Informed Consent Form

Synergistic Treatment of Negative Symptoms and Cognitive Function Deficits in Long-Term Hospitalized Schizophrenia Patients Using tACS

Research Institution:

Principal Investigator :

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Approved No. of ethic committee: PDJW-KY-2025-012

Informed Consent Form

You are invited to participate in a clinical research study. This informed consent form provides you with information to help you decide whether to participate in this clinical research study. Please read it carefully, and if you have any questions, please ask the researcher responsible for this study.

Your participation in this study is voluntary, and this research has been reviewed by the Ethics Review Committee of this research institution.

Study Objective

The study aims to evaluate the efficacy of transcranial alternating current stimulation (tACS) on negative symptoms and cognitive function in long-term hospitalized patients with schizophrenia. Additionally, this research will investigate the potential impact of related biomarkers and genetic factors on the therapeutic effect of tACS intervention.

Trial procedures (including all invasive operations)

1. Baseline assessment: Participants will undergo negative symptom and cognitive assessments, eye movement tracking, and EEG recording in a virtual reality environment before and after the study.

2. Blood extraction: Venous blood (2 ml) will be drawn before and after treatment for genetic and inflammatory factor detection.

3. tACS Intervention: All schizophrenia patients underwent tACS intervention for 20 days, with two sessions per day, each lasting 40 minutes, with the tACS intervention group receiving real electrical stimulation and the sham stimulation group receiving placebo stimulation.

tACS Device Introduction

The tACS device and electrodes were provided by Nexalin Technology, Inc. (CA, USA). The device has been approved by the US FDA and China's NMPA for clinical treatment of mental health patients (501K=K024377, Stimulator, Transcranial Electrical Treatment, CFR 882.5800, US Patent #6904322B2). Both real and sham treatments were administered using 3 Nexalin-specific electrodes: one placed on the frontal lobe (corresponding to Fp1, Fpz, Fp2 regions in the international 10-20 system EEG electrode placement, with electrode size of 4.45 cm×9.53 cm) and two on the bilateral mastoid processes (electrode size of 3.18 cm×3.81 cm), with one electrode on each side.

Trial Period: 4.30.2025-12.30.2026

Long-term Hospitalized Schizophrenia Patient

Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Diagnosed with schizophrenia according to DSM-5 and hospitalized continuously for more than six months

2. Age between 18 and 65 years old

3. Willing to participate in the research and sign the informed consent form

4. Stable condition, with a change of less than 15% in the total PANSS score during at least 2 months prior to the study

5. Education level of primary school or above

6. Normal vision or normal after correction

Exclusion Criteria:

1. Comorbid diagnoses of other mental disorders according to DSM-5

2. History of severe neurological diseases, epilepsy, or craniocerebral trauma

3. Presence of severe organic diseases with unstable vital organ functions (such as heart, liver, or kidney)

4. Infectious skin diseases

5. Concomitant use of other drugs that may affect the results during the study, such as benzodiazepines or psychostimulants

6. Females who are pregnant or breastfeeding

7. Patients with claustrophobia

8.Those with a history of alcohol or drug abuse

9.Those who have previously received ineffective or intolerable TACS treatment

Risks and Discomforts

This study will collect blood samples from patients and normal controls. Patients will receive intervention using marketed medical device alternating current stimulation. The potential risks of these measures are relatively small, known risks include fainting during blood draw for sensitive individuals, and dizziness caused by alternating current stimulation, but these are generally mild and the overall risk is controllable. In extremely rare cases, there may be other currently unknown risks.

Benefits

Participants may experience potential cognitive improvements and alleviation of negative symptoms through this study, and provide data support for future non-pharmacological treatments for schizophrenia. Additionally, participants will receive genetic data based on the research, offering new information for personalized treatment.

Alternative Treatments Available for Subjects

Conventional antipsychotic medication; psychotherapy (such as cognitive behavioral therapy); social support and rehabilitation services.

Responsibilities of the Subjects

1. Participate in all interventions and assessments according to the research protocol

2. Attend all experiments and assessments on time without unauthorized absences

3. Promptly report any discomfort, symptom changes, or health conditions to the researchers

4. Proactively communicate with researchers if experiencing any unexpected health issues or emotional changes

5. Sign the informed consent form, understanding the research content and associated risks and benefits

Research Participation Costs

Participants will not need to pay any fees for research-related tests and treatments throughout the entire study period. All interventions: 20 sessions of tACS intervention treatment, cognitive function and negative symptom assessments, brain wave and eye movement detection, serum factors, gene testing, and related medical services will be covered by the research team.

Subject Compensation

Each participant who completes this study will receive a 300 yuan nutrition subsidy.

Privacy Information Protection

All information related to you personally, including identity, medical history, condition, physical examination, and laboratory test results will be strictly confidential under legal premises. Research findings may be published, but your personal information will not be disclosed.

Explanation of voluntary participation in the trial

Your participation in this research is entirely voluntary. You can decide whether to participate after understanding all the details of the study, and you may withdraw at any time during the process. Regardless of your final decision, it will not affect the doctor's treatment and care for you. However, if you decide to participate, we still hope you can cooperate to complete the entire study to obtain comprehensive data.

Contact information for questions about the trial and subject rights, and in case of trial-related injuries

You have ample time to consider whether to participate in the study and sign the informed consent form.

We will assign a number to each participant and establish a file. Your information will be used solely for this research. Your test content and personal data will be kept strictly confidential. Researchers cannot discuss your test content or personal circumstances with anyone outside the research, and any published research results will not disclose any of your personal information.

Informed Consent Form Signature Page

I have read this informed consent form.

I have had the opportunity to ask questions and all my questions have been answered.

I understand that participation in this research is voluntary.

I can choose not to participate in this research, or withdraw at any time after notifying the researchers without facing discrimination or retaliation, and my medical treatment and rights will not be affected.

I will receive a signed copy of the "Informed Consent Form".

Participant Name (Print): _____

Participant Signature: _____

Legal Guardian Name (Print): _____

Legal Guardian Signature: _____

Date: _____Year _____Month _____Day

I have accurately informed the participant about this document, and they have accurately read this informed consent form, and I certify that the participant had the opportunity to ask questions. I certify that they voluntarily agreed.

Researcher Name (Print): _____

Researcher Signature: _____

Date: _____Year _____Month _____Day