INFORMED CONSENT FORM

Study Official Title:

The Effects of Transcranial Temporal Interferential Electrical Stimulation on Cognitive Function, Dual-Task Performance and Neuroplasticity in Individuals With Mild Cognitive Impairment

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Principal Investigator: Weijie Fu, PhD Shanghai University of Sport

Tel: +86 21 6550 7368 Email: fuweijie@sus.edu.cn

Co-Investigator (Clinical Contact): Zhen Xu, PhD

Tel: +86 135 0590 5809 Email: xuzhen0226@163.com

Study Site: Shanghai University of Sport

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1. INTRODUCTION

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask the research team if there is anything that is not clear or if you would like more information.

2. PURPOSE OF THE STUDY

Mild cognitive impairment (MCI) is a condition where a person has slight memory or thinking problems that are noticeable but do not interfere with daily activities. MCI can sometimes lead to dementia, but not everyone with MCI develops dementia. There are currently no effective medications to treat MCI. This study aims to test a new non-invasive brain stimulation technique called **transcranial temporal interference stimulation (tTIS)** . tTIS uses small electrodes placed on the scalp to deliver very weak electrical currents to a deep brain region called the hippocampus, which is important for memory. This technique is safe, painless, and does not require surgery. We want to see if a single 20-minute session of tTIS can improve memory, thinking, and walking ability in people with MCI.

3. STUDY PROCEDURES

If you agree to participate, you will be asked to attend three visits to our research center.

Visit 1 (Screening and Baseline, about 3 hours)

- You will be asked about your medical history and medications.
- You will complete a short memory and thinking test (Montreal Cognitive Assessment, MoCA) and a questionnaire about your daily activities.
- If you are eligible, you will undergo a brain MRI scan (about 45 minutes) to obtain a detailed picture of your brain structure. This scan will be used to create a personalized stimulation plan.

- You will perform some simple tasks:
    - Walking at your normal speed while a camera system records your movements.
    - Standing on a balance platform with eyes open/closed.
    - A computer-based memory task (face-name association).
- You will have a resting-state EEG recording (a cap with sensors placed on your scalp) to measure your brain's electrical activity.

Visit 2 (First Intervention, about 2.5 hours)

- You will receive a 20-minute brain stimulation session. The stimulation is delivered through electrodes placed on your scalp. You will feel a mild tingling or itching sensation when the current starts and stops.
- Immediately after stimulation, you will repeat the same memory, walking, and balance tests as in Visit 1, and undergo another EEG and a short fMRI scan (about 30 minutes).

Visit 3 (Second Intervention, about 2.5 hours)

- After a 7-day break (washout period), you will return for the second stimulation session. This time you will receive the *other* type of stimulation (either active or sham, whichever you did not receive first). You will not know which type you are getting.
- The tests and scans after stimulation are identical to Visit 2.

Important Notes

- The study is **randomized** and **double-blind**: You will be assigned by chance to receive either active stimulation first or sham stimulation first. Neither you nor the researchers who test you will know which stimulation you receive during each session (the investigator who programs the stimulator will not be involved in testing).
- The sham stimulation feels exactly the same as active stimulation (you will feel the start and end sensations) but does not deliver the therapeutic electric field.
- All study procedures are non-invasive and carry very low risk.

4. POTENTIAL RISKS AND DISCOMFORTS

tTIS Stimulation:

The most common sensations are mild tingling, itching, or a slight pulling sensation under the electrodes. Some people may experience temporary slight headache, fatigue, or dizziness. These effects usually disappear immediately after stimulation or within a few hours. In our pilot study with 14 participants, no serious side effects were reported.

MRI Scan:

MRI uses a strong magnetic field and radio waves to create images of the brain. It is safe for most people. However, you will be asked to lie still inside a narrow tube for about 45 minutes. You may feel a bit closed-in; if you have claustrophobia, please let us know. You will be given earplugs to reduce the noise. If you have any metal inside your body (e.g., pacemaker, surgical clips, metal fragments), you cannot have an MRI scan. You will be screened for these before the scan.

EEG Recording:

The EEG cap may cause mild pressure on the scalp. The conductive gel may leave a slight residue that can be washed off easily.

Possible discomfort during tests:

The walking and balance tests may cause mild fatigue. You can rest at any time.

Safety Monitoring:

Throughout the study, your vital signs (blood pressure, heart rate) will be monitored before and after each stimulation session. A trained researcher will stay with you during the stimulation and ask about your feelings every 5 minutes. If you experience any discomfort, you can stop the stimulation at any time. Emergency equipment and a direct contact with a nearby hospital are available in case of any unexpected medical event.

5. POTENTIAL BENEFITS

You may not receive direct medical benefit from participating. However, the information we gain from this study may help develop new non-invasive treatments for people with MCI in the future. You will receive detailed feedback on your cognitive and walking performance, as well as a copy of your brain MRI images if you wish.

6. ALTERNATIVES

If you decide not to participate, you may continue with your usual care. This study does not replace any medical treatment you may be receiving.

7. CONFIDENTIALITY

All information collected during the study will be kept strictly confidential. Your name will not appear on any study documents; instead, you will be assigned a unique code number. Data will be stored on password-protected computers in locked facilities. Results will be published only as group data, with no individual identification. Access to your personal information is limited to the research team and authorized regulatory bodies.

8. VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation is entirely voluntary. You may refuse to participate or withdraw at any time without giving a reason and without any negative consequences to your medical care or legal rights. If you withdraw, any data already collected may still be used for analysis unless you specifically request its removal.

9. COMPENSATION

You will receive a transportation allowance of 100 RMB per visit to cover travel expenses. No other compensation will be provided.

10. CONTACT INFORMATION

If you have any questions about the study, please contact:

- **Zhen Xu** at +86 135 0590 5809 or xuzhen0226@163.com

If you have concerns about your rights as a research participant, you may contact the **Shanghai University of Sport Research Ethics Committee** at +86 21 6550 8179 or lunli@sus.edu.cn.

11. CONSENT STATEMENT

I have read the above information (or it has been read to me). I have had the opportunity to ask questions and any questions have been answered to my satisfaction. I understand that I can withdraw at any time. I voluntarily agree to take part in this study.

Participant's Name (print): _____

Participant's Signature: _____

Date: _____

Person Obtaining Consent

(print): _____

Signature: _____

Date: _____