INPLASY PROTOCOL

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None declared.

The efficacy and safety of filiform-fire needle combined with acupoint application therapy for diarrhea-predominant irritable bowel syndrome A protocol for systematic review and meta-analysis

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Review question / Objective: **This study aimed to evaluate the current status of filiform fire needle combined with acupoint application therapy in the treatment of diarrhea-predominant irritable bowel syndrome, with the aim of illustrating the effectiveness and safety of combined acupuncture therapies.**
Condition being studied: **Irritable bowel syndrome (IBS-D) is a common disease of the intestinal system, and diarrhea-predominant irritable bowel syndrome accounts for about a quarter of all cases of IBS. The purpose of this study was to evaluate the efficacy and safety of filiform fire needle combined with acupoint application therapy in the treatment of diarrhea-predominant irritable bowel syndrome, as well as summarize the relevant studies and literature with RCTs, for providing certain reference for clinical trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 May 2022 and was last updated on 04 May 2022 (registration number INPLASY202250024).

INTRODUCTION

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METHODS

Participant or population: Patients with diarrhea-predominant irritable bowel syndrome.

Intervention: The filiform-fire needle combined with acupoint application therapy.

Comparator: Other TCM treatments.

Study designs to be included: RCT.

Eligibility criteria: Studies will be screened based on inclusion and exclusion criteria, and the Cochrane risk bias assessment tool will be used to evaluate the quality of the literature. Review Manager 5.3 was used for mate analysis. Efficiency based on house-Brackmann facial nerve grading system. Secondary outcomes will include Sunnybrook Facial nerve Grading System, Portmann Score, Facial Disability Index Scale, and adverse events.

Information sources: According to the retrieval strategies, randomized controlled trials (RCTs) on filiform fire needle combined with acupoint application therapy for IBS-D will be obtained from four international electronic databases (PubMed, Cochrane Library, EMBASE, Web of Science) and four Chinese electronic databases (CNKI, VIP, Wanfang, SinoMed),regardless of publication date or language.

Main outcome(s): This study aimed to evaluate the current status of filiform fire needle combined with acupoint application therapy in the treatment of diarrhea-predominant irritable bowel syndrome, with the aim of illustrating the effectiveness and safety of combined acupuncture therapies.

Quality assessment / Risk of bias analysis: 2 reviewers will attend in the quality assessment process and any major disagreements will be resolved by discussion to determine the final study set included. Two reviewers will evaluate the methodological quality of the included literature according to the tool for risk of bias assessment provided in the Cochrane Collaboration Evaluation Manual, assessing the risk of bias, mainly referring to the generation of random serials, the implementation of allocation concealment and blinding, and the completeness of the result data, selected report results, other sources of bias, etc.

Strategy of data synthesis: If the studies included were sufficiently homogeneous, the quantitative integration was performed by Review Manager 5.3. The incorporative results of enumeration data were represented by relative risk (RR), and continuous variables were merged for statistic by mean difference (MD) with 95% confidence interval (CI). If $I2 \leq 50\%$, $P > .1$, meta-analysis was conducted in a fixed-effects model. Otherwise, the sources of heterogeneity will be further analyzed. A random-effects model was applied for meta-analysis after excluding significant clinical heterogeneity, as well as the analysis of sensitivity and risk of bias.

Subgroup analysis: Several planned subgroup analyses will be performed: the efficacy of filiform-fire needle therapy alone and in combination with other therapies ,different stages of IBS (e.g., ≤3 months, >3 months), different treatment duration of filiform-fire needle therapy for IBS (e.g., ≤1 month, >1 month), and different sizes of the fire needles (e.g., the length and diameters of the fire needle).

Sensitivity analysis: A sensitivity analysis will be performed to verify the robustness and stability of the pooled results by eliminating low-quality studies.

Country(ies) involved: China.

Keywords: diarrhea-predominant irritable bowel syndrome, filiform fire needle, acupoint application therapy.

Contributions of each author:

Author 1 - Zhao Boyi - Author 1 drafted the manuscript.
Author 2 - Ren Yuanyuan.
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Author 4 - Meng Xiangwei.
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