Informed consent form

(ICF)

Program Title: **Clinical effect and mechanism study of Five Elements Music Therapy(FEMT) on depression disorder**

Program number: NA

Program version number: 03 May 15, 2025

Informed consent form version number: 03 May 15, 2025

Research institution: Shanghai Mental Health Center

Principal investigator (physician in charge of the study) : Lanying Liu

1. **Preface**

You will be invited to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Please read it carefully and ask the investigator in charge of the study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the ethics review committee of our research institution.

2. Research objectives

(1) To verify the clinical efficacy of traditional Chinese medicine Five-element music therapy for depressive disorders; (2) Using ERP technology to explore the mechanism of action of traditional Chinese medicine Five-element music therapy in the intervention of depressive disorder; (3) Through this study, we will further promote the development of non-pharmaceutical traditional Chinese medicine treatment methods for depression, with the aim of promoting their application.

3. Significance of the study

In traditional Chinese medicine, depression is classified into categories such as "yuzheng", "zangzao" and "Baihe disease", and is also named "yubing" according to the diagnostic and therapeutic criteria of Internal medicine. Its main causes are emotional injury and physical weakness. The key pathogenesis lies in the failure of the liver to regulate the flow of qi, the failure of the spleen to transform and transport, and the failure of the heart spirit to nourish, which leads to the imbalance of qi, blood, Yin and Yang in the zang-fu organs. Therefore, the traditional Chinese medicine treatment of depression mainly focuses on soothing the liver and strengthening the spleen, and has

achieved good clinical results through intervention methods such as decoctions, acupuncture, massage and guiding.

As an important part of music therapy, the Five Elements music therapy of traditional Chinese medicine has its own characteristics. Through different modes of music, it can play the role of qi circulation and transformation, balance Yin and Yang, and regulate qi and blood in the body, improving the overall physical and mental discomfort of patients, reducing anxiety and depression, and improving the quality of life. Current research has found that traditional Chinese five-element music therapy can significantly improve depression and anxiety, as well as improve sleep quality. However, there is still no standard or regulated five-element music therapy in China. This project intends to use the theory of the Five Elements Music therapy of traditional Chinese medicine, adopt the model of medical and engineering integration and multi-disciplinary combination, produce the music pieces for the Five Elements Music therapy of traditional Chinese medicine, and provide the intervention of the Five Elements music therapy of traditional Chinese medicine, observe the clinical efficacy of the Five Elements music therapy of traditional Chinese medicine on depressive state, use ERP to dynamically observe the changes in brain waves, use eye movement instrument to record eye movement data and pulse diagnosis instrument to record pulse phase, To study its mechanism of action. This study will further promote the development of non-pharmaceutical traditional Chinese medicine treatments for depression, with the aim of promoting their application.

This project intends to recruit 80 patients with depressive disorders at the Shanghai Mental Health Center. It will apply a blind randomized controlled trial design by evaluators to study the effect of Five-Element music therapy combined with Western medicine on depressive disorders. The project, which lasts for one year, is funded by the Shanghai Science and Technology Development Foundation. The study has been approved by the Ethics Committee of Shanghai Mental Health Center.

4. Research process

4.1 Research Screening

If you agree to participate in this study, we will communicate with you or your family members in detail to inform you about the study and also ask you to provide information related to the disease, including some personal information, the course of onset, medication use, family history, previous

medical visits and the results of some tests that have been done. We will number each participant and file them. Before the formal study, we will conduct some necessary checks and evaluations on you. If the results of the checks and evaluations meet the requirements, we will proceed with the formal study. Even if you agree to participate in this project, there is still a possibility that you may not be able to participate, and our researchers will tell you the specific reasons.

We will invite 80 people with depressive disorders to participate in this study.

Inclusion criteria:

1) Conforming to the ICD-10 diagnostic criteria for depressive episodes;

2) Hamilton Depression Scale -17 items score ≥14;

3) No gender restrictions, age 18-60;

4) Confirmed by at least two physicians with the title of attending physician or above;

5) Have sufficient visual and auditory levels to ensure that the necessary examinations and tests for the study can be completed;

6) Sign the written informed consent form and agree to be enrolled in the trial as required by the study plan.

