INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of massage adjuvant therapy in the treatment of diabetic peripheral neuropathy: A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **Our study will explore the effectiveness and safety of the application of massage in diabetic peripheral neuropathy.**
Condition being studied: **The incidence of diabetic peripheral neuropathy is increasing year by year. If patients cannot receive timely and effective treatment, diabetic peripheral neuropathy may lead to diabetic foot ulcers or even amputation. This risk factor has aroused widespread concern around the world. massage is gradually being applied in the adjuvant treatment of diabetic peripheral neuropathy, but there is no systematic review of the adjuvant treatment of diabetic peripheral neuropathy by massage. Our study will explore the effectiveness and safety of the application of massage in diabetic peripheral neuropathy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 February 2022 and was last updated on 09 February 2022 (registration number INPLASY202220025).

INTRODUCTION

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METHODS

Search strategy: The documents we need are retrieved from 8 electronic databases by computer. The deadline is February 9, 2021. In The Chinese database, the main search terms are extended according to the requirements, while in the English database, all the literatures in each database are retrieved by MeSH subject terms plus free words.

Participant or population: Patients meeting the diagnostic criteria for DPN will be selected for our study. There are no restrictions on source, nationality, race, gender, age, etc.

Intervention: On the basis of the control group, the experimental group was assisted with massage therapy, including massage, manipulation, Chinese massage, Thai massage, Japanese shiatsu and other similar massage interventions. The experimental group was treated with massage , It also includes other similar massage interventions such as Tuina, manipulation,Chinese massage, Thai massage, Japanese shiatsu, and so on.

Comparator: The control group only received conventional treatment of Western medicine.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: All the studies we selected were RCTS of massage therapy for DPN. Studies that are not RCTS will be excluded: for example, animal studies, case reports, reviews, and basic studies. Regardless of race, nationality, age or sex, patients meeting DPN diagnostic criteria will be selected for our study.The control group was given hypoglycemic treatment and symptomatic treatment, and the treatment group was combined with massage treatment on the basis of the control group. The massage method chosen may vary from one RCT to another.

Information sources: A computer search of (PubMed, Cochrane, Web of Science, Sinomed, Embase, China National Knowledge Infrastructure, WanFang Data, Chongqing VIP Information) 8 electronic databases will be conducted on February 10, 2022. A randomized controlled trial of traditional Chinese massage therapy for diabetic peripheral neuropathy was screened. Primary outcome measures: response rate and nerve conduction velocity. Secondary outcome measures: pain, blood glucose, and incidence of adverse reactions. The quality evaluation of the literature was carried out by two researchers according to the RCT bias risk assessment tool in the Cochrane evaluation manual Handbook5.4, and meta-analysis was performed using RevMan 5.4 software.

Main outcome(s): Efficiency, nerve conduction velocity.

Additional outcome(s): Pain, blood sugar, incidence of adverse reactions.

Quality assessment / Risk of bias analysis: Two investigators evaluated the quality of the included studies according to the Randomised controlled trial bias risk Assessment Tool (Cochrane Evaluation Handbook 5.4). The main evaluation items include: "random sequence generation", "selective reporting", "blindness", "distribution concealment", "incomplete result data", etc. Each assessment item is classified as "low risk", "unclear risk" and "high risk". If there is any disagreement, we will discuss with a third party to resolve it.

Strategy of data synthesis: The two researchers will independently extract data information and compile the collected data information into Excel tables. The extracted

information was as follows: publication year, first author, gender, age, course of disease, course of treatment, intervention measures, outcome indicators, sample size, adverse reactions, etc. If there is any disagreement, it will be decided by a third party. If the included literature data information is incomplete, we will try to contact the original author to complete the information, otherwise the study will be excluded.

Subgroup analysis: Subgroup analysis was performed based on age, course of disease, duration of treatment, and different interventions to explore the sources of heterogeneity.

Sensitivity analysis: Sensitivity analysis was used to explore the sources of significant heterogeneity in the studies. 2.5.7. Assessment of reporting biases.

Language: Chinese and English studies will be selected.

Country(ies) involved: China.

Keywords: systematic review and meta-analysis, massage, diabetic peripheral neuropathy, protocol.

Dissemination plans: We upload our findings to peer-reviewed journals.

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