INPLASY PROTOCOL

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Acupuncture and Related Therapies for anxiety and depression in Diarrhoea-Predominant Irritable Bowel Syndrome(IBS-D): A Network Meta-Analysis

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Review question / Objective: **Acupuncture-related therapies are effective Diarrhoea-Predominant Irritable Bowel Syndrome(IBS-D), therefore, our aim was to evaluate and rank the effect of different acupuncture-related therapies for the anxiety-depression status of IBS-D patients.**
Eligibility criteria: **The published randomized controlled trials (RCTs) of acupuncture-related therapies for the treatment of IBS-D, regardless of age and sex. Clear diagnostic criteria were required to confirm the diagnosis of IBS-D, Such as Rome I, Rome II, Rome III, Rome IV, and Chinese expert consensus. Interventions in the treatment group included various types of acupuncture-related therapies, including simple acupuncture (ACU), electroacupuncture (EA), warm acupuncture (WA), moxibustion (MOX), or a combination of acupuncture and drugs; the control group is anti-diarrheal or anti-spasmodic western medicine, or placebo, or comparison between various acupuncture-related therapies. The results of the report are required to include at least one of the following outcome indicators: (1) primary outcome: Hamilton anxiety rating scale(HAMA), hamilton depression rating scale(HAMD), self-rating anxiety scale (SAS), self-rating depression scale(SDS), secondary outcome: Response rate. The language of the publication was limited to Chinese or English.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2022 and was last updated on 29 March 2022 (registration number INPLASY202230162).

INTRODUCTION

Review question / Objective: **Acupuncture-related therapies are effective Diarrhoea-Predominant Irritable Bowel Syndrome(IBS-D), therefore, our aim was to evaluate and rank the effect of different acupuncture-**

related therapies for the anxiety-depression status of IBS-D patients.

Condition being studied: Irritable bowel syndrome(IBS) is a functional bowel disease characterized by abdominal pain, irregular bowel movements, and changes in stool characteristics. Epidemiological reports indicate that the global prevalence rate is approximately 15%. It also varies slightly from country to country, with a rate of 19.58-23.40% in China, 10-25% in North America and Europe. The prevalence also differs between the genders, and overall, the prevalence is higher in females than in males. According to the clinical symptoms of irritable bowel syndrome, it could be divided into four types: irritable bowel syndrome with predominant diarrhea (IBS-D), irritable bowel syndrome with predominant constipation (IBS-C), irritable bowel syndrome with mixed bowel habits (IBS-M), irritable bowel syndrome unclassified (IBS-U), among which IBS-D is the most general. Currently, the drugs commonly used to treat IBS are mainly symptomatic treatment, such as anti-spasmodics, antidiarrheal drugs or prokinetic drugs and laxatives, etc. Although these drugs can provide limited relief for the symptoms of IBS, long-term use has certain side effects, such as ischemic colitis, etc. The previous systematic evaluation also indicated that IBS patients had significantly higher levels of anxiety and depression than the healthy group, and these negative psychological states may further aggravate the symptoms. However, psychological problems are often complex and it is difficult to handle many different symptoms with one medicine. Antipsychotics commonly used in the clinic may improve patients' symptoms, but long-term use may have many adverse effects (e.g., drug resistance and dependence) and therefore long-term use is not advised. In recent years, more and more clinical studies have shown the effectiveness of acupuncture for IBS, and recent systematic review and meta-analysis have confirmed this view. The effects of acupuncture are global in that in besides improving the symptoms of IBS, it can also improve the psychological status of patients, which is reflected in the treatment of many diseases. However, among the clinical studies in which acupuncture was the main intervention for the treatment of IBS-D, there were many types of acupuncture involved and there was a lack of original studies for direct comparison between different acupuncture methods. We used a network Meta-analysis to estimate direct and indirect evidence to evaluate and rank the included interventions with aim to inform the selection of the best interventions for the clinical treatment of IBS-D.

