INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Traditional chinese medicine for irritable bowel syndrome: a protocol for meta-analysis

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Review question / Objective: **The aim of this meta-analysis of randomized controlled trails is to evaluate the efficacy between different traditional chinese medicine for irritable bowel syndrome.**
Condition being studied: **Irritable bowel syndrome is a common functional gastrointestinal disorder, which been characterized by recurrent abdominal pain or abdominal discomfort and abnormal bowel Habits. The global prevalence of IBS is estimated to be as high as 15%,and it is estimated that IBS has a prevalence of approximately 10% to 20% in western countries. According to the Rome IV Criteria, IBS patients can be subgrouped into IBS with diarrhea, IBS with constipation, mixed IBS , and IBS unclassifable. The etiology of irritable bowel syndrome remains unclear. Lucky, acupuncture and Chinese medicine have better therapeutic effect on irritable bowel syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 October 2020 and was last updated on 15 October 2020 (registration number INPLASY2020100052).

INTRODUCTION

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METHODS

Participant or population: Patients who are diagnosed with IBS according to Manning or Rome I, II, or III criteria will be included in the analysis, regardless of their age, gender, ethnicity, or background.

Intervention: The intervention measures of the experimental group were only TCM, such as Chinese herbal medicine, Chinese patent medicine, acupuncture, moxibustion, massage, and so on. It can be monotherapy or combination. RCT comparing the above 2 therapies can also be included, and those who combine Western medicine will be excluded.

Comparator: The control group received conventional treatment of Western medicine, including the use of PPI, gastrointestinal motility drugs, or a combination of both.

Study designs to be included: Randomized controlled trails will be included.

Eligibility criteria: Two authors independently complete the following process: according to the above search strategy to complete the process of document retrieval, import documents into EndNote X7 for centralized management. Then, according to the inclusion and exclusion criteria, filter the literature by reading the title and abstract. If it is not possible to determine whether the article meets the requirements based on the inclusion and exclusion criteria, then read the full text to select. In the entire literature screening process, if the 2 authors have different opinions, the third author joins the discussion to get a common opinion.

Information sources: The China National Knowledge Infrastructure, Wanfang Database, Chinese Science and Technology Periodical Database, Chinese Biomedical Literature Database, Pubmed, Embase, Web of Science, and the Cochrane library.

Main outcome(s): The main outcome include effectiveness, basic recovery, marked effect, improvement; remission rate , relapse rate, clinical absolute score, and relative score.

Additional outcome(s): Secondary outcome indicators: including any related adverse reactions, the concentration of serotonin in Serum.

Quality assessment / Risk of bias analysis: The 2 authors will independently assess the risk of bias of the included studies based on the bias risk assessment tool recommended in the Cochrane “Risk of bias” assessment tool. Including 7 items: random sequence generation, allocation concealment, blind participants and personnel, blind assessment of results, incomplete result data, selective reports, and other biases. The results in each field will be divided into 3 levels: low bias risk, high bias risk, and unclear bias risk. The 2 authors will exchange assessment results and check whether the assessment results are consistent. If there is a disagreement, the third author will participate in the discussion and determine the final result.

Strategy of data synthesis: When meta-analysis is available, RevManV5.3 will be applied to analyze data. Data will use a random effects model with 95% CIs as substantial heterogeneity is expected among included studies. If the I2 test is >75%, we will not perform meta-analysis if the heterogeneity cannot ascertain possible causes from both clinical and methodological diversity. The fixed-effects model will be utilized for data synthesis if the I2 is <50%, while the random-effects

model will be performed for data synthesis when the I2 is in the range of 50% to 75%.

Subgroup analysis: If the Chi-squared test and Higgins I2 test detect obvious heterogeneity between studies, we will conduct a subgroup analysis from the following aspects: different types of TCM, treatment time, clinic classification, course of disease, and so on.

Sensibility analysis: In order to ensure the Credibility of the research results, we will conduct a sensitivity analysis of the included literature and will eliminate low-quality literature.

Language: The language is limited to Chinese and English.

Country(ies) involved: China.

Keywords: Irritable bowel syndrome, network meta-analysis, protocol, traditional Chinese medicine.

Contributions of each author:
Author 1 - Chengjiao Yao - The author drafted the manuscript.
Author 2 - Yilin Li - The author provided statistical expertise.
Author 3 - Mengjun Pu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Fengjiao Xie - The author read, provided feedback and approved the final manuscript.
Author 5 - Qin Xiong - The author provided feedback and approved the final manuscript.
Author 6 - Lihong Luo - The author contributed to the development of the selection criteria.
Author 7 - Peiming Feng - The author provide scientific research ideas and guidance.