

INPLASY PROTOCOL

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None declared.

Efficacy and safety of acupuncture combined Chinese Herbal Medicine for diabetic peripheral neuropathy: A protocol for systematic review and meta-analysis

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Review question / Objective: Acupuncture combined with Chinese herbal medicine has been widely utilized for pain management in patients with diabetic peripheral neuropathy (DPN). However, its results are still inconsistent, and no systematic review has specifically addressed this issue. Thus, this systematic review will comprehensively and systematically investigate the effectiveness and safety of acupuncture combined with Chinese herbal medicine for pain relief in DPN.

Condition being studied: Diabetic peripheral neuropathy (DPN) is one of the diabetic microvascular complications. It is also one of the main causes of death in diabetes. The main clinical symptoms are limb pain, numbness, burning or other abnormal feelings. In the late stage of DPN, muscle atrophy, weakness, foot ulceration, infection, gangrene, and even amputation. Research shows that when the duration of diabetes exceeds 15 years, 94% of patients will have varying degrees of neuropathy, and 25% of diabetic neuropathy patients can have serious consequences such as foot ulcers and amputation. The disease has brought a heavy burden to the patients and their families, and the patients themselves are even more miserable. At the same time, it has caused a huge economic burden to the state, society and families.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 October 2021 and was last updated on 02 October 2021 (registration number INPLASY2021100004).

INTRODUCTION

Review question / Objective: Acupuncture combined with Chinese herbal medicine

has been widely utilized for pain management in patients with diabetic peripheral neuropathy (DPN). However, its results are still inconsistent, and no

systematic review has specifically addressed this issue. Thus, this systematic review will comprehensively and systematically investigate the effectiveness and safety of acupuncture combined with Chinese herbal medicine for pain relief in DPN.

Condition being studied: Diabetic peripheral neuropathy (DPN) is one of the diabetic microvascular complications. It is also one of the main causes of death in diabetes. The main clinical symptoms are limb pain, numbness, burning or other abnormal feelings. In the late stage of DPN, muscle atrophy, weakness, foot ulceration, infection, gangrene, and even amputation. Research shows that when the duration of diabetes exceeds 15 years, 94% of patients will have varying degrees of neuropathy, and 25% of diabetic neuropathy patients can have serious consequences such as foot ulcers and amputation. The disease has brought a heavy burden to the patients and their families, and the patients themselves are even more miserable. At the same time, it has caused a huge economic burden to the state, society and families.

METHODS

Participant or population: All participants were diagnosed with diabetic peripheral neuropathy, and gender, race and age were not restricted.

Intervention: The intervention method of the treatment group was acupuncture combined with Chinese herbal medicine. There are no requirements for medication time, medication frequency and drug dosage form. The control group received simple Western medicine treatment or placebo.

Comparator: The main outcome measures included fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin. The secondary outcomes included: (1) Toronto clinical scoring system will be used for evaluation, including symptom score, sensory function score and reflex score. (2) Electromyography

(EMG) detection: the motor conduction velocity and terminal latency of tibial nerve, common peroneal nerve and median nerve were measured before and after treatment. (3) TCM syndrome score was established according to clinical symptoms and signs, and measured once before and after treatment.

Study designs to be included: We will select clinical randomized controlled trials published before September of 2021, and without any regional and language restrictions. Animal studies, case reports, retrospective studies, and reviews will be excluded. About duplicate articles, we will prefer to the one with more comprehensive data.

Eligibility criteria: 3.1. Inclusion criteria 3.1.1 Type of studies. We will select clinical randomized controlled trials published before September of 2021, and without any regional and language restrictions. Animal studies, case reports, retrospective studies, and reviews will be excluded. About duplicate articles, we will prefer to the one with more comprehensive data. 3.1.2. Type of participants. All participants were diagnosed with diabetic peripheral neuropathy, and gender, race and age were not restricted. 3.1.3. Type of interventions. The intervention method of the treatment group was acupuncture combined with Chinese herbal medicine. There are no requirements for medication time, medication frequency and drug dosage form. The control group received simple Western medicine treatment or placebo.

Information sources: The keywords such as "Chinese herbal medicine," "Acupuncture," "Diabetic neuropathy," "Neuropathy," "Peripheral neuropathy," "Diabetic," "Diabetic polyneuropathy," "Diabetes mellitus," and "Diabetic neuropathies" were used to search in the following electronic databases: Medline, Web of Science, PubMed, Cochrane Library, Excerpta Medica Database, Sinomed, China National Knowledge Infrastructure, WanFang, and China Science and Technology Journal Database, and there is no regional and

language restrictions. We will consider article published between database initiation and September 2021. The search strategy for PubMed is presented in the following Table 1.

Main outcome(s): The main outcome measures included fasting blood glucose, postprandial blood glucose, glycosylated hemoglobin.

Additional outcome(s): The secondary outcomes included: (1) Toronto clinical scoring system will be used for evaluation, including symptom score, sensory function score and reflex score. (2) Electromyography (EMG) detection: the motor conduction velocity and terminal latency of tibial nerve, common peroneal nerve and median nerve were measured before and after treatment. (3) TCM syndrome score was established according to clinical symptoms and signs, and measured once before and after treatment.

Quality assessment / Risk of bias analysis: Grading of Recommendations Assessment, Development, and Evaluation will be used to evaluate the quality of evidence for key outcomes. The quality of evidence will be graded into 1 of 4 levels: high, moderate, low, and very low.

Strategy of data synthesis: 3.3. Data selection and extraction 3.3.1. Electronic searches. The keywords such as “Chinese herbal medicine,” “Acupuncture,” “Diabetic neuropathy,” “Neuropathy,” “Peripheral neuropathy,” “Diabetic,” “Diabetic polyneuropathy,” “Diabetes mellitus,” and “Diabetic neuropathies” were used to search in the following electronic databases: Medline, Web of Science, PubMed, Cochrane Library, Excerpta Medica Database, Sinomed, China National Knowledge Infrastructure, WanFang, and China Science and Technology Journal Database, and there is no regional and language restrictions. We will consider articles published between database initiation and September 2021. The search strategy for PubMed is presented in the following Table 1. 3.3.2. Searching other resources. A review or meta-

analysis of relevant RCT systems will be conducted via electronic search. We will also manually search the references of relevant articles that is not included in the electronic database to further identify eligible studies. 3.3.3. Data extraction. Two researchers independently completed the evaluation of the research according to the conformity assessment form and extracted the research results. The extracted data includes author, gender, age, publication date, country, region, sample size, intervention details, follow-up information, safety, results, and so on. The above information will be repeatedly checked by 2 researchers, and any disputes about data extraction will be resolved through negotiation.

Subgroup analysis: If necessary, we will undertake a subgroup analysis based on the different patient demographics, study quality, types of interventions and comparators, and outcome measurements.

Sensitivity analysis: Sensitivity analysis will be performed to determine the robustness of the review results with respect to the following aspects: impact of sample size, effect of missing data, and methodological quality.

Country(ies) involved: China.

Keywords: Keywords: acupuncture combined with Chinese herbal medicine, diabetic peripheral neuropathy, effectiveness, protocol, safety, systematic review.

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