INPLASY PROTOCOL

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None declared.

Clinical evidence of acupuncture and related therapy in patients with Chemotherapy-induced peripheral neuropathy: A protocol of Systematic Review and Meta-analysis

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Review question / Objective: **This protocol will provide objective clinical evidence for the safety and effectiveness of acupuncture and related therapies (such as fire-needle, acupoint injection, moxibustion, massage, etc) for patients with Chemotherapy-induced peripheral neuropathy.**
Condition being studied: **Chemotherapy-induced peripheral neuropathy (CIPN) is a neuropathic pain, with an abnormal limbs, allergic allergies, etc. However, there is no targeted drug to deal with it. If there is a severe neurotoxicity, the patient needs to reduce chemotherapeutic drug dosage or even stop drugs, and then reduce the treatment effectiveness and shorten the total survival period, seriously damage the patient's psychological, physiological and quality of life, and aggravate the patient's disease burden. According to the main clinical symptoms of CIPN, it belongs to "Bi-zheng" of TCM. At present, the relevant research department has shown that electric acupuncture, bee-needle, acupoint injection and other therapys can effectively improve the symptoms of peripheral neuropathy caused by CIPN. In order to providing a reliable reference for future clinical treatment, we will assume systematic evaluation and meta-analysis to evaluate the efficacy and safety of acupuncture and related therapy in treatment of CIPN.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2021 and was last updated on 06 May 2021 (registration number INPLASY202150025).

INTRODUCTION

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METHODS

Search strategy: Two researchers will conduct the search in the databases mentioned above. Any discrepancies will be solved via discussion or, if necessary, by consulting a third researcher. The search aims to find both published and unpublished publications. A two-step strategy will be used. Published RCTs will be retrieved by searching the Central Registers of Medline, Embase, and Cochrane Controlled Trials. We will use the following search terms: "randomized controlled trial" AND "Chemotherapy-induced peripheral neuropathy" AND "acupuncture" OR "electroacupuncture" OR "ear acupuncture" OR "5 element needle" OR "wrist-ankle acupuncture" OR "fire needle" OR "moxibustion" OR "acupoint acupressure" OR "transcutaneous electrical acupoint stimulation" OR "TEAS" OR "tui-na" OR "massage". The reference list of included articles will be manually examined to identify additional studies for inclusion in the systematic review. Similar meta-analyses have been published, with references to alternative and complementary medicine textbooks, and clinical guidelines for related trials set by the WHO's International Clinical Trials Registry Platform (ICTRP).

Participant or population: Adult cancer patients (age> =18years) of either sex, type of cancer and Chemotherapy drugs. Neuropathic pain or numbness caused by the cancer Chemotherapy. Unlimited participant ethnicity.

Intervention: Acupuncture and related therapies are defined as acupuncture techniques and meridian acupoint stimulation methods, including but not limited to acupuncture, electro-acupuncture, ear acupuncture, 5 element needle, wrist-ankle acupuncture, fire needle, moxibustion, acupoint injection, acupoint application with herb, acupoint acupressure, transcutaneous electrical acupoint stimulation (TEAS), tui-na, massage and combined interventions.

Comparator: Blank control, placebo control, sham acupuncture control, and neurotrophic drugs control are the comparator interventions. We will investigate the following comparisons: 1. The experimental group and the control group each had routine nursing, and the effect was evaluated either with or without acupuncture intervention. 2. Acupuncture and related therapies are only compared to placebo or sham treatment. 3. Acupuncture and related therapies plus active treatment or drug treatment, compared with active treatment or drug treatment. 4. Acupuncture and related therapies plus active treatment methods or drugs, compared with placebo or sham treatment plus active treatment methods or drugs.

Study designs to be included: There is no limit to the treatment cycle and the type of CIPN, the systematic review will include high-quality RCTs in English that assess its effectiveness and safety in improving CIPN and reducing related symptoms. Exclusion criteria included non-RCTs, retrospective

studies, review studies, case reports, animal experiments.

Eligibility criteria: Studies will be included so long as inclusion criteria are met. The eligibility criteria are summarized using the PICOS approach (patients/participants, intervention, comparisons/control, outcomes, and study design type).

Information sources: Databases and timeframes Four English (PubMed, Embase, the Cochrane Library, the Web of Science) and four Chinese databases (China national knowledge infrastructure (CNKI), Wanfang Data E-Resources (Wanfang), VIP Citation Database (VIP), and China Biology Medicine (CBM)) will be searched dating until 30rd April 2021 with no language restrictions, and translations will be sought where necessary.

Main outcome(s): Clinical symptom relief as a curative effect, defined by original studies. The primary outcome is rating by NCI-CTC V2.0. Secondary outcomes are quality of life and anxiety score, such as Karnofsky or EORTC QLQ-C30.

Additional outcome(s): According to the Survivor Guidebook, released by the Oncology Clinical Practice Guide, we will additionally evaluated to the patient tolerance, compliance, and safety of this study.

Data management: Two researchers will use the data extraction form to extract the participants, and the following information will be extracted according to the CONSORT statement format: general informa- tion (year of publication, author, title, abstract, registration number, funding), research methods (research purpose, trial design, subjects, interventions, outcomes, randomization, blinding), results (number of randomized cases, subjects, baseline data, number of included cases, outcomes, and adverse reactions). We will enter the data into Review Manager (RevMan V.5.3). If necessary, we will contact the authors of the included studies for missing information or for clarification.

Quality assessment / Risk of bias analysis: The risk of bias in 6 areas (sequence generation, allocation hiding, blindness, incomplete data evaluation, selective results reporting, and other sources of bias) will be assessed with the Cochrane Deviation Risk Collaborative Tool by 2 reviewers. This will provide reasons to judge potential risk. Any disagreement will be resolved by discussion with a methodology expert.

Strategy of data synthesis: If a meta-analysis is possible, the results of the binary data will be expressed as RR using RevMan V.5.3, and the results will be expressed as standardized mean difference (SMD) for continuous data. If 2 test results are less than 50%, the data will be synthesized using a fixed effects model. If they are between 50% and 75%, the data will be synthesized using a random effects model. If they are over 75%, we will investigate possible causes from a clinical and methodological perspective and perform a subgroup analysis.

Subgroup analysis: Subgroup analysis will be based on intervention (acupuncture, electroacupuncture, ear acupuncture, 5 element needle, wrist-ankle acupuncture, fire needle, moxibustion, acupoint acupressure, transcutaneous electrical acupoint stimulation (TEAS), tui-na, massage) or overall bias. The severity of the CIPN will also be considered.

Sensitivity analysis: We will conduct a sensitivity analysis to verify the robustness of the research conclusions, assess the methodological quality, the study design, the effect of sample size and missing data, and the effect of the analysis method on the results of this review. The meta-analysis will be repeated, and lower quality studies will be excluded. These results will then be compared and discussed.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Chemotherapy-induced peripheral neuropathy; Acupuncture; Acupuncture related therapy.

Contributions of each author:

Author 1 - Shiyu Lin - The author is the guarantors of this article and will act as an arbitrator in the event of a dispute.
Author 2 - Qing'e Xiao - The author established search strategies, independently complete the research selection, data extraction and assessment of the risk of bias.
Author 3 - Ziyin Chen - The author established search strategies and complete the research selection independently.
Author 4 - Junyue Jiao - The author independently complete the research selection, data extraction and assessment of the risk of bias.
Author 5 - Siyu Chen - The author read, provided feedback and approved the final manuscript.
Author 6 - Yuexuan Chen - The author deal with software and write the original draft.
Author 7 - Xi Xiao - The author review and modify the final versions of this protocol.