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Informed Consent Form

You are invited to participate in the study "Efficacy of MRI-guided rTMS for posttraumatic stress disorder by modulating amygdala activity: study protocol for a randomized controlled trial". This study will be conducted in the First Affiliated Hospital of the Air Force Medical University and a total of 48 participants will be voluntarily invited to participate. Ethical approval for this study has been obtained from the Medical Ethics Committee of the First Affiliated Hospital of the Air Force Medical University (approval No. KY20222176-X-1).

1. Why do we carry out this study?

PTSD is a psychiatric disorder that occurs after an individual has experienced severe psychological trauma, and is characterized by intrusive experiences, hypervigilance, avoidance symptoms, and negative cognitive and emotional changes. PTSD severely impairs the ability of the patient to live and work, and creates a serious burden on the family and society. Currently, the first line of treatment for PTSD is medication and psychotherapy, but there are still a significant number of patients who do not achieve remission after treatment. Repetitive transcranial magnetic stimulation (rTMS) is an emerging treatment that is expected to improve the remission rate of PTSD patients. This study will be conducted to validate the efficacy of MRI-guided rTMS for patients with PTSD.

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, traumatic experiences characteristics (time of occurrence, number and type) and treatment will be collected before treatment commencement. and you will be performed an MRI scan and clinical scale evaluation. Then you will be assigned to either the rTMS or sham stimulation group. You will receive the rTMS or sham stimulation twice a day for about 10 minutes each. Each treatment will be separated by 50 min for 10 consecutive days. During this period, you will be introduced to conventional medication at the same time, with the main therapeutic drug being paroxetine.

Outcome data on efficacy of safety will be collected at baseline, treatment day 5, treatment day 10, and 2 weeks, 4 weeks, 8 weeks after completion of intervention.

3. What are the treatment options available?

(1) Medication, including SSRIs, SNRIs, anxiolytics, and sleeping pills;

(2) Psychotherapy, including cognitive-behavioral therapy and exposure therapy.

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) Significant medical illness or diseases that may affect the central nervous system;

(2) Abnormal EEG or MRI evidence of brain;

(3) Contraindications to the MRI scans or TMS, such as metal or electronic implants, claustrophobia, etc;

(4) Alcohol and drug abuse;

(5) Strong suicidal ideation or previous suicidal behavior;

(6) Pregnancy, lactation, or planning pregnancy during the trial period.

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

rTMS is a safe, easily tolerated method of physical therapy, and numerous studies have found rTMS to be highly safe when applied to patients with PTSD. Common adverse events include mild headache, dizziness, and localized sensory abnormalities. These discomforts often resolve on their own within an hour or so after treatment. Moreover, as the patient adapts to the treatment, these discomforts do not recur. However, there is a small chance that rTMS will induce seizures. This is likely to occur in patients with epilepsy or in people with abnormal EEGs. Therefore, before you are introduced to rTMS, we will exclude participants with seizures as well as abnormal EEG during screening to avoid this situation. rTMS will be administered by experienced therapists to ensure that participants are treated promptly in case of adverse events. If serious adverse events occur during the study, the participant will be taken by the investigator to the emergency department or the specialist clinic.

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 us to clarify whether MRI-guided rTMS has a clinically significant effect on PTSD, so that we may be able to develop more effective treatments for other patients with PTSD..

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. The medication you receive will be charged at the usual outpatient rate. 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 First Affiliated Hospital of the Air Force Medical 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 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 the First Affiliated Hospital of the Air Force Medical University

Contact number: 029-84771794