Official Title: A Multimodal MRI-Based Study on the Rapid Antidepressant Mechanisms of Acupuncture and Individualized Treatment Response Prediction in Depression

Informed Consent Form

NCT Number： Not yet assigned

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Informed Consent Form for the Study on the Rapid Antidepressant Mechanism of Acupuncture in Depression Based on Multimodal Magnetic Resonance Imaging and Individualized Efficacy Prediction

Part 1: Information for the Subject

Hello, we are about to conduct a study titled "The Rapid Antidepressant Mechanism of Acupuncture in Depression Based on Multimodal Magnetic Resonance Imaging and Individualized Efficacy Prediction." Please read this consent form carefully before deciding whether to participate. You may ask questions and request clarification at any time while the researcher explains the study to you. You may also discuss it with your family, friends, or doctor before making a decision. If you are currently participating in another clinical study, please inform the research staff. This study is conducted by Yuquan Hospital of Tsinghua University (Tsinghua University Integrated Chinese and Western Medicine Hospital). The contents of this informed consent form have been reviewed by the Ethics Committee.

I. Research Background and Significance

Depression is a common mood disorder. Existing pharmacotherapies have limitations such as delayed onset of action, variable efficacy, and side effects. Acupuncture, a traditional Chinese medical therapy, has the potential for rapid onset of action and few side effects, but its mechanism of action remains unclear. This study aims to explore the rapid-onset mechanism of acupuncture treatment for depression using multimodal magnetic resonance imaging (MRI) and to establish an individualized efficacy prediction model, thereby providing a basis for precision treatment of depression.

II. Inclusion Criteria

Subjects must meet the diagnostic criteria for depression according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) of the American Psychiatric Association, and also satisfy the following conditions: age 18-59 years, no previous

antidepressant medication or have discontinued medication for more than 6 weeks, and a Hamilton Depression Rating Scale (HAMD-17) total score of >7 and ≤ 24.

III. Research Objectives

1.To verify the rapid amelioration effect of acupuncture on depressive symptoms in patients with depression;

2.To elucidate whether acupuncture exerts rapid antidepressant effects by regulating the glutamate-glutamine cycle in brain regions such as the prefrontal cortex and the functional connectivity of the default mode network;

3.To establish an individualized subtype identification and efficacy prediction model for depression based on multimodal MRI.

IV. Possible Adverse Effects and Management

1.Needle Syncope (fainting during acupuncture): Immediately stop acupuncture, have the subject lie down to rest, drink warm water, and apply pressure to the philtrum (GV26) or Neiguan (PC6) if necessary.

2.Subcutaneous Hematoma (bruising): Minor hematomas may resolve on their own. For more severe cases, apply cold compresses initially, followed by warm compresses after 24 hours.

3.Infection at the Needle Site: Strict aseptic technique will be followed. If infection occurs, it will be managed according to surgical principles.

4.MRI-Related Discomfort (e.g., claustrophobia, anxiety): Immediately stop the scan, provide reassurance, and allow withdrawal from the study if necessary.

5.Fluctuation of Illness: If depressive symptoms worsen or suicidal ideation appears, the psychiatric emergency protocol will be initiated immediately, and a doctor will be contacted.

During the study, your symptoms may not improve or may temporarily fluctuate. We will closely monitor you and provide necessary support. Note: Individuals with metal implants, cardiac pacemakers, etc., are not suitable for MRI examination.

V. Alternative Diagnostic and Therapeutic Options and Benefits of Participating in the Study

Current standard treatment options for depression include：(1) Medication (e.g., SSRIs): Usually takes 2-4 weeks to take effect and may be associated with side effects such as nausea, insomnia, and sexual dysfunction.(2) Psychotherapy (e.g., Cognitive Behavioral Therapy): Effect is slower to manifest and requires multiple sessions.

There may be no direct benefit to you from participating in this study, although your condition may improve. Regardless of whether you benefit, you will contribute to depression research and help future patients.

VI. Voluntary Participation Principle

Participation in this study is entirely voluntary. You may refuse to participate without any negative impact on your current or future medical care. Even after agreeing, you may withdraw from the study at any time without discrimination or affecting your normal medical services. Please inform the researcher promptly upon withdrawal so that we can provide you with health advice and guidance.

VII. Cost Explanation

The costs of the acupuncture treatment and MRI scans involved in this study are covered by the research project. All other routine medical expenses are your own responsibility.

VIII. Research-Related Injury and Compensation

If an injury directly related to the acupuncture intervention occurs, the hospital will bear the corresponding reasonable medical expenses and provide compensation in accordance with applicable laws and regulations.

IX. Privacy and Confidentiality

All of your research data will be kept confidential. Information that could identify you will be used only within the research team and will not be disclosed to outsiders without your permission. Research records will be stored securely, and access will be granted only to authorized personnel. Relevant regulatory authorities may review original records for the

purpose of verifying research data, under the condition of confidentiality. No personal information will be included in any publication of the research results.

X. New Information Notification

If any new information becomes available that may affect your willingness to continue participating in the study, we will inform you promptly. You will then decide whether to continue or withdraw.

XI. Contact Information

If you have questions related to the research, please contact the researcher, Dr. _____, at telephone: _____.

If you have questions regarding the rights of research subjects, please contact the Ethics Committee of Yuquan Hospital of Tsinghua University (Tsinghua University Integrated Chinese and Western Medicine Hospital) at telephone: _____.

Part 2: Informed Consent Signature Page

Subject's Informed Consent Statement:

I have understood the purpose, procedures, risks, and potential benefits of the above study as explained to me. I have had the opportunity to ask questions and have received satisfactory answers. I have also been informed of whom to contact if I have questions or wish to obtain further information. I have read this informed consent form and agree to participate in this study. I understand that I may withdraw unconditionally at any time during the research period. I am informed that I will sign this informed consent form in duplicate, which will bear both my signature and the investigator's signature, and that I will retain one copy and the investigator will retain the other.

Signing this informed consent form indicates that I: ☐ Consent □ Do Not Consent to participate in the study.

Subject

Name (Print): _____ Signature: _____

Phone Number: _____

Date/Time: _____ Year _____ Month _____ Day _____ Hour _____ Minute

Emergency Contact Name: _____

(Relationship to subject: _____)

Emergency Contact Phone Number: _____

Guardian Declaration (if applicable)

I confirm that I have fully explained the contents of this consent form to the subject and ensured their understanding, and that the subject is voluntarily participating in this study.

Name (Print): _____ Signature: _____

Phone Number: _____

Date/Time: _____ Year _____ Month _____ Day _____ Hour _____ Minute

Investigator's Declaration

I have explained the relevant information of this study (research background, objectives, procedures, risks, and benefits) to the subject and guardian (if applicable). I have given him/her sufficient time to read the informed consent form, discuss it with others, and have answered his/her questions regarding the study. I have provided the subject and guardian (if applicable) with contact information for any questions. I have informed the subject and guardian (if applicable) that they may withdraw unconditionally from this study at any time.

Investigator

Name (Print): _____ Signature: _____

Phone Number: _____

Date/Time: _____ Year _____ Month _____ Day _____ Hour _____ Minute