INPLASY PROTOCOL

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None declared.

Effect of auricular point pressing therapy on primary dysmenorrhea A protocol for systematic review and meta-analysis

Wang, X[1]; Zhang, L[2]; Ma, M[3].

Review question / Objective: **P: Participants in those included RCTs must be diagnosed with primary dysmenorrhea. I: The experimental group was pressed with auricular point pressing therapy alone, and there was no limitation on the position, time, course of treatment and materials. C: The control group was blank control, placebo control or other basic treatment. O: The primary outcomes include: (1)Visual analog scale (VAS): the measurement of pain before and after the treatment period. (2)Dysmenorrhea symptom score: the measurement of remission of dysmenorrhea symptoms before and after the treatment period. (3)Clinical effectiveness rate: an overall relief to menstruation related symptoms measured by changes of relevant scale scores or self-report before and after the treatment period. The secondary outcomes include: (1)Adverse events: fever, infection, bruising, numbness, local pain or ulcer, and so on. (2) Recurrence rate.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2021 and was last updated on 14 June 2021 (registration number INPLASY202160046).

INTRODUCTION

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effectiveness rate: an overall relief to menstruation related symptoms measured by changes of relevant scale scores or self-report before and after the treatment period. The secondary outcomes include: (1)Adverse events: fever, infection, bruising, numbness, local pain or ulcer, and so on. (2) Recurrence rate.

Condition being studied: Primary dysmenorrhea (PD), also known as functional dysmenorrhea, refers to the abdominal pain, swelling, nausea, vomiting, diarrhea and other symptoms that occur during menstrual period in women without genital lesions. These symptoms greatly affect women's daily life, and even bring psychological stress in severe cases. Clinical studies have found that auricular point pressing therapy is widely used in primary dysmenorrhea, but its effect has not been systematically reviewed. Therefore, the purpose of this study is to investigate the safety and effectiveness of auricular point pressing therapy in primary dysmenorrhea.

METHODS

Participant or population: Participants in those included RCTs must be diagnosed with primary dysmenorrhea.

Intervention: The experimental group was pressed with auricular point pressing therapy alone, and there was no limitation on the position, time, course of treatment and materials.

Comparator: The control group was blank control, placebo control or other basic treatment.

Study designs to be included: All the randomized controlled trials (RCTs).

Eligibility criteria: Participants in those included RCTs must be diagnosed with primary dysmenorrhea, which is defined by the Clinical Guideline of primary dysmenorrheas diagnostic standards from the Society of Obstetricians and Gynecologists of Canada. Patients combined with severe cardiac or hepatic or renal diseases will not be taken into account in this study.

Information sources: 2.2.1. Electronic searches. We'll retrieve 8 databases, the electronic databases, including the PubMed, Embase, Cochrane Library, Web of Science, CBM, CNKI, Wanfang Database, VIP, The retrieval date was established from the database to June 14, 2021. And will searching the relevant literature by combining subject words with free words. The PubMed search strategy is shown in Table 1. 2.2.2. Searching other resources. We will search a reference list for identifying published journals, books, conference articles, and gray literature related to this research topic.

Main outcome(s): (1)Visual analog scale (VAS): the measurement of pain before and after the treatment period. (2)Dysmenorrhea symptom score: the measurement of remission of dysmenorrhea symptoms before and after the treatment period. (3)Clinical effectiveness rate: an overall relief to menstruation related symptoms measured by changes of relevant scale scores or self-report before and after the treatment period.

Quality assessment / Risk of bias analysis: Two independent authors will evaluate the bias risk in each included study using Cochrane Collaboration's "Risk of bias" assessment tool[19]. Any disagreement will be resolved via consultation with a third author. The main items to be considered are as follows: "randomization plan", "group concealment", "blinding method", "incomplete data reporting", "selective outcome report" and "other sources of bias".

Strategy of data synthesis: This study utilizes EndNote X8 to exclude duplicate literatures. Firstly, two independent authors will read the titles and abstracts of the selected studies to evaluate the studies suitable for further evaluation. Secondly, two independent authors will examine all relevant records as full-texts and separate studies under included or excluded studies.

It is planned to resolve any disagreement through consensus by a third author. The following baseline characteristics are extracted from the included studies by the two independent authors: first author, published year, study design, study settings and country, mean age, number of participants, intervention method, and relevant outcomes. The selection process will be shown in Figure 1.

Subgroup analysis: If there is significant heterogeneity in the results, we will conduct a subgroup analysis to investigate differences in characteristics of participants, and treatment durations., etc.

Sensitivity analysis: Through the study of large weight of elimination effect, the sensitivity analysis was performed to test the stability of the results of meta-analysis.

Country(ies) involved: China.

Keywords: auricular point pressing therapy, meta-analysis, primary dysmenorrhea, protocol, systematic review.

Contributions of each author:
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Author 3 - Mengjie Ma.