Supplementary Section

The Effects of Priming Intermittent Theta Burst Stimulation on Upper Limb Motor Recovery After Stroke: Study Protocol for a Proof-of-Concept Randomized Controlled Trial

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Table S1. Trial registration data

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT04034069
Date of registration in primary registry	First posted: July 26, 2019 Late Update: October 18. 2019
Secondary identifying numbers	HSEARS20190718003
Source(s) of monetary or material support	The Hong Kong Polytechnic University Department of Rehabilitation Sciences
Primary sponsor	The Hong Kong Polytechnic University Department of Rehabilitation Sciences
Secondary sponsor(s)	No applicable
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Public title	The Effects of Priming Intermittent Theta Burst Stimulation on Upper Limb Motor Recovery After Stroke
Scientific title	The Effects of Priming Intermittent Theta Burst Stimulation on Upper Limb Motor Recovery After Stroke
Countries of recruitment	Hong Kong SAR, China
Health condition(s) or problem(s) studied	Stroke
Intervention(s)	Active comparator: cTBS + iTBS, in addition to robot-assisted training
	Active comparator: Sham cTBS + iTBS, in addition to robot-assisted training
	Placebo comparator: Sham cTBS + sham iTBS, in addition to robot-assisted training
Key inclusion and exclusion criteria	Ages eligible for study: 18-64 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria: Chronic stroke patients (≥ 6

	months after stroke onset), with upper limb impairment (FTUHK from 2 to 7).
	Exclusion criteria: Not free of TMS contraindications; primary neurological disease excluding stroke, notable cognitive impairment (AMT < 6), extreme spasticity in anyhemiplegic upper limb (MAS > 2)
Study type	Interventional
	Allocation: randomized intervention model. Parallel assignment masking: single-blinded (outcomes assessor)
	Primary purpose: intervention
Date of first enrolment	September 2019
Target sample size	36
Recruitment status	Recruiting
Primary outcome(s)	FMA-UE and ARAT
Key secondary outcomes	Kinematic metrics (i.e., size of active range of motion, mean velocity, hand path ratio)

Abbreviations: cTBS: Continuous Theta Burst Stimulation; iTBS: Intermittent Theta Burst Stimulation; AMT: Abbreviated Mental Test; MAS: Modified Ashworth Scale; FMA-UE: Fugl-Meyer Assessment - Upper Extremity Scores; ARAT: Action Research Arm Test

Appendix: Template of written consent form

Research Consent Form
The Hong Kong Polytechnic University
Department of Rehabilitation Sciences

Title of research project:
The Effects of Priming Intermittent Theta Burst Stimulation (iTBS) on Upper Limb Motor Recovery After Stroke: A Randomized Controlled Trial

Research setting:
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University

Research investigator:
Mr. Jack Jiaqi Zhang (PhD candidate, Department of Rehabilitation Sciences, The Hong Kong Polytechnic University)
Dr. Kenneth N.K. Fong (Associate Professor, Department of Rehabilitation Sciences, The Hong Kong Polytechnic University)

The purpose of this study is to investigate whether priming iTBS can enhance the therapeutic response to robot-assisted training for rehabilitating the hemiplegic upper limb functions in stroke patients. Participants need complete 10 training sessions. During each training session, participants will receive two sessions of transcranial magnetic stimulation in a form of theta burst stimulation (TBS). Immediately after the brain stimulation, participants will perform motor training assisted by robotic devices. Assessment for hemiplegic upper limb functions will be conducted in baseline, after 5-session, after 10-session and two weeks follow up. Some participants will be invited to join EEG examinations

Benefits for participants and society
The study will provide preliminary evidence of the effect of priming iTBS on stroke rehabilitation and its neural mechanisms. By participating in this study, you can receive several sessions of upper limb motor training and you do not have to pay any additional research-related payment. After the completion of 10-session of training, you will receive a transportation allowance of HK$100. For participants who join the EEG examinations, additional HK$400 will be paid as a compensation of time.

