Project Name: Multimodal Neuromodulation for Post-Stroke Motor Dysfunction Using Transcranial Focused Ultrasound

Version: V2.0

Date: April 27, 2026

INFORMED CONSENT FORM

Dear Ms./Mr. _____:

We are conducting a research study entitled "Multimodal Neuromodulation for Post-Stroke Motor Dysfunction." This study has been reviewed and approved by the Medical Ethics Review Committee of Taizhou People's Hospital and complies with relevant Chinese regulations and ethical principles protecting the rights of research participants as outlined in the Declaration of Helsinki.

Before agreeing to participate in this research, you should understand the specific content of the study. Please read this informed consent form carefully and feel free to ask any questions.

1. Why is this research being conducted?

We are conducting a clinical research study on multimodal neuromodulation for stroke. This study will utilize advanced neuromodulation technology aimed at improving patients' motor function, cognitive abilities, and quality of life. By combining electroencephalography (EEG), magnetic resonance imaging (MRI), and other signal analyses, we will evaluate how transcranial focused ultrasound technology promotes the remodeling and functional recovery of damaged neural networks by activating or inhibiting neural activity in specific brain regions. The goal is to improve patients' motor and cognitive functions, reduce long-term disability, and enhance quality of life. The study also aims to optimize stimulation parameters to achieve maximum rehabilitation outcomes and explore the potential mechanisms of neuroprotection and functional reconstruction following stroke.

2. Who will be invited to participate in this research?

If you meet the following criteria, we will invite you to participate in this study:

1) Diagnosed with first-episode ischemic stroke confirmed by imaging;
2) Unilateral limb motor impairment;
3) Modified Ashworth Scale for upper limb ≤3, Brunnstrom stage II-V, Upper Extremity Fugl-Meyer Assessment (FMA-UE) score between 15 and 60 (inclusive);
4) Age 18-75 years, with onset time between 21 days and 6 months, in subacute or recovery phase;
5) Stable vital signs, no consciousness disorders, informed consent to the research, able to cooperate with treatment, and approved by the hospital ethics committee.

If you meet any of the following criteria, you should not participate in this study:

6) MRI contraindications;
7) Infarction involving the thalamus;
8) Risk of intracranial hemorrhage;
9) Metallic foreign bodies in the skull, cardiac pacemakers, or cochlear implants;
10) Unstable condition, severe cognitive impairment or mental disorders preventing understanding of research content or cooperation with assessment;
11) Fractures, joint contractures, severe limb spasticity, or other conditions affecting limb motor function;
12) Use of medications affecting cortical excitability.

3. **How many people will participate in this research, and how long is the study period?**

We plan to enroll 60 participants in this study. Each participant will receive a seven-day cycle of neuromodulation intervention and assessment.

4. **How will this research be conducted?**

The study will randomly assign participants to either an intervention group or a control group. Both groups will receive standard medical treatment (including antiplatelet therapy, neuroprotective agents, circulatory improvement, plaque stabilization, glucose and blood pressure management, and symptomatic support) and basic rehabilitation therapy (physical therapy and occupational therapy). The neuromodulation group will additionally receive one week of transcranial focused ultrasound stimulation on top of standard treatment. The control group will undergo the same assessment and operational procedures as the experimental group on top of standard treatment, but will receive sham stimulation.

The study period is one week, divided into three main phases: pre-test, modulation, and post-test:

13) Pre-test requires head MRI and CT scans, as well as scale assessments and EEG collection.
14) During the week, participants will receive modulation for 5 consecutive days, once daily for 12 minutes each session. EEG and task testing will be collected before, during, and after each modulation session.
15) Post-test requires head MRI scans and scale assessments, to be conducted within two days after completion of all modulation procedures.

5. **What are the risks of participating in this research?**

The likelihood of safety issues or serious adverse reactions during the study is expected to be low, and adverse events will be monitored regularly throughout the study. During neuromodulation, there may be slight warming where the electrodes contact the skin, which is a normal phenomenon that will resolve after the neuromodulation session ends. If you experience any other discomfort, please inform your treating physician immediately, and they will address your symptoms.

6. **What are the potential benefits of participating in this research?**

Direct benefits: (Promoting recovery of hemiplegic upper limb motor function, improving activities of daily living; there may also be no symptom improvement.)

Social benefits: By establishing evidence-based medicine and precision screening protocols, this research promotes the delivery of quality rehabilitation resources to underserved areas and reduces the long-term social care burden and medical expenses caused by disability.

7. **Will participating in this research increase my medical expenses?**

The costs of neuromodulation treatment and MRI examinations involved in this study will be covered by the research team and will not increase your medical expenses.

8. **If I do not participate in this research, are there alternative treatment options?**

If you do not participate in this research, you can improve your condition through traditional medication or rehabilitation training. Medication may have side effects, dependency, and drug resistance. Rehabilitation training may require higher time costs and longer effectiveness cycles.

9. **What compensation will I receive for participating in this research?**

Participation in this study is voluntary. Participants who complete the entire study will receive RMB 600 in compensation.

10. **Compensation for Injury**

If a participant suffers injury during the research that requires medical treatment, the costs will be covered by the research team.

11. **Confidentiality and Privacy Authorization**

Your health information is protected by relevant Chinese laws. By signing this informed consent form, you agree that physicians and relevant technical personnel may collect, use, and share your health information data. Your medical records will be fully preserved at the hospital where you receive care. Research personnel, the ethics review committee, and relevant national authorities will be permitted to review your medical records. Any public reports regarding this study will not disclose your personal identity, and your personal privacy will be protected.

12. **Voluntary Participation/Withdrawal**

This study has been approved by the hospital's Medical Ethics Review Committee. Your participation is entirely voluntary. You may choose not to participate or withdraw from the study at any time without affecting your medical care or rights, and you will not be discriminated against by medical staff.

If you do not understand the research risks and complications described above, you may consult with the physician. If you have questions, suggestions, or opinions, you may communicate with the physician.

13. **Obtaining New Information and Re-Consent**

During the study, if the researcher becomes aware of the latest developments related to this research or your disease, you will be informed promptly. If the informed consent form is revised, the researcher will promptly inform you of the new version to obtain your consent and signature again.

14. **If I have questions or difficulties, whom should I contact?**

After reading this informed consent form and discussing it with your physician, if you have additional questions or concerns, please contact the following persons:

Principal Investigator: _____ Phone: _____

If you have any questions regarding your rights, you may contact the following during normal working hours on national legal working days:

Taizhou People's Hospital Clinical Research Ethics Committee Phone: 0523-86361059

PARTICIPANT SIGNATURE PAGE

Participant Informed Consent Statement

I have read this informed consent form and have had the opportunity to ask questions, all of which have been answered.

I understand that participation in this study is voluntary.

I may choose not to participate in this study or withdraw at any time by notifying the researcher without facing discrimination or retaliation, and my medical care and rights will not be affected.

If I require other treatment, or if I fail to comply with the study protocol, or if research-related injury occurs, or for any other reason, the study physician may terminate my participation in this study.

I will receive a signed copy of this "Informed Consent Form."

Participant Signature: _____ Mobile Phone: _____
Date: ____/____/____

Legal Guardian Signature (relationship to participant): _____ (if applicable)
Mobile Phone: _____ Date: ____/____/____

Impartial Witness Signature: _____ (if applicable)
Mobile Phone: _____ Date: ____/____/____

Researcher Disclosure Statement

I have accurately presented this document to the participant, who has read this informed consent form, and I confirm that the participant had the opportunity to ask questions. I certify that their consent is voluntary.

Researcher Signature: _____ Mobile Phone: _____ Date: ____/____/____