

# INPLASY PROTOCOL

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**Support:** H2021423008.

**Review Stage at time of this submission:** Preliminary searches.

**Conflicts of interest:**  
None declared.

## Effects of traditional chinese medicine intervention on the gut microbiota in patients with chronic heart failure

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**Review question / Objective:** The purpose of this study was to clarify the changes of gut microbiota abundance in patients with chronic heart failure after TCM intervention.

**Condition being studied:** Chronic heart failure. Our team consists of six people who are responsible for all aspects of the study. We are committed to the prevention and treatment of chronic heart failure and have made some achievements in this field.

**Information sources:** PubMed, Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Library, and EMBASE, China National Knowledge Infrastructure, Chinese Biomedicine Database, VIP Chinese Periodical Data-base, Wan Fang Database, World Health Organization's International Clinical Trials Registry Platform.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2022 and was last updated on 01 June 2022 (registration number INPLASY202260006).

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### METHODS

**Search strategy:** We will search the following sources without restrictions for date, language, or publication status: PubMed, Cochrane Central Register of

### INTRODUCTION

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Controlled Trials (CENTRAL) Cochrane Library, and EMBASE, China National Knowledge Infrastructure, Chinese Bio-medicine Database, VIP Chinese Periodical Data-base, Wan Fang Database. We will apply a combination of Medical Subject Heading (MeSH) and free-text terms incorporating database-specific controlled vocabularies and text words to implement search strategies. We will also search the ongoing trials registered in the World Health Organization's International Clinical Trials Registry Platform. Besides, the previous relevant reviews conducted on complementary and alternative therapies for chronic heart failure and reference lists of included studies will also be searched.

**Participant or population:** Study participants were adult patients who had been diagnosed with chronic heart failure regardless of gender, race, and area.

**Intervention:** Taking measures of Chinese medicine enema, oral Chinese medicine, such as Chinese herbal compounds, Chinese patent medicine, and single Chinese medical herbs, which can be administered in the form of decoctions, granules, or powders.

**Comparator:** Individuals treated with either Western medicine or placebo, or those who were treated with either Western medicine or placebo did not receive any intervention.

**Study designs to be included:** Randomized controlled trial (RCT).

**Eligibility criteria:** Refer to ESC guidelines for the diagnosis of chronic heart failure.

**Information sources:** PubMed, Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Library, and EMBASE, China National Knowledge Infrastructure, Chinese Bio-medicine Database, VIP Chinese Periodical Data-base, Wan Fang Database, World Health Organization's International Clinical Trials Registry Platform.

**Main outcome(s):** Gut microbiota as well as its metabolites (fecal metabolome and ribosomal RNA sequencing), including, but not limited to the changes in the following measures indicators.

**Data management:** Data will be extracted from the eligible studies by 2 authors independently with same pre-designed data extraction table.

**Quality assessment / Risk of bias analysis:** The methodological quality and risk of bias (ROB) of all included studies were assessed by 2 authors independently using the Cochrane Collaboration's tool. The ROB in randomization, allocation, and loss of follow-up of the included RCTs was evaluated according to the systematic review of interventions in The Cochrane Manual 5.3.

**Strategy of data synthesis:** We will pool the results using a random-effects meta-analysis, with standardized mean differences for continuous outcomes, and calculate 95% confidence intervals and 2 sided P values for each outcome. Heterogeneity between the studies in effect measures will be assessed using the I<sup>2</sup> statistic, and we will consider an I<sup>2</sup> value greater than 50% as being indicative of substantial heterogeneity. 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 NMA model for each outcome to estimate the overall treatment effects. In our NMA, we will use WinBUGS 14.3 and Stata 14.0. If results of the meta-analysis are significantly heterogeneous, subgroup analyses of the control groups might be performed.

**Subgroup analysis:** Subgroup analysis was conducted according to the course of disease < 6 months and ≥ 6 months.

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**Sensitivity analysis:** We will conduct sensitivity analyses based on study quality.

**Language:** No language restriction.

**Country(ies) involved:** China.

**Keywords:** chronic heart failure, gut microbiota, meta-analysis, traditional Chinese medicine.

**Contributions of each author:**

**Author 1 - Yang zeqi.**

**Author 2 - Guo qiuhong.**

**Author 3 - Han yangyang.**

**Author 4 - Gao fan.**

**Author 5 - Tian jiaye.**

**Author 6 - Bai ran.**