Exclusion criteria:

1) The presence of serious heart, liver or kidney diseases, organic brain diseases, serious cardiovascular diseases, tumors, blood history, rheumatism, malnutrition and neurodegenerative diseases; Depressive episodes secondary to other mental or physical illnesses;

2) A history of abuse of tobacco, alcohol and other psychoactive substances;

3) Comorbidities with other mental illnesses;

4) Had participated in other drug clinical trials before inclusion.

4.2 Study groups:

After completing the baseline examination, patients with depressive disorder will receive two different five-element music therapies in addition to their original antidepressants, based on the results of the computer-generated randomization table.

4.3 Intervention Program:

Experimental group:

1) A self-made piece of music, "Five Elements Music 1", was selected to intervene in the patients. The duration of the music intervention was adjusted according to the patients' daily life schedule, usually during the midday break and 1 hour before bedtime. 2) Before the intervention, give the patient a comprehensive explanation of the purpose, process, etc. of the intervention and wear headphones to listen to music for 30 minutes; During the intervention, have the patient slightly close their eyes, relax their body, and ensure that the surrounding environment is quiet and free of background noise. After listening to the music, rest for 5 to 10 minutes and then slowly open your

eyes. 3) Play music through headphones using a mobile phone, computer, tablet, etc. at a volume of 20-60 dB, play a short sound before the experiment starts, and ask the patient if they feel comfortable with the volume. It would be best if the patient felt pleasant and comfortable. Try to minimize interference from external factors during the intervention. 4) Daily completion status needs to be checked in the pre-established wechat group to ensure daily completion status. The doctor will notify the patient in the wechat group if necessary. 5) The duration of the music intervention is directly related to the patient's own sleep state. Generally, music is played during the midday break and 1 hour before bedtime, twice a day, for 4 weeks, a total of 28 days. 6) In the course of the traditional Chinese medicine Five Elements music intervention, antidepressant drug treatment (fluoxetine hydrochloride) was combined. Other antipsychotic drugs, antidepressants and mood stabilizers should not be combined during the treatment.

Control group:

Except for the selection of the self-made music piece "Five Elements Music 2" to intervene in the patients, all other intervention procedures were the same as those in the experimental group.

4.4 Observation indicators:

The treatment observation period is 4 weeks, during which no other antipsychotic drugs, antidepressants or mood stabilizers other than medication can be used. Clinical and laboratory indicators were followed up for 4 weeks. ERP electroencephalogram measurement, eye movement examination and pulse recording by pulse diagnosis instrument were conducted before treatment and at the end of the 4th week. Hamilton Depression Scale (HAMD-17), Hamilton Anxiety Scale (HAMA), Neuropsychological State Repeatability Scale (RBANS) and TESS were used for treatment before treatment, at the end of the 2nd week and at the end of the 4th week The efficacy and safety of the treatment were evaluated.

5. Risks and discomfort

The investigation may take you about an hour, and communicating and talking with us may be a bit uncomfortable for you. The current high-level clinical research evidence for the Five Elements music therapy is still insufficient, and its effectiveness for depressive states has not been fully confirmed. There may be a risk that patients' conditions do not improve significantly. Throughout the study, professional physicians will monitor the patients' conditions regularly, follow up and control the patients' conditions in a timely manner after changes, and ensure the patients' safety by terminating the study and adopting other drug treatment regimens or referring them to other professional medical clinics. At the end of each examination, we assess the adverse reactions of the subjects and record them in detail. We can help you understand your mental health status and explain your health status. All your information will be kept confidential.

6 Benefit

The assessment of you will help to make a diagnosis of the disease, provide the necessary advice for your treatment, or provide useful information for the study of the disease.

7 Alternative treatment options

You may choose other antidepressants or traditional Chinese medicine decoctions for symptomatic treatment. Antidepressants can quickly improve depressive symptoms, but there may be adverse drug reactions such as gastrointestinal reactions, etc. Traditional Chinese medicine decoctions have fewer adverse drug reactions, but there is a risk of long intervention time, slow onset, and poor symptom control.

