INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of far infrared in the treatment of primary dysmenorrhea Systematic reviews and meta-analysis

Yuan, LX[1]; Ding, CH[2]; Sun, Y[3]; Li, Q[4]; Shi, GD[5]; Li, SL[6]; Li, H[7].

Review question / Objective: **To analyze and evaluate the efficacy and safety of far-infrared therapy in the treatment of primary dysmenorrhea.**
Condition being studied: **Primary dysmenorrhea (PD), also known as functional dysmenorrhea, is a common gynecological disease. It is defined as recurrent lower abdominal cramps that occur before or during menstruation and lack any identifiable pathological conditions. Headache, back and thigh pain, nausea, vomiting, fatigue, irritability, breast tenderness, and general malaise are the common symptoms accompanying PD.**
Information sources: **We're going to use systematic electronic search, including PubMed, Cochrane Database of Systematic Reviews, EMBASE, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM); Chinese Scientific Journal Database(VIP database); and Wan-Fang Database (WF). We will also manually search relevant conference proceedings, Clinical trial registries, and unpublished studies or references. The manual review of references in published articles will be conducted to identify other relevant studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2021 and was last updated on 24 April 2021 (registration number INPLASY202140119).

INTRODUCTION

Review question / Objective: **To analyze and evaluate the efficacy and safety of far-infrared therapy in the treatment of primary dysmenorrhea.**

Condition being studied: **Primary dysmenorrhea (PD), also known as functional dysmenorrhea, is a common gynecological disease. It is defined as recurrent lower abdominal cramps that**

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METHODS

Participant or population: Female patients of reproductive age who meet the diagnostic criteria for PD will be included, regardless of age, occupation, or ethnic background. Patients diagnosed with pelvic pathology or secondary dysmenorrhea will be excluded.

Intervention: The treatment group was treated with FIR alone or FIR combined with western medicine.

Comparator: The control group is treated with oral medications(such as NSAIDs and OCs), placebo, no treatment, or other active treatments.

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

Eligibility criteria: Only randomized controlled trials will be included in this study.

Information sources: We're going to use systematic electronic search, including PubMed, Cochrane Database of Systematic Reviews, EMBASE, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM); Chinese Scientific Journal Database (VIP database); and Wan-Fang Database (WF). We will also manually search relevant conference proceedings, Clinical trial registries, and unpublished studies or references. The manual review of references in published articles will be conducted to identify other relevant studies.

Main outcome(s): The total effective rate (TER) and visual analogue scale (VAS) score.

Additional outcome(s): The seven-point verbal rating scale (VRS); Cox menstrual symptom scale (CMSS); the 36-item Short Form health survey (SF-36); pain intensity after a follow-up period; Incidence of adverse events.

Quality assessment / Risk of bias analysis: The risk of bias in the included articles will be evaluated by three independent reviewers according to the tool recommended by Cochrane Handbook V.5.1.0, which consists of the following 7 items:random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data addressed, selective outcome reporting, and other bias.Based on the results of each study, the two researchers respectively carried out“low-risk,”“high-risk,”or“unclear risk”assessments on the above 6 projects.Inconsistency will be negotiated with the third review author.

Strategy of data synthesis: Review Manager software(RevMan 5.3.5)will perform this meta-analysis. The random effects model will be used to estimate the primary and secondary outcomes of the merge. The forest plot will display the results of the meta-analysis. If the product is not suitable for meta-analysis, we will conduct a descriptive analysis. Only when there were more than 10 RCTs could we use funnel charts to assess publication bias.

Subgroup analysis: If the included studies are sufficient, subgroup analysis(such as the treatment time of far-infrared therapy, the severity of PD)will be performed to determine the heterogeneity.

Sensitivity analysis: Sensitivity analysis will be conducted to test the robustness of critical decisions made during the review process. The central decision nodes includes sample size; the impact of data loss; and methodological quality.

Country(ies) involved: China.

Keywords: **Far infrared, Primary dysmenorrhea, efficacy, safety, meta-analysis, systematic review.**

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