INPLASY PROTOCOL

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TCM nonpharmacological interventions for premenstrual disorders: A protocol for systematic review and network meta-analysis

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Review question / Objective: Traditional Chinese medicine (TCM) nonpharmacological interventions are gaining an increasing popularity for premenstrual disorders, yet their comparative effectiveness and safety remains controversial. Premenstrual disorders affect up to 12% of women and becomes more and more common among women of childbearing age. Traditional Chinese medicine (TCM) nonpharmacological interventions are gaining an increasing popularity for PMDD, yet their comparative effectiveness and safety remains controversial.

Condition being studied: Premenstrual disorders affect up to 12% of women and becomes more and more common among women of childbearing age. Traditional Chinese medicine (TCM) nonpharmacological interventions are gaining an increasing popularity for premenstrual disorders, yet their comparative effectiveness and safety remains controversial. Therefore, this study will aim to compare their effectiveness and safety for premenstrual disorders by systematic review and network meta-analysis.

INTRODUCTION

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METHODS

Search strategy: The strategy will be created according to the Cochrane handbook guidelines. The established search strategy for PubMed was displayed, as follows(see Table 1): The following electronic databases will be searched: Web of Science, PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), Wanfang Database and Chinese Scientific Journal Database (VIP). In addition, 'grey literature' such as conference proceedings and theses will be allowed from their inception to 2021 by two reviewers independently.

Participant or population: We considered trials among women of reproductive age diagnosed with premenstrual dysphoric disorder or premenstrual syndrome using any diagnostic method, such as DSM (III, IV, IV-R, V), ICD and other diagnostic tools[23] regardless of nationality.

Intervention: TCM non-pharmacological interventions for premenstrual disorders will be included, including acupuncture, moxibustion, cupping, massage, scraping and traditional Chinese exercise like Taichi, Baduanjin, Wuqinxi referring to related studies.

Comparator: Comparators will include placebo, and other positive interventions.

Compared with the same kind of traditional Chinese medicine non pharmacological intervention measures, but in different research stages, the selection of acupoints was taken as the same node in network analysis.

Study designs to be included: The randomized controlled trials (RCTs) will be only included and no language restrictions. Studies with non-RCT design, quasi-experiment design, missing data, duplicate publications, animal experiments and reviews or case reports will be excluded.

Eligibility criteria: The PICOS (participant, intervention, comparison, and study design) principle has been applied in the study design.

Information sources: Web of Science, PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), Wanfang Database and Chinese Scientific Journal Database (VIP).

Main outcome(s): The change of premenstrual symptoms was the primary outcome. Due to multiple outcome measures in trials, the outcomes assessed with validated instruments will be preferred, i.e. Premenstrual Syndrome Diary (PMSD)[25], PMTS, Dialy Symptom Report (DSR), COPE, Daily Record of Severity of Problems (DRSP) and visual analog scales (VAS) to assess overall PMDD symptoms, and psychiatric subscales to assess specific depressive and anxiety PMDD symptoms for inclusion in our meta-analysis, such as Beck Depression Inventory (BDI), Hamilton Depression Rating (HDRS) and Mood Disorders Questionnaire (MDQ). Additionally, we assessed harm outcomes (such as discontinuation rates and adverse events) and patient satisfaction as reported by the authors.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias using the approach recommended by Cochrane Handbook for Systematic Reviews of Interventions[28].

The following risk of bias domains will be assessed: sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias) and other bias. If all domains are at low risk of bias, the overall risk of bias of individual studies will be categorized as low risk of bias. Otherwise, overall risk of bias will be categorized as high risk of bias. The 'risk of bias's summary will be presented graphically.

Strategy of data synthesis: STATA/SE 15.1 (StataCorp, 2017) was used to command "network meta" to draw the intervention network diagram. Bayesian network meta-analysis was carried out by software Gemtc14.3 to compare the direct evidence and indirect evidence of the intervention measures included in the study. Markov chain Monte Carlo fitting consistency model is used for Bayesian inference in Gemtc14.3. The potential scale reduced factor (PSRF) was evaluated in the software. If the PSRF value is ≥ 1.2, it indicates that the current simulation times are not enough to achieve good convergence. Thus, the simulation times was increased for re-evaluation. When the PSRF value is 1.00-1.05, it indicates that the convergence of the iterative effect is good, When the PSRF value is close to or equal to 1, it indicates that the convergence is good, and the conclusion of analysis is reliable. The consistency model is used for mesh meta-analysis. When there is a closed loop between intervention measures, inconsistency test shall be carried out. Point division model shall be used for inconsistency test. If P > 0.05, consistency model shall be used for analysis; Otherwise, the inconsistent type is used for analysis. Based on Gemtc14.3, the Bayesian analysis model in the software calculates the efficacy probability ranking of each intervention measure, and infers the possibility of each measure becoming the most effective treatment.

Subgroup analysis: If there is significant heterogeneity in the included trials, then we will conduct a subgroup analysis based on the different treatments, for example, types of acupuncture (acupuncture, manual acupuncture, electroacupuncture and so on) and different outcomes.

Sensitivity analysis: A sensitivity analysis will be conducted to identify whether the review conclusions are robust according to the following criteria: missing data, sample size, heterogeneity qualities and statistical model.

Country(ies) involved: China.

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