METHODS

Participant or population: The published randomized controlled trials (RCTs) of acupuncture-related therapies for the treatment of IBS-D, regardless of age and sex. Published studies on the psychological status of medical staff in the post-epidemic era, such as depression, anxiety, psychology, stress, insomnia, sleep disorders, etc.

Intervention: Interventions in the treatment group included various types of acupuncture-related therapies, including simple acupuncture (ACU), electro-acupuncture (EA), warm acupuncture (WA), moxibustion (MOX), or a combination of acupuncture and drugs.

Comparator: The control group is anti-diarrheal or anti-spasmodic western medicine, or placebo, or comparison between various acupuncture-related therapies.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: The published randomized controlled trials (RCTs) of acupuncture-related therapies for the treatment of IBS-D, regardless of age and sex. Clear diagnostic criteria were required to confirm the diagnosis of IBS-D, Such as Rome I, Rome II, Rome III, Rome IV, and Chinese expert consensus. Interventions in the treatment group included various types of acupuncture-related therapies, including

simple acupuncture (ACU), electroacupuncture (EA), warm acupuncture (WA), moxibustion (MOX), or a combination of acupuncture and drugs; the control group is anti-diarrheal or anti-spasmodic western medicine, or placebo, or comparison between various acupuncture-related therapies. The results of the report are required to include at least one of the following outcome indicators: (1) primary outcome: Hamilton anxiety rating scale(HAMA), hamilton depression rating scale(HAMD), self-rating anxiety scale (SAS), self-rating depression scale(SDS), secondary outcome: Response rate. The language of the publication was limited to Chinese or English.

Information sources: Our literature search was performed from database establishment until January 15, 2022, including the following databases: PubMed, EMBASE, Cochrane Library, the China Biology Medicine (CBM), the China National Knowledge Infrastructure (CNKI), Wanfang Data, and the Chinese Scientific Journal Database (VIP). The search was conducted using a combination of medical subject headings (MeSH) terms and free words. In addition, the references included in the medical literature were retrospectively supplemented to obtain the associated references.

Main outcome(s): The results of the report are required to include at least one of the following outcome indicators: (1) primary outcome: Hamilton anxiety rating scale(HAMA), hamilton depression rating scale(HAMD), self-rating anxiety scale (SAS), self-rating depression scale(SDS), secondary outcome: Response rate.

Quality assessment / Risk of bias analysis: Our two researchers evaluated the included studies in accordance with the bias risk assessment tool recommended in the Cochrane Handbook 5.1.

Strategy of data synthesis: Statistical analysis was performed using RevMan5.4, Stata 15.0 and WinBUGS 1.4.3 software. SAS, SDS, HAMA, and HDMA scores were numerical variables, and the difference before and after treatment was used as the effect size; the response rate was categorically variable, risk ratio(RR) with 95% confidence intervals(CI) was used. In some research the change between baseline and after treatment failed to show, and the missing data were estimated using the formula from the Cochrane Handbook 5.1: Firstly, the standard pairwise meta-analysis was performed using the RavMan manager. Second, Stata15.0 was used to draw an NMA evidence relationship diagram. Then, WinBugs1.43 was run to set the number of iterations to 50 000 for NMA; 95% confidence interval (95% CI) of inconsistency factors (IF) was used to judge the consistency of the closed-loop. Next, Stata 15.0 program was applied to create funnel plots to determine whether there was evidence of small sample effects in the included studies. Finally, the surface under the cumulative ranking curve (SUCRA) was generated using Stata 15.0 to show the SUCRA scores for all interventions, with higher SUCRA scores implying higher treatment class.

Subgroup analysis: We perform subgroup analysis based on different outcome indicators.

Sensitivity analysis: We will try to exclude low-quality studies and use different statistical models to analyze the same data for sensitivity analysis.

Language: The language of the publication was limited to Chinese or English.Our two researchers evaluated the included studies in accordance with the bias risk assessment tool recommended in the Cochrane Handbook.

Country(ies) involved: China.

Keywords: Acupuncture; Diarrhoea-Predominant Irritable Bowel Syndrome; Anxiety; Depression; Network meta-analysis

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