INPLASY PROTOCOL

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

Conflicts of interest:
None declared.

Acupuncture with or without acupoint application for primary dysmenorrhea: protocol for a systematic review and meta-analysis

Zhao, XW[1]; Zhao, JY[2]; Jiang, HL[3]; Sun, JB[4]; Zhi, XY[5].

Review question / Objective: **To evaluate the efficacy and safety of acupuncture with or without acupoint application therapy for primary dysmenorrhea.**

Condition being studied: **Primary dysmenorrhea (PD) refers to a woman's menstrual period in genital no organic disease, abdominal pain, under the belly and other discomfort for the characteristics of disease of department of gynaecology, also called functional dysmenorrhea, main clinical manifestation is: under the menstrual abdomen spastic pain, radiation to the lumbar di ministry, vulva and anus and inner thighs, some patients accompanied by nausea, vomiting, dizziness, fatigue, symptoms such as edema, even collapse.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2022 and was last updated on 12 March 2022 (registration number INPLASY202230051).

INTRODUCTION

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METHODS

Search strategy: Terms: (take PubMed as an example) primary dysmenorrhea; acupuncture; acupuncture therapy; acupoint application; acupoint ; randomly ;randomized controlled trial; controlled clinical trial; randomized; trial; groups. We plan to search the following databases: 1) Embase ; 2) Cochrane Library; 3) Pubmed; 4) Chinese databases SinoMed(previously called the Chinese Biomedical Database); 5) Chinese National Knowledge Infrastructure; 6) VIP Database for Chinese Technical Periodicals; 7) Wanfang Data.

Participant or population: Patients with abdominal pain before or after menstruation or during menstruation, mainly concentrated in the lower abdomen, and with none of the other symptoms, including headache, dizziness, nausea and vomiting, diarrhea, waist and leg pain.

Intervention: We will include trials that apply acupuncture with or without acupoint application.

Comparator: Group of acupuncture will be compared with those without acupuncture treatment, sham acupuncture group, or conventional treatment.

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

Eligibility criteria: Published or unpublished randomized controlled trials without language restriction.

Information sources: We're going to use systematic electronic search, including PubMed, Embase, Cochrane library, SinoMed, China National Knowledge Infrastructure (CNKI), WanFang Database(WF), and Chinese Scientific Journal Database (VIP).

Main outcome(s): The extent of pain in the lower abdomen measured by visual analog scale (VAS), and relief from symptoms.

Additional outcome(s): 1. Quality of life(QoL); 2. Adverse events.

Data management: (1) We will use NoteExpress and Excel software to extract data. The content will be saved in electronic form. (2) Different review authors will independently screen the titles and abstracts of records obtained by searching the electronic databases to determine potential eligibility. Full texts screening and data extraction will be conducted after wards independently. Any disagreement regarding study selection will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use NoteExpress. (3) The research team designed structured data extraction tables, including: the first author, nationality, publication year, patients' basic information, sample size, intervention measures of test group, intervention measures of controlled group, qualitative evaluation method, target outcome (including primary outcome measures and secondary outcome measures), etc. Different review authors will independently extract data. Any disagreement regarding data extraction will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use Excel.

Quality assessment / Risk of bias analysis: Two of our researchers will use the bias risk tool provided by the Cochrane Collaboration to evaluate the quality of the literature using RevMan 5.4 software. This recommended tool includes 7 important items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of results evaluation, incomplete result data, selective result reporting, and other biases. Make "Low risk," "High risk," and "unclear risk" judgments for each research literature. Finally, a "risk of deviation" summary and a chart are generated to show the results. As with the previous process, it will be independently assessed by 2 researchers.

If there is disagreement, it will be discussed with the 3rd researcher.

Strategy of data synthesis: This study will use RevMan5.4 software for data integration and analysis. The measurement data will use the mean difference (MD) as the effect indicator, and the count data will use the odds ratio (OR) as the effect index. Each effect indicator will be given as a point estimate with 95% confidence interval. The heterogeneity and size of each study result will be judged using statistical methods. For studies with no statistical heterogeneity, the analysis will be performed using a fixed-effect model, whereas a randomized effects model will be applied if for studies with significant statistical heterogeneity.

Subgroup analysis: A subgroup analysis will be conducted for the efficacy of acupuncture with or without acupoint application in patients with primary dysmenorrhea at different ages and treatment time.

Sensitivity analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Language: No restriction.

Country(ies) involved: China.

Other relevant information: None.

Keywords: acupuncture, acupoint appliation, primary dysmenorrhea, network meta-analysis, randomized controlled trials.

Dissemination plans: We plan to publish a systematic review based on this protocol.

Contributions of each author:

Author 1 - Xuewei Zhao - Author 1 conceive and design this protocol.
Email: zxw19932020@126.com
Author 2 - jinying Zhao - Author 2 revise this protocol; search strategy.
Author 3 - Hailin Jiang - Author 3 revise this protocol; search strategy.Data collection; analysis of results.
Author 4 - Jiabao Sun - Author 4 data collection; analysis of results.
Author 5 - Xiaoyu Zhi - Author 5 data collection; analysis of results.