INPLASY PROTOCOL

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Corresponding author:
Jieyun Li

1129339806@qq.com

Author Affiliation:
Lanzhou University

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Massage therapy for women dysmenorrhea : A systematic review and meta-analysis

Li, JY[1]; Li, JW[2]; Yang, KH[3].

Review question / Objective: **Dysmenorrhoea may begin soon after the menarche, after which it often improves with age, or it may originate later in life after the onset of an underlying causative condition. Dysmenorrhoea is common, and in up to 20% of women it may be severe enough to interfere with daily activities. In recent years, the massage is widely used in clinical treatment of dysmenorrhea, the good curative effect, quick effect, no significant adverse reactions and side effects, and is accepted by patients. We will conduct a systematic review and meta-analysis aimed to answer the following clinical question: Can the message works for dysmenorrhoea?**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 April 2020 and was last updated on 22 April 2020 (registration number INPLASY202040142).

INTRODUCTION

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analysis aimed to answer the following clinical question: Can the message works for dysmenorrhoea?

Condition being studied: Dysmenorrhea (dysmenorrhea) is one of the most common gynecological diseases in women during their period, and more than half of the patients have dysmenorrhea.It can be divided into one or two levels. Primary dysmenorrhea is defined as pain that occurs before or during menstruation in women who have normal pelvic examination results and normal ovulation function.Secondary dysmenorrhea is defined as painful menstruation in women with a clear gynecologic pathology, and it is more common in women between 40 and 50 years of age. We searched different databases for randomized controlled clinical trials (RCTS).Preliminary searches revealed a total of 1,706 studies.Next, manually search the list of references and bibliographies for these studies to identify other possible studies, and then filter the remaining 1585.1531 studies were excluded for various reasons (637 unrelated subjects, 46 animal studies, 9 unpublished master's theses, 10 without detailed results, 19 in non-chinese or English and 555 in non-control group, 167 in non-quantitative data, 50 in non-randomized control group).Excluding these studies, a total of 38 randomized controlled trials were included in the meta-analysis.

METHODS

Participant or population: Women with more than 6.0 points (in 0-10.0 VAS scale) in menstrual cramps or more than 20 points on the dysmenorrhea scale (range 13-52).

Intervention: Massage.

Comparator: Other treatments or placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Women with more than 6.0 points (in 0-10.0 VAS scale) in menstrual cramps or more than 20 points on the dysmenorrhea scale (range 13-52) 2. no underlying disease 3. adults women.

Information sources: A comprehensive search for relevant studies published in English or Chinese between January 1, 1951 and March 30,2020 was conducted in databases such as PubMed, the Cochrane Library, Chinese Biomedical Literature Database, Web of Science and EMBASE. Moreover, the reference lists of the studies were searched manually to identify additional studies not indexed in databases.Reference lists of identified trials and review articles were manually scanned to identify any other relevant studies. The ClinicaTrial.gov website was also searched for randomized trials that were registered as completed but not yet published.

Main outcome(s): The change in the visual analogue scale (VAS) pain score and dysmenorrhea scale after 1 week, 2 weeks and 4weeks massage treantment.

Quality assessment / Risk of bias analysis: Risk of bias of each individual study was evaluated by two reviewers. To assess the quality of RCTs, we used the assessment tool for “risk of bias” from the Cochrane Handbook version 6.1.0. Studies were judged based on criteria to evaluate random sequence generation, allocation concealment, blinding of participants/ personnel and outcome assessment, incomplete outcome data and selective reporting. RCTs considered to be at low risk of bias, if allocation concealment, blinding of participants and outcome assessors were all coded “low” and the number of dropouts and reasons for dropout were reported. Otherwise, the RCTs considered to be at high risk of bias. If the risk of bias couldn’t be determined in any of the segments (e.g. information not provided) the risk of bias was classified as unclear.

Strategy of data synthesis: Data were further analyzed by using Stata 12.0 and Review Manager 5.3. To estimate effect sizes for continuous outcomes, we will computed standardized mean differences

(SMD) or Weight mean differences (WMD) with 95% confidence intervals(95%CI). Furthermore, post-intervention outcomes were pooled using a random-effects model, for this model generates a more reliable estimate than the fixed effect analysis; especially when there is substantial heterogeneity. The primary outcome measurement of efficacy was the change score after massaging , according to the criteria used in each trial. We allowed for heterogeneity in treatment effects between studies, the extent of heterogeneity interpreted by the total percentage of variation between the studies concerned, measured with the I2 statistic classified as low (I2≤25%), moderate (I2>25% and <75%), or high (I2≥75%). Additionally, the Q-statistic was used to assess the presence of heterogeneity. PQ statistic≥0.05 was considered to indicate no significant heterogeneity among the included studies. Publication bias was assessed by visually inspection of funnel plots and using the Begg's test. Begg's test was interpreted by the P value, the P value less than 0.05 indicates publication bias.

Subgroup analysis: 1.Primary dysmenorrhea and Secondary dysmenorrhea 2. Different continents 3. Different treatment time.

Sensibility 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.

Country(ies) involved: China.

Keywords: Massage; Meta-analysis; Dysmenorrhea.