

# INPLASY PROTOCOL

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

**Conflicts of interest:** No.

## Short and long-term efficacy of massage for functional constipation: A systematic review and meta-analysis protocol

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**Review question / Objective:** Is massage treatment effectiveness and safe for patients?

**Condition being studied:** Functional constipation (FC) is a prevalent clinical disease that affects a considerable proportion of the population of all ages. Persistent FC significantly reduces quality of life and influences physical and emotional well-being, as well as consumes many substantial healthcare resources. Massage originates from Traditional Chinese Medicine (TCM), and emerging evidence of several randomized controlled trials (RCTs) published suggests that massage has positive effects for FC. Thus a systematic review will be designed to appraise the effectiveness and safety of massage for improvement of FC in patients based on high-quality RCTs.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 May 2020 and was last updated on 01 May 2020 (registration number INPLASY202050001).

### INTRODUCTION

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emotional well-being, as well as consumes many substantial healthcare resources. Massage originates from Traditional Chinese Medicine (TCM), and emerging evidence of several randomized controlled trials (RCTs) published suggests that massage has positive effects for FC. Thus a systematic review will be designed to appraise the effectiveness and safety of massage for improvement of FC in patients based on high-quality RCTs.

## METHODS

**Participant or population:** The adult patients (aged 18 years or older) who have been confirmedly diagnosed with FC.

**Intervention:** massage.

**Comparator:** No treatment, waiting list membership, usual care, placebo, conventional pharmacological therapies, diet or physical activity therapy, and any other active treatments.

**Study designs to be included:** Randomized controlled trials.

**Eligibility criteria:** 1.non-randomized trials; 2. non-clinical trials; 2. articles not in English or Chinese; 3. articles which data analysis did not fulfill protocol criteria.

**Information sources:** PubMed, Embase, the Cochrane Library, Web of Science, China National Knowledge Infrastructure(CNKI), Chinese Scientific Journal Database(VIP), and WanFang Data, Chinese Clinical Trial Register (ChiCTR) were all searched.

**Main outcome(s):** The primary outcome measure of the study was the difference in weekly spontaneous bowel movements before and after treatment.

**Quality assessment / Risk of bias analysis:** The Risks of bias will be assessed according to the Cochrane Handbook Version 5.1.0. by 2 reviewers. The following factors were assessed: 1. Randomization sequence generation: was the allocation sequence adequately generated? 2. Treatment allocation concealment: was the

allocated treatment adequately concealed from study participants and clinicians and other healthcare or research staff at the enrolment stage? 3. Blinding: were the personnel assessing outcomes and analyzing data sufficiently blinded to the intervention allocation throughout the trial? 4. Completeness of outcome data: were participant exclusions, attrition, and incomplete outcome data adequately addressed in the published report? 5. Selective outcome reporting: is there evidence of selective outcome reporting and might this have affected the study results? 6. Other sources of bias: was the trial apparently free of any other problems that could produce a high risk of bias? Disagreements were solved by discussion until a consensus was reached.

**Strategy of data synthesis:** Data analysis will be performed with Review Manager 5.3 software provided by the Cochrane Collaboration. Effective Rate was calculated by relative risk, and the HAMA score will be calculated by mean difference. Heterogeneity is recognized as significant when  $I^2 \geq 50\%$ . A fixed-effect model will be performed when there is no significant heterogeneity, otherwise a random-effects model will be performed.

**Subgroup analysis:** The subgroup analysis will include factors like the design of the trial, study quality, durations, frequencies, a period of follow-up, types or forms of acupuncture intervention (this is the main the factor causing heterogeneity), the degree of FC severity, FC measurements, the characteristics of patients, geographical area, time-point of outcomes, and other different control interventions. The incidence rates of different types of adverse events with descriptive techniques will be also tabulated and assessed in this review.

**Sensibility analysis:** Sensitivity analysis will also be employed to explore possible factors that may lead to heterogeneity, such as intervention measures, control measures, length of treatment or quality of articles, etc. If quantitative synthesis is not

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appropriate, we will conduct a narrative synthesis.

**Language:** English and Chinese.

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

**Keywords:** massage, constipation, protocol, systematic review.

**Contributions of each author:**

**Author 1 - Ying Tang - drafted the manuscript.**

**Author 2 - Kejin Shi - Data curation.**

**Author 3 - Jie Zhu - Software.**

**Author 4 - Mao Li - Formal analysis.**

**Author 5 - Yong Wen - Investigation.**

**Author 6 - Xiaomin Wang - Project administration.**

**Author 7 - Fengyi He - Methodology.**

**Author 8 - Zhao Jin - Supervision.**