Informed Consent Form

Dear_____

In order to further clarify the cognitive function after brain injury, infer prognosis, explore new effective treatment, now invite you to participate in a clinical scientific research, topic: Effects of individualized repeated transcranial magnetic stimulation on patients with disorders of consciousness: An exploratory, single-center, cross-randomized, double-blind, controlled clinical trial.This informed consent form will inform you of why do this study, what will be done, the benefits and risks you may face.If you have any questions, please ask.You can decide whether you will participate in this study after full knowledge.

1. Introduction: Why do we invite you to participate in the study?

At present, the mechanism of consciousness disorder after brain injury has not been clear, and its accurate diagnosis, prognosis inference and treatment are a major clinical problems at present.The existing clinical effects of multisensory stimulation, hyperbaric oxygen, neuroregulation and drug treatment are unsatisfactory, and in-depth research is urgently needed.

Repeated transcranial magnetic stimulation (rTMS) is a noninvasive treatment emerging in recent years, is developed on the basis of intracranial magnetic stimulation technology of neural regulation technology, its principle is through magnetic signal without attenuation through the skull, induction field, induction current in the cortex, the cell membrane depolarization, achieve the effect of excited cerebral cortex, is an important means of consciousness disorder treatment.

2. Do I have to participate in this study?

You may participate in the study.You can completely refuse to participate, and we will not therefore change the routine treatment for you.Patients participating in other invasive / non-invasive neuroregulatory treatments will not be in the scope of our study.You can also always withdraw from this study if you participate in it.

3. Why did this study?

The aim was to explore how to optimize the selection and implementation of the rTMS individualized stimulation regimen in patients with disorder of consciousness (DOC).We determined the degree of damage

of different brain networks in each patient through individualized evaluation of each subject, and decided rTMS treatment targets based on previous research and literature summary, regarded as effective in patient awakening and restoring perception.

4. How will the study be conducted?

If you agree to participate, we will inform the process and benefits and risks of the study.We will determine the coma Recovery Scale revision (CRS-R), resting state EEG assessment within 48h before rTMS and within 24h after clinical behavioral assessment CRS-R, and EEG.Treatment will receive rTMS treatment and routine rehabilitation once a day at 10Hz, for a total of 20 sessions (10 days off and another 10 sessions after 10 sessions).You will be randomized to treatment groups across strategies throughout the trial, and we will ensure that the treatment is properly.

5. How long will I be involved in the study?

It took a total of 1 month, about 20 minutes per treatment, and the evaluation was about 1 hour, which was completed at the same time in the normal rehabilitation process of hospitalization, and did not delay the hospitalization.We also hope that after the trial treatment and evaluation, we will remain in contact with you and your family over the next 6,12 months or more to follow up on the recovery of the project participants.We will invite you to return to the hospital or to your residence to reevaluate the test recovery if necessary, and we hope you can understand and support it.

6. Can I stop attending the research?

You can quit the study at any time, and please inform the investigator.

The investigator may terminate your study for your best interests and will inform you.

7. What risks will I encounter in the research?

In general, as in routine hospital rehabilitation, there is no increased special risk;

Epilepsy: Studies have shown the risk of high-frequency rTMS for seizure induction, but we used parameters as safe as possible and screened patients at high risk; another risk is leakage.In this regard, we will promise to fulfill the due confidentiality obligation of your records.

8. What are my possible benefits?

The rTMS is an important treatment means in modern rehabilitation. We will choose a more accurate

target stimulation for the individualized patient condition, which may help to clarify the cognitive function, predict the probability of consciousness recovery, and help the family to make reasonable decisions for the subsequent treatment.It also helps to explore the neural mechanisms of consciousness disorders after brain injury.

9. Do I have to pay for my participation in this study?

The study-related CRS-R, professional EEG examination and rTMS treatment are all borne by the researcher (free of charge), and the costs incurred in other normal diagnosis and treatment shall be borne by the patient.

10. Can I get compensation and possible compensation for participating in this study?

As one of the clinical evaluation programs, we will not compensate you for participating in this study.If the damage is indeed related in this study, we will reasonably judge and deal with it properly.

11. Who should I contact with if I have a question?

Your doctor will promptly inform you if there is any important new information during the study that may affect your willingness to continue participating in the study.If you have your study data, or after the study you want to know the findings of this study.You can ask any questions about this study at any time, and please contact Dr. Xie (principal investigator) at +86 13903019604. The Ethics Committee has reviewed and approved the study. If you have any questions related to your rights / interests, or if you want to reflect the difficulties, grievances and concerns involved in this study, or to provide comments and advice on this study, please contact the Ethics Committee of Pearl River Hospital, Southern Medical University at +86 020-62783254, email: zjyyllxs@126.com.

12. What medical information will we collect?

We need to collect some medical information about you with your permission, otherwise you can not participate in the study.We only collect information.

13. Who gets access to your medical information?

Only those involved in clinical research, ethics committee members, and those involved in supervising whether the research activities comply with the rules and regulations of the hospital are allowed access to your medical information.

Consent to participate in the study

Before signing, I confirm the following facts:

- I have read (or have read to me) the entire consent document.All of my questions were answered satisfactorily.
- The researchers have explained to me the purpose, procedures, and possible benefits and risks of the study.
- I agree to let the research team use and share my medical information and other information gleaned from the research.
- I volunteered for this study.I agree to follow the study procedures as required.I have been told that I can quit the study at any time.

Please note: You will obtain this copy of the signed and dated consent form, if necessary.Please keep this consent form properly where you can easily find.It helps you to remember what we are discussing today.

Subjects signed:_____Date: _ _ _ _ _ _ _

Contact number of the subject:_____

Signing of the legal agent (if applicable):_____Date: _ _ _ _ _ _ _

Contact number of the legal agent:_____

Investigator's signature:_____Date: _ _ _ _ _ _ _

Work telephone number of the investigator:_____