

INPLASY PROTOCOL

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None declared.

Curative efficiency and adverse events of alternative therapy and medicine for functional constipation in adults: A protocol for systematic review and meta analysis

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Review question / Objective: Population: Adult with functional constipation. Intervention: Medicine or alternative therapy(acupuncture or massage). Comparison: Other treatment. Outcome: Frequency and quantity of defecation.
Information sources: Related studies in the following databases will be searched from its creation to Jan 17, 2022: PubMed, Embase, Scopus, Web of Science, the Cochrane Library, China National Knowledge Infrastructure, VIP and Wanfang.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 January 2022 and was last updated on 17 January 2022 (registration number INPLASY202210091).

INTRODUCTION

Review question / Objective: Population: Adult with functional constipation. Intervention: Medicine or alternative therapy(acupuncture or massage). Comparison: Other treatment. Outcome: Frequency and quantity of defecation.

Condition being studied: Functional constipation (FC) is a common gastrointestinal disorder with the main clinical manifestations being difficult bowel movements, hard or lumpy stools, and thinning. The prevalence of functional constipation has been reported to be around 20% of adults in the USA and 14% of adults in the UK. FC poses a significant

clinical and financial burden to patients. For a small proportion of patients, changes in lifestyle habits, such as a vegetarian diet or increased aerobic activity, can alleviate their symptoms. Most patients, however, also require medical treatment. Currently, the treatments used include gastrointestinal stimulants, enemas, osmotic agents and stimulant laxatives. There is some efficacy in FC. However, after prolonged use of these treatments, many side effects can occur. Therefore, a safe and effective treatment for FC has been desired. Complementary and alternative medicine (CAM) is often used to treat chronic diseases as well as for disease prevention. In China and some other Asian countries, acupuncture and abdominal tuina have been used as a form of CAM for the treatment of gastrointestinal disorders for approximately 3000 years. Studies have shown that acupuncture can modulate gastrointestinal motility and acid secretion; electro-acupuncture (EA) can alter the motility of the gastrointestinal tract; and abdominal tuina can induce rectal muscle waves, stimulate somatic autonomic reflexes and intestinal sensation, and promote rectal loading and peristalsis. In recent years, a growing number of clinical studies have used CAM to intervene in functional constipation. Although many clinical studies have reported a positive effect on functional constipation, there is no scientific evidence. Therefore, the aim of this meta-analysis is to evaluate the efficacy and poor prognosis of CAM and pharmacological treatment of functional constipation to provide a better basis for clinical decision making.

METHODS

Participant or population: All patients with functional constipation will be included without limitation of age, race, sex, economic level, and severity.

Intervention: The intervention group will choose alternative therapy (acupuncture or massage) or medicine (Lactulose, Polyethylene glycol, Milk of magnesia, Mineral oil, Bisacodyl, Senna, Sodium

picosulfate, Bisacodyl, Sodium phosphate, Sodium docusate, Sodium lauryl Sulfoacetate, probiotics, Lubiprostone, Linaclotide, Plecanatide, Prucalopride).

Comparator: Controlled interventions included control groups with no treatment, sham/placebo groups, or other conventional treatments.

Study designs to be included: Only randomized controlled trials (RCTs) will be included in this study.

Eligibility criteria: We will include only the literature of randomized controlled trials (RCTs) of alternative therapy for functional constipation. Nonrandomized controlled studies case reports, case series and reviews will not be included in this study.

Information sources: Related studies in the following databases will be searched from its creation to Jan 17, 2022: PubMed, Embase, Scopus, Web of Science, the Cochrane Library, China National Knowledge Infrastructure, VIP and Wanfang.

Main outcome(s): The primary outcome was frequency and quantity of defecation.

Additional outcome(s): Secondary endpoints included faecal incontinence, disimpaction, need for additional therapies and adverse events.

Quality assessment / Risk of bias analysis: The quality of all RCTs will be evaluated with the Cochrane Collaboration tool. Two authors (Tingting Pang and Jiahui Li) will independently conduct quality evaluations, and any controversy will be addressed by discussion with another author (Chang Liu).

Strategy of data synthesis: The meta-analysis of data from included outcomes will be performed using the RevMan V.5.4.1, and we will choose a randomized or fixed effect model for data statistics according to the results of the heterogeneity test. The enumeration data were expressed as relative risk (RR), and the weight mean difference (WMD) was used as the

measurement data; each effect amount was expressed in 95% confidence interval (CI). The specific methods were as follows: If the heterogeneity was low ($I^2 < 50\%$), the fixed-effects model was used for data synthesis. If there is high heterogeneity ($I^2 > 50\%$), the random-effects model will be used for data synthesis after excluding possible heterogeneity sources. The investigation methods included subgroup and sensitivity analyses. If data cannot be synthesized, we provide a descriptive analysis to solve this problem.

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Subgroup analysis: If there was high heterogeneity ($I^2 > 50\%$) among the included studies, we conducted a subgroup analysis to analyze the sources of heterogeneity according to the following factors: age, sex, race, courses, sample sizes, different doses of the drug, treatment time, different subtypes of functional constipation, and other possible factors affecting the results.

Sensitivity analysis: To test the stability and reliability of the results of this study, we conducted a sensitivity analysis according to the following points: method quality, sample size, and missing data. After that, we will perform a data analysis again and compare the results. If there was no directional change after the sensitivity analysis, the results were stable.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Functional constipation; Acupuncture; Massage; Laxative; Systematic review; Meta-analysis network meta-analysis.

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