INPLASY PROTOCOL

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

Conflicts of interest: None declared.

The effectiveness of five-element music therapy on anxiety and depression in perimenopausal women: A protocol of systematic review and meta-analysis

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Review question / Objective: The effectiveness of five-element music therapy on anxiety and depression in perimenopausal women.

Condition being studied: Five elements of traditional Chinese medicine music therapy is based on Chinese medicine theory as guidance, and the five organs (liver, heart, spleen, lung, kidney), volunteers (anger, joy, thought, sad, fear), through five different tones (palace, business, Angle, sign, feather) played a variety of melody and produce specific sound waves and frequency, make the human body viscera vibration biological effect, to adjust emotion, improve physical and mental symptoms of a treatment. Studies have shown that pentagram therapy has a good efficacy in improving anxiety and depression in perimenopausal women, but the relevant systematic evaluation to quantitatively evaluate its efficacy is lacking. Therefore, this study will systematically evaluate the five elements of music in traditional Chinese medicine The efficacy of menstrual anxiety and depression provides an evidence-based basis for its clinical application.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 June 2022 and was last updated on 23 June 2022 (registration number INPLASY202260091).

INTRODUCTION

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METHODS

Participant or population: Perimenopausal women, with at least one of the symptoms of depression or anxiety.Regardless of nationality, race, weight, and duration of the disease.

Intervention: The experimental group was intervened with Five-element music therapy or modified Five-element music therapy as a monotherapy or in combination with conventional therapy. The control group was treated with routine treatment or nursing or blank control. Other intervention measures in the experimental group and the control group are basically the same. there is no limitation on the intervention time, course of treatment.

Comparator: None.

Study designs to be included: Studies on pentagram therapy for perimenopausal mood disorders will all be included in a systematic review.The included literature has no restrictions on language type, use of blinding, or allocation concealment requirements, and as long as its study is approved, we will include the study in both clinical and case-control studies.

Eligibility criteria: The design of the inclusion and exclusion criteria for this study enabled the design of the five main principles of search principles based on the Participant-Intervention-Comparator-Study (PICOS).

Information sources: We will search in PubMed, Embase, MEDLINE, Cochrane Library (Cochrane Library), web of science, Intellectual Knowledge Network of China (CNKI), Wanfang Data Knowledge Service Platform (WanFang), China Biomedical Literature Database (CBM), and VIP database.The retrieval time was from the establishment of the database until 1 June 2022.

Main outcome(s): primary outcome. (1))depression, measured by depression-related scale. It mainly includes Back Depression Inventory (BDI), Hamilton Depression scale (HAMD), Self-Rating Depression Scale (SDS)andGeriatric Depression Scale-15 (GDS-15). (2)Anxiety, measured by an anxiety related scale. It mainly includes Self-Rating Anxiety Scale (SAS) , Inventory Beck Anxiety (BAI), Hamilton Anxiety Scale (HAMA), and Penn State Worry Questionnaire (PSWQ). Secondary outcome. (1)estrogenic hormone level (FSH, E2,LH),(2)Sleep quality will be evaluated using the Pittsburgh Sleep Quality Index(PSQI),(3)Patient Health Questionnaire-9 [PHQ-9]).

Quality assessment / Risk of bias analysis: Two researchers (WY and RQP) assess the risk of bias independently, using a collaboration tool recommended by the Cochrane Handbook 5.1. There are 6 points that should be evaluated: random allocation, allocation concealment, blinding, Integrity of outcome data, selective outcome reporting and other biases. Disagreement will also be settled by discussion.

Strategy of data synthesis: RevMan 5.3.5 software provided by Cochrane collaboration will be used for statistical analysis. Relative risk (RR) and its 95% confidence interval (CI) will be used for Enumeration data;standardised mean difference (SMD) or weighted mean difference (WMD) and its 95% confidence interval will be used for Measurement data.The 95% confidence interval will be used to express the effect size of the

data.It is considered statistically significant when P <0.05.

Subgroup analysis: If heterogeneity exists, we will perform a subgroup analysis.We will perform subgroup analysis according to the characteristics of participants' age, disease duration, length of treatment.

Sensitivity analysis: Sensitivity analysis was mainly focused on study characteristics or types such as methodological quality.To explore the impact of the study on the pooled effect size and the robustness of the results by reestimating the pooled effect size after excluding a high risk of bias or a low quality study and comparing it with the results of the Meta-analysis before the exclusion.

Country(ies) involved: China.

Keywords: Five elements music, Perimenopausal emotional disordes, Depression, Anxiety.

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