Potential risks

Although TBS is safe for most people, there may be unnecessary risks for some people. We need screen whether the participants have implanted metal objects, such as cardiac pacemakers, surgical aneurysm stents, artificial cochlear implants, or pregnancy. Before TBS, the participants should remove all metal objects on the body, such as hearing aids, dentures, orthopedic frames, watches, glasses, jewelry, any metal object on clothes, etc. In addition, it is very rare that TBS may induce seizure. Participants with a seizure/epilepsy history will not be included for this study. Other adverse effects include mild headaches and discomfort, mild cognitive or psychiatric symptoms (mild depression or mania). When strictly following the safety guidelines, those adverse effects are extremely rare.

Data confidentiality

Every participant has the right to obtain his or her personal data and publicly reported research results, if needed. According to the Law in Hong Kong (in particular the Personal Data (Privacy) Ordinance, Chapter 486), you have the right to keep your personal data confidential, such as any collection, storage, reservation, management, control and use (analysis/comparison) regarding the personal data. The information will not be transferred in Hong Kong and other places. If you have any questions, you can consult the Office of the Privacy Commissioner for Personal Data or contact their office (telephone number: 2827 2827) to properly supervise or supervise your personal data protection so that you can fully understand the meaning of legal protection of privacy information.

After agreeing to participate in the study, you authorize the following:

• In order to monitor this study, you need authorize the principal investigator and his or her research team and research ethics committee to obtain, use and retain your personal data in the manner specified in this study and this consent form, and

• In order to check and verify the completeness of the research data and reach the consistency between research regulations and any relevant requirements, you need authorize relevant government agencies (such as the Hong Kong Department of Health, Hospital Authority) to obtain your personal data

Voluntary participation:

Your participation in this research program is entirely voluntary. You may choose not to participate or may stop participating in this study at any time without any changes or loss of medical care that you accept now and in the future.

New information

If there is any new information about the study that will affect your decision to continue participating in this study, you will be notified in first time. You will be notified during the study if there are significant changes in this study that can influence your health or your willingness to participate in the study. You may have to sign a new consent form to indicate that you have been informed of new information about the study.

Exit and termination of this study

You are free to decide whether or not to participate in the study, and you may withdraw your consent at any time during the course of the study and withdraw from the study without giving any reason. It will not cause any unpleasantness or affect the medical care of your doctors in the future. The research principle investigator may also suspend the study when it is necessary. If no special request is made to destroy the data collected prior to the drop out, we will continue to use it. Participants will be given enough time to consider whether to participate in the study.

Study results

The results of this study may be published in medical journals or at medical conferences. Information related to your identity will not appear in any publicly available reports related to this study.

Contact person

If you need further information, you can contact the research investigators -- Mr. Jack Jiaqi ZHANG at 65261304 or Dr. Kenneth N.K. FONG, Department of Rehabilitation Sciences, Hong Kong Polytechnic University, 27666716.

If you have any questions about the rights enjoyed as a research participant, you can contact Ms. Chung (Secretary of the Research Committee of the Department of Rehabilitation Sciences, The Hong Kong Polytechnic University) at 27664329.

Your participation in this study will require you to sign and keep a copy of the consent form.

Consent form

Title of research project: The Effects of Priming Intermittent Theta Burst Stimulation (iTBS) on Upper Limb Motor Recovery After Stroke: A Randomized Controlled Trial

1. I am sure that I have read and understood the information sheet of the above research study (and I have the opportunity to ask any question about this study.
2. I understand that some of my current medical records may be checked by researchers at the Hong Kong Polytechnic University. I therefore allow these researchers to check my records.
3. I agree to use the data collected in this study for stroke research. I allow the data yielded from this study to be used for publication. I understand that my identity will be treated confidentially. Any shared and published data will be completely anonymous, so I will not be identified.
4. I understand that my participation is voluntary, and I am free to withdraw at any time without any reason. The medical care or legal rights I accept now and, in the future, will not be affected.
5. My signature of this informed consent does not mean that I waive any legal rights.
6. I agree to participate in the above research projects.
7. I understand that I will get a copy of this consent form.

Participant name	Signature	Date
Witness name (If applicable)	Signature	Date
Researcher name	Signature	Date