

ALL ITEMS FROM THE WORLD HEALTH ORGANIZATION TRIAL REGISTRATION DATA SET

Data category	Information
Primary registry and trial identifying number	<i>ClinicalTrials.gov NCT04987151</i>
Date of registration in primary registry	<i>July 26, 2021</i>
Secondary identifying numbers	-
Source(s) of monetary or material support	<i>The study is not funded</i>
Primary sponsor	<i>The study is not funded</i>
Secondary sponsor(s)	<i>The study is not funded</i>
Contact for public queries	-
Contact for scientific queries	-
Public title	<i>Comparison of three different exercise training modalities (aerobic, strength, and mixed) in patients with schizophrenia: study protocol for a multi-centre randomised wait-list controlled trial</i>
Scientific title	<i>Comparison of three different exercise training modalities (aerobic, strength, and mixed) in patients with schizophrenia: study protocol for a multi-centre randomised wait-list controlled trial</i>
Countries of recruitment	<i>Spain</i>
Health condition(s) or problem(s) studied	<i>Exercise training; Schizophrenia</i>

Data category	Information
Intervention(s)	<i>Three physical exercise programs: strength, aerobic, and mixed (strength and aerobic)</i>
Key inclusion and exclusion criteria	<p><i>Inclusion criteria: (1) age between 18–65 years; (2) Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) diagnosis of schizophrenia; and (3) able to read and understand the Spanish language.</i></p> <p><i>Exclusion criteria: (1) acute suicidality; (2) representing an acute danger to others; (3) other psychiatric diagnoses or acute psychiatric illnesses; (4) other disorders that could prevent the person from completing the exercise training; (5) participation in similar programs or interventions at the time of enrolment.</i></p>
Study type	<p><i>Interventional</i></p> <p><i>Allocation: randomized</i></p> <p><i>Intervention model: simple allocation strategy</i></p> <p><i>Masking: single-blinded (evaluator)</i></p> <p><i>Primary purpose: prevention</i></p> <p><i>Phase III</i></p>
Date of first enrolment	<i>October 2021</i>
Target sample size	<i>105</i>
Recruitment status	<i>Not recruiting</i>
Primary outcome(s)	<i>Positive symptomatology, negative symptomatology, and general symptomatology (using the Positive and Negative Syndrome Scale)</i>
Key secondary outcomes	<i>Body composition (by assessing body mass index, body fat mass and waist circumference), physical activity levels (International Physical Activity Questionnaire-Short Form), and quality of life (abbreviated World Health Organization Quality of Life questionnaire).</i>