Project Name: Clinical Application of Portable Intelligent Multi Joint Isokinetic Training and Evaluation System Technology

Project number：2021004

Sponsor: Qianfoshan Hospital

Responsible Party: Principal Investigator

Investigator: Ran Shi

Official Title: doctor

Affiliation: Qianfoshan Hospital

Starting and ending years: January 2024 to December 2024

November 21, 2023

Clinical Trials - Informed Consent Form

Dear patient

Your current illness is post stroke hemiplegia, and we invite you to participate in a clinical study. Participating in this study is entirely your own choice. This informed consent form will provide you with some information. Please read it carefully and make a careful decision whether to participate in the intended research. If you have any questions about this study, you can ask your doctor or researcher for an explanation. You can discuss with family and friends to help you decide whether to voluntarily participate in this clinical study. You have the right to refuse to participate in this study or withdraw from the study at any time without penalty or loss of your due rights.

If you agree to participate, we will need you to sign this informed consent form and indicate the date. You will receive a signed and dated copy for your storage.

Your participation in this study is voluntary and has been reviewed by our medical ethics committee.

【Research Name】 Clinical Application of Portable Intelligent Multi Joint Isokinetic Training and Evaluation System Technology

【Research Unit】Qianfoshan Hospital in Shandong Province

【Main Researcher】 Shi Ran

【Why should this study be conducted?】 By constructing and improving the clinical trial system of our project team, we collect clinical data from different disease rehabilitation processes, test and verify the stability, rehabilitation effect, and feasibility of promoting the intelligent isokinetic training and evaluation system to the market. At the same time, we accumulate important clinical data.

【How to conduct this study】 This study is a single center randomized controlled study. You will be randomly assigned to the treatment group, the control group, and the two treatment groups to receive conventional rehabilitation therapy (once a day, 40 minutes a time, 5 times a week), occupational therapy (once a day, 30 minutes a time, 5 times a week), low-frequency electricity (once a day, 20 minutes a time, 5 times a week), and acupuncture and moxibustion therapy (once a day, 20 minutes a time, 5 times a week), Comply with the recommendations on rehabilitation treatment in the 2017 edition of the "Guidelines for Early Rehabilitation Treatment of Stroke in China"; Intelligent isokinetic therapy adds isokinetic muscle strength training to the lower limb flexion and extension muscles of hemiplegia in the above treatments. The intelligent portable isokinetic tester of this project team was used for isokinetic training of the affected knee flexor and extensor muscles. The patient's seat backrest was adjusted to 85 °, and the waist and shoulder cross straps were fixed. The proximal thighs of the test subjects were fixed with nylon buckles, the lateral condyle of the femur was the axis, and the length of the arm was 12 on the scale. The distal ankle of the lower leg was fixed above the ankle. Before training, passive

joint movements were performed on the knee and ankle joints to avoid joint damage, And conduct three low resistance warm-up exercises. Choose 60 °/s, 90 °/s, and 120 °/s angular velocity isokinetic training based on the patient's specific situation. Train 10 times for each angular velocity, with 15 seconds of rest between each cycle, and 2 minutes of rest between each cycle. Train for 4 cycles according to the patient's tolerance, with an appropriate amount of training to cause moderate muscle fatigue and no fatigue on the second day (a total of 25 minutes per training session). Train each muscle group once a day, 5 days a week, for a total of 3 weeks. The control group received 110 minutes of daily training, while the observation group received 135 minutes of daily training. Traditional isokinetic therapy has the same treatment parameters as the intelligent isokinetic group in this project group.

During the treatment and follow-up period, researchers will use relevant clinical observation tables to collect all data that needs to be observed after 3 weeks of treatment, and finally summarize the data for statistical analysis.

【Conditions for participating in the study】The conditions for participating in the study meet the diagnostic criteria for cerebral infarction and cerebral hemorrhage in the 2007 edition of the Chinese Guidelines for the Prevention and Treatment of Cerebrovascular Diseases, and have been confirmed by head CT or MR examination; All of them are first-time onset, with a course of ≤ 1 month, and the lower limb of the hemiplegic side is classified as stage III or above. All participants signed an informed consent form. All patients have stable vital signs, stable condition, cooperative examination, no severe cognitive, visual, hearing

impairment, no sensory aphasia, no orthopedic diseases, no lower limb muscle pain, no history of congenital diseases or other brain diseases, no history of organic or functional mental illness.

