INPLASY PROTOCOL

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The authors report no conflicts of interest in this work.

Efficacy and safety of different acupuncture treatments for chronic functional constipation: a systematic review and a network meta-analysis protocol

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Review question / Objective: **This study will evaluate the efficacy of different acupuncture therapies in the treatment of chronic functional constipation (CFC) through a network meta-analysis in order to provide an optimal ranking for the clinical treatment of CFC.**
Condition being studied: **As an important part of Traditional Chinese medicine, acupuncture and moxibustion has unique advantages in the treatment of chronic functional constipation. This treatment is safe and economical, has significant curative effect and has no side effects, and is a popular treatment method. Moreover, a large number of clinical experiments have confirmed the efficacy of acupuncture and moxibustion in the treatment of chronic functional constipation. However, the current meta-analysis has not reported the comparison of therapeutic effects between different acupuncture and moxibustion therapies. Therefore, this study adopted the reticular Meta analysis method to compare the efficacy of acupuncture and moxibustion therapy with drugs and different acupuncture and moxibustion therapy, so as to provide reference for the clinical treatment of chronic functional constipation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 November 2020 and was last updated on 25 November 2020 (registration number INPLASY2020110108).

INTRODUCTION

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METHODS

Participant or population: CFC diagnosis should be consistent with the Roman (III, IV) diagnostic criteria, without limiting patients' gender, age, race, time and source of cases, etc.

Intervention: Acupuncture will be regarded as acupoint-based therapy. (e.g., needle, head needle, body acupuncture, electroacupuncture, abdominal needle, warm acupuncture, moxibustion, auriculotherapy, acupoint injection, acupoint embedding, medium frequency electrical stimulation, etc.).

Comparator: The control group received western medicine treatment, including lactulose, casserole, domperidone and so on. Studies of different types of acupuncture will be included.

Study designs to be included: We will include reports of randomized controlled trials (RCTS) conducted in English or Chinese.

Eligibility criteria: A randomized controlled clinical trial of acupuncture and moxibustion in the treatment of CFC was conducted in Chinese or English only. Other types of trials will be excluded, such as reviews, case reports, animal studies, case studies, conference articles, etc.

Information sources: Systematic retrieval was conducted from six electronic databases, namely PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM) and Wanfang Database, from the date of establishment to October 31, 2020. The search strategy adopts the combination of subject words and free words, and adjusts the search words according to the search results.

Main outcome(s): The main result was the frequency of weekly defecation.

Additional outcome(s): Secondary outcomes included Bristol fecal score (fecal traits), quality of life, psychological status, adverse reaction rate, and safety assessment.

Quality assessment / Risk of bias analysis: Assessment of quality in included studies. The quality of the studies will be assessed according to the Cochrane risk of bias assessment tool. The main contents include: sequence generation, allocation concealment, blinding (or masks), incomplete data assessment, selective outcome reporting and other sources of bias. Then, the risk of bias for included studies will be classified as “low", “unclear” and “high” risk of bias. The above content evaluation will be performed by 2 researchers, and any differences will be resolved through discussions or consultation with the third reviewer . The Grading of Recmmendations Assessment, Development, and Evaluation (GRADE) system will be used to grading the quality of the evidence for main outcomes. Evidence quality will be graded as “high”, “moderate”, “low” or “very low” according to the GRADE rating standards.

Strategy of data synthesis: First, heterogeneity test was performed on the included clinical trials to check whether the included studies could be combined. When

I2≤50%, the fixed-effect model will be used to merge the data. When it is greater than 50% of I2 >, the random effects model is used for processing. Classification variables were expressed by Relative risk (RR), and numerical variables were standardized mean difference (SMD). Both of them gave a 95% confidence interval (CI). Traditional two-by-two analysis was used for direct comparison, while network meta-analysis was used for indirect comparison. For data analysis, we will use RevMan 5.3 and the associated "NetMeta" package. The evaluation of inconsistencies in the direct and indirect comparison results will use the Z-test and the results will be represented by a network diagram.

Subgroup analysis: If there are significant heterogeneities in the included studies, the STATA software will be used for subgroup analysis and meta-regression analysis according to the characteristics of the test subjects, sample size, different acupuncture intervention methods, quality of included trials, etc.

Sensibility analysis: We will evaluate the robustness of the meta-analysis results through sensitivity analysis, and exclude such as small-sample trials and low-quality trials to explore the impact of trial quality on efficacy estimates. In addition, we will conduct a second meta-analysis based on the results of the sensitivity analysis, summarize in tables and discuss.

Language: We will include reports of randomized controlled trials (RCTS) conducted in English or Chinese.

Country(ies) involved: China.

Keywords: acupuncture, chronic functional constipation, network meta-analysis, systematic review.

Contributions of each author:
Author 1 - Pan Cheng - drafted the manuscript.
Author 2 - Zhenhai Chi - drafted the manuscript.
Author 3 - Lin Jiao - provide financial support.