INPLASY PROTOCOL

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Effectiveness of acupuncture for anxiety and depression in irritable bowel syndrome: a protocol for systematic review and meta-analysis

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Review question / Objective: Effectiveness of acupuncture for anxiety and depression in irritable bowel syndrome.

Condition being studied: Irritable bowel syndrome (IBS) is the most commonly gastrointestinal diseases. The Rome Foundation's global study on 33 countries shows the total prevalence of IBS under the Rome IV Diagnostic Criteria was 3.8%. It is well established that people with IBS have higher levels of anxiety and depression. The impact of the acupuncture associated with anxiety and depression has been widely studied in Western countries. Acupuncture may be a promising choice for the treatment of anxiety and depression in IBS.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 February 2021 and was last updated on 03 February 2021 (registration number INPLASY202120014).

INTRODUCTION

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gastrointestinal diseases. The Rome Foundation's global study on 33 countries shows the total prevalence of IBS under the Rome IV Diagnostic Criteria was 3.8%. It is well established that people with IBS have higher levels of anxiety and depression. The impact of the acupuncture associated with anxiety and depression has been

widely studied in Western countries. Acupuncture may be a promising choice for the treatment of anxiety and depression in IBS.

METHODS

Participant or population: All patients with IBS, regardless the gender, age, race, country and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome IV criteria or the Manning criteria).

Intervention: The experimental group is defined as acupuncture treatment, such as body acupuncture, warm acupuncture, electro-acupuncture, auricular acupuncture, fire needling, elongated needle or moxibustion.

Comparator: The control group that will include non-acupuncture techniques, such as sham acupuncture, placebo, adjuvant chemotherapy or other pharmacotherapy. The acupoint numbers, retaining time and frequency will not be restricted in this protocol.

Study designs to be included: All RCTs which compared acupuncture with either placebo or other drugs. RCTs conducted in adults (participants aged >16 years) without regional and language restrictions.

Eligibility criteria: 1.Type of studies. All randomised controlled trials (RCTs) reported will be included without regional and language restrictions. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded. 2.Type of participants. All Postoperative patients with GC, regardless the age, gender, race, country and GC type. 3. Type of interventions. Any type of acupuncture treatment will be included, such as body acupuncture, electroacupuncture, auricular acupuncture, warm acupuncture, fire needling, elongated needle and moxibustion. Neither the number of treatments nor the length of treatment will be restricted in this review. 4. Type of comparators. Control interventions may include one of the

following treatment methods: general care, sham acupuncture, placebo, physical/mental training therapy, adjuvant chemotherapy or other pharmacotherapy. 5. Types of outcome measures. The primary outcome measure will be the Time to First Flatus. Secondary outcome measures include the time of f.

Information sources: 1. Type of studies.All RCTs which compared acupuncture with either placebo or other drugs. RCTs conducted in adults (participants aged >16 years) without regional and language restrictions. 2. Type of participants.All patients with IBS, regardless the gender, age, race, country and IBS type. Diagnosis of IBS based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria or the Manning criteria).3.Type of interventions.The experimental group is defined as acupuncture treatment, such as body acupuncture, warm acupuncture, electroacupuncture, auricular acupuncture, fire needling, elongated needle or moxibustion. 4. Type of comparators. The control group that will include non-acupuncture techniques, such as sham acupuncture, placebo, adjuvant chemotherapy or other pharmacotherapy. The acupoint numbers, retaining time and frequency will not be restricted in this protocol. 5. Types of outcome measures. Primary outcomes. The primary outcomes assessed will be the Hamilton Anxiety (HAMA) scale. Secondary outcomes. Secondary outcome measures include the Self-Rating Depression Scale (SDS), the Self-Rating Anxiety Scale (SAS), the Hamilton Depression (HAMD) scale and the rate of adverse effects (AEs).

Main outcome(s): The primary outcomes assessed will be the Hamilton Anxiety (HAMA) scale.

Additional outcome(s): Secondary outcome measures include the Self-Rating Depression Scale (SDS), the Self-Rating Anxiety Scale (SAS), the Hamilton Depression (HAMD) scale and the rate of adverse effects (AEs).

Quality assessment / Risk of bias analysis:

The risk of bias for included studies will be evaluated by two reviewers using the Cochrane Collaboration's tool for assessing risk of bias. It includes the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. Any disagreement should be solved in consultation with a third reviewer.

Strategy of data synthesis: Weighted mean difference (WMD) or standardised mean difference (SMD) will be adopted as statistical indicators in the analysis of continuous outcomes and the relative risk (RR) will be used to assess the treatment effect for dichotomous outcomes. 95% of the confidence intervals (CIs) will be determined in pooled estimates.

Subgroup analysis: If there is significant heterogeneity between the study results, we will perform a subgroup analysis to investigate differences in gender, age, outcome styles, etc.

Sensitivity analysis: We will perform sensitivity analyses to verify robustness of results. It includes the impact of methodological quality, study design and sample size.

Country(ies) involved: China.

Keywords: irritable bowel syndrome, acupuncture, depression, anxiety, complementary therapy.

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