Informed Consent Form
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Study Title: Clinical Research on the Combination of Medicinal Stick Therapy and Repeated Facilitation Therapy for Lower Limb Dysfunction in Stroke Patients

Principal Investigator: Ye Jiangen

Sponsor: The Second Affiliated Hospital of Nanchang University

Dear Participant:

You are invited to participate in the clinical research on the combination of medicinal stick therapy and repeated facilitation therapy for lower limb dysfunction in stroke patients. This research is funded by The Second Affiliated Hospital of Nanchang University. Your condition may meet the inclusion criteria for this study, so we would like to invite you to participate. This informed consent form will introduce the purpose, procedures, benefits, risks, inconveniences or discomforts of the study to you. Please read it carefully and make a decision on whether to participate in the study after careful consideration. When the research staff explain and discuss the informed consent form with you, you can ask questions at any time and ask the research staff to explain any parts you do not understand. You can also discuss with your family, friends, and your doctor before making a decision.

I. Research Background

The background of this study is that stroke (including ischemic and hemorrhagic strokes) is a common acute cerebrovascular disease in clinical practice, mainly caused by local blood circulation disorders in the brain. Stroke is a major public health issue in China and globally. The current number of stroke patients in China ranks first in the world. A survey shows that the mortality rate of stroke in China is 115 per 100,000, making it one of the leading causes of death in China. Studies have found that among the surviving stroke patients, 60% suffer from varying degrees of disability. Additionally, the incidence of stroke in China is increasing at a rate of 8.7% per year . The 2017 "China Stroke Prevention and Treatment Report" shows that the current number of stroke patients aged 40 and above in China is 12.42 million, and the age of onset is becoming younger, with 70% of the survivors having varying degrees of disability, causing a heavy burden on society and families. Early rehabilitation treatment can improve the function of stroke patients, reduce the disability rate, and improve the quality of life. This has become a key issue that rehabilitation researchers at home and abroad urgently need to solve. Currently, stroke rehabilitation treatment mainly includes traditional Chinese medicine rehabilitation and Western medicine rehabilitation. Traditional Chinese medicine rehabilitation includes acupuncture, massage, moxibustion, herbal steam baths, medicinal stick therapy, and acupoint application. Western medicine rehabilitation includes physical therapy, PNF techniques, Rood technique repetitive facilitation therapy, etc. The application of medicinal stick therapy in traditional stroke rehabilitation treatment is not common, and repetitive facilitation therapy treatment is a new technology in modern physical therapy, which is gradually being promoted. Whether the two different treatment techniques can be combined organically, leverage their respective advantages, is one of the problems that rehabilitation medicine still needs to solve。

2. Current Research Status of Drug Rod Therapy

The stick therapy is a long-standing treatment method in Chinese folk medicine. In the Qing Dynasty medical work "Medical Canon of the Golden Mirror", it was called "Zhen Ting" (meaning to strike or knock), where

"Zhen" refers to striking or knocking, and "Ting" refers to a wooden stick. This therapy involves soaking the stick in the medicinal liquid or wine and then striking specific parts of the body to achieve the therapeutic effect. The stick therapy is a unique external treatment method based on traditional Chinese medicine theory, combining the striking of the stick with external Chinese medicine treatment. Various ethnic minorities in China, based on the stick therapy of traditional Chinese medicine and combined with their own ethnic theories and practices, have formed distinctive stick therapy methods. For example, the Miao ethnic group uses bamboo branches mixed with medicinal liquid to treat cervical spondylosis; the Zhuang ethnic group uses the stick fire therapy to treat stage I shoulder-hand syndrome after stroke; the Mongolian ethnic group uses the stick combined with specific techniques to treat lumbar intervertebral disc protrusion; the Yao ethnic group uses special prescriptions made from local medicinal herbs such as fierce tigers, blue nine bulls, and black nine bulls to treat shoulder-hand syndrome after stroke. As a traditional Chinese medical therapy, the stick therapy has been used in some studies for the treatment of limb dysfunction after stroke. From the perspective of rehabilitation theory, massage also has the effects of relieving muscle spasms, separating adhesion tissues, promoting tissue repair, improving blood circulation, and promoting the dissipation of inflammatory mediators, thereby better promoting the functional rehabilitation of paralyzed limbs. A systematic review and analysis of stick therapy for patients with stroke-induced hemiplegia found that the stick therapy can significantly improve patients' muscle strength, balance, gait, daily living ability, and self-efficacy, and has better efficacy compared to other physical therapies. Another study on the combined application of stick therapy and traditional rehabilitation training also confirmed that the stick therapy can promote local blood circulation, improve local tissue nutrition, relax muscles, activate meridians, and have multiple effects such as external drug treatment, massage, and manipulation, and can improve neurological function, relieve spasticity of the hemiplegic limb, and have a clear therapeutic effect on the spastic state caused by upper motor neuron injury, thereby ensuring the successful completion of motor therapy and enabling patients to better participate in rehabilitation training and daily activities, improving their quality of life, and playing a promoting role in the rehabilitation process. Recently, the country has vigorously promoted the development of traditional Chinese medicine, and clearly proposed that during the "14th Five-Year Plan" period, efforts will be made to improve the level of integration of Chinese and Western medicine and promote the coordinated development of traditional Chinese and Western medicine in general hospitals.

