

# INPLASY PROTOCOL

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**Support:** None.

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

**Conflicts of interest:**  
None declared.

## INTRODUCTION

**Review question / Objective:** The aim of this systematic review is to provide a program to evaluate the effectiveness and safety of acupuncture therapy in affecting

## Efficacy and safety of acupuncture therapy to regulate the gut microbiome in the treatment of overweight or obese patients with type 2 diabetes: a systematic review and network meta-analysis with randomized controlled trials (protocol)

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**Review question / Objective:** The aim of this systematic review is to provide a program to evaluate the effectiveness and safety of acupuncture therapy in affecting the gut microbiome to improve the occurrence and development of obese type 2 diabetes.

**Condition being studied:** Obesity and type 2 diabetes are very common worldwide and have become a global health problem. The imbalance of the gut microbiome is one of the key mechanisms leading to obesity and type 2 diabetes. Acupuncture therapy, as a traditional Chinese medicine treatment with a long history, can improve the occurrence and development of obesity and type 2 diabetes by adjusting the composition of the patient's gut microbiome. There is still a lack of systematic reviews on the efficacy of acupuncture to regulate the intestinal flora in obese patients with type 2 diabetes.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 October 2021 and was last updated on 31 October 2021 (registration number INPLASY2021100121).

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## METHODS

**Participant or population:** Participants with body mass index (BMI)  $\geq$  24 kg / m<sup>2</sup> and diagnosed with T2DM will be included in the study. At the same time, the participants included are not limited to gender, age, region, nationality and race. Relevant cases of obesity caused by major diseases, pregnancy and drugs were excluded.

**Intervention:** Patients received acupuncture intervention, but the location, duration and frequency of acupuncture were not limited. Intervention measures can include body acupuncture, scalp acupuncture, hand acupuncture, ear acupuncture, electroacupuncture, fire needle, plum blossom needle, abdominal needle and other puncture methods. Studies using moxibustion, acupoint injection, acupoint pressing, medical acupuncture, and transcutaneous electrical nerve stimulation will be excluded. The intervention method is limited to single acupuncture treatment, non-acupuncture treatment, acupuncture combined with medicine or other RCTs of Chinese medicine are not included in the study.

**Comparator:** Control interventions can include: no treatment, placebo (ie sham acupuncture), anti-diabetic drugs or lifestyle interventions (diets, exercise).

**Study designs to be included:** Our research only includes acupuncture to regulate the gut microbiome to treat obese T2DM related RCTs. Studies involving quasi-

randomized controlled trials, non randomized controlled trials and animal experiments will be excluded.

**Eligibility criteria:** (1) Participants with body mass index (BMI)  $\geq$  24 kg / m<sup>2</sup> and diagnosed with T2DM will be included in the study. At the same time, the participants included are not limited to gender, age, region, nationality and race. Relevant cases of obesity caused by major diseases, pregnancy and drugs were excluded. (2) We will select clinical randomized controlled trials published before December 2021, and the language is limited to Chinese and English. (3) The intervention method was limited to a single acupuncture treatment. (4) Control interventions can include: no treatment, placebo (ie sham acupuncture), anti-diabetic drugs or lifestyle interventions (diets, exercise).

**Information sources:** PubMed, Embase, Cochrane Library, Web of science, Nature, ClinicalTrials.gov, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Clinical Trial Registry, China Biology Medicine disc (CBMdisc). The language is limited to Chinese and English.

**Main outcome(s):** Fasting blood glucose (FBG), Glycosylated hemoglobin (HbA1c), 2 hours postprandial blood glucose (2hBG), BMI, the abundance of Firmicutes, Bacteroidetes and Bifidobacteria in the intestine, and the ratio of Firmicutes/Bacteroidetes were evaluated as the main results.

**Additional outcome(s):** Total cholesterol, triglycerides, low-density lipoprotein, insulin secretion (INS), waist circumference, hip circumference and other changes in the species and abundance of gut microbiome related to the development of obesity and T2DM.

**Quality assessment / Risk of bias analysis:** The risk of bias will be independently assessed by two reviewers using the

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Cochrane Risk of Bias Tool for the included studies. Evaluation includes random sequence generation, allocation concealment, blinding of participants and experimenters, blindness of result evaluation, integrity of the result data, selective outcome reporting, and other biases. Each study will be classified as low risk of bias, moderate risk of bias, high risk of bias, and no information (unclear). Any disagreements will be resolved through further discussion among all authors.

**Strategy of data synthesis:** We will use REVMAN v5.3 for data synthesis. If  $I^2 > 50\%$ , it indicates that the study is heterogeneous, and a random effects model is selected for analysis and processing. If  $I^2 \leq 50$ , it means that the research is homogeneous, and the fixed effects model is used for comprehensive analysis. And by providing descriptive or subgroup analysis to explore the possible reasons from the clinical and methodological perspectives.

**Subgroup analysis:** If the number of studies is large enough ( $>10$ ), we will conduct a subgroup analysis based on the type of acupuncture therapy, the number and name of acupuncture points, and the duration of treatment. To explore the difference of the time of acupuncture treatment, the location and quantity of acupuncture points on the improvement of gut microbiome and obesity T2DM.

**Sensitivity analysis:** If there is significant heterogeneity in the included studies, sensitivity analysis will be performed to check the robustness and reliability of the results. The language is limited to Chinese and English.

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**Country(ies) involved:** China.

**Keywords:** obese type 2 diabetes, Acupuncture, Gut Microbiome Composition, systematic review, protocol.

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