publication), essential characteristics (country, language, number of study centers, total sample size), participants (age, gender), diagnostic indicators, relevant quality assessment indicators (random sequence generation method, allocation hiding method, blinding, completeness of outcome data, presence of selective publication, other biases) interventions (type of acupuncture, frequency/treatment/time), control treatment measures (including name, dose, frequency, and duration), and outcome measures (good data and time points per measurement or follow-up, adverse effects).

Quality assessment / Risk of bias analysis: The overall quality of evidence is evaluated by GRADEPro software, and Cochrane Collaboration Risk of Bias Tool is employed for the methodological quality.

Strategy of data synthesis: The heterogeneity of each pair-wise comparison will be tested by the χ^2 test (test level $\alpha=0.1$). If there is no heterogeneity, a fixed-effect model will be used. If there is significant heterogeneity between a set of studies, we will use a random-effects model (REM) for meta-analysis. We will explore the reasons for the existence of heterogeneity from various aspects such as the characteristics of the subjects and the degree of variation of the interventions. The source of heterogeneity is further determined by means of sensitivity analysis. We will perform a network meta-analysis using the package "netmeta" (version 0.5-0) from R (version 4.0.2), which uses the analogy between the treatment network and the electrical network to construct an NMA model that accounts for the relevant treatments in a

multi-arm trial Effect. The main analysis will be based on a network of treatment methods that will be constructed to compare the effects of different acupuncture protocols. The package "igraph" will be executed to visualize the network. The risk of bias assessment will use the package "fmsb." to display the results, and the package "ggplot2" will be executed to visualize the ranked probability distribution. We will perform a sensitivity analysis to calculate 95% confidence intervals.

Subgroup analysis: We will perform subgroup analyses to identify evidence for different forms of acupuncture (electroacupuncture, warm acupuncture, fire acupuncture, etc.), different treatment durations (long or short term), or different types of outcome data (post-treatment or pre-treatment versus post-treatment differences). Blinding (open trials, single-blinded volunteers, double-blinded volunteers and investigators), quality of evidence (low risk, high risk, unclear risk), and age of volunteers will also be included. In addition, treatment duration and combination therapy (acupuncture alone or acupuncture with other treatments) will be considered. We will quantify the differences between subgroups and test for statistical significance by conducting subgroup analysis through meta-regression models.

Sensitivity analysis: First, RevMan5.4.1 will be used to pool the data. We will test the heterogeneity of the included experimental studies. The heterogeneity of each pairwise comparison will be tested by the chi-square test (significance level $\alpha=0.1$). If $I^2 \leq 50\%$, there is no heterogeneity, and a fixed-effects model will be used. If $I^2 \geq 50\%$, significant heterogeneity exists among the studies in the group, and we will use a random-effects model for the meta-analysis. We will explore the reasons for the existence of heterogeneity in terms of the demographic characteristics of the subjects, the degree of variation in the interventions, and other factors. A sensitivity analysis will also be used to identify the sources of heterogeneity.

Language: Chinese.

Country(ies) involved: China.

Keywords: Lumbar disc herniation; acupuncture; network meta-analysis; protocol.

Contributions of each author:

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