Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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
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karaj
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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
Schizopherenia 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

PANSS/ Brain MRI

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Doctor Mohammad Norisephr
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Deputy of Research and Technology-45 meters Golshahr - Alley Safarian - Karaj. Alborz.IRAN
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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 updating data

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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