8. Restricted drugs

If you choose this trial protocol, your antidepressants will be restricted during the intervention treatment and can only be treated with fluoxetine hydrochloride; Fluoxetine hydrochloride is an antidepressant that is currently widely used in clinical practice and is recommended by guidelines as a first-line antidepressant.

9. Responsibilities

As a research subject, you have the following duties: to provide true information about your medical history and current physical condition; Inform the study doctor of any discomfort you experienced during this study; Do not take restricted medications, foods, etc. Tell the research doctor whether you have been involved in other studies recently or are currently involved in other studies.

10 Privacy issues

If you decide to participate in this study, your personal data during the trial and in the trial will be confidential. Your medical information will be used by the study physician and other researchers for the study. This information may include your name, address, phone number, medical history, and information received during your research visit. Your behavioral and electroencephalogram data will be identified by study number rather than your name. Information that can identify you will not be disclosed to members outside the study group unless you have given permission. All study members and study sponsors are required to keep your identity confidential. Your file will be kept in a locked filing cabinet for researchers' access only. To ensure that the research is conducted as required, government authorities or members of the ethics review committee may access your personal data at the research unit if necessary. No personal information about you will be disclosed when the results of this study are published.

11. Compensation/Indemnity

This study will compensate you with a subsidy of 30 yuan for transportation expenses within the city.

If you are injured as a result of participating in this study: You can receive free treatment and/or corresponding compensation in the event of damage related to this clinical study.

You may choose not to participate in this study or notify the investigator at any time to withdraw from the study. Your data will not be included in the study results and your medical treatment and benefits at our center will not be affected as a result.

If you need additional treatment, or if you fail to comply with the study plan, or if a research-related injury occurs, or for any other reason, the study physician may terminate your continued participation in this study.

12. The expected cost of participating in the trial

There was no additional charge for all scale tests, electroencephalogram (EEG) tests, eye movement tests, and pulse diagnosis instrument tests in this study.

13. Legal rights

The above section does not limit your right to seek legal aid. By signing this informed consent form, you do not waive any legal rights.

14. Contact information for consultation

You can stay informed about the information, materials and research progress related to this study at any time. If you have any questions related to this study, you can contact Liu Lanying at 13516816012. For questions regarding the rights of participants in this study, you can contact the Ethics Committee of Shanghai Mental Health Center at 021-34773308

Informed consent form signature page

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- ✓ I have read this informed consent form.
- ✓ I have had the opportunity to ask questions and all of them have been answered.
- ✓ I voluntarily agree to participate in this study and to allow my information to be provided to the researchers for analysis.
- ✓ If I meet the inclusion criteria of the study and agree to participate in the study, the doctor will include me in the study.
- ✓ I have been informed of the duration of my participation in the study.
- ✓ I have been informed of the operations and checks I will undergo during the study.
- ✓ I am aware of the possible risks and benefits of participating in this study.
- ✓ By signing this informed consent form, I do not waive my legal rights.
- ✓ I voluntarily signed this informed consent form prior to joining this study.
- ✓ I can choose not to participate in this study, or withdraw at any time after notifying the researcher without being discriminated against or
  Retaliation will not affect any of my medical treatment or rights.
- ✓ If I need additional treatment, or if I fail to comply with the research plan, or if a research-related injury or occurs
- ✓ The study physician may terminate my continued participation in this study for any other reason.
- ✓ I will receive a copy of the signed "informed consent Form".

Subject name (in regular script) :_____

The subjects signature: _____

Date :_____ year _____ month _____ day

Legal guardian name (in regular script) :_____

Legal guardian signature: _____

Date :_____ year _____ month _____ day

I accurately informed the subject of this document, he/she accurately read this informed consent form, and testified that the subject had the opportunity to ask questions. I certify that he/she

consented voluntarily.

Researcher name (in regular script) :_____

The researchers signature: _____

Date: _____ year _____ month _____ day