INTRODUCTION

Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Moxibustion for Diarrhoea-Predominant Irritable Bowel Syndrome.

Condition being studied: Irritable bowel syndrome (IBS) is a high incidence of intestinal dysfunction. IBS has a prevalence ranging from 1.1 to 29.2% in the whole population according to the Rome III criteria, with the diarrhoea-predominant type accounting for about 23.4%. Many patients have refractory irritable bowel syndrome and are looking for complementary therapies that may be effective and less likely to have side effects. The purpose of this study was to evaluate the efficacy and safety of Moxibustion in the treatment of diarrhea predominant irritable bowel syndrome.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 August 2021 and was last updated on 05 September 2021 (registration number INPLASY202180003).
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**METHODS**

**Participant or population:** Participants who were diagnosed with Diarrhoea-Predominant Irritable Bowel Syndrome regardless of age, gender, and race. Diagnosis of IBS-D based on specific diagnostic criteria (Rome I criteria, Rome II criteria, Rome III criteria, Rome IV criteria, or the Manning criteria).

**Intervention:** Moxibustion was the main intervention (e.g., herb partitioned moxibustion, moxibustion with mugwort stick, direct moxibustion).

**Comparator:** The series of Moxibustion therapy involves many techniques, such as moxa stick moxibustion, moxa cone moxibustion, direct moxibustion, indirect moxibustion. Moreover, many distinctive complex moxibustion manipulations are organically combined such as partitioned moxibustion, moxa-moxibustion, warm-moxibustion. Studies that combine moxibustion with other therapies, such as acupuncture, massage, drugs, and physical interventions will be included if they can prove that massage is effective.

**Study designs to be included:** The included studies will be Randomized controlled trials (RCTs) in this systematic review regardless of publication status and language. We will include an assessment of moxibustion compared with control interventions, including inactive controls (such as placebo, no treatment) and active controls (such as drugs and acupuncture). Conference literature and papers, reviews, case series, case reports, experience summary and animal research will be excluded. Animal trials, clinical experience, case reports and studies with incorrect designs or incomplete data will be excluded.

**Eligibility criteria:** The PICOS principles will be consulted to establish the inclusion and exclusion criteria of this systematic review.

**Information sources:** Studies will be obtained from the China National Knowledge Infrastructure, Wan Fang Data, Chinese Scientific Journals Database, PubMed, Embase and Cochrane Library, regardless of publication date or language.

**Main outcome(s):** The primary outcomes include the effective rate of clinical symptoms, IBS-D score, and the total score of gastrointestinal symptom rating Scale (GSRS total score). The secondary outcomes will assess abdominal distension and incidence of adverse event.

**Quality assessment / Risk of bias analysis:** Two researchers (XH and XQ) will be designated to assess the quality of the included RCTs independently by utilizing the Cochrane Risk of Bias assessment tool. As specified by Cochrane Handbook V.5.1.0, the following sources of bias will be considered: random sequence generation, allocation concealment, participant blinding, outcome assessor blinding, incomplete outcome data, selective reporting, and other sources of bias. Each domain will be rated as having a high, low, or unclear risk of bias as appropriate. The reviewers will resolve any disagreements through discussion, and a third reviewer (YJ) may be involved if no consensus is reached.

**Strategy of data synthesis:** Studies will be obtained from the China National Knowledge Infrastructure, Wan Fang Data, Chinese Scientific Journals Database, PubMed, Embase and Cochrane Library, regardless of publication date or language. The databases will be retrieved by combining the subject words with random words.
**Subgroup analysis:** If there is high heterogeneity in the included studies, we will perform subgroup analyses to explore the differences in age, sex, race, lesion location, and course of the disease/treatment.

**Sensitivity analysis:** To ensure robustness of the combined results, sensitivity analyses will be performed to assess the impact of studies with a high risk of bias. We will compare the results to determine whether lower-quality studies should be excluded.

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

**Keywords:** moxibustion, Diarrhoea-predominant irritable bowel syndrome, systematic review, Traditional Chinese Medicine.

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