Appendix. Informed Consent Form

West China Hospital, Sichuan University

Participant Informed Consent

Name:	**Gender:**	**Age:**	**Inpatient ID:**

Title of study: The effectiveness of cerebellar vermis intermittent theta burst stimulation in improving trunk control and balance function for patients with subacute stroke: a randomized controlled trial

Investigator: Qiang Gao

Funding: NSFC 82172540 from the National Natural Science Foundation of China

What is the study about?

(1) The aim of the study is to determine the effects of cerebellar vermis intermittent theta-burst stimulation (iTBS) on trunk control, muscle activation and balance function in stroke patients. We will recruit 46 patients who meet the inclusion criteria as follows: (1) a diagnosis of ischemic stroke according to the *Diagnostic criteria of cerebrovascular diseases in China (version 2019)*, (2) aged between 18 and 65 years, (3) first-ever unilateral ischemic stroke confirmed by imaging examination, (4) subacute stroke participants with the stroke onset ranging from 2 weeks to 6 months, (5) having motor deficit and balance dysfunction, with a Fugl-Meyer Assessment for Lower Extremities (FMA-LE) <34 points and BBS score <56 points. Patients were excluded if they presented one of the following: (1) diagnosis of coexisting other neurological diseases, (2) injury of cerebellar or brain stem, (3) having contraindications for iTBS (e.g., history of seizures, intracranial metallic implants, microprocessor implants in the body, tumours, and pregnancy), (4) cognitive impairment with a Mini-Mental State Examination (MMSE) score <27, (5) treatment with benzodiazepines, baclofen, antiepileptics and antidepressants.

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How long will I be in the study?

Your part in the study will last **6 weeks** with 3 weeks of intervention and 3 weeks of follow-up (excluding assessment).

What will happen in this study?

You will be randomized into either the experimental or control group according to the random number table. If you assigned to the experimental group will receive cerebellar vermis iTBS after routine daily conventional physical therapy, otherwise you will receive sham stimulation after routine daily conventional physical therapy. The overall intervention periods are five days a week for three consecutive weeks. You will be assessed before treatment, after 3 weeks of intervention and after 3 weeks of follow-up. The measures including clinical scales, balance tests via the Balance Master system, and the surface electromyography recording.

If you are eligible and wish to join the study, you must sign this consent form. If you do not sign the consent form you cannot join the study.

We will review this consent form with you. You will be given enough time to review the consent and have all your questions about the study answered. We will give you a signed copy of the consent for your records before treatment in person.

Study stuff will not know which group or study treatment you are assigned to. You should not join the study if you are not willing to take the study treatment (or join the group) you are assigned to.

What if I have questions?

You can contact the therapist at working hours if you have questions about the study. Qiang Gao (the director of therapists) is in charge of the study.

Do I have to be in the study?

You decide if you want to be in the study. Deciding not to take part will not affect your relationship with your therapist. If your therapist is an investigator for the study, you may get a second opinion from another therapist not involved in the study.

You can leave the study at any time and you do not have to give a reason. Leaving the study will not affect your relationship with your therapist.

The study investigators may ask you to leave the study if it is in your best interest. The study investigator may ask you to leave the study if you do not follow the study rules.

What if I don't want to be in the study?

You can choose not to be in the study and you do not have to give a reason. You can choose to (talk to your doctor/therapist about other options, investigate outside resources on your own, etc.).

Are there any costs?

All study-related treatments are free.

Will I be paid for being in the study?

You will not be paid for being in the study.

Are there any risks?

There is always a small risk of a breech of confidentiality to your personal health information. However, these risks have been addressed and minimized as much as is possible.

You will be told about any new information that may affect your willingness to participate in the study.

There are some possible risks and side effects as follows: headache, nausea, neck pain, seizure, mood changes, fatigue, tinnitus, dizziness, sleepiness and syncope.

If you experience any side effects while on the study contact investigator (Qiang Gao) at any time as soon as possible.

What if I feel I've been hurt by taking part in the study?

If you feel you have been injured or harmed by taking part in this study, please contact investigator (Qiang Gao) at any time. If you feel you were harmed while taking part in this study, you may be treated at West China Hospital, Sichuan University. However, West China Hospital does not offer to pay the cost of this treatment.

If you feel your rights have been violated or you have harmed by this study, please contact your therapist.

Are there any benefits?

It is possible you may receive some benefit from cerebellar vermis iTBS and conventional physical therapy. iTBS is a novel form of rTMS, which can produce long-term potentiation and is more rapid and efficacious than standard rTMS. Cerebellar vermis is a cardinal structure involved in balance and motor control, which is responsible for regulating the trunk, head, neck and proximal limb muscles to control posture and maintain balance. There is no guarantee, however, that you will receive any benefit at all. Your participation will help us learn more about the effects of cerebellar vermis iTBS on trunk control, muscle activation and balance function in subacute stroke patients.

Your privacy is important

Protecting your privacy is very important to us.

During this study we will ask about your (past) and (current) medical history. This information will be used to determine your eligibility for the study and provide data for the study. Your personal health information will be kept private and only authorized study staff will have access to this information. We will use a study number instead of your name. All paper forms will be kept in a locked, secure office. All electronic data will be stored on password-protected computers. Your name will not be used in any publications or presentations about this study.

During the study, you may not be given access to medical information about you that is part of the study. When the study is over, you may request certain medical information collected about you that is part of your study medical record.

None of your personal information will be shared outside of West China Hospital.

By signing this consent form, you are stating that we can use your health information in the ways mentioned above for this study. You are not waiving any of your legal right by signing this form.

You have the right to take away your permission to use your health information collected as part of the study. In order to do this, you must send a written request to: Qiang Gao, department of rehabilitation, West China hospital, Sichuan University

Once your letter is received, no additional information about you will be collected from you for this study. Any data that were collected before we receive your letter will continue to be used for the study. Taking away your permission to use your

health information will not affect your relationship with West China Hospital.

We are collecting only the personal health information that we need for the specific purpose of this study. Your personal health information cannot be used for additional research purpose.

The West China hospital may be required to provide copies of your personal information to government agencies as required by law.

Your permission to use your identifiable health information when the study is complete.

Signatures:

By signing this consent form, it means the following:

- I know my rights have not been waived by signing.
- I have had all of my questions answered and I know whom to ask if I have more questions.
- I have read this form and understand it.
- I want to join the study.
- I know I can leave the study at any time and do not have to give a reason.

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Signature of Participant Date