**Shanghai University of Medicine & Health Sciences**
**Shanghai Yangpu District Mental Health Center**
**Institute of Mental Health**

# Scientific Research Project Plan
# (2023 Edition)

**Project Code: YJYZD202406**
**Project Title: Effects of Combined Exercise and Peripheral Magnetic Stimulation on Biopsychosocial Functional Impairments in Older Adults with Schizophrenia**
**Project Duration: May 2024 – April 2026**
**Institutions: Shanghai University of Medicine & Health Sciences; Shanghai Yangpu District Mental Health Center**
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## Summary

Research Topic: Effects of Exercise and Peripheral Magnetic Stimulation on Biopsychosocial Functional Impairments in Patients with Late-Onset Schizophrenia (LOS)
Category: Applied Research
Discipline: Health Care Medicine (Code: 3201410)
Related Disciplines: Gerontology (3201430), Sports Medicine (3201420), Physical Therapy (32017)
Funding Applied (10,000 CNY): 10

## Abstract

This study aims to investigate the clinical efficacy and potential mechanisms of exercise and Peripheral Magnetic Stimulation (PMS) therapy in older adults with schizophrenia. The project consists of two trials: (1) evaluation of the immediate effects of PMS on EEG activity in older adults with schizophrenia (n=40; PMS group vs. sham group, 20 each), and (2) comparison of PMS+exercise vs. exercise-only on functional gains (n=40, 20 each) over 8 weeks. We expect to provide a new, effective treatment option and deepen understanding of PMS mechanisms, producing 1–2 core Chinese journal articles and 1–2 SCI papers.

## 1. Clinical Trial Integrity Statement

The study will strictly comply with international ethical standards (e.g., Declaration of Helsinki), relevant regulations, and ethics committee requirements. All participants will voluntarily join after signing informed consent, and their privacy and rights will be protected. The research team pledges fairness in design, execution, and data analysis; randomization will follow the pre-set scheme, with blinding applied where appropriate. Data will be collected, stored, and analyzed per SOPs by independent statisticians, ensuring accuracy, transparency, and reliability. All funding sources and conflicts of interest will be disclosed. The study will be halted if participant safety is at risk, and results will be reported objectively regardless of outcome.

## 2. Research Plan & Objectives

This project targets older adults (≥60) diagnosed with schizophrenia under ICD-10 or DSM5, clinically stable, and free from major neurological comorbidities.
Trial 1: PMS vs. sham PMS (no active stimulation) to assess immediate EEG effects. Trial 2: PMS+exercise vs. exercise-only over 8 weeks to compare lower-limb function, muscle strength, mass, and cognition.

### Primary Outcomes

- 6-minute walk test (6MWT)
- Sit-to-stand test (STS)
- MRI-based muscle fat ratio
- MoCA cognitive assessment
- SANS negative symptom scale
- PANSS total and subscales
- EEG pre-post intervention changes

## 3. Technical Approach

Simple randomization using R sample() function, allocation concealment by third party, and blinding applied where possible. Data analysis will include intention-to-treat and perprotocol as appropriate.

## 4. Innovation Points

- First application of PMS in older schizophrenia patients
- Integration of PMS with exercise therapy tailored to physiological/psychological needs
- Focus on lower-limb function, muscle content, creatine kinase, and depressive symptoms
- EEG immediate effect assessment for deeper neurofunctional insights

## 5. Data Management & Safety

All data handled per SOPs, with restricted access, double-check entry, and encryption. Adverse events will be monitored, classified, and reported within 24 hours to the ethics board. Participants with serious adverse reactions will be withdrawn and given necessary medical care.

## 6. Post-Trial Care

Patients with persistent symptoms will receive follow-up treatment plans, referrals, and ongoing monitoring. Educational and psychological support will be provided as needed.

## 7. Expected Outcomes & Benefits

Social: Improved quality of life, reduced burden on families and society, enhanced public awareness, and contribution to psychiatric treatment research.
Economic: Reduced healthcare utilization, improved productivity and participation, growth of related industries, and attraction of talent and investment.

Application Prospects: Medical institutions, pharmaceutical companies, government health agencies, academic institutions, insurance providers.