

# INPLASY PROTOCOL

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

**Conflicts of interest:** No.

## Effectiveness and safety of Acupuncture in the treatment of Chronic Severe Functional Constipation: A protocol for systematic review and meta-analysis

Zhu, D<sup>1</sup>; Jiao, L<sup>2</sup>; Chen, R<sup>3</sup>.

**Review question / Objective:** This study comprehensively searched the literature to further systematically evaluate the efficacy and safety of acupuncture in the treatment of Chronic Severe Functional Constipation, with a view to clinically treating Chronic Severe Functional Constipation, alleviating its related clinical symptoms and preventing its further development, and providing the latest evidence-based medical evidence.

**Condition being studied:** Constipation refers to feces staying in the intestine for a long time, the constipation is blocked and there are a series of symptoms, such as difficulty or effort in defecation, reduced number of bowel movements, poor bowel movements, and thousands of stools. It is a common clinical condition. According to the prevalence According to medical investigations, the prevalence of chronic constipation increases with age, and it has a certain relationship with gender. Women are at high risk. In addition, low economic and cultural levels, anxiety, depression, etc. are also factors that induce and aggravate chronic constipation. The repeated occurrence of chronic constipation can affect the work and quality of life of modern people to varying degrees. Historical records and modern studies have confirmed that acupuncture is effective in treating constipation. Studies on the spectrum of acupuncture and moxibustion in the digestive system also indicate that constipation is a commonly used and effective condition of acupuncture. Compared with general medical treatment, acupuncture is safer without side effects.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 July 2020 and was last updated on 01 July 2020 (registration number INPLASY202070002).

### INTRODUCTION

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with a view to clinically treating Chronic Severe Functional Constipation, alleviating its related clinical symptoms and preventing its further development, and providing the latest evidence-based medical evidence.

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## METHODS

**Search strategy:** 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database .The retrieval time was from the time the database was built to June 1, 2020. The search uses the keyword search. Chinese search terms include constipation, astriction, astriction, Functional severe constipation, acupuncture, Electroacupuncture, random. English search terms include "constipation" and "acupuncture or acupuncture Therapy ".This study does not limit the scope of language retrieval. In addition, we manually searched other literature, as well as unpublished research and conference materials. If the test report

data is unknown or lacking, we will contact the author by email.

**Participant or population:** All cases included in the trial were patients with Functional severe constipation and met the clinical diagnostic criteria of the International Rome IV diagnostic criteria for constipation without age and race restrictions.

**Intervention:** The treatment group was mainly acupuncture therapy. The comparison group consisted of those receiving routine care or any intervention other than acupuncture therapy.

**Comparator:** All cases included in the trial were patients with Functional severe constipation and met the clinical diagnostic criteria of the Rome IV diagnostic criteria for constipation, without age and race restrictions.

**Study designs to be included:** A randomized controlled trial (RCT) study on acupuncture therapy treatment of Functional severe constipation, published in any language.

**Eligibility criteria:** Types of study:All randomized controlled trials (RCT s) study on acupuncture therapy treatment of Functional severe constipation.Others such as case reports, animal experiments, non-RCTs, or RCT protocol will be excluded.

**Information sources:** 8 electronic databases including PubMed, Web of Science, the Cochrane Database, EMBASE, China Knowledge Network (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Science and Technology Periodical Database (VIP) and China Biomedical Literature (CBM) Database.

**Main outcome(s):** complete spontaneous bowel movements.

**Additional outcome(s):** 1. Self-assessment of quality of life for patients with constipation (PAC-QOL) scale; 2. Adverse event.

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**Quality assessment / Risk of bias analysis:**

Two reviewers performed rigorous methodological quality evaluation of the included studies with reference to the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features.

**Strategy of data synthesis:** Meta analysis was performed using RevMan5.3 provided by the Cochrane collaboration network. Relative risk (RR) was used for the two categorical variables, and mean difference (MD) was used for the continuous variables. Both were expressed with 95% confidence intervals (CI). The heterogeneity test between the results of the included studies was performed using the  $I^2$  test. The  $I^2$  value reflects the proportion of the total variation in the effect size due to the existence of heterogeneity. ( $I^2 > 50\%$ , indicating that heterogeneity is more obvious. If there is no obvious heterogeneity between the research results ( $I^2 < 50\%$ ), the fixed effect model is used to merge them; if there is significant heterogeneity ( $I^2 > 50\%$ ), the source of the heterogeneity is analyzed first, which may lead to heterogeneity Factors for subgroup analysis. If statistical heterogeneity exists in each subgroup without clinical heterogeneity, a random effects model is used for analysis. If the heterogeneity is too large and the results cannot be combined, a descriptive analysis is used and a sensitivity analysis is performed if necessary.

**Subgroup analysis:** Subgroup analysis will be handled according to the differences in acupuncture methods, patient conditions, and control.

**Sensibility analysis:** Sensitivity analyses will be performed to verify the robustness of the review conclusions. The impacts of study design, methodological quality, and missing data will be evaluated. Sensitivity analyses were planned by studies considered being at low risk of bias.

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

**Keywords:** acupuncture; Functional severe constipation; meta-analysis; systematic review.

**Contributions of each author:**

Author 1 - Daocheng Zhu - Author 1 drafted the manuscript.

Author 2 - Lin Jiao - The author provided statistical expertise.

Author 3 - Rixin Chen - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.