INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The effectiveness of herbal acupoint application for functional diarrhea Protocol for a meta-analysis and data mining

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Review question / Objective: **This review aimed to systematically evaluate the efficacy of herbal acupoint application for functional diarrhea. And , it will provide potential core prescriptions for clinical applications. This review will help better to explain and apply the therapy in clinic.**

Condition being studied: **Functional diarrhea (FDr), one of the most common functional gastrointestinal diseases, is a kind of functional bowel disease characterized by repeated paste feces or watery feces. An important risk factor for FDr is prior Infectious diarrhea. In majority of studies show that, FDr prevalence ranges within 5%~11% and may reach 17% in some regions.Many patients have to take measures to avoid the impact of diarrhea on their daily life, such as lifestyle modification, taking medication. Recently, herbal acupoint application has started to play an increasingly important role in clinic. Many clinical trials were carried out to provide more data supporting.However, there is a lack of systematic evaluation and analysis of acupoints and herbs. Our study will provide efficacy assessments for clinical applications.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 July 2021 and was last updated on 30 July 2021 (registration number INPLASY202170094).

INTRODUCTION

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METHODS

Participant or population: This review will include patients of any age who had been diagnosed with functional diarrhea without limitations related to gender, race, study area and education status.The diagnosis of functional diarrhea needs to be consistent with ROME II or III or ㈱. Participants were also included although ROME II or III or ㈱ criteria were not mentioned, if they were diagnosed as diarrhea and were excluded for specific pathological cause, such as underlying structural or metabolic diseases.

Intervention: In the intervention group, patients received all types of acupoint herbal patching treatment, regardless of herbal regimen, acupoints selected, patching time.

Comparator: In the control group, patients received medication, no treatment, sham or placebo acupoint catgut embedding, acupuncture/electro-acupuncture and etc. The other interventions between the control group and the intervention group should be the same.

Study designs to be included: Randomized controlled trials (RCTs) will be included. Randomised controlled trials (RCTs) comparing acupoint herbal patching for FDr with no treatment, placebo, or conventional drugs will be included. All eligible trials will be included regardless of language and publication types. Articles of the following research types will be excluded: case series, observational studies (including cohort and case-control studies) and retrospective studies, qualitative studies, animal experiments, review articles.There are no restrictions on study area, race, patient age, and gender.

Information sources: In attempt to identify all eligible studies, we will search the following eight databases from their inception to 30 Juny 2021, without language restrictions: the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, EMBASE, the Web of Science, the Chinese Biomedical Literature Database (CBM), the Chinese Scientific Journal Database (VIP database), the Wan-Fang Database and the China National Knowledge Infrastructure (CNKI). We will also searching the following three databases for prospectively registered and ongoing trials: the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal (http://apps.who.int/trialsearch/Default.aspx) ; ClinicalTrials.gov (http://ClinicalTrials.gov/) and Chinese Clinical Trials Registry (http://www.chictr.org.cn) . Besides, we will screen the references of included studies to identify other potential clinical trials.

Main outcome(s): 1.Clinical effective rate; 2. Bristol stool scale , number of daily bowel movements, Clinical symptom scale of diarrhea.

Quality assessment / Risk of bias analysis: Two review authors (Baiyan Liu and Bing Yan) will independently evaluate each included study and will follow the domain-based evaluation as developed by the Cochrane Handbook for Systematic Reviews of Interventions. They will assess the following domains: (1) selection bias (random sequence generation and allocation concealment), (2)performance bias (blinding of participants and personnel), (3) detection bias (blinding of outcome assessment), (4) attrition bias

(incomplete outcome data), (5) reporting bias (selective reporting), (6) other bias (such as pre-sample size estimation, early stop of trial). Each domain will be divided into three categories: 'low risk', 'high risk', or 'unclear risk'. We will use the GRADE approach to assess the overall quality of evidence supporting the primary outcomes. The overall quality of the evidence for each outcome will be determined after considering each of these factors and graded as: high, moderate, low, very low.

Strategy of data synthesis: First, the NoteExpress 3.2.0 software will be uesd to exclude duplicate references from different databases. Two review authors (Baiyan Liu and Bing Yan) will independently assess the title and abstracts of all citations found from the above search strategy. A copy of the full text article is obtained for the potentially eligible studies. These review authors will independently read the full text articles to include eligible studies; disagreement will be resolved by consensus through discussion with a third review author (Xuewei Zhao). If conclusion still cannot be met, we will contact the author of the article to determine the eligibility of the study. In the end, the following data will be extracted: author, year of publication, country where the study was conducted, study period, original inclusion criteria, total number of people included in the study, acupoints, doses of herbs and time of application and etc.

Subgroup analysis: Subgroup analysis will be conducted to evaluate the specific influence of intervention type, age, course of disease, treatment duration on pooled results. If the data is insufficient, qualitative synthesis will be conducted instead of quantitative synthesis. In addition, sensitivity analysis will be performed to examine the robustness of the results by eliminating low quality trials. We will also use Spss software (Version19.0) for complex network analysis to explore the potential core prescription of acupoint herbal patching for functional diarrhea.

Sensitivity analysis: The sensitivity inspection will be conducted to inspect the robustness of the study. We will eliminate low qualities articles one by one to inspect the reliability of this meta-analysis' results.

Country(ies) involved: China.

Keywords: Herbal acupoint application, complementary and alternative therapy, functional diarrhea, data mining, protocol, systematic review.

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