INPLASY PROTOCOL

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No conflicts of interest.

Clinical observation of acupuncture in the treatment of painful diabetic peripheral neuropathy : Protocol of systematic review and meta-analysis

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Review question / Objective: **The aim of this clinical randomized controlled trial meta-analysis will jointly evaluate the efficacy and safety of acupuncture for the treatment of painful diabetic peripheral neuropathy from both peripheral sensitization and central sensitization perspectives, regardless of primary mental status.**
Condition being studied: **Diabetic peripheral neuropathy (DPN) is one of the most common complications of diabetes mellitus (DM), and about 46.6% of DM patients in China have DPN. About 11.4% and 40.5% of the patients have severe and moderate pain, respectively, and 3.7% of them have lower limb ulcers or even amputation, and more than 2/3 of PDPN patients have different degrees of depression and anxiety, which brings great burden to the society and patients' families. While the pathogenesis of PDPN is not well understood, modern medical treatment techniques have difficulty in showing significant advantages in the treatment of PDPN, such as blood glucose control, nerve nutrition and pain management.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 January 2021 and was last updated on 14 January 2021 (registration number INPLASY202110046).

INTRODUCTION

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METHODS

Participant or population: Adults only, patients aged ≥18 years with a confirmed diagnosis of PDPN, race, gender, history and symptoms not specified.

Intervention: Acupuncture is the main intervention modality (e.g., acupuncture, electroacupuncture, Warm Acupuncture, moxibustion, fire acupuncture, ear acupuncture, skin acupuncture)

Comparator: Primary controls included: sham acupuncture, positive drugs, placebo, and rehabilitation therapy.

Study designs to be included: Clinical randomized controlled trials (RCTs).

Eligibility criteria: Type of studies: a randomized controlled trial (RCT) on the use of acupuncture for pain relief in patients with PDPN only. Type of intervention: studies included any type of acupuncture method regardless of duration, frequency, dose, and other relevant parameters; type of control: therapies other than acupuncture. Type of participants: adults only, patients aged ≥18 years with a confirmed diagnosis of PDPN, race, gender, history and symptoms not specified; Type of outcome: at least 1 outcome indicator related to PDPN pain. Primary outcomes: resting-state functional magnetic resonance images of the brain (rs-fMRI), superficial peroneal nerve sensory nerve conduction velocity (SCV), bilateral dorsal CPT values of the first toe, improvement of signs and symptoms of diabetic peripheral neuropathy, and subjective pain level. The secondary outcomes: fasting glucose, serum C-peptide, lipids, glycated serum protein, depression and anxiety status in PDPN patients.

Information sources: We will search articles in these electronic database including PubMed, EMBASE, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), WanFang database and VIP(China Science Technology Journal Database). All the publications until 2021 will be searched.

Main outcome(s): Superficial peroneal nerve sensory nerve conduction velocity (SCV), bilateral dorsal CPT values of the first toe, Michigan Diabetic Peripheral Neuropathy Screening Inventory (MNSI), Neuropathic Pain Symptom Inventory (NPSI), Leeds Neuropathic Signs and Symptoms Score (LANSS), Brief Pain Inventory (BPI), McGill Pain Questionnaire.

Quality assessment / Risk of bias analysis: In this paper, risk of bias is assessed using the Cochrane Risk of Bias Assessment Tool, which focuses on selection (including random sequence generation and allocation concealment), implementation (including blinding of investigators and subjects), measurement (blinded evaluation of study outcomes), follow-up (completeness of outcome data), reporting (selective reporting of study results), and other (other sources of bias). The risk of bias was evaluated for a total of 7 entries in 6 areas (other sources of bias). For each entry, "low risk of bias," "high risk of bias," and "unclear" were determined based on the risk of bias assessment guidelines.

Strategy of data synthesis: The meta-analysis will be performed using RevMan 5.4 software provided by the Cochrane

Collaboration. Continuous data will be expressed as mean differences (MDs) with 95% confidence intervals (CI), while dichotomous data will be expressed as relative risks (RR) with 95% CI. The I2 test will be used to quantify inconsistency between included studies. Studies will not be considered heterogeneous when the I2 value is less than 50%. Heterogeneity data will be pooled using a random effects model.

Subgroup analysis: If necessary, the data will be analyzed in groups according to different factors, such as differences in acupuncture method, frequency of treatment, control group and follow-up time.

Sensibility analysis: Sensitivity analysis will assess the stability of the meta-analysis results based on the following criteria: study quality, sample size, missing data, quality of heterogeneity, and statistical model.

Language: Chinese, English.

Country(ies) involved: China.

Keywords: Acupuncture; Painful diabetic peripheral neuropathy; Meta-analysis.

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