The repetitive stimulation therapy was founded by Professor Kawamori and Mi of Japan in 2006. Through clinical practice and promotion, in 2015, RFE was included in the "Japanese Revised Stroke Rehabilitation Guidelines" and was prioritized as an effective method. This method combines various reflex methods such as stretch reflex, skin reflex, muscle reflex, and posture reflex, and repeatedly and multiple times stimulates patients with repetitive stimulation to strengthen the specific nerve conduction pathway and trigger the contraction of target muscles, thereby achieving the purpose of self-learning. Compared with traditional nerve stimulation techniques, the repetitive stimulation therapy can improve the efficiency and accuracy of nerve impulse conduction. RFE is based on the theory of motor learning and brain plasticity, and through the therapist's manipulation stimulation to help patients perform a series of actions such as stretch emission, thereby increasing the neural excitation level around the damaged brain area, and at the same time, through continuous visual and auditory stimulation and the actual occurrence of limb movement produced by repetitive stimulation techniques, forming a complete neural conduction loop, thereby establishing the correct neural conduction pathway through motor learning. RFE emphasizes allowing the healthy side to bear full

weight during walking to better maintain the stability of the trunk and make the affected limb easier to take steps forward; standing step training improves the ability of the affected limb to move forward; hip, knee, and ankle joint training in the supine position can reduce the influence of spastic muscle groups on the balance function during standing and enhance walking function. The training of various specific patterns of lower limb movements can enhance the excitability of neural tissue in the damaged cerebral cortex, and after patients master specific movements proficiently, Repeated reinforcement can promote the formation of new neural pathways, thereby achieving better motor functions. RFE integrates the advantages of various traditional neuro-rehabilitation stimulation methods, simplifying many complex issues and effectively solving problems such as "the theories of advanced neuro-rehabilitation techniques are profound and difficult to understand; the systems are large and difficult to integrate; the conditions are strict and difficult to implement". Studies have shown that RFE improves the efficiency and accuracy of effective nerve conduction between the cerebral cortex, spinal cord, and joint effectors more than traditional neuro-stimulation techniques. Repeated stimulation therapy can activate the brain neurons of patients, promoting the regeneration of related cranial nerves and the improvement of limb circulation, thereby providing assistance for the reorganization of brain functions and bringing effective reinforcement to the repair of brain structure.

Current stroke rehabilitation treatment mainly includes Western medicine rehabilitation and traditional Chinese medicine rehabilitation. Western medicine rehabilitation includes repeated stimulation methods, PNF, Rood techniques, and neuromuscular facilitation techniques; traditional Chinese medicine rehabilitation includes acupuncture, massage, moxibustion, herbal steam baths, and drug rod therapy. Drug rod therapy has been widely used in traditional stroke rehabilitation treatment. Repeated stimulation therapy is a new technology in modern physical therapy and is gradually being promoted. Whether the two different treatment techniques can be combined organically, exerting their respective advantages, is one of the problems that rehabilitation medicine still needs to solve.

II. Research Objectives

The purpose of this study

(1) Explore the therapeutic efficacy of the drug rod therapy combined with repeated stimulation therapy for the lower limb dysfunction in stroke patients.

(2) Provide a new treatment option for stroke patients with lower limb dysfunction

III. Research Process

1、Who will be invited to participate in this research?

(1) Inclusion criteria: ① All meet the diagnostic criteria for hemiplegia after stroke; ② All undergo CT or MRI examinations to confirm and verify the diagnosis of stroke; ④ Age 18-65 years old; ⑤ First onset and disease duration < 3 months; ⑥ Good blood pressure control; ⑦ Signed informed consent form and voluntarily cooperative.

(2) Exclusion criteria: ① Complicated with severe cardiovascular, respiratory failure, liver and kidney function impairment, malignant tumors and other serious diseases; ② Patients with consciousness disorders or cognitive impairments; ③ Patients with mental abnormalities and unable to cooperate; ④ Patients with severe limb deformity or spasticity; ⑤ Patients with eczema, inflammation, infection, scar on acupoints or skin; ⑥ Patients who have received related treatment before enrollment.

(3) Withdrawal criteria: Patients who interrupt treatment for various reasons during the study (such as requesting withdrawal, death, etc.).The researcher will assess whether you meet the study

requirements after you sign the informed consent form.

2. How many people will participate in this research?

Approximately 60 people will participate in this research being conducted at the Second Affiliated Hospital of Nanchang University. The research will commence in January 2025 and conclude in December 2027.

3. Research Steps

If you agree to participate in this study, please sign this informed consent form.

Collect the data of the patients admitted to the department. First, assess the admitted patients, group the factors included in the study, implement according to the formulated treatment plan, re-assess after the implementation period is over, and finally conduct a unified analysis.

