INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effectiveness of Xiao-Chai-Hu-Tang for patients of chronic fatigue syndrome：A protocol for systematic review and meta-analysis

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Review question / Objective: **Effectiveness of Xiao-Chai-Hu-Tang for patients of chronic fatigue syndrome.**
Condition being studied: **As one of the common clinical diseases, chronic fatigue syndrome (CFS) has a higher incidence and a long duration. Modern medicine lacks effective treatment for this disease, which seriously affects the patient's physical and mental health and quality of life, causing family and society a heavy economic burden. In recent years, with the advancement of science and technology, researchers have gradually deepened their understanding of the pathogenesis of CFS, and its treatment methods have also been greatly enriched. In particular, the application of traditional Chinese medicine has made up for the shortcomings of modern medical treatment. In the past, clinical studies on Xiao-Chai-Hu-Tang (XCHT) for the treatment of CFS have gradually increased, but there is a lack of systematic efficacy evaluation. This study aims to systematically study the effectiveness of XCHT in the treatment of CFS.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2021 and was last updated on 22 May 2021 (registration number INPLASY202150084).

INTRODUCTION

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and its treatment methods have also been greatly enriched. In particular, the application of traditional Chinese medicine has made up for the shortcomings of modern medical treatment. In the past, clinical studies on Xiao-Chai-Hu-Tang (XCHT) for the treatment of CFS have gradually increased, but there is a lack of systematic efficacy evaluation. This study aims to systematically study the effectiveness of XCHT in the treatment of CFS.

METHODS

Participant or population: The diagnosis of CFS patients conforms to international or domestically recognized diagnostic standards.

Intervention: The treatment drug of the experimental group is XCHT. The mode of administration is oral, and the dosage form is decoction or granule.

Comparator: The control group received conventional medication or placebo treatment.

Study designs to be included: There have been publicly published literatures on RCT with XCHT or XCHT for the treatment of chronic fatigue syndrome, whether blinded or non-blinded.The Chinese medicinal materials contained in XCHT include Bupleurum, Scutellaria, Ginseng, Pinellia, Ginger, Licorice, Jujube, and the dosage form, usage and dosage are not restricted.

Eligibility criteria: (1) Non-RCT documents. (2) Included in the literature, exclude case reports, animal experiments, cytology experiments, injury reports, reviews and comments, etc. (3) Missing information affects the results or it is impossible to obtain complete data and full-text documents. (4) Treated patients with organs, blood system and organic diseases are not included in the literature. (5) Those who have no specific drug components in the combined measures or the experimental group combined with western medicine and other prescriptions cannot evaluate the results will not be included in the literature.

Information sources: The scope of document retrieval is mainly the following 9 databases, including PubMed, EMBASE, Science Network, Cochrane Library, Chinese Biomedical Literature, Wanfang Chinese Digital Journals and Conference Database, China National Knowledge Infrastructure Database and VIP China Science and Technology Journal Database (VIP). We will search data from the above 9 Chinese and English databases.

Main outcome(s): The main outcome indicator is the total effective rate.

Additional outcome(s): Secondary outcome indicators include symptom score, Checklist Individual Strength, Multidimensional Fatigue Inventory, etc.

Quality assessment / Risk of bias analysis: The methodological quality evaluation of literature data will use the Cochrane Collaboration's risk bias assessment tool. [36]The evaluation content includes: ①Generation and application of random serial numbers; ②Randomized allocation and concealment measures; ③Methods of implementing blinding; ④Methods for withdrawal and withdrawal; ⑤Whether to report research results selectively; ⑥Whether There are other sources of bias. The final quality of the research data is expressed as a score, with a score ≤ 3 as low-quality literature and excluded; literature with a score ≥ 4 was included in this analysis cohort. This process is carried out by two researchers independently for statistics and evaluation. If there is any objection, the results will be negotiated with the experts.

Strategy of data synthesis: The Meta analysis uses RevMan5.3 software for analysis. When calculating the effect size, the binary data uses odds ratio (OR) and its 95% confidence interval (CI) as the effect results for statistical analysis, and the continuity index uses standard average

deviation or weighted average deviation for analysis.

Subgroup analysis: If there is a large heterogeneity between the results of the study, we will conduct a subgroup analysis to investigate the gender, age, and different drug doses, and compare the differences in the effect estimates between the subgroups.

Sensitivity analysis: After excluding specific studies one by one (low-quality studies, studies with different inclusion and exclusion standards, etc.), the robustness of the research results are determined by whether the combined effect size changes significantly before and after.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: chronic fatigue syndrome; scheme; Xiao-Chai-Hu-Tang; systematic review.

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