INPLASY PROTOCOL

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None declared.

Efficacy and safety of acupuncture combined with probiotics in the treatment of type 2 diabetes mellitus with intestinal microbiota disorder: A protocol for systematic review and meta analysis

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Review question / Objective: **Efficacy and safety of acupuncture combined with probiotics in the treatment of type 2 diabetes mellitus with intestinal microbiota disorder: A protocol for systematic review and meta analysis.**
Eligibility criteria: **1.The literatures of type 2 diabetes patients were included without restriction on gender, age, race, disease course and blood glucose control of the subjects. 2. The relevant literatures included in human intestinal flora do not strictly restrict the test methods and key indicators of fecal specimens. 3. Relevant literatures with no statistically significant difference in general data between the experimental group and the control group were included. 4.There is no restriction on whether blind method or distributive hiding method is used to include Chinese and English literatures whose research type is correlation study. 5. References that clearly indicated standard deviation (SD), mean value or which could be calculated by formula were included.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 September 2022 and was last updated on 01 September 2022 (registration number INPLASY202290001).

INTRODUCTION

Review question / Objective: **Efficacy and safety of acupuncture combined with probiotics in the treatment of type 2 diabetes mellitus with intestinal microbiota disorder: A protocol for systematic review and meta analysis.**

Rationale: **Type 2 diabetes mellitus (T2DM) is a high prevalence metabolic disease. It is characterized by a long disease course,**

complicated and diverse long-term complications, and is difficult to cure.In recent years, acupuncture combined with probiotics in the treatment of type 2 diabetes mellitus has become a new research hotspot.To systematically review literature evidence to evaluate the efficacy and safety of acupuncture combined with probiotics in the treatment of type 2 diabetes mellitus with intestinal microbiota disorder.

Condition being studied: Type 2 diabetes; Acupuncture; Probiotics; systematic review; meta-analysis; protocol.

METHODS

Participant or population: The patients of type 2 diabetes (using WHO 1999 diagnostic criteria[13]). These types of patients will not be included: patients with acute complications of diabetes; patients with severe heart disease, liver and kidney dysfunction, mental illness, or a relevant drug allergic history and patients during pregnancy or lactation.The literatures of type 2 diabetes patients were included without restriction on gender, age, race, disease course and blood glucose control of the subjects.

Intervention: Both groups were cured with conventional diabetes treatments recommended by the American Diabetes Association (ADA) guidelines, including diet, exercise, and hypoglycemic and lipid-lowering therapies.[7] The experimental group was treated with acupuncture combined with probiotics,while the control group applied for placebo or no treatment. In addition, the 2 groups did not take any drugs that interfered with the outcome indicators.

Comparator: While the control group applied for placebo or no treatment. In addition, the 2 groups did not take any drugs that interfered with the outcome indicators.

Study designs to be included: Six databases including PubMed, Cochrane library, EMBASE, the China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), and Wanfang databases were searched from inception to June 2022 for the relevant RCTs of the intestinal microbiome-bile acid pathway (BAS) in the treatment of type 2 diabetes, with "Gastrointestinal Microbiome" and "Type 2 Diabetes Mellitus" as search terms, a subject word plus free words as search form.

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Main outcome(s): The following information was collected from each study: publication year, country, ethnicity, speci-men source, gender and age,case and control numbers, the primary outcomes include 2 hour plasma glucose, fasting plasma glucose,

hemoglobin A1c, homeostasis model assessment of insulin resistance, and fasting plasma insulin.

Quality assessment / Risk of bias analysis: The sixth edition of the Cochrane Handbook for systematic reviews of interventions will be used to assess the broad categories of biases in the included study. Bias will be evaluated from the following seven aspects: random sequence generation, allocation hiding, blindness of participants and personnel, blindness of result evaluation, incomplete outcome data, selective reports and deviations from other sources. These studies will be divided into low-risk, high-risk and ambiguous risks. Inconsistencies will be resolved through discussions with other reviewers.

Strategy of data synthesis: We used the Review Manager(RevMan 5.3, Cochrane Collaboration, Nordic Cochrane Center, Copenhagen, Denmark) for statistical analyses. Standardized mean differences (SMDs) and 95% confidence intervals (CIs) were used to calculate the difference of ADAMTS-5 gene .When some studies reported using the of results of the median of the first and third quartiles (M (P25, P75)), approximation methods were used to calculate the mean and standard deviation (X±S) [9];X=(P25+M+P75)/3 and S =(P75–P25)/1.35. Besides, all standard errors of the correlation coefficient (SE) were calculated as follows [10];SE =√((1-r)/(n-1))2 to combine the r of the random-effect model. Q-statistic (P < 0.05) and I2 statistics (I2>5 0%) were used to evaluate the heterogeneity among studies. In individual studies, we used the Cochrane Collaboration's tool to assess the risk of bias. P <0.05 indicates statistical significant.

Subgroup analysis: If feasible, we will conduct subgroup analysis BAsed on different interventions, controls, treatment duration and outcome indicators.

Sensitivity analysis: A sensitivity analysis will be conducted to investigate the robustness of the research conclusions. Methodological quality, sample size, and the impact of missing data will be included. Therefore, the impact of low-quality research on the overall results will be assessed.

Country(ies) involved: China.

Keywords: Type 2 diabetes; Acupuncture; Probiotics; systematic review; meta-analysis; protocol.

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