INFORMED CONSENT FORM

Study Official Title:

Effects of Transcranial Temporal Interference Stimulation Combined With Tai Chi Training on Cognitive Function, Dual-Task Performance, and Neuroimaging Mechanisms in Individuals With Mild Cognitive Impairment

Unique Protocol ID: 102772026RT012

NCT Number: not yet assigned

Secondary ID: None

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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 an 8-week combined intervention using **individualized transcranial temporal interference stimulation (tTIS)** and cognitively enhanced Tai Chi training. tTIS uses small electrodes placed on the scalp to deliver weak electrical currents to the hippocampus, a deep brain region important for memory. The stimulation plan is personalized using each participant's brain MRI. We want to determine whether active tTIS combined with Tai Chi can improve memory, thinking, and cognitive-motor dual-task performance compared with sham tTIS combined with the same Tai Chi training, and to examine related changes in brain structure and function.

3. STUDY PROCEDURES

If you agree to participate, you will take part in 24 intervention sessions over 8 weeks and attend three main assessment visits at our research center.

Visit 1 (Screening and Baseline, about 2-3 hours)

- You will be asked about your medical history and medications.
- You will complete memory and thinking assessments, including the Montreal Cognitive Assessment (MoCA), Mini-Mental State Examination (MMSE), and computerized memory and attention tasks.
- If you are eligible, you will undergo a brain MRI scan (about 45 minutes). The structural MRI will also be used to create your personalized stimulation plan.
- You will perform single-task and dual-task walking tests, including the Timed Up and Go test and gait assessment.
- You will complete memory and cognitive tasks such as Go/No-Go, n-back, face-name matching, and memory similarity tasks. During selected tasks, functional near-infrared spectroscopy (fNIRS) sensors will be placed on your scalp to measure changes in brain blood oxygenation.
- You will complete questionnaires about mood, sleep, daily function, and quality of life.

8-Week Intervention Period

- You will be randomly assigned in a 1:1 ratio to one of two groups: active individualized tTIS plus Tai Chi, or sham tTIS plus the same Tai Chi program.
- You will attend three intervention sessions per week for 8 weeks. Each tTIS session lasts 20 minutes. Active stimulation uses two high-frequency currents that create a 5-Hz interference pattern at the hippocampal target; sham stimulation uses the same electrode

placement and start/end sensations but does not provide effective stimulation during the main stimulation period.

- Each Tai Chi session lasts about 60 minutes and uses an 8-form cognitively enhanced Tai Chi program. Training includes warm-up, core Tai Chi practice, cognitive-enhanced dual-task practice, and cool-down.

Visit 2 (Post-Intervention Assessment, Week 8, about 2-3 hours)

- You will repeat the memory, thinking, walking, gait, and questionnaire assessments. You will also undergo repeat MRI and fNIRS assessments.

Visit 3 (Follow-Up Assessment, Week 24, about 1-2 hours)

- Sixteen weeks after the 8-week intervention ends, you will return for a follow-up visit. Selected memory and thinking tests and questionnaires will be repeated to evaluate whether the effects are maintained.

Important Notes

- The study is randomized and quadruple-blind: assignment is determined by chance, and participants, care providers, investigators, and outcome assessors will remain unaware of group allocation. Preset stimulation codes will be used so that the person operating the stimulator also does not know whether active or sham stimulation is being delivered.
- The sham stimulation uses the same electrode placement and similar start and end sensations as active stimulation, but it does not deliver the therapeutic electric field during the main stimulation period.
- All study procedures are non-invasive. You may ask to pause or stop any procedure at any time.

4. POTENTIAL RISKS AND DISCOMFORTS

tTIS Stimulation:

The most common sensations are mild tingling, itching, warmth, or a slight pulling sensation under the electrodes. Some people may experience temporary headache, fatigue, dizziness, or mild skin redness. These effects are usually short-lived. Because you will receive repeated sessions, these temporary sensations may occur more than once. Any unexpected symptoms will be evaluated by the research team.

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 closed-in; if you have claustrophobia, please let us know. You will be given earplugs to reduce the noise. If you have metal inside your body (e.g., pacemaker, surgical clips, metal fragments), you may not be able to have an MRI scan. You will be screened for these before the scan.

fNIRS Recording:

fNIRS is a non-invasive optical recording method. Sensors placed on the scalp may cause mild pressure or temporary discomfort from the cap or sensor contact. The procedure does not deliver electrical current into the brain.

Tai Chi and Physical Testing:

Tai Chi, walking, and dual-task tests may cause mild fatigue, muscle soreness, or temporary loss of balance. There is a small risk of stumbling or falling. Training and testing will be supervised, and you may rest or stop at any time.

Cognitive Testing:

Memory and computer-based tasks may cause temporary mental fatigue, frustration, or eye strain. Breaks will be provided when needed.

Safety Monitoring:

Throughout the intervention period, your blood pressure and heart rate will be monitored before and after stimulation sessions. A trained researcher will remain available during stimulation and will record any discomfort or adverse events. After each stimulation session, you will be asked about possible side effects and your perception of the stimulation condition. If you experience significant discomfort, the procedure will be stopped and appropriate evaluation will be provided. Emergency procedures and contact with nearby medical services are available if needed.

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 treatment strategies for people with MCI in the future. You will receive feedback on your cognitive and walking performance, and you may receive 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 secure 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

If you complete the scheduled study assessments, you will receive an assessment report, an explanation of the results, and a small gift. If you withdraw early, compensation or reimbursement may be adjusted according to the study procedures you have completed.

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: _____