Informed Consent Form/Notice Page

Dear Sir or Madam:

We would like to invite you to participate in a clinical trial investigating the "Key Technology Study of Acupoint-Modulated Brain Electric Field Therapy for the Treatment of Post-Stroke Cognitive Impairment."

Before deciding whether to participate in this study, please read the following carefully to understand the study's content, its rationale, and the potential benefits, risks, and discomforts. This study has been reviewed by the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University and complies with relevant Chinese laws and regulations and ethical principles such as the Declaration of Helsinki to protect the rights and interests of human subjects.

Study Introduction

a、Research Background

Post-stroke cognitive impairment is a common complication of stroke, and patients may experience cognitive impairment within six months of the stroke event. Post-stroke cognitive impairment is defined as a clinical phenomenon secondary to stroke characterized by cognitive decline. The prevalence of post-stroke cognitive impairment is approximately 30%-50% within six months, of which 10% will progress to dementia. Furthermore, patients face a 61% mortality risk within five years. Countries worldwide have issued targeted guidelines, calling for increased attention and investment in this significant complication. However, current treatments for post-stroke cognitive impairment are limited to secondary stroke prevention measures and medications similar to those used to treat Alzheimer's disease, both of which lack high-level clinical evidence. Therefore, effective treatments are urgently needed to improve patient outcomes.

b、Research Objectives

Based on an analysis of the objective characteristics of post-stroke cognitive impairment, this study explores the interventional mechanisms of acupuncture in improving post-stroke cognitive impairment, systematically elucidates the evolution of stroke syndromes in Traditional Chinese Medicine (TCM), and establishes individualized, precise treatment plans. Furthermore, based on a prospective cohort study, this study explores the establishment of precise TCM diagnostic and treatment guidelines for post-stroke cognitive impairment and identifies the therapeutic advantages of acupuncture in improving post-stroke cognitive impairment and its associated symptoms.

c、What will I need to do if I participate in the study?

If you meet the inclusion criteria and agree to participate, you will need to cooperate with us in the following:

① Cooperate in collecting relevant post-stroke indicator information. ② Cooperate in completing cognitive function tests: MMSE, MoCA, and other relevant assessment scales. This project plans to recruit 68 patients with post-stroke cognitive impairment from various centers (34 in the sham electroacupuncture group and 34 in the electroacupuncture group). The expected treatment duration for participants is two months. Researchers will scientifically evaluate the effectiveness and safety of acupuncture in treating symptoms and signs of post-stroke cognitive impairment and improving patients' mental status.

d、What are the inclusion and exclusion criteria?

1. Inclusion criteria

(1) Meet the Western medical diagnostic criteria for vascular cognitive impairment in accordance with the Western medical diagnostic criteria for vascular cognitive impairment in the "Guidelines for the Diagnosis and Treatment of Vascular Cognitive Impairment in China (2024 Edition)" formulated by the Vascular Cognitive Impairment Branch of the Chinese Stroke Society.

(2) Meet the Traditional Chinese Medicine diagnostic criteria for vascular cognitive impairment in the "Guidelines for the Diagnosis and Treatment of Vascular Mild Cognitive Impairment in Traditional Chinese Medicine (2024)";

(3) Mini-Mental State Examination (MMSE) score is 12-24 points, Montreal Cognitive Assessment (MoCA) score is <24 points; cognitive impairment exists but does not reach the level of severe dementia; National Institutes of Health Stroke Scale (NIHSS) score is ≤8 points; Ascertain Dementia 8 (AD-8) score is <2 points;

(4) Aged between 35 and 80 years old; (statistical analysis should be stratified by age)

(5) Have basic communication skills, mainly Mandarin (communication language is sufficient), and have at least one stable caregiver;

(6) Sign the informed consent form.

2. Exclusion criteria:

(1) Patients with serious primary chronic diseases of the heart, liver, kidney, and other internal organs, as well as endocrine and hematopoietic systems, or serious cardiovascular and cerebrovascular diseases;

(2) Patients with skin diseases such as herpes and ulcers or a constitution prone to scarring, who are not suitable for acupuncture treatment;

(3) Unsuitable for repeated MRI examinations, such as claustrophobia, after aneurysm embolization, etc.;

(4) Patients with cognitive impairment or other serious neurological or psychiatric diseases before the onset of the current disease, whose control is unstable;

(5) Patients determined by other clinical trial personnel to be unsuitable for this study;

(6) Patients who have participated in clinical research on related diseases in the past 3 months.

e、What benefits will I get from participating in this study?

Participating in this study can help you identify the TCM syndrome types of post-stroke cognitive impairment. This study can also help determine which treatment methods can be more safe and effective for other patients with similar conditions as you.

f、What are the risks of participating in this study?

Currently, there are no clear treatment risks associated with acupuncture. However, depending on patient constitution, needle dizziness and palpitations may occur, but these risks are relatively low. Acupuncture treatment for post-stroke cognitive impairment is not known to cause serious adverse reactions, including dizziness and fatigue. During the trial, you may experience other discomforts. Please inform your study physician immediately, and they will address any discomfort.

g、Will participating in this study increase my medical expenses?