4. The impact of participating in this study on the daily lives of the subjects

When you decide whether to participate in this study, please carefully consider the possible impacts of the listed examinations and follow-ups on your daily work, family life, etc. Also, think about the time for each follow-up visit and the transportation issues. If you have any questions about the examinations and procedures involved in the trial, you can consult us.

You need to inform the researchers about the medications you have been taking for a long time, and consult your researchers before taking any new medications during the trial.

Taking into account your safety and to ensure the validity of the research results, you cannot participate in any other clinical studies related to drugs and medical devices during the research period.

5. The information and biological specimens collected during the research

NOT

IV. Risks and Benefits

1. What are the risks of participating in this study?

No risks

2. What benefits can be gained from participating in the study?

It provides more advanced and comprehensive rehabilitation treatment methods for stroke rehabilitation. It shortens the hospitalization time of patients, improves their quality of life, saves funds for patients, and even saves a large amount of funds for the national medical insurance, creating better social and economic effects.

V. Alternative Treatment Plans No

VI. Is it mandatory to participate and complete this research?

Your participation in this research is entirely voluntary. If you do not wish to participate, you can refuse to do so, and it will have no negative impact on your current or future medical care. Even if you agree to participate, you can change your mind at any time and inform the researchers to withdraw from the study. You will not be discriminated against or retaliated against for withdrawing from the trial, and it will not affect your access to normal medical services. When you decide not to continue with this research, we hope you will inform your researchers in time. The researchers can provide suggestions and guidance based on your health condition.

The sponsor or regulatory agency may also terminate this research during the study period. If the study is prematurely terminated, we will notify you promptly, and the researchers will provide suggestions for your next treatment plan based on your health condition. For participants who withdraw halfway, for safety reasons, we have a final follow-up plan. You have the right to refuse. If you withdraw and discover new information related to your health and rights after the withdrawal, we may contact you again.

VII. Regarding research costs and related compensation

1. Costs of the drugs/instruments and related examinations used in the research

Free provision of the drug stick

2. Handling of research-related injuries?

If your health condition is damaged during participation in this research, please inform Ye Jiangen, contact number 13970069010. We will take necessary medical measures. If the damage is related to the research, the research team will bear the related treatment costs and provide corresponding compensation/guarantee in accordance with relevant laws and regulations. This research will not cause irreversible losses to the participants, so no insurance will be purchased for the participants.

VIII. What do I need to do if I participate in the research?

1. Provide accurate past medical history and current condition information.

2. Inform the researchers of any health problems you experience during the research.

3. Inform the researchers of any new drugs, medications, vitamins or herbs you are taking during the research.

4. Do not take any medication or treatment without the permission of the researchers, including prescription drugs and over-the-counter medicines (including vitamins and herbs).

5. Take the research medication as prescribed and visit as required.

6. Do not participate in other medical research.

7. Follow the instructions of the researchers.

8. You can ask at any time if you have any unclear points.

IX. Will the personal information of the participants be kept confidential?

If you decide to participate in this research, your participation in the research and your personal information during the research will be kept confidential. Your personal basic information-related data and information of biological samples will be identified by the research number rather than your name. Information that can identify your identity will not be disclosed to members outside the research team unless you give your permission. All research members and the research sponsor are required to keep your identity confidential. Your file will be stored in a locked filing cabinet and can only be accessed by the researchers. To ensure the research is conducted in accordance with regulations, members of government management departments or ethics committees may, as required, have access to your personal information at the research institution. When the research results are published, no personal information of you will be disclosed.

X. If there are problems or difficulties, who should I contact?

If you have any questions related to this research, contact Ye Jiangen, contact number 13970069010. If you have any questions related to your own rights as a participant, you can contact the Biomedical Research Ethics Committee of the Second Affiliated Hospital of Nanchang University, phone number: 0791-86209562, email: efyiec_iit@163.com.

Subject's Signature Page

Informed Consent Statement:

I have been informed of the purpose, background, process, risks, and benefits of this study. I have had sufficient time and opportunity to ask questions, and I am satisfied with the responses.

I have also been informed that if I have any questions, difficulties, concerns, suggestions for the study, or need to obtain further information, or to provide assistance for the study, I should contact whom.

I have read this informed consent form and agree to participate in this study.

I understand that I can choose not to participate in this study or to withdraw from the study at any time during the study without any reason.

I am aware that if my condition worsens, or if I experience a serious adverse event, or if my study doctor deems it not in my best interest to continue the study, he/she will decide to withdraw me from the study. Without my consent, the funding party or regulatory agency may also terminate the study during the study. If this happens, the doctor will promptly notify me and the study doctor will discuss with me other treatment options.

I will receive a copy of this informed consent form, which includes the signatures of me and the researcher.

Subject's Signature: Contact Information: Date:

(Note: If the subject is without or has limited capacity for civil conduct, then the signature and date of the legal guardian must be provided)

Guardian's Signature: Contact Information: Date:

(Notes: If the subject or the guardian is unable to read this informed consent form, a fair witness must certify that the researcher has informed the subject or their guardian of all the contents of the informed consent form. The fair witness must sign and date the document.)

Signature of impartial witness: Contact information: Date:

Researcher's Signature: Contact Information: Date: