## INPLASY PROTOCOL

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Conflicts of interest: None declared.

# Efficacy and safety of acupuncture for chronic diarrhea:a systematic review and meta-analysis

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Review question / Objective: Studies have shown that with the increase of people 's life, work pressure and bad eating habits, people with chronic diarrhea are increasing year by year. Acupuncture therapy for chronic diarrhea has curative effect, has been used as a treatment to alleviate the symptoms of chronic diarrhea, but its effectiveness and safety is still not accurate conclusion. Therefore, this systematic review and meta-analysis program aims to evaluate the efficacy and safety of acupuncture in the treatment of chronic diarrhea. P: Patients with chronic diarrhea. I: Any acupuncture in the form of penetrating skin, such as electroacupuncture, abdominal acupuncture, warm acupuncture, etc. Acupuncture with or without drugs. C: Conventional western medicine treatment or Chinese herbal medicine treatment or no treatment and sham acupuncture treatment. O: 1. Changes of weekly defecation at the end of treatment or follow-up. 2. The score change from baseline in stool consistency assessed using the Bristol Stool Form Scale. 3. Adverse effects assessment. S: All relevant randomized controlled trials (RCTs) in English and Chinese will be included. While NonRCTs, quasi-RCTs, cohort studies, reviews, case reports, experimental studies, expert experience, the data of the included study is missing or incomplete, and duplicate publications will be excluded.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2022 and was last updated on 06 May 2022 (registration number INPLASY202250037).

#### INTRODUCTION

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life, work pressure and bad eating habits, people with chronic diarrhea are increasing year by year. Acupuncture therapy for chronic diarrhea has curative effect, has

been used as a treatment to alleviate the symptoms of chronic diarrhea, but its effectiveness and safety is still not accurate conclusion. Therefore, this systematic review and meta-analysis program aims to evaluate the efficacy and safety of acupuncture in the treatment of chronic diarrhea. P: Patients with chronic diarrhea. I: Any acupuncture in the form of penetrating skin, such electroacupuncture, abdominal acupuncture, warm acupuncture, etc. Acupuncture with or without drugs. C: Conventional western medicine treatment or Chinese herbal medicine treatment or no treatment and sham acupuncture treatment. O: 1.Changes of weekly defecation at the end of treatment or follow-up. 2. The score change from baseline in stool consistency assessed using the Bristol Stool Form Scale. 3. Adverse effects assessment. S: All relevant randomized controlled trials (RCTs) in English and Chinese will be included. While NonRCTs, quasi-RCTs, cohort studies, reviews, case reports, experimental studies, expert experience, the data of the included study is missing or incomplete, and duplicate publications will be excluded.

Condition being studied: Research selection, data extraction and quality assessment will be conducted independently by two reviewers. Two reviewers independently assess the methodological quality of included studies according to the Cochrane Collaboration bias risk tool. All valid data will be imported into RevMan 5.4 software for analysis and synthesis.

#### **METHODS**

Participant or population: Patients with chronic diarrhea. Regardless of race, gender, course of disease, economic status or education level, or geographical differences. Patients with chronic diarrhea

Intervention: Any acupuncture in the form of penetrating skin, such as electroacupuncture, abdominal acupuncture, warm acupuncture, etc. Acupuncture with or without drugs.

Comparator: Conventional western medicine treatment or Chinese herbal medicine treatment or no treatment and sham acupuncture treatment.

Study designs to be included: All relevant randomized controlled trials (RCTs) in English and Chinese will be included. While NonRCTs, quasi-RCTs, cohort studies, reviews, case reports, experimental studies, expert experience, the data of the included study is missing or incomplete, and duplicate publications will be excluded.

Eligibility criteria: Standard for Chronic Diarrhea in Diarrhea Diagnosis and Treatment Program of China, Beijing, Ministry of Health of the People 's Republic of China, October 1993.

Information sources: From its establishment to May 6, 2022, six English databases (PubMed, Web of Science, Medline, EMBASE, Springer Cochrane Library and WHO International Clinical Trials Registry Platform) and 4 Chinese databases (Wanfang Database, China Scientific Journal Database, CNKI and Chinese Biomedical Literature Database) will be searched according to the rules of each database.

Main outcome(s): 1. Changes of weekly defecation at the end of treatment or follow-up. 2. The score change from baseline in stool consistency assessed using the Bristol Stool Form Scale. 3. Adverse effects assessment.

Quality assessment / Risk of bias analysis: The basic process of including literature will be pursued in reference to the Cochrane Collaboration System Evaluator's Manual (5.1.0).

Strategy of data synthesis: RevMan version 5.3 software provided by the Cochrane Collaboration. The software will be used to obtain forest plots and test the heterogeneity between the included studies. Risk ratio (RR) with 95% CIs will be used for dichotomous data, while the continuous data will be analyzed by mean difference (MD) or standard MD (SMD) with

95% CIs.Heterogeneity will be assessed by visual inspection of the forest plots and detected by standard χ2 test and I2 test.When P>0.1,I2<50%, it will be considered as no significant heterogeneity between the trials, and the fixed effect model will be applied for statistics, otherwise, the random effect model will be chosen. When heterogeneity occurs, sensitivity analysis or meta regression will be performed to assess the source of heterogeneity.

Subgroup analysis: When heterogeneity is detected, subgroup analysis (e.g., different types of acupuncture, patient age, research quality) will be used to identify the source of heterogeneity.

Sensitivity analysis: In trials with sufficient data, sensitivity analyses will be taken to test the robustness and reliability of the results. Sensitivity analysis will be based on heterogeneity, sensitivity analysis may be performed. When heterogeneity occurs the certain low-quality or unblinded studies would be excluded.

Country(ies) involved: China.

**Keywords:** Acupuncture, chronic diarrhea, protocol, systematic review.

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