

INPLASY PROTOCOL

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Conflicts of interest:
None.

Effectiveness of needle warming moxibustion for pain relief in patients with primary dysmenorrhea: a protocol for systematic review and meta-analysis

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Review question / Objective: The study will evaluate the curative effect and adverse effects of needle warming moxibustion therapy for primary dysmenorrhea, in order to provide a reference for clinical treatment.

Condition being studied: Primary dysmenorrhea (PD) is one of the most common gynecological diseases for women in reproductive age which is characterized by obvious lower abdominal pain (bulging or cramping pain) during, before or after menstruation with or without headache, dizziness, diarrhea, waist soreness and pain. It is distinguished from secondary dysmenorrhea without any pelvic pathology such as endometriosis, adenomyosis, or pelvic inflammatory diseases. In severe cases, symptoms such as nausea, vomiting, cold sweating, cold hands and feet, and even fainting may occur, which will have a great impact on the normal work and life of the patient. Recent trials indicated that needle warming moxibustion (NWM) can be effective for pain relief in patients with PD. However, there is no strong evidence to prove it. Therefore, we designed this study to evaluate the effectiveness and safety of warm needling moxibustion in treating primary dysmenorrhea.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 December 2020 and was last updated on 05 December 2020 (registration number INPLASY2020120027).

INTRODUCTION

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METHODS

Participant or population: Participants are female patients in reproductive age with primary dysmenorrhea, regardless of race or educational and economic status. patients with any gynecological pathology will be excluded.

Intervention: NWM or NWM combine with other conventional treatments.

Comparator: The controls can be placebo, sham acupuncture or moxibustion, other TCM interventions, pharmacotherapy or blank control.

Study designs to be included: The review will include randomised controlled trials (RCT) with no language limitation.

Eligibility criteria: The review will only include randomised controlled trials of NWM treatment for women with PD .Crossover trials will not be included unless there first-phase data are available. NonRCTs reviews, case report, observational studies, animal experimental

studies, expert experience, conference article and duplicated publications will be excluded.

Information sources: Electronic searches will be carried out up to December 2020 in the databases of The Cochrane Library, PubMed, MEDLINE, EMBASE, CNKI, WanFang, CBM and VIP. The International Prospective Register of Systematic Reviews (PROSPERO), The Chinese Clinical Trial Registry Center and Clinical Trials was also searched for ongoing trials.

Main outcome(s): Pain intensity after treatment measured by valid scale as follows: 1.visual anaolgue scale (VAS). 2.numeric rating scale (NRS). 3.the Cox Menstrual Symptom Scale(CMSS).

Additional outcome(s): 1.Quality of life measured by valid questionnaires 2.Total effective rate(TER). 3.Associated symptoms. 4.Pain intensity after follow-up. 5.Side effects and adverse events.

Quality assessment / Risk of bias analysis:

Two reviewers will assess the methodological quality of all the random control trials based on the Cochrane Handbook 5.1.0 for Systematic Reviews of Interventions, which comprises selection bias(random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias(selective reporting)and other bias. The studies will be evaluated as being of "low risk of bias," "high risk of bias," or "unclear risk of bias". At the same time, the included clinical trials will be awarded a score from 0 to 5 points according to Jadad scale evaluation criteria, which include reference to the generation of random sequences, blind enforcement, and withdrawal.

Strategy of data synthesis: We will synthesize and analyze the data by RevMan V.5.3(version 5.3 for windows; The Nordic Cochrane Centre, Copenhagen, Denmark). In the Cochrane Handbook, when heterogeneity was not significant ($I^2 \leq 50\%$),

a fixed effect model will be used to calculate the relative risk (RR) and weighted mean difference (WMD). when $I^2 \geq 50\%$, heterogeneity was regarded as statistically significant, and we will use a random-effect model to synthesize the data. The obvious clinical heterogeneity will be treated by the method of subgroup analysis or sensitivity analysis, or just descriptive analysis.

Author 8 - Zhongyu Zhou.

Subgroup analysis: To make sure heterogeneity between included studies, subgroup analysis will be conducted only if there are sufficient number of articles in each subgroup. Criteria of subgroup analysis are as follows: 1. Different meridian and acupoint selection. 2. Different duration, frequency of intervention and follow-up period. 3. Different types of comparators, different types of population, and different methodical quality of included studies.

Sensibility analysis: If there are sufficient studies, sensitivity analyses will be conducted to identify whether the following findings are robust. The lower quality articles will be excluded, then we will perform a second meta-analysis. The results of the 2 metaanalysis will be compared, analyzed and discussed. 1. Methodological qualities (e.g. random sequence generation, allocation concealment or participants/outcome assessment blinding). 2. Analysis-related issues (e.g. process of handling missing data).

Country(ies) involved: China.

Keywords: The Key words are primary dysmenorrhea, PD and needle warming moxibustion.

Contributions of each author:

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