Informed consent form of the healthy control group

(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 plans to recruit 40 healthy control groups at the Shanghai Mental Health Center. 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

If you agree to participate in the study, we will communicate with you or your family in detail to inform you about the study. We will need to collect some of your relevant data during the study, and a professional will assess you. You will need to fill out a general information questionnaire, including your name, age, gender, marital and reproductive history, smoking and drinking history, disease duration, previous physical illness history, family history, current medication use, etc. The Hamilton Depression Scale (HAMD-17), Hamilton Anxiety Scale (HAMA), Neuropsychological State Repeatability Test (RBANS), Treatment TESS, ERP electroencephalogram test, eye

movement test and pulse recording instrument will be conducted.

We will invite 40 healthy individuals to participate in this study.

Inclusion criteria:

Aged 18 to 60, should be a healthy person without mental or physical illness.

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) Having participated in other drug clinical trials prior to inclusion.

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. Your ERP EEG test data samples are collected by professionals for you, and there may be some very small risks during the collection process, such as scalp irritation, eye fatigue, and mild headache. These adverse reactions are usually very mild and rarely occur. We can help you understand your mental health and explain your health. The information you have 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. Responsibilities

Provide true information about your medical history and current physical condition: Inform the doctor of any discomfort you have experienced during this study period; Tell the study doctor if you have been involved in other studies recently or are currently involved in other studies, and if you receive information that may affect the subject's continued participation in the trial, the subject or their legal representative will be informed promptly.

8. 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.

9. 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.

10. 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.

11. 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.

12. Contact information for consultation

You are available at any time for information and research progress related to this study. 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

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

Scheme version number: 02, March 3, 2025

Informed consent form version number: 02 March 3, 2025

Research institution: Shanghai Mental Health Center

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

- ✓ 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 may choose not to participate in this study, or withdraw at any time after notifizing the investigator 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
- ✓ For any other reasons, the research physician may terminate my continued participation in this study.
- ✓ 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