

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of aerobic exercise as auxiliary therapy on the improvement of the negative and cognitive symptoms of patients with chronic schizophrenia in a randomized clinical case-control study .

#### Protocol summary

##### Study aim

Determination of the Effect of Aerobic Exercise as an Adjuvant Therapy on the Improvement of Negative and Cognitive Signs in Schizophrenic Patients

##### Design

A double-blind randomized clinical trial with case-control groups

##### Settings and conduct

Randomized double blind randomized clinical trial, Imam Hossein Hospital, Karaj and Roozbeh Tehran

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: having diagnostic criteria for DSM-V for patients with schizophrenia; the PANSS60 is the lowest score; age 18 to 50 years old; obtain informed consent from patient care; at least 2 years after the onset of the disease; minimum patient score based on negative subscore 20. Exit criteria: significant neurological or organoleptic disease, cardiovascular disease and history of cardiac surgery, or any cardiovascular procedure, clinically and laboratory examinations, and case study and biographies of the family; there is another diagnosis in axis I based on DSM-V; IQ of less than 70 based on Clinical Clinical suspic; get the ECT in the last two weeks; having Major Depression Criteria or Top 4 Scores Based on PANSS Depression; the desire and suicide attempt in Hamilton; patients drinking alcohol simultaneously; patients with a history of drug use in the last 6 months; women of childbearing age are not admitted without adequate prophylaxis; CHF and liver patients.

##### Intervention groups

Patients with chronic schizophrenia

##### Main outcome variables

Negative and cognitive symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190316043072N1**

Registration date: **2019-03-31, 1398/01/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-31, 1398/01/11**

Update count: **0**

##### Registration date

2019-03-31, 1398/01/11

##### Registrant information

##### Name

Atefeh Zandifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3255 4132

##### Email address

zandifaratefe@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-01, 1397/08/10

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of aerobic exercise as auxiliary therapy on the improvement of the negative and cognitive symptoms of patients with chronic schizophrenia in a randomized clinical case-control study .

## Public title

The effect of aerobic exercise as auxiliary therapy on the improvement of the negative and cognitive symptoms of patients with chronic schizophrenia in a randomized clinical case-control study .

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having diagnostic criteria for DSM-V for patients with schizophrenia The PANSS60 is the lowest score Age 18 to 05 years old Obtain informed consent from patient care at least 2 years after the onset of the disease Minimum patient score based on Negative subscore 20

### Exclusion criteria:

Significant neurological or organoleptic disease, cardiovascular disease and history of cardiac surgery, or any cardiovascular procedure, clinically and laboratory examinations, and case study and biographies of the family. There is another diagnosis in axis I based on DSM-Vo IQ of less than 70 based on Clinical Clinical suspiciono Drug abuse (except nicotine and caffeine) An anti-psychoactive oral intake in the past week or an anti-psychoactive effect in the past montho Get the ECT in the last two weekso Having Major Depression Criteria or Top 4 Scores Based on PANSS Depression The desire and suicide attempt in Hamiltono Patients drinking alcohol simultaneously Patients with a history of drug use in the last 6 months Women of childbearing age are not admitted without adequate prophylaxis CHF and liver patients All patients are undergoing ECG and biochemical tests for liver and kidney disease. All patients undergo five stages including basal and weekly visits in weeks 2- 4 and 6.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator
- Outcome assessor

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

50 patients were randomly assigned to control group and control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Researcher and analyst are not aware of patients who are under an intervention or non-intervention

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

##### Street address

North Taleghani Blvd. Taleghani Square. Karaj. Alborz.IRAN

##### City

karaj

##### Province

Alborz

##### Postal code

3149779453

#### Approval date

2018-10-13, 1397/07/21

#### Ethics committee reference number

IR.ABZUMS.REC.1397.107

## Health conditions studied

### 1

#### Description of health condition studied

Schizophrenia disorder

#### ICD-10 code

F20-29

#### ICD-10 code description

Schizophrenia, schizotypal and delusional disorders(F20-F29)

## Primary outcomes

### 1

#### Description

Aerobic exercise

#### Timepoint

Weeks: 0, 2, 4, 6 and 8

#### Method of measurement

PANSS/ Brain MRI

### 2

#### Description

Negative and cognitive symptoms

#### Timepoint

Weeks: 0, 2, 4, 6 and 8

#### Method of measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with chronic schizophrenic disorder are randomly divided into two groups, if they have inclusion criteria. The intervention group is 25 people. In a 8-week program, 2mg of risperidone tablets are given at a dose of 6mg per day, and they are taking 3 days a week in aerobic exercises for 30 minutes per session.

#### Category

Treatment - Other

### 2

#### Description

Control group: control group of 25 people. In a 8-week program, risperidone tablets are given at a dose of 2 milligrams per day and not aerobic exercise.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein Hospital, Karaj

##### Full name of responsible person

Dr. Atefe Zandifar

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North Taleghani Blvd. Taleghani Square. Karaj. Alborz.IRAN

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zandifaratefe@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Doctor Mohammad Norisephr

#### Street address

Deputy of Research and Technology-45 meters Golshahr - Alley Safarian - Karaj. Alborz.IRAN

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Karaj

#### Province

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#### Postal code

3198764653

#### Phone

+98 26 3464 4255

#### Email

Research@abzums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

medical University Tehran . And Alborz University of Medical Sciences. Considering the patients are from Roozbeh Hospital in Tehran and Imam Hossein Hospital in Alborz. According to the approval of the project in both Rosabeh and Alborz research centers

#### Proportion provided by this source

50

#### 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

Karaj University of Medical Sciences

##### Full name of responsible person

Dr. Atefe Zandifar

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After publishing the article, people can access all the data without mentioning the patients' names

**When the data will become available and for how long**

Once the article is printed, people can access the data at any time

**To whom data/document is available**

Analyst / and eventually in the resulting research without the names of the sick

**Under which criteria data/document could be used**

For scientific use and benefit from the results to help patients with schizophrenia disorder after the publication of the article.

**From where data/document is obtainable**

After the publication and publication of the article, access to data is accessible by protecting the privacy of patients without their names.

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

After the publication and publication of the article, access to data is accessible by protecting the privacy of patients without their names.

**Comments**