No. To compensate for the inconvenience, this study will waive your registration fee for follow-up

visits. Participating in this study can help you identify and diagnose the Traditional Chinese Medicine (TCM) syndromes underlying post-stroke cognitive impairment. This study will also help determine which treatments are safer and more effective for other patients with similar conditions. This study will waive your acupuncture fees, near-infrared imaging, MRI, and EEG fees for post-stroke cognitive impairment treatment. Other medication and testing costs are not covered. We will regularly examine you for potential side effects and adverse reactions caused by clinical treatment and implement preventive measures. If any adverse reactions are caused by the interventions in this study, the investigator will cover the corresponding examination and treatment costs.

h、What compensation will be provided for participating in this study?

During the follow-up period (weeks 12-24 after enrollment), transportation and other financial compensation will be provided as appropriate.

i、Compensation for Damages

This study's treatment methods are safe and effective. If you sustain an injury related to this study, and the Hangzhou Medical Association confirms that the injury is related to the study, we will provide compensation. Predetermined, pro-rata compensation for participants' participation in the study

j、Is personal information confidential?

Your participation in this study will be recorded in the case report form. All trial results (including personal information, laboratory test results, etc.) appearing in the original medical records will be kept completely confidential to the extent permitted by law. Your name will not appear on the CRF; only your initials and the number assigned to you at the time of enrollment will appear. If necessary, only your initials and the number will appear in relevant research summaries, articles, and public publications.

If necessary, the drug regulatory authorities, medical ethics committee, or project funding agency may review the data of participating subjects in accordance with regulations. However, they will not use the data for other purposes or disclose it to other parties without permission.

k、How can I get more information?

You can ask any questions about this study at any time and contact Dr. Chen Bowen and Dr. Fu Luyao at 13967988987 and 18457100195, respectively.

If any important new information becomes available during the study that may affect your decision to continue participating, your doctor will promptly notify you.

l、Am I required to participate in this study?

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits.

m、Can I withdraw from the study midway?

You have the right to withdraw from the study at any time. If you choose to withdraw from the study, your benefits will not be affected, and you will not be discriminated against or retaliated against. If you choose to participate in this study, we hope you will complete the entire study.

Your doctor or investigator may terminate your participation in the study at any time based on your best interests.

If you withdraw from the trial for any reason, you may be consulted about your use of the trial

drug. If the doctor deems it necessary, you may also be asked to undergo laboratory tests and a physical examination. You may refuse these tests and will not be discriminated against or retaliated against.

n、Are there other treatments currently available? What are the advantages and disadvantages of the treatments used in this study?

If you do not participate in this trial, there are other clinical treatments available. Other treatments:

Method 1: Auricular acupressure therapy is simple and easy to perform, with reliable efficacy, but may cause skin discomfort.

Method 2: Western medicine works quickly but is prone to adverse symptoms such as rebound insomnia and addiction.

Advantages and disadvantages of the treatments used in this study:

Advantages: Acupuncture treatment is highly effective, safe, and easy to use.

Disadvantages: Acupuncture treatment varies from person to person, there is a risk of needle sickness, and long-term adherence is required.

o、What to Do Now?

Whether to participate in this study is your decision. You can discuss this with your family or friends before making a decision.

Before you decide to participate, please ask your doctor as many questions as possible until you fully understand the study.

p、Medical Ethics Committee

If you have any complaints about the study, please contact the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University.

Contact number: 0571-87238255.

Thank you for reading the above information. If you decide to participate in this study, please tell your doctor, who will arrange all trial matters for you.

Please keep this document.

Informed Consent • Consent Signature Page

Consent Statement

1. I have read this Informed Consent Form. The project responsible has explained the purpose, content, risks, and benefits of this trial to me in detail.

2. I have discussed and asked questions about this study, and these questions have been answered to my satisfaction.

3. I have sufficient time to make a decision.

4. I voluntarily agree to participate in the clinical study described in this document.

5. If I withdraw from the study due to this product, I will promptly inform my physician of any changes in my condition.

6. If I need to take any other treatment due to changes in my condition, I will consult my physician in advance or disclose this information to my physician afterward.

7. I consent to the review of my research materials by representatives of the drug regulatory authority, ethics committee, or project funding agency.

8. I will receive a signed and dated copy of this Informed Consent Form.

Finally, I agree to participate in this trial study and promise to follow the doctor's instructions.

Subject's Signature: Date: Year Month Day

Subject's Contact Number:

I confirm that I have explained the details of this study to the subject, including his/her rights and possible benefits and risks, and provided him/her with a copy of the signed Informed Consent Form.

Doctor's Signature: Date: Year Month Day

Research Doctor's Contact Information:

(This page is a required part of the Subject's Informed Consent Form. Each "Subject's Informed Consent Form" must be signed and dated by the subject or legal representative and the research doctor to be valid.)