Shanghai University of Medicine & Health Sciences
Patient Informed Consent Form

Informed Consent Form

Dear Volunteer,

Hello! You are invited to participate as a subject in the study "Effects of Combined Exercise and Peripheral Magnetic Stimulation on Biopsychosocial Functional Impairments in Older Adults with Schizophrenia" conducted by the School of Rehabilitation, Shanghai University of Medicine & Health Sciences. This study is classified as □ Basic ☑ Clinical □ Drug research, with a total of 40 participant enrollments. To ensure the smooth progress of this study and to fully protect your rights, please read the following information carefully before you agree to participate.

1. Nature and Purpose of the Study
You are invited to participate in this research, which aims to investigate the effects of combined exercise and Peripheral Magnetic Stimulation (PMS) on biopsychosocial functional impairments in individuals with schizophrenia. This includes examining changes in brain activity, cognitive function, lower-limb muscle strength, muscle mass, and functional mobility, as well as the effects of exercise alone in patients with schizophrenia.

Once you confirm participation, you will be assigned a participant ID and will provide general information (height, weight, gender, date of birth). You will then undergo assessment with the PANSS, SANS, and MoCA scales to comprehensively evaluate your condition and help clarify your treatment needs.

You will participate in the following experiments:
1. Immediate EEG after PMS intervention: At the same time and place, you will undergo EEG recording to capture immediate brain changes after PMS. Before testing, you may familiarize yourself with the EEG equipment, including the fit and comfort of the EEG cap. The PMS treatment procedure will be explained to you before treatment. EEG data will be recorded to reflect brain signal changes following PMS intervention.

2. Exercise and PMS intervention: You will be assigned to either an exercise group or an exercise + PMS group. In the exercise group, you will follow an exercise prescription led by a professional rehabilitation therapist. These exercises are simple and will not impose an extra physical burden. Exercise will be performed three times per week. Before starting exercise, you will undergo baseline assessments, including the functional sit-to-stand test, palm-sized ultrasound, and 6-minute walk test (6MWT).
- Functional sit-to-stand test: A simple, safe clinical assessment of lower-limb strength, balance, and functional activity. Upon hearing "start," you will repeatedly perform "stand up → fully extend knees and hips → sit down" as many times as possible in 30 seconds.
- Palm-sized ultrasound: A portable ultrasound imaging device used in a comfortable position, operated by a trained examiner, and causing no discomfort.
- 6-minute walk test: A safe, simple assessment of cardiopulmonary function and exercise

endurance, measuring the maximum distance you can walk in 6 minutes on a straight path under the examiner's instructions.

Total testing time is approximately 1 hour. After testing, the principal investigator will explain the meaning of each score, describe the procedures, and provide exercise rehabilitation guidance within the professional scope.

2. Possible Risks
- During testing, you may experience fatigue and sweating due to exercise; in the 6MWT, there is a small chance of tension or discomfort.
- If fatigue or discomfort worsens, the investigator will stop the test and advise rest or provide massage and reassurance, continuing to monitor you until symptoms resolve.
- You may stop any task at any time or choose to participate in only certain parts without penalty. If you wish to discuss your feelings about the study, the research team can refer you to a psychologist for counseling.

If any research-related harm occurs, the responsible department will compensate according to the severity of the harm and in accordance with relevant national laws and regulations.

3. Benefits
This study aims to explore the effects of combined exercise and PMS on improving functional impairments in older adults with schizophrenia. Your participation may offer potential benefits:
1. Improved physiological function: PMS may modulate neural activity and help relieve physical discomfort caused by disease or medication side effects (e.g., muscle stiffness, bradykinesia).
2. Better psychological state: Exercise has been proven to promote endorphin release, potentially reducing anxiety and depression and improving overall mood. PMS may also positively impact cognitive function (e.g., attention, memory), helping to mitigate schizophrenia-related cognitive deficits.
3. Enhanced social functioning: By improving physical and mental state, you may find it easier to participate in family and social activities (e.g., self-care, interpersonal communication), thus improving social adaptability.
4. Additional support and attention: You will receive free professional exercise guidance and PMS treatment, along with regular comprehensive assessments of physical, psychological, and social function. The research team will monitor your health and provide feedback or suggestions as needed.

The study protocol has been reviewed and approved by the Scientific Research Ethics Committee of Shanghai University of Medicine & Health Sciences and will be conducted strictly in accordance with the approved plan.

4. Voluntary Participation and Withdrawal

Please ensure you fully understand the study content before participation. The investigators and principal investigator are obligated to provide detailed information and answer your questions. Your participation is voluntary, and you have the right to withdraw at any stage without penalty.

5. Confidentiality
All results and data obtained in this study belong to the implementing institution and may be used free of charge, but your legal rights will not be infringed. Your personal information will be kept confidential by the university. The ethics committee and investigators may access your data but will not disclose it to third parties. Unless required by law, your identity will not be revealed. Study results may be published for scientific purposes without disclosing your identity.

This informed consent form is in duplicate—one copy for the research department and one for the participant.

Study Title: Effects of Combined Exercise and Peripheral Magnetic Stimulation on Biopsychosocial Functional Impairments in Older Adults with Schizophrenia
Principal Investigator: Han Jia
Phone: 18521777440

If you have fully understood and agree to the above, please sign at the bottom right of this consent form.

As the researcher in this clinical study, I have fully informed you of the above details.
Principal Investigator Signature: _____ Date: ____ / ____ / ____

I confirm that the investigator has fully explained the purpose, methods, rights, and obligations of this study, and has satisfactorily answered all my questions. I voluntarily agree to participate and will cooperate in completing the study.

Participant (or Legal Representative) Signature: _____ (Relationship: _____)
Phone: _____ Date: ____ / ____ / ____