INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **No.**

Effectiveness of acupuncture combined mecobalamin in the treatment of elderly diabetic peripheral neuropathy: a protocol of systematic review and meta-analysis

Duan, YH[1]; Liu, AX[2]; Su, HX[3]; Lv, JH[4]; Gong, XY[5]; Wang L[6].

Review question / Objective: **Can acupuncture combined mecobalamin (AM) effectively treat elderly diabetic peripheral neuropathy (EDPN)?**
Condition being studied: **Acupuncture; mecobalamin; diabetic peripheral neuropathy**
Information sources: **We will perform searches via the bibliographic electronic databases of Cochrane Library, PUBMED, EMBASE, CINAHL, PsycINFO, WANGFANG, and China National Knowledge Infrastructure. We will search all those databases from inception to March 1, 2020 with no restrictions of lanague and publication status. The search terms are diabetic neuropathy, peripheral neuropathy, neuropathy, diabetic, diabetic polyneuropathy, diabetic neuropathies, diabetes mellitus, elderly, acupuncture, acupuncture therapy, acupuncture ear, auriculotherpay, electroacupuncture, acupoint, and mecobalamin. The example of search strategy for Cochrane Library will be presented. Similar search strategies for other electronic databases will be adapted and applied. In addition, we will identify conference abstracts, dissertations, and reference lists of relevant reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040094.

INTRODUCTION

Review question / Objective: **Can acupuncture combined mecobalamin (AM) effectively treat elderly diabetic peripheral neuropathy (EDPN)?**

Condition being studied: **Acupuncture; mecobalamin; diabetic peripheral neuropathy.**

METHODS

Participant or population: **Studies on adult patients, 65 years old or above, who were**

diagnosed as EDPN will be included in this study. No limitations of location, educational background, and gender will be imposed.

Intervention: Any forms of AM therapy used to treat patients with EDPN will be included in the experimental group.

Comparator: Any other treatments, but not AM, used to manage participants with EDPN will be entered in the control group.

Study designs to be included: Any randomized controlled trials (RCTs) performed on assessing the efficacy and safety of AM for the treatment of patients with EDPN will be included.

Eligibility criteria: Any randomized controlled trials (RCTs) performed on assessing the efficacy and safety of AM for the treatment of patients with EDPN will be included. We will not consider other studies, such as non-clinical trials, non-controlled trials, and non-RCTs.

Information sources: We will perform searches via the bibliographic electronic databases of Cochrane Library, PUBMED, EMBASE, CINAHL, PsycINFO, WANGFANG, and China National Knowledge Infrastructure. We will search all those databases from inception to March 1, 2020 with no restrictions of lanague and publication status. The search terms are diabetic neuropathy, peripheral neuropathy, neuropathy, diabetic, diabetic polyneuropathy, diabetic neuropathies, diabetes mellitus, elderly, acupuncture, acupuncture therapy, acupuncture ear, auriculotherpay, electroacupuncture, acupoint, and mecobalamin. The example of search strategy for Cochrane Library will be presented. Similar search strategies for other electronic databases will be adapted and applied. In addition, we will identify conference abstracts, dissertations, and reference lists of relevant reviews.

Main outcome(s): The primary outcome includes glycemic profile, as measured by fasting blood glucose or glycated hemoglobin. The secondary outcomes consist of neuropathic pain intensity, as assessed by visual analogue scale or other relevant tools; plantar tactile sensitivity, as evaluated by Semmes-Weinstein monofilament; sensory nerve conduction velocity and motor nerve conduction velocity, as checked by electromyography; quality of life, as evaluated by Health-Related Quality of Life scale or associated scores; and adverse events.

Data management: Before data collection, a data extraction sheet will be built by our study team. Two authors will separately collect relevant information from each eligible study. Any discrepancies will be handled by discussion and consultation from a third experienced author. The following items will be extracted: study title, first author, year of publication, number of patients in different groups, age, gender, course of EDPN, study design, study setting, study duration, types of interventions, controls, dosage, all endpoints, safety, funding information, and any other relevant information.

Quality assessment / Risk of bias analysis: The study quality assessment will be done using Cochrane Risk of Bias Tool, which contained seven domains. The outcome of each domain will be classified as high risk of bias, unclear risk of bias, and low risk of bias. The whole process will be performed by two authors, and inconsistence will be solved by consultation a third author.

Strategy of data synthesis: ReMan 5.3 software is used for data synthesis and meta-analysis if possible. Mean difference or standardized mean difference and 95% confidence intervals (CIs) will be used to calculate quantitative data, and dichotomous data will be exerted as risk ratio and 95% CIs. Statistical heterogeneity across studies was done with I^2 statistic. $I^2 \leq 50$ indicates homogeneity among studies, and a fixed-effects model will be employed for pooled analysis. $I^2 > 50\%$ suggests obvious heterogeneity, and a random-effects model will be employed for synthesized analysis. When there is homogeneity of the merged outcome results across sufficient studies, meta-

analysis will be conducted. Otherwise, we will carry out subgroup analysis to explore causes of obvious heterogeneity. We will also report a narrative synthesis using detailed written commentary on the different study characteristics (such as location, duration), patient characteristics (such as gender, course of EDPN, et al), different interventions and controls (such as dosage, frequency, et al), and outcome measurements.

Subgroup analysis: If necessary, subgroup analysis will be conducted based on the different study qualities, interventions, controls and outcome measurements.

Sensibility analysis: Sensitivity analysis will be undertake to check the stability of merged outcome results by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: Acupuncture; mecobalamin; diabetic peripheral neuropathy; effectiveness; safety.