【How long will I be participating in this study? 】Your participation in this study will last for 3 weeks, during which time you will receive continuous treatment from the inpatient department.

【What are my responsibilities?】 If you decide to participate in this study, you must come to the hospital for treatment according to the follow-up time agreed upon by the doctor and you. Your follow-up is very important as the doctor will determine whether the treatment you receive is truly effective and provide timely guidance.You must follow the doctor's instructions for treatment, and please fill out your treatment records promptly and objectively. And bring along other medications you are taking, including medications that you need to continue taking if you have other comorbidities.

【What are the possible risks of my participation in this study】Isokinetic muscle strength training equipment is a commonly used rehabilitation treatment device in clinical practice, and there have been no research reports indicating the presence of adverse reactions. If adverse reactions occur during treatment, researchers will also take corresponding treatment measures for treatment.

【What may be the benefits of participating in this study】You may benefit from this study, as you will receive detailed evaluation, monitoring, and treatment

beyond routine monitoring. Your condition may improve, and this study may be helpful for other patients with similar conditions.

【What fees do I need to pay】 During the research process, the cost of intelligent isokinetic muscle strength training will be waived. Other drugs and routine examination items are currently commonly implemented in the clinical diagnosis and treatment process, therefore, the cost of these items will be paid by you (if it is within the scope of medical insurance payment, it can be paid by medical insurance). The treatment and examination required for other diseases that you have merged at the same time will also be borne by you.

【Medical treatment and compensation for research related injuries】 If any damage related to this study occurs and is recognized by authoritative institutions stipulated by national laws and regulations as requiring corresponding responsibility, the project team will provide you with free treatment and compensate in accordance with national laws and regulations.

【What if I don't want to participate in this study or withdraw midway through the study】 You can choose not to participate in this study, or notify the researcher at any time to withdraw from the study. Your data will not be included in the research results, and any medical treatment and rights will not be affected as a result.

【How will my personal information be processed】 If you decide to participate in this study, your participation and personal information during the

study will be kept confidential. Your sample will be identified by the study number number instead of your name. Information that can identify you will not be disclosed to members outside of the research team unless your permission is obtained. Your file is for researchers' reference only. To ensure that the research is carried out in accordance with regulations, if necessary, members of government management departments or ethics review committees may access your personal data at the research unit in accordance with regulations

【Who can I contact to gain a detailed understanding of this study】If you need further information about the research materials during the research process, or if you feel that any of your symptoms are causing you problems at any time, or if you have suffered research related injuries, please contact your bed doctor/researcher at 89268146.

【Who can I contact to understand my rights as a research subject】This informed consent form and this study have been approved by the Medical Ethics Committee (EC) of Qianfo Mountain Hospital in Shandong Province. EC is a group of researchers and non researchers who oversee research involving human subjects. They follow the relevant guidelines and rules of the National Food and Drug Administration (CFDA). If you have any questions about your rights as a research subject, please contact the Medical Ethics Committee of Qianfoshan Hospital in Shandong Province (89268458).

【Declaration of Consent】

I have read this informed consent form.

I have the opportunity to ask questions and all questions have been answered.

I understand that participating in this study is voluntary.

I can choose not to participate in this study, or withdraw at any time after notifying the researchers without discrimination or retaliation, and my medical treatment and rights will not be affected as a result.

If I need other treatment, or if I fail to comply with the study plan, or if there is any injury related to the study or for any other reason, the study physician may terminate my participation in this study.

I agree to participate in this clinical study and have received a signed copy of the 'informed consent form'.

Patient (subject) name (in block letters): Contact number:

Patient (subject) signature: Date: MM/DD/YYYY

Name of the legal representative of the patient (subject) (in block letters):

Signature of the legal representative of the patient (subject): Date: MM/DD/YYYY

Relationship with patients (subjects):

Patient (subject) legal representative contact phone number:

Researcher's name (in block letters):

Researcher's signature: Date: MM/DD/YYYY