INPLASY PROTOCOL

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Conflicts of interest:
None declared.

A comparison of efficacy and safety of complementary and alternative therapies for functional constipation in children A protocol for systematic review and meta-analysis

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Review question / Objective: **Through a mesh meta-analysis, this study will compare the efficacy and safety of complementary and alternative therapies for functional constipation in children, and evaluate and prioritize different interventions. It is expected to provide a reasonable basis for clinicians to use pediatric complementary and alternative medicine for functional constipation in children.**
Condition being studied: **Constipation in children is a major global health problem and can occur in children of all ages. More than 95% of children with constipation and above suffer from functional constipation. Functional constipation is especially common in preschool children which seriously affects the physical and mental health of children, reduces the quality of life of families and increases social burden.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 September 2021 and was last updated on 19 December 2021 (registration number INPLASY202190030).

INTRODUCTION

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pediatric complementary and alternative medicine for functional constipation in children.

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METHODS

Participant or population: Children under 18 years of age who met the relevant criteria for functional constipation were enrolled. Patients with other organic diseases will be excluded.children with functional constipation Patients under 18 years of age.

Intervention: Traditional Chinese medicine therapy, including Chinese herbal medicine, acupoint application, massage, acupuncture, moxibustion, scraping, ear point sticking pressure, etc.

Comparator: Conventional Treatment in Western medicine, including adjustment of diet and lifestyle, probiotics, laxatives.

Study designs to be included: Only randomized controlled trials (RCTS) were included in this study and relevant literature included in a systematic review/ meta-analysis was screened.

Eligibility criteria: Inclusion criteria are as follows: 1. All participants met the diagnostic criteria related to functional constipation. 2. There is no limit to the severity of the disease. 3. The course of disease is 1 month or more. 4. Age between 0 and 18.5. No gender or race restrictions.

Information sources: The retrieval period is from database establishment to June 2021, including Cochrane Library, PubMed, EMBASE, Chinese Biomedical Literature Database, CNKI Journal full-text database, Wanfang Academic Journal full-text database, VIP Chinese Science and Technology journal database, and other electronic databases.

Main outcome(s): Outcome measures include total clinical response rate, clinical symptom score, and incidence of adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the methodological quality of the included literature according to the quality assessment criteria of the Cochrane Systematic Review Manual. After completion of the assessment, cross-check and resolve disputes through discussion or by a third reviewer.

Strategy of data synthesis: Meta-analysis was performed using RevMan5.3 software. Relative risk (RR) was used as the effect index for dichotomous variables, mean difference (MD) was used as the effect index for continuous variables, and 95% confidence interval (CI) was used for interval estimation. Heterogeneity was tested by Q test and I2 test. If $P \geq 0.1$ and $I2 \leq 50\%$, there was no significant heterogeneity between studies, and fixed effect model was used for analysis. If $P < 0.1$ and $I2 > 50\%$, it indicates that there is significant heterogeneity between studies. The random-effect model is adopted, and sensitivity analysis is conducted to find the source of heterogeneity. If necessary, subgroup analysis is performed to determine whether there is clinical and methodological heterogeneity.

Subgroup analysis: If significant heterogeneity exists, we will perform subgroup or descriptive analysis, or narrative and qualitative summaries.

Sensitivity analysis: Sensitivity analysis will be performed based on sample size, missing data results, and methodological quality included in the study. If necessary, low-quality studies will be excluded and meta-analyses repeated to test the stability of pooled results.

Country(ies) involved: China.

Keywords: Functional constipation in children; Complementary and alternative therapies; Net meta-analysis; Plan; Systematic review.

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