INPLASY PROTOCOL

To cite: Cui. Acupuncture for chronic constipation in patients with diabetes mellitus: a systematic review protocol. Inplasy protocol 202110079. doi: 10.37766/inplasy2021.1.0079

Received: 19 January 2021

Published: 20 January 2021

Corresponding author:
Sufen Cui

csf1240136177@163.com

Author Affiliation:
Affiliated Hospital of North Sichuan Medical College

Support: **Project of Sichuan Development.**

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

Conflicts of interest:
None.

Acupuncture for chronic constipation in patients with diabetes mellitus: a systematic review protocol

Cui, S[1].

Review question / Objective: **Does acupuncture work for chronic constipation in patients with diabetes mellitus?**
Condition being studied: **The prevalence of diabetes mellitus has reached epidemic proportions in both developed and developing countries, affecting more than 366 million people worldwide. As one of the several gastrointestinal symptoms, chronic constipation is the most commonly reported. Measures of general health, social functioning and mental health are significantly impaired in patients suffering from chronic constipation. There is no satisfying treatment for this.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2021 and was last updated on 20 January 2021 (registration number INPLASY202110079).

INTRODUCTION

Review question / Objective: **Does acupuncture work for chronic constipation in patients with diabetes mellitus?**

Condition being studied: **The prevalence of diabetes mellitus has reached epidemic proportions in both developed and developing countries, affecting more than 366 million people worldwide. As one of the several gastrointestinal symptoms, chronic constipation is the most commonly reported. Measures of general health, social functioning and mental health are significantly impaired in patients suffering**

from chronic constipation. There is no satisfying treatment for this.

METHODS

Participant or population: Participants were patients with a clear diagnosis of diabetes mellitus.

Intervention: Acupuncture therapy will include body acupuncture, manual acupuncture, fire needling, plum blossom needling, warm needling, and electroacupuncture. Other stimulation methods such as laser acupuncture, dry needling, transcutaneous electrical nerve stimulation, moxibustion, and cupping will be excluded.

Comparator: Comparison interventions will include sham acupuncture (sham acupuncture at selected acupoints, sham acupuncture at non-acupoints, needling at inappropriate/inactive acupoints, nonpenetrating sham acupuncture, and pseudo-acupuncture interventions), placebo control, western medicine, no treatment (waiting list control), usual care, and other conventional therapies. Additionally, the review will include trials evaluating acupuncture combined with another treatment compared with other typical treatments alone.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Diabetes mellitus criteria.

Information sources: The following electronic databases will be searched from their respective inception dates to 1st December 2020: PubMed, the Cochrane Library, Embase, WorldSciNet, the Allied and Complementary Medicine Database (AMED), the Web of Science, China National Knowledge Infrastructure (CNKI), the Chongqing VIP Chinese Science and Technology Periodical Database (VIP) and the Wanfang Database.

Main outcome(s): The primary outcome was the change from base- line in mean CSBMs per week, calculated as the total number of CSBMs divided by the number of weeks in the assessment period, during weeks 1 to 8.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration's risk of bias tool will be employed to evaluate the methodological quality of eligible RCTs. The tool focuses on each study's selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), selective reporting bias and other bias. Two independent reviewers will evaluate the quality of RCTs with this tool. Any discrepancies between the two reviewers will be settled through discussion or the introduction of a third reviewer

Strategy of data synthesis: The data for statistical analysis will be extracted into an excel file. Dichotomous data will be investigated by using a risk ratio with 95% CIs. For continuous outcomes, data will be analyzed by using a standard mean difference (SMD) with 95% CIs or a weighted mean difference (WMD). The WMD will be used for the same scale or the same assessment instrument; SMD will be used for different assessment tools. A network meta- analysis based on frequentist framework will be conducted by using the net-meta package in R software (www.r-project.org, version 3.2.0), integrating direct and indirect evidences of included RCTs. A network plot will be made to show the number and interrelations of interventions and direct comparison between interventions. The interventions results will be ranked based on their P values. Consistency will be assessed by implementing Cochran's Q statistics, and if with obvious heterogeneity, a meta-regression process will be performed to determine its potential source with a net-heat plot.

Subgroup analysis: A subgroup analysis will be performed to determine the potential heterogeneity and inconsistency clinically and statistically. This include age,

gender and disease duration of patients, trial blinding, evidence quality and so on. Meta-regression analysis will be implemented to quantify the inter-subgroup difference and explore statistical significance.

Sensibility analysis: Sensitivity analysis will be conducted to test the robustness of the review conclusions if possible. The impacts of sample size, study design, methodological quality, and missing data will be evaluated.

Country(ies) involved: China.

Keywords: systematic review, acupuncture, chronic constipation, diabetes mellitus.

Contributions of each author:
Author 1 - Sufen Cui.