INPLASY PROTOCOL

To cite: Ren et al. Chinese herbal medicine for the treatment of small intestinal bacterial overgrowth (SIBO): a protocol for systematic review and meta analysis. Inplasy protocol 202080004. doi: 10.37766/inplasy2020.8.0004

Received: 01 August 2020

Published: 01 August 2020

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Support: **STCIPHUCM (KTY2019001)**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Chinese herbal medicine for the treatment of small intestinal bacterial overgrowth (SIBO): a protocol for systematic review and meta analysis

Ren, X[1]; Du, Y[2]; Di, Z[3].

Review question / Objective: **The objective of this systematic review is to identify, analyze and synthesize research evidence on the effectiveness of Chinese herbal medicine for the treatment of small intestinal bacterial overgrowth (SIBO).**
Condition being studied: **In recent years, with the changes in people's lifestyle and diet, the incidence of SIBO has been increasing year by year. At present, SIBO has been systematically reviewed and meta-analyzed to investigate its relationship with digestive diseases, such as inflammatory bowel disease, irritable bowel syndrome, chronic liver disease and its therapeutic medication. Traditional Chinese medicine has obvious advantages in the treatment of this disease. And CAM is widely used to treat the disease. Over the past few decades, a number of randomized controlled trials (RCTs) and systematic evaluations have been conducted to evaluate the effectiveness and safety of different types of CAM methods, so there is an urgent need to summarize and further evaluate these studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 August 2020 and was last updated on 30 October 2020 (registration number INPLASY202080004).

INTRODUCTION

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METHODS

Participant or population: Inclusion: Adults with SIBO (as diagnosed using any recognised diagnostic criteria). Exclusion: Adolescents (under 18 years of age) and elderly people (over 70).

Intervention: Use traditional chinese medical herbal treatment.

Comparator: The control group included placebo, no treatment, and western medicine.

Study designs to be included: We will include randomized controlled trials (RCTs). Quasi-RCTs will also be included.

Eligibility criteria: In this review, only randomized controlled trials (RCTs) evaluating CHM for adults with SIBO (as diagnosed using any recognised diagnostic criteria) were eligible for inclusion, regardless of publication status or language. Quasi - RCTs were excluded, such as allocation by medical record number, visiting sequence, and date of birth. Baseline assessments were necessary.

Information sources: Retrieving PubMed, Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Library, and EMBASE, China National Knowledge Infrastructure, Chinese Bio-medicine Database, VIP Chinese Periodical Database, Wan Fang Database, including Chinese and English literature , The search strategy consisted with the following terms : " (intestine, small) or (bacterially) or (overgrowth) " and " (Chinese herbal therapy) or (asian continental ancestry group) or (phytotherapy).

Main outcome(s): 1 - Overall efficiency. 2 - Reflux disease diagnostic questionnaire (RDQ) score. 3 - symptom total score.

Quality assessment / Risk of bias analysis: The methodological quality of eligible studies will be assessed by two review authors independently according to the Cochrane Handbook for Systematic Reviews of Interventions. The following characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), other bias. Based on the assessments of the studies against these seven domains, they will be classified as being of “low risk”, “high risk” or “unclear risk” of bias. Any disagreements will be resolved by discussion or discussed with another reviewer if necessary.

Strategy of data synthesis: We will pool the results using a random-effects meta-analysis, with standardised mean differences for continuous outcomes, and calculate 95% confidence intervals and two sided P values for each outcome. Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic, and we will consider an I^2 value greater than 50% as being indicative of substantial heterogeneity.

Subgroup analysis: If results of the meta-analysis are significantly heterogeneous, subgroup analyses of the control groups might be performed.

Sensibility analysis: We will conduct sensitivity analyses based on study quality. We will use stratified meta-analyses to explore heterogeneity in effect estimates according to: study quality; study populations; the logistics of intervention provision; and intervention content. We will also assess evidence of publication bias. We will perform a Bayesian network meta-

analysis model for each outcome to estimate the overall treatment effects. In our NMA, we will use WinBUGS 14.3 and Stata 14.0.

Country(ies) involved: China.

Keywords: small intestinal bacterial overgrowth; Chinese herbal therapy; systematic review; meta analysis.

Contributions of each author:

Author 1 - Xuetong Ren - (RXT) initiated the study and participated in its design , database search , study selection , data extraction and drafting the manuscript .
Author 2 - Yanru Du - The author developed the research design and supervised all aspects of the study.
Author 3 - Zirui Di - The author participated in the study design and helped to search databases extract and assess studies and draft the manuscript.