INPLASY PROTOCOL

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Conflicts of interest:
None.

Comparison of efficacy and safety between chiropractic and single western medicine treatment for functional constipation(FC): a protocol for systematic review and network meta-analysis

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Review question / Objective: **(1) Is chiropractic therapy effective in solving the defecation difficulty of FC patients? (2) How is the efficacy and safety of chiropractic therapy compared with single western medicine therapy.**
Condition being studied: **Functional constipation (FC) is one of the most common diseases. Chiropractic has been widely used in the treatment of FC. Previous studies have provided an inaccurate assessment of the role of chiropractic in FC. We will compare chiropractic therapy with single western medicine to discuss the efficacy and safety of chiropractic in FC.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 December 2020 and was last updated on 05 December 2020 (registration number INPLASY2020120029).

INTRODUCTION

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METHODS

Participant or population: Patients who have been diagnosed with functional constipation will be included.

Intervention: Interventions of chiropractic or chiropractic combined with other treatments will be included. To control the heterogeneity, we will exclude studies reporting chiropractic therapy combined with Chinese medicine. Because the effectiveness of Chinese medicine could not be evaluated.

Comparator: The control group was treated with single western medicine, including one or more western medicine. We will exclude the studies which applying Chinese medicine, or other methods that we can't define the therapeutic effects as a control.

Study designs to be included: To systematically evaluate the efficacy and safety of Chiropractic and single western medicine for FC, we will include RCTs that the treatment group was treated with chiropractic or chiropractic combined with other treatments, while the control group was treated with western medicine.

Eligibility criteria: Patients who were diagnosed as FC according to ROME II, III, or IV criteria will be included regardless of race, sex, education status or severity of disease. Patients can be included if they meet other clinical research guidelines and have no pathological cause or organic disease. Studies with participants that included special populations, such as pregnant women, lactating women, addicts, strokes or those diagnosed with constipation due to other diseases, will be excluded.

Information sources: The following electronic databases will be searched from their inception to December 2020, including PubMed, Embase, Web of Science, Cochrane Central Register of Controlled Trials (Central), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM) and Wanfang Database.Because of language limitation, only RCTs published in English and Chinese were included.

Main outcome(s): The primary outcome is overall response rate(ORR),defecation frequency and stool consistency (Bristol Fecal score)and weekly stool frequency (including spontaneous bowel movement (SBM), and complete SBM (CSBM)) at the end of all sessions.

Additional outcome(s): The secondary outcomes involved quality of life (QoL), mean transit time, patients using laxatives, and adverse event reporting in studies.

Quality assessment / Risk of bias analysis: Two reviewers (XXW and XZH) will independently evaluate the quality of included RCTs by using the Cochrane Collaboration's tool for assessing risk of bias (Cochrane Manual V.5.1.0). The following domains will be accessed: random sequence generation, allocation sequence concealment, blinding, data integrity, selective reporting, and other sources of bias. The assessment results will be divided into 3 levels: low risk, high risk, and uncertain risk. In the process, the discrepancy will be discussed by the two reviewers to reach an agreement, or judged by a third reviewer (PDZ).

Strategy of data synthesis: Two authors will independently finish the data analysis by RevMan 5.3 software. For dichotomous data, such as ORR and adverse events, we expressed the results for each study as the risk ratios (RRs) with 95% confidence intervals (CIs). And for the continuous data, such as CSBM, SBM and Bristol score,we expressed the results as the difference or

standard mean difference (SMD) with 95% CI. If there are any data issues, we will deal with them according to the method described in the Cochrane handbook.The heterogeneity of the study will be evaluated by Q-test and I2 statistics.When the I^2 test is less than 50%, the study is not considered to have a large heterogeneity. When the I^2 values are above 50%, there is significant heterogeneity between trials. To investigate the contributors to the heterogeneity, we will use sensitivity and subgroups analysis. If the heterogeneity is too high, the meta-analysis will not be performed, we will conduct a descriptive systematic review. We will use the Egger test to detect the symmetry of funnel plots to assess the reported biases.Dissymmetry funnel plot indicates high risk of reporting bias, while symmetric funnel plot indicates low risk.When the number of included studies in each outcome is sufficient, we will use a funnel plot that evaluates the reported bias. (n>10). If the funnel plot is asymmetric, Egger regression test will be used.

Subgroup analysis: Some factors may contribute to the heterogeneity, such as participants' age or gender , the severity of constipation, pathogenic factors, disease duration, intervention time, intervention cycle, measurement methods.

Sensibility analysis: To ensure the stability and reliability of the results, a sensitivity analysis will be performed. The sample size, studies design, methodological quality, and missing data will be assessed. Excluding the studies which were poor quality or potential contributors to heterogeneity, the meta-analysis will be reused. We will compare the results and discuss.

Country(ies) involved: China.

Keywords: chiropractic; functional constipation; meta-analysis; protocol.

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