

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The Effect of Aerobic Exercise on the Severity of Suicidal Ideation and Disease Symptoms in Schizophrenic Patients

Protocol summary

Study aim

Determining the Effect of Aerobic Exercise on the Severity of Suicidal Ideation and Disease Symptoms in Schizophrenic Patients.

Design

A Randomized Controlled Clinical Trial, Single-blinded, on 30 Schizophrenic Patients. Even and odd numbers are used for random allocation.

Settings and conduct

The intervention of aerobic exercises will be carried out at the Mahdis Birjand Chronic Patients Care Center during 8 weeks and on even days of the week for 30 minutes, including warm-up, running and invisible rope jumping and cooling down.

Participants/Inclusion and exclusion criteria

Willingness to cooperate in research. Have at least one period of hospitalization with a diagnosis of schizophrenia. Age between 18 and 65 years. In terms of physical health, have enough health to participate in the sports program. Not suffering from mental illness except schizophrenia Not participating in another research project simultaneously

Intervention groups

For the intervention group, 30 minutes of aerobic exercises will be performed during 8 weeks on even days of the week, and for the control group, in order to consider ethical principles, a 30-minute session of aerobic exercises will be held after the end of the intervention.

Main outcome variables

Severity of Suicidal Ideation; Symptoms of Schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240121060758N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Sara Sheykh fendereski

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3235 3523

Email address

sara12345678sh@chmail.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-15, 1402/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aerobic Exercise on the Severity of Suicidal Ideation and Disease Symptoms in Schizophrenic Patients

Public title

The Effect of Aerobic Exercise on the Severity of Suicidal Ideation and Disease Symptoms in Schizophrenic

Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate in research. Have at least one period of hospitalization with a diagnosis of schizophrenia. Age between 18 and 65 years. In terms of physical health, have enough health to participate in the sports program.
Exclusion criteria:
Suffering from another mental illness except schizophrenia. Participating in another research project at the same time

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, aerobic exercises will be performed for 8 weeks on even days of the week for 30 minutes, and at the end of the intervention, the control group will be taught the ethical considerations of aerobic exercises in one session. To consider single blinding, the participants will be informed that the intervention will take place at two different times.

Placebo
Not used

Assignment
Other

Other design features
In this study, aerobic exercises will be performed for 8 weeks on even days of the week for 30 minutes, and at the end of the intervention, the control group will be taught the ethical considerations of aerobic exercises in one session.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical

Sciences

Street address
Ghafari Blvd., Birjand University of Medical Science

City
Birjand

Province
South Khorasan

Postal code
9717853076

Approval date
2024-01-20, 1402/10/30

Ethics committee reference number
IR.BUMS.REC.1402.456

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

The Score of Suicidal Ideation in the Beck Questionnaire

Timepoint

Before the Start of the Intervention, The Second Week, The Fourth Week After the Start of the Intervention and After the End of the Intervention

Method of measurement

Beck Suicidal Ideation Questionnaire

2

Description

Score of Positive and Negative Syndrome Scale Questionnaire

Timepoint

Before the Start of the Intervention, The Second Week, The Fourth Week After the Start of the Intervention and After the End of the Intervention

Method of measurement

Positive and Negative Syndrome Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic exercises will be performed for 15 patients with schizophrenia during 8 weeks on even days of the week for 30 minutes. These exercises

include 5 minutes of warm-up (soft running, combined movements of arms and legs and stretching), 20 minutes of main exercise including 10 minutes of running with an intensity of 60 to 80% of the maximum heart rate and 10 minutes of invisible rope jumping in 5 sets (30 times in each set). After each set, patients will rest for 1 minute by running slowly in place and breathing deeply. At the end, it is 5 minutes to cool down and return to the initial position.

Category

Rehabilitation

2**Description**

Control group: For 15 patients with schizophrenia, after the end of the intervention, aerobic exercises will be performed during one session for 30 minutes. These exercises include 5 minutes of warm-up (soft running, combined movements of arms and legs and stretching movements), 20 minutes of main exercise. It consists of 10 minutes of running at an intensity of 60-80% of maximum heart rate and 10 minutes of in situ invisible rope jumping in 5 sets (30 times per set). After each set, patients will rest for 1 minute by running slowly in place and breathing deeply. At the end, it is 5 minutes to cool down and return to the initial position.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mahdis Birjand Chronic Patients Care Center

Full name of responsible person

Mehdi Majidi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

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Fax**Email**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Sara Sheykh fendereski

Position

Psychiatric Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

based on ethical issues

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The Effect of Aerobic Exercise on the Severity of Suicidal Ideation and Disease Symptoms in Schizophrenic Patients

When the data will become available and for how long

After the publication of the article

To whom data/document is available

nobody

Under which criteria data/document could be used

Under no circumstances

From where data/document is obtainable

nobody

What processes are involved for a request to access data/document

Unpublishable

Comments