INPLASY PROTOCOL

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Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None.

Acupuncture with or without moxibustion for functional diarrhea: a protocol for a systematic review of randomized controlled trial

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Review question / Objective: **To evaluate the efficacy and safety of acupuncture therapy for functional diarrhea.**
Condition being studied: **Functional diarrhea (FD) is a common clinical functional bowel disease, characterized by persistent or repeated defecation or watery stool syndrome without abdominal pain. Current research shows that the incidence of FD in China is 1.54%, which is relatively high in Asia and seriously affects people's life and work. Acupuncture therapy has been traditionally used to treat various kind of health problems including FD. This protocol aims to evaluate the efficacy and safety of acupuncture therapy for functional diarrhea.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 July 2020 and was last updated on 03 July 2020 (registration number INPLASY202070015).

INTRODUCTION

Review question / Objective: **To evaluate the efficacy and safety of acupuncture therapy for functional diarrhea.**

Rationale: **The current treatment of functional diarrhea is not ideal, acupuncture with or without moxibustion are widely used in clinical practice, but there is no evaluation of existing evidence.**

Condition being studied: **Functional diarrhea (FD) is a common clinical functional bowel disease, characterized by persistent or repeated defecation or watery stool syndrome without abdominal pain. Current research shows that the incidence**

of FD in China is 1.54%, which is relatively high in Asia and seriously affects people's life and work. Acupuncture therapy has been traditionally used to treat various kind of health problems including FD. This protocol aims to evaluate the efficacy and safety of acupuncture therapy for functional diarrhea.

METHODS

Search strategy: Terms: (take PubMed as an example) functional diarrhea; Acupuncture; Acupuncture Therapy; moxibustion; acupoint; randomly; randomized controlled trial; controlled clinical trial; randomized; trial; groups We plan to search the following databases: 1) Embase ; 2) Cochrane Library; 3) Pubmed; 4) Chinese databases Sino-Med (previously called theChinese Biomedical Database); 5) Chinese National Knowledge Infrastructure; 6)VIP Database for Chinese Technical Periodicals; 7)Wanfang Data.

Participant or population: People with diarrhea diagnosed by the Rome IV criteria: 1) at least 25% of feces are loose feces or watery feces, without obvious abdominal pain or discomfort; 2) symptoms appear at least 6 months before diagnosis, and meet the above diagnostic criteria in the past three months; 3) exclude patients who meet the diagnostic criteria of diarrheal irritable bowel syndrome (IBS-D). There are no restrictions on the sex, age and race of the subjects, regardless of the education and economic situation of the patients.

Intervention: Acupuncture therapy or acupuncture plus any other conventional treatment.

Comparator: Group of acupuncture will be compared with no treatment, sham acupuncture, or conventional treatment.

Study designs to be included: Systematic reviews of randomized controlled trials.

Eligibility criteria: Published or unpublished systematic reviews of parallel groups or randomized controlled trials without language restriction. Cross-over trials will be included if data of the first period are reported separately.

Information sources: Embase, Cochrane Library, Pubmed, Sino-Med, Clinical Trials, ICTRP, Chinese National Knowledge Infrastructure(CNKI), VIP Database for Chinese Technical Periodicals, Wanfang Data, and Chinese Clinical Trial Registry.

Main outcome(s): Describe the outcomes of the review including all relevant details such as timing and effect measures.

Additional outcome(s): 1) characteristics of feces; 2) Other related symptoms of functional diarrhea after treatment; 3) Quality of Lifescale; 4) Anxiety scale, depression scale and other emotion-related scales; 5) follow-up; 6) Adverse events (any adverse events as reported in trials).

Data management: (1)We will use NoteExpress and Excel software extract data. The content will be saved in electronic form. (2)Different review authors will independently screen the titles and abstracts of records obtained by searching the electronic databases to determine potential eligibility. Full texts screening and data extraction will be conducted afterwards independently. Any disagreement regarding study selection will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use NoteExpress . (3)The research team designed structured data extraction tables, including: the first author, nationality, publication year, patients' basic information, sample size, intervention measures of test group, intervention measures of controlled group, qualitative evaluation method, target outcome (including primary outcome measures and secondary outcome measures), etc. Different review authors will independently extract data. Any disagreement regarding data extraction will be resolved through discussion or

arbitrated by the third author if necessary. In this step, we will use Excel.

Quality assessment / Risk of bias analysis: The methodological quality, report quality and evidence quality will be evaluated by "The Cochrane Collaboration's tool for assessing risk of bias".

Strategy of data synthesis: Two reviewers will independently screen the literatures and include studies according to the prespecified selection criteria. Any disagreement will be resolved by discussion. Statistical analysis will be conducted using RevMan5.3 software provided by Cochrane.

Subgroup analysis: If a sufficient number of appropriate literatures are identified, we will perform subgroup analysis between variations of both manipulating needle and selecting acupoiont.

Sensibility analysis: We will perform a sensitivity analysis of the main outcomes to replace arbitrary or unclear alternative decisions or the scale of values of decisions. A sensitivity analysis will be performed for trials judged"high risk of bias" or "uncertain risk of bias" and the results of it will be compared with that of trials judged "low risk of bias".

Language: No restriction.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Functional diarrhea; Acupuncture; Randomized controlled trial; Systematic review; Meta-analysis.

Dissemination plans: We plan to publish a systematic review based on this protocol.

Contributions of each author:
Author 1 - Qin-qi Feng - The author drafted and improved the manuscript.
Author 2 - Si-miao Yao - The author improved the manuscript.
Author 3 - Nai-jia Dong - The author improved the manuscript.
Author 4 - Yan-di Wan - The author improved the manuscript.
Author 5 - Xun Li - The author provided statistical expertise, contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 6 - Jian-ping Liu - The author provided statistical expertise, read, provided feedback, and approved the final manuscript.