

INPLASY PROTOCOL

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The authors have no conflict of interest to disclose.

Traditional Chinese medicine fumigation as auxiliary treatment of diabetic peripheral neuropathy A protocol for systematic review and meta-analysis

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Review question / Objective: We aim to systematically review the effectiveness and safety of traditional Chinese medicine fumigants for diabetic peripheral neuropathy.

Condition being studied: Diabetic peripheral neuropathy is one of the most common complications of diabetes, and about half of diabetic patients will be affected. It can lead to foot infections and even severe consequences of amputation. This is usually a heavy burden for the healthcare system and patients. However, there is no safe and effective clinical treatment for diabetic peripheral neuropathy. Clinical practice shows that traditional Chinese medicine fumigants can improve the symptoms of diabetic peripheral neuropathy and increase nerve conduction speed. The purpose of this study is to provide a high-quality comprehensive evaluation of the efficacy and safety of traditional Chinese medicine fumigants in the treatment of diabetic peripheral neuropathy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 November 2020 and was last updated on 30 November 2020 (registration number INPLASY2020110137).

INTRODUCTION

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METHODS

Participant or population: Diabetic peripheral neuropathy patients must meet the diagnostic criteria of the "China Type 2 Diabetes Prevention Guidelines" issued by the Diabetes Branch of the Chinese Medical Association in 2017, regardless of race, gender and age. Neuropathy caused by other reasons and severe chronic wasting disease, pregnant and lactating patients is not included.

Intervention: The experimental group was treated with traditional Chinese medicine fumigants.

Comparator: The control group applied for placebo, neurotrophic drugs, or no treatment.

Study designs to be included: All randomized controlled trials (RCTs) about traditional Chinese medicine fumigants for diabetic peripheral neuropathy will be included regardless of language.

Eligibility criteria: All randomized controlled trials (RCTs) about TCMF for DPN will be included regardless of language. The following studies: case series, quasi-RCTs Case reports, non-RCTs, cell experiments, animal experiments will be excluded. **Participants:** Diabetic peripheral neuropathy patients must meet the diagnostic criteria of the "China Type 2 Diabetes Prevention Guidelines" issued by the Diabetes Branch of the Chinese Medical Association in 2017, regardless of

race, gender and age. Neuropathy caused by other reasons and severe chronic wasting disease, pregnant and lactating patients is not included. **Types of interventions:** The experimental group was treated with traditional Chinese medicine fumigants, the control group applied for placebo, neurotrophic drugs, or no treatment.

Information sources: The following electronic databases will be comprehensively searched including: PubMed, Cochrane Library, EMBASE, MEDLINE, CNKI, CBM, VIP, WAN FANG, World Health Organization International Clinical Trials Registry Platform, Chinese Clinical Trial Register, Clinical Trials, and Grey Literature Database. all the literature retrieved is from the time when the database establishment to 20 November 2020. There are no language restrictions or regional restrictions. Missing literature information will be supplemented by contacting the original author.

Main outcome(s): The improvement in clinical efficacy and nerve conduction velocity is the main result.

Additional outcome(s): The secondary results mainly consist of fasting blood glucose, 2 hours postprandial blood glucose, blood lipids, glycosylated hemoglobin and adverse events.

Quality assessment / Risk of bias analysis: The Cochrane collaborative tools will be used to assess the risk of literature bias. Two investigators used RevMan 5.3.0 to assess method quality independently. Evaluate the following seven aspects. Including: randomness, the blindness of participants and researchers, sequence generation, allocation hiding, blindness of result evaluation, selective result reporting, incomplete result data and other biases. The quality of each experiment was assessed as low, unclear, or high biased. Resolve differences through discussion between the two reviewers or seeking third-party consultation.

Strategy of data synthesis: For data analysis, RevMan 5.3.0 that is provided by the Cochrane Collaboration will be used. We will use the chi-square test and I² statistic to evaluate the heterogeneity of similar studies. If $P \geq 0.05$ and $I^2 \leq 50\%$, we believe it is low heterogeneity. As a result, we will use a fixed-effects model. If $P < 0.05$ and $I^2 > 50\%$, it means there is heterogeneity. we will use a random-effects model. For the enumeration data, odds ratio (OR) with a 95% confidence interval (CI) will be used to represent. We will use mean difference (MD) with 95% CI to express the measurement data. The statistically significant difference is thought of as $P < 0.05$.

Subgroup analysis: If the studies show significant heterogeneity, we will conduct a subgroup analysis of different traditional Chinese medicine fumigation prescriptions to explore whether the Chinese medicine fumigation prescriptions cause heterogeneity.

Sensibility analysis: Furthermore, if necessary, a sensitivity analysis will be performed.

Country(ies) involved: China.

Keywords: Traditional Chinese medicine fumigation, effectiveness and safety, systematic review, diabetic peripheral neuropathy, protocol.

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