

Version 3.0

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## Informed Consent Form

You are invited to participate in the study "rTMS for poststroke pusher syndrome: a randomised, patient-blinded controlled clinical trial". This study will be conducted in the West China Hospital, Sichuan University and a total of 34 participants will be voluntarily invited to participate. Ethical approval for this study has been obtained from the Biomedical Ethics Committee of West China Hospital, Sichuan University (approval No. 2022-133).

### 1. Why do we carry out this study?

Poststroke pusher syndrome (PS) severely affects the posture and balance of stroke patients, resulting in limited mobility and increased risk of falls. Studies have shown that pushing behaviours persisted at three months, with motor recovery and functional abilities significantly poorer than non-pushers. Patients with PS require longer duration of rehabilitation and more supplemental care after discharge from the inpatient rehabilitation setting. Therefore, patients with PS should be treated as early as possible. However, various interventions for PS have been reported but their efficacy remains uncertain. A more effective intervention needs to be developed. The study is to assess the efficacy and safety of repeated transcranial magnetic stimulation (rTMS) for patients after stroke with PS.

### 2. What do you need to do if you participate in this study?

If you agree to participate in this study, the information of your age, sex, stroke characteristics (duration, type, lesion side and lesion location) and handedness will be collected before treatment commencement, and you will be assessed with 4 measurement scales. Then you will be assigned to either the rTMS or sham stimulation

group. You will receive the rTMS or sham stimulation once a day during weekdays for about 9-10 minutes for a total of 15 sessions in three weeks, with 5 sessions per week. In addition, you will receive usual rehabilitation with exercise therapy provided according to your impairments and recovery, including (1) physiotherapy and occupational therapy, (2) speech-language therapy, (3) treatment of dysphagia, (4) cognitive rehabilitation. The usual rehabilitation lasts approximately 4 hours daily on weekdays for 3 weeks.

Outcome data on efficacy of safety will be collected after 1 week, 2 week and 3 week of both groups.

### **3. What are the treatment options available?**

- (1) Balance training by using balance board, balance ball, balance master and other instruments to improve balance;
- (2) postural training performed by the therapist to correct posture to the upright position.

### **4. Who should not participate in this study?**

If you have any of the following conditions, you are not eligible to participate in this study.

- (1) Have visual field deficits or eye muscle paralysis;
- (2) Orthopaedic conditions limiting your participation, e.g., fracture, severe osteoporosis, contractures of the lower extremities;
- (3) Having an unstable medical condition, or being unable to safely perform mild to moderate exercise;
- (4) Metal implants, cardiac pacemaker, brain tumor, meningitis or epilepsy.

### **5. What are the risks of participating in this study?**

The rTMS has been shown to be safe and well tolerated when applied to stroke patients.

You may experience the following discomfort after rTMS therapy:

- (1) Transient headache (common): It usually does not require any treatment.
- (2) Local annoyance in the stimulated area (very common): It does not require any

treatment and rarely requires the suspension of rTMS. If the discomfort is reported to be excessive, the session will be suspended until the discomfort subsides.

- (3) Temporary loss of hearing (rare): In such a case, the session will be suspended until the discomfort subsides within 24 hours. Then the intervention will be resumed if the patient agrees.
- (4) Epileptic crises (rather rare): They may occur in predisposed individuals with history of epileptic seizures. To minimize this risk, participants who have suffered from seizures during the acute phase or have a diagnosis of epilepsy will be excluded from the trial (exclusion criterion). If a convulsive episode occurs during treatment with rTMS despite the above precautions, the latter will be immediately suspended, and the patient will be treated according to the standard hospital protocols for epileptic seizures.

During the study period, we will closely monitor these adverse effects and take appropriate action in a timely manner.

## **6. What are the possible benefits of participating in this study?**

Your condition may improve if you participate in this study. This study will help determine whether rTMS can be used as a more effective and safer method to treat other patients with similar conditions.

## **7. Do I need to pay any fees to participate in this study?**

There is no payment required to participate in the study. Incentive of reducing other therapy fees will be provided for you. You will be provided corresponding treatment and compensation in accordance with relevant national regulations in case of any injury occurred in relation to the study.

## **8. Is personal information confidential?**

All your information will be kept confidential in the West China Hospital, Sichuan University. Your medical record will only be accessible to the researchers, research authorities and the ethics committee. Your personal identity will not be disclosed in any

public report of this study. We will make every effort to protect the personal data privacy of each participant in accordance to the requirements of the ethics committee and legal authorities.

### 9. Do I have to participate in the study?

Participation in this study is completely voluntary. You may refuse to participate or withdraw from the study at any stage of the study without being subjected to any discrimination or retaliation. Your rights to appropriate medical treatment will not be affected. If you decide to withdraw from the study, please contact your doctor for proper treatment.

**Participant declaration:** I have read the above information of this study. The researcher has fully explained to me the purpose, the procedures, the possible risks and potential benefits of this study, and answered all my relevant questions.

I volunteer to participate in the study.

**I agree**  **or refuse**  to use my research data and biological specimens for research other than this study.

Name of participant in block letters:

Participant 's signature:

Date:

Phone number of participant:

Legal representative name in Block letters: (if applicable)

Relationship with participant:

Legal representative signature:

Date:

Reasons for signing by legal representative:

Name of Witness in block letters: (if applicable)

Signature of witness:

Date:

Reasons for signing by witnesses:

**Physician statement:** I have explained the study details to the participant and provided him/her with an original signed informed consent form. I confirm that I have explained this study to the subject in detail, especially the ethical principles and information of risks and benefits, fee and compensation, injury and compensation, voluntariness and confidentiality that may arise from participating in the study.

Doctor's signature:

Date:

Contact number of the doctor:

**Biomedical Ethics Committee of West China Hospital, Sichuan University**

**Contact number: 028-85422654, 028-85423237**