# INPLASY PROTOCOL

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

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Review question / Objective: This study will comprehensively summarize the current trials to determine the effectiveness of the Five Phases Music Therapy on anxiety and depression in perimenopausal women.

Condition being studied: 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.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 June 2022 and was last updated on 29 June 2022 (registration number INPLASY202260113).

## **INTRODUCTION**

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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.

### **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: 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 casecontrol ones, as long as their research is approved.

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: In order to obtain the English literature, PubMed, PsycINFO, Cochrane Library, EMBASE, Medline, and Web of Science are searched. By contrast,

CNKI, VIP CBM, and Wangfang are searched in order to obtain Chinese literature. At the same time, 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", "menopausal", "Perimenopausal Depression", "Depression", "Anxiety", "Depressive Symptom", "Depressive disorder", "Emotional Depression", and so on.

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 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. For enumeration data, the relative risk(RR)and its 95% confidence interval (CI)will be used, whereas for measurement data, the standardised mean difference (SMD) or weighted mean difference (WMD)and its 95% confidence interval will be used. The 95% confidence interval will be calculated to express the effect size of the data. It is statistically significant when P<0.05.

Subgroup analysis: Subgroup analysis will be conducted if there is heterogeneity. We will perform subgroup analyses based on characteristics such as age, duration of illness, length of treatment, etc.

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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