INPLASY PROTOCOL

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None.

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The efficacy of the Five Phases Music Therapy (FPMT) in the treatment for anxiety and depression during perimenopause: A protocol of systematic review and meta-analysis

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Review question / Objective: Perimenopause is a critical phase of psychological disorders such as depression and anxiety. As women approach the later stages of the menopausal transition, there is an abrupt rise in the prevalence of depression and a reduction in the quality of their life. In spite of the wide application of the Five Phases Music Therapy (FPMT) to address the psychological issues of women during perimenopause in recent years, there is no evidence-based medicine in this field. Therefore, this study aims to assess the efficacy of FPMT in the treatment for anxiety and depression among women during perimenopause through a systematic review and offer a reference and basis for its clinical application.

INTRODUCTION

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efficacy of FPMT in the treatment for anxiety and depression among women during perimenopause through a systematic review and offer a reference and basis for its clinical application.

Condition being studied: The Five Phases Music Therapy (FPMT) in traditional Chinese medicine is a treatment modality guided by the basic theory of traditional Chinese medicine. It combines the five organs (i.e. liver, heart, spleen, lung, and kidney) and five spirits (i.e. anger, joy, anxiety, worry, and fear) to produce a variety of melodies and specific sound waves and frequencies through five different tones (i.e. Gong, Shang, Jiao, Zheng, and Yu) so that a biological effect of vibration can be generated in the internal organs of the human body to regulate the emotions of patients and relieve their physical and mental symptoms[7]. Although studies have shown that [8-10] FPMT has been widely used in the treatment for various gynecological diseases including perimenopause syndrome and has good efficacy in alleviating anxiety and depression in women during perimenopause, there is a lack of relevant systematic reviews to quantitatively evaluate its efficacy. Therefore, this study will systematically evaluate the efficacy of FPMT in treating anxiety and depression during perimenopause and provide an evidence-based basis for its clinical application.

METHODS

Search strategy: We will search the databases of PubMed, EMBASE, Medline,Cochrane Library,PsycINFO and Web of Science for English language literatures. While the Chinese literature comes from CNKI, CBM, VIP, and Wangfang database. And articles published up to 1 June 2022 were included.The keywords of our search strategy will be "Music"、"Five elements music"、"Five-tone therapy", "Five-element music"、"Five notes", "Guqin music"、"menopause", "Perimenopausal"、"Perimenopausal

Depression"、"Depression"、"Anxiety", "Depressive Symptom"、"Depressive disorder"、"Emotional Depression",and so on.

Participant or population: Women during perimenopause suffering anxiety or depression are the objects of this study no matter what their race, weight, nationality, and duration of illness are.

Intervention: FPMT was used separately or combined with the conventional therapy as one of the intervention measures for the experimental group. The control group was treated with the conventional therapy or given nursing or blank control. Other intervention measures taken for the experimental group and the control group are mostly the same, without restrictions on the course of treatment and the intervention time.

Comparator: None.

Study designs to be included: This systematic review will include researches on the treatment for mood disorders during perimenopause through FPMT, regardless of the type of language and the use of blinding or allocation concealment requirements in the literature, and we will include studies, both clinical and case-control ones, as long as their research is approved.

Eligibility criteria: Exclusioncriteria (1) animal experiments; (2) studies published repeatedly; (3) full-text articles that could not be retrieved through online databases, libraries or study authors; (4) incomplete or obviously incorrect information; and (5) study subjects with serious physical illnesses such as heart, kidney or liver disease or inpregnancy.

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June 2022 were included.The keywords of our search strategy will be "Music"、 "Five elements music"、 "Five-tone therapy", "Five-element music"、 "Five notes", "Guqin music"、 "menopause", "Perimenopausal"、 "Perimenopausal Depression" 、 "Depression"、 "Anxiety", "Depressive Symptom"、 "Depressive disorder" 、 "Emotional Depression",and so on. If it is unable to get a complete report or there is incomplete data, the corresponding author was contacted in order to make sure that the preliminary search work is comprehensive and that the valuable research data is complete. In addition, reference lists of each related article and review are also searched in order to find out some other eligible research.

Main outcome(s): Primary outcome. (1) Depression, which was measured by depression-related scales including Back Depression Inventory (BDI), Hamilton Depression scale (HAMD), Self-Rating Depression Scale (SDS), and Geriatric Depression Scale-15 (GDS-15);(2) Anxiety, which was measured by anxiety-related scales including the Self-Rating Anxiety Scale (SAS), Inventory Beck Anxiety (BAI), Hamilton Anxiety Scale (HAMA), and Penn State Worry Questionnaire (PSWQ). Secondary outcome. (1) The estrogenic hormone level (FSH, E2, LH); (2) Sleep quality, which was measured with the Pittsburgh Sleep Quality Index (PSQI); (3) Patient Health Questionnaire-9 (PHQ-9).

Quality assessment / Risk of bias analysis: Based on the recommendation from the Cochrane Handbook, a collaboration tool was adopted by two researchers to evaluate the risk of bias independently. What needs to be evaluated includes 6 aspects: random allocation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective outcome reporting, and other sources of bias.[14] Moreover, the evaluation of the risk of bias was divided into three levels ranging from the low level and the high level to the unclear level.[15] In addition, a third researcher or group discussion was taken in order to deal with the related disagreements.

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 there is heterogeneity, we will conduct a subgroup analysis. We will perform subgroup analyses based on characteristics such as age, duration of illness, length of treatment, etc. If quantitative synthesis is not appropriate, we will conduct a narrative synthesis.

Sensitivity analysis: Sensitivity analysis focuses on research features or categories such as methodological quality. Researches with a high risk of bias or a particularly low quality were excluded to re-estimate the combined effect size and compare the results with those of the Meta-analysis before the exclusion, so as to explore how the study affected the combined effect size and the reliability of the results.

Country(ies) involved: China.

Keywords: Five Phases Music Therapy, Perimenopause, Depression, anxiety, systematic review.

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