

# 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)

###### Phone

+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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Birjand, South Khorasan Province

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Mahdi.mirhoseini99@bums.ac.ir

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

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Yousefi

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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**

Birjand University of Medical Sciences  
**Full name of responsible person**  
Dr. Davood Oudi  
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Assistant Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Sara Sheykh fendereski  
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Psychiatric Nursing Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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4916698173  
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sara12345678sh@chmail.ir

## 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