Clinical Trial Informed Consent Statement

Dear Participant:

Hello! Thank you for participating in this study. Before you decide whether to participate in this clinical trial, please read the following content carefully. The researcher will answer your questions in detail to ensure that you fully understand the relevant information and make a voluntary decision.

I. Basic Information of the Trial

1. Trial Name: Scalp Acupuncture Combined with mNGF Acupoint Injection in the Treatment of Post-Stroke Cognitive Impairment
2. Trial Number: LL202418
3. Research Unit: Department of Rehabilitation Medicine, Jingzhou First People's Hospital
4. Principal Investigator: Physician Zhou Huating (Contact: 15271727429), Physician Ma Tian (Contact: 13554555862)
5. Funder: None
6. Ethical Approval: This study has been approved by the Medical Ethics Committee of Jingzhou First People's Hospital.

II. Research Objectives

This study aims to systematically evaluate the clinical efficacy of scalp acupuncture combined with mouse nerve growth factor (mNGF) acupoint injection on the recovery of cognitive function, activities of daily living, and motor function in patients with post-stroke cognitive impairment (PSCI). By comparing with conventional cognitive training and conventional training combined with scalp acupuncture, the study seeks to clarify the synergistic effect and safety of this combined intervention, provide more targeted integrated traditional Chinese and Western medicine treatment strategies for the clinical rehabilitation of PSCI, and promote the application value of non-pharmacological and pharmacological synergistic interventions in neurological function repair.

III. Trial Procedures

1. Trial Design: This study is a randomized controlled trial. You may be assigned to the experimental group or the control group.
2. Participation Content: You will need to receive specific treatments and regular follow-ups. Please refer to the research protocol for specific arrangements.
3. Duration: The expected participation time is 12 weeks, requiring 3 visits.

IV. Participation Criteria

1. Inclusion Criteria: Diagnosed with stroke and currently in the recovery phase; disease duration ≤ 6 months, excluding other causative factors; no liver or kidney dysfunction, no bleeding tendency, no severe cardiovascular disease; aged between 18 and 79 years; Montreal Cognitive Assessment (MoCA) score < 26; activities of daily living are normal or mildly impaired, unrelated to motor or sensory symptoms, with an Activities of Daily Living (ADL) scale score between 20 and 60; education level above primary school.
2. Exclusion Criteria: Presence of significant visual or hearing impairments; severe complications of the circulatory or respiratory systems; diagnosed psychiatric disorders; incomplete clinical data that cannot be supplemented; diagnosed malignant tumors or infectious diseases; poor compliance due to pain sensitivity.
3. Withdrawal Mechanism: You have the right to withdraw from the study at any time without affecting your medical rights; if medically necessary, the researcher may also terminate your participation.

V. Potential Risks and Benefits

1. Risks and Discomforts:

- Possible local pain and soreness; subcutaneous bleeding and bruising; allergic reactions to drugs; peripheral nerve damage; infection; fainting reaction (syncope).
- Time investment is required to cooperate with the research process.

2. Expected Benefits:

- You may obtain treatment opportunities.
- The research results may promote medical progress and benefit more patients.

VI. Privacy and Confidentiality

1. Your personal information and research data will be kept strictly confidential and used only for research purposes.

2. The Ethics Committee, regulatory agencies, etc., have the right to access the data, but your identity will not be disclosed unless required by law or with your consent.

VII. Voluntary Principle

1. Participation is completely voluntary. You can withdraw at any time for any reason without explanation, and it will not affect your medical rights.

2. Researcher Contact Information: Zhou Huating (Contact: 15271727429), Ma Tian (Contact: 13554555862), available at any time to answer your questions.

VIII. Declaration and Signature

I have read and understood the above content carefully, and all my questions have been satisfactorily answered. I voluntarily participate in this study and agree to allow the Ethics Committee, etc., to access my research data.

Researcher Declaration:

I have fully explained the content of this study to the subject and confirmed their understanding and voluntary participation.

Researcher Signature: 周华婷 Date: 2025年4月10日

Subject Signature: [illegible] Date: 2025年4月10日

Legal Guardian (if applicable) Signature: [illegible] Date: 2025年4月10日

Contact Information:

Researcher Name: Zhou Huating Tel: 15271727429 Ma Tian Tel: 13554555862

Research Institution Address: Jingzhou First People's Hospital