

INPLASY PROTOCOL

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None declared.

Therapeutic effect of Chinese Tuina on diabetic peripheral neuropathy: a systematic review and meta-analysis

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Review question / Objective: Diabetic peripheral neuropathy (DPN) is one of the chronic microvascular complications of diabetes mellitus (DM). Chinese Tuina is a promising external treatment of traditional Chinese medicine (TCM), which can promote blood circulation, increase the support of tissues, accelerate metabolism and facilitate the improvement of neurological function, thereby improving the quality of life of patients with DPN. Although increasing clinical studies reveals the efficacy of Chinese Tuina therapy and its safety on DPN patients, whether Chinese Tuina therapy is indeed improving DPN remains unclear. In this study, we intended to evaluate the clinical efficacy and safety of Chinese Tuina in the treatment of DPN.

Patient, Participant, or population: Inclusion criteria: Patients with diabetic peripheral neuropathy (diagnosed clinically using any accepted diagnostic criteria).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 September 2022 and was last updated on 08 September 2022 (registration number INPLASY202290037).

INTRODUCTION

Review question / Objective: Diabetic peripheral neuropathy (DPN) is one of the chronic microvascular complications of diabetes mellitus (DM). Chinese Tuina is a promising external treatment of traditional

Chinese medicine (TCM), which can promote blood circulation, increase the support of tissues, accelerate metabolism and facilitate the improvement of neurological function, thereby improving the quality of life of patients with DPN. Although increasing clinical studies reveals

the efficacy of Chinese Tuina therapy and its safety on DPN patients, whether Chinese Tuina therapy is indeed improving DPN remains unclear. In this study, we intended to evaluate the clinical efficacy and safety of Chinese Tuina in the treatment of DPN.

Condition being studied: Diabetic peripheral neuropathy (DPN) is one of the chronic microvascular complications of diabetes mellitus (DM). Chinese Tuina is a promising external treatment of traditional Chinese medicine (TCM), which can promote blood circulation, increase the support of tissues, accelerate metabolism and facilitate the improvement of neurological function, thereby improving the quality of life of patients with DPN.

METHODS

Search strategy: We will search several databases including PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (Wang Fang), Chinese Biomedical Literature Database (CBM), VIP Database for Chinese Technical Periodicals (VIP), MEDLINE, and Clinical Trial Register (CTR) for eligible randomized controlled trials (RCTs). No filters will be applied and no language or data restrictions. We will use the following search terms: (1) “Diabetic peripheral neuropathy”, “DPN”, “diabetes” and their Medical Subject Headings (MeSH) terms connected with “OR”; (2) “Tuina” and “Massage” and their Medical Subject Headings (MeSH) terms connected with “OR”; (3) The above search terms of (1), (2) were connected with term “AND. The specific search strategy was adjusted according to the characteristics of different databases. We also used related search terms to obtain in the Chinese Clinical Registry and the International Clinical Trials Registry Platform (ICTRP) .In addition, we will attempt to use supplemental retrieval. For example, we manually search for the original literature to find possible related trials, and try to obtain gray literature from other sources.

Participant or population: Inclusion criteria: Patients with diabetic peripheral neuropathy (diagnosed clinically using any accepted diagnostic criteria).

Intervention: The experimental group performed Chinese Tuina therapy on any part of the patient's meridians or acupoints. The only difference between the experimental group and the control group should be Chinese Tuina therapy.

Comparator: The control group received conventional treatment and nursing such as health education and oral or intramuscular vitamins and methylcobalamin.

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

Eligibility criteria: Our study will include patients of any age group identified as having diabetic peripheral neuropathy by any accepted diagnostic criteria.

Information sources: We will search several databases including PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (Wang Fang), Chinese Biomedical Literature Database (CBM), VIP Database for Chinese Technical Periodicals (VIP), MEDLINE, and Clinical Trial Register (CTR) for eligible randomized controlled trials (RCTs). No filters will be applied and no language or data restrictions. We will use the following search terms: (1) “Diabetic peripheral neuropathy”, “DPN”, “diabetes” and their Medical Subject Headings (MeSH) terms connected with “OR”; (2) “Tuina” and “Massage” and their Medical Subject Headings (MeSH) terms connected with “OR”; (3) The above search terms of (1), (2) were connected with term “AND. The specific search strategy was adjusted according to the characteristics of different databases. We also used related search terms to obtain in the Chinese Clinical Registry and the International Clinical Trials Registry Platform (ICTRP) .In addition, we will attempt to use supplemental retrieval. For example, we manually search for the original literature to find possible related

trials, and try to obtain gray literature from other sources.

Main outcome(s): The primary outcome was the total effective rate.

Additional outcome(s): The secondary outcomes were NCV (sensory, motor or mixed) , TCSS score and so on.

Quality assessment / Risk of bias analysis: Risks of bias were independently assessed using the Cochrane Bias Risk tool, including the following areas: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias. The quality of the included studies will be assessed by two authors. After the initial assessment, if no consensus is reached, the third author will be consulted. The quality assessment will not be used as a selection or exclusion criteria and will be reported in the review.

Strategy of data synthesis: The review will provide a narrative synthesis of the results from the included studies and structure them around the type of intervention, the characteristics of the target population, the type of outcome, and the intervention content. The pooled data for each trial will be used to calculate the standardized mean difference and risk ratio for the primary and secondary outcomes. It will use the Q test and the I^2 statistic to calculate the heterogeneity between studies, $I^2 > 50\%$ is considered to be substantial heterogeneity.

Subgroup analysis: Analysis of subgroups in the case of large heterogeneity: stimulation site (extremities, back, abdomen, feet); stimulation site (Single point, double point and multiple points) and whether accompanied by other diseases.

Sensitivity analysis: Sensitivity analysis is also one of the indispensable methods to deal with heterogeneity. The sensitivity analysis, we will conduct, is to explore the impact of trial bias risk on preliminary results. If there is significant statistical

heterogeneity, sensitivity analysis will exclude low-quality studies, and repeat meta-analysis based on sample size and insufficient data to assess quality and robustness.

Country(ies) involved: China.

Keywords: Chinese Tuina; Diabetic peripheral neuropathy; Systematic review; Meta-analysis.

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