

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The assessment of the aerobic exercise effect on the schizophrenic patients social and emotional cognition

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Determining the effect of aerobic exercise on social and emotional cognition of schizophrenia patients

Last update: **2021-04-27, 1400/02/07**

Update count: **0**

#### Design

Before after trial without control group and with 30 participants

#### Registration date

2021-04-27, 1400/02/07

#### Settings and conduct

The study will be conducted at Parham Psychiatric Center in Kashan. Participants with schizophrenia will be selected if eligible for the study. The study is not blind.

#### Registrant information

##### Name

Aliakbar Ataei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 9111

##### Email address

ataei-a@kaums.ac.ir

#### Participants/Inclusion and exclusion criteria

Inclusion criteria : No underlying disease such as lung or heart problems Age 20 to 60 years Confirmation of the diagnosis of schizophrenia Patient desire to participate The patient's ability to participate in regular exercise programs Obtain consent from the patient's legal guardian before participating in the study exclusion criteria: Trauma during exercise Physical problems during exercise Absence for more than three sessions Clearance from the center Changing the general medication protocol of the patient Drug use Change in the patient's mental state

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Intervention groups

The intervention group includes patients with schizophrenia who receive the intervention in the form of aerobic exercise for 6 months (twice a week). The research is an intervention before and after and has no control group.

#### Expected recruitment start date

2021-04-11, 1400/01/22

#### Expected recruitment end date

2021-10-22, 1400/07/30

#### Actual recruitment start date

2021-04-30, 1400/02/10

#### Actual recruitment end date

2021-10-22, 1400/07/30

#### Trial completion date

2021-10-22, 1400/07/30

#### Main outcome variables

Stroop test of colored words; Numerical width stroop test score; Test the spacing of words

#### Scientific title

The assessment of the aerobic exercise effect on the schizophrenic patients social and emotional cognition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210406050873N1**

Registration date: **2021-04-27, 1400/02/07**

##### Public title

Aerobic exercise effect on the schizophrenic

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

No underlying disease such as lung or heart problems  
Age 20 to 60 years Confirmation of the diagnosis of schizophrenia Patient desire to participate The patient's ability to participate in regular exercise programs

### Exclusion criteria:

Physical problems during exercise Absence for more than three sessions Clearance from the center Change in the patient's mental state

## Age

From **20 years** old to **60 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

Actual sample size reached: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

Parastar boulevard

##### City

Kashan

##### Province

Isfahan

##### Postal code

۸۷۱۵۹۷۳۴۴۶

#### Approval date

2021-03-16, 1399/12/26

#### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.007

## Health conditions studied

### 1

#### Description of health condition studied

اسکیزوفرنی

#### ICD-10 code

F20

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

Stroop test of colored words

#### Timepoint

The beginning of the study and 6 months after that

#### Method of measurement

Stroop test of colored words

### 2

#### Description

Numbers test stroop score

#### Timepoint

The beginning of the study and 6 months after that

#### Method of measurement

Numbers test stroop score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this study, the intervention is aerobic exercise that is twice a week for 6 months. In this study, aerobic exercise means fast and regular movements of the neck, arms, legs and back in a specific exercise package for 30 minutes each time (twice a week) by a sports coach, and the same movements are repeated in each session, which include movements such as butterfly, raising the opposite arm and leg, hitting around, rope, etc. In order to perform proper exercise in aerobic activity, heart rate is an indicator of activity intensity.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Parham Rehabilitation and Treatment Center

##### Full name of responsible person

dr. Afshin ahmadvand

##### Street address

Kashan, Shahid Rajaei St., at the beginning of Amir Emad St., in front of Parsian Bank

**City**

kashan

**Province**

Isfahan

**Postal code**

8715973446

**Phone**

+98 21 5554 9111

**Email**

ataei-a@kaums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

hamidreza banafsheh

**Street address**

Kashan - 5 km from Ravandi pole - end of Parstar Boulevard - Deputy of research and technology

**City**

kashan

**Province**

Isfahan

**Postal code**

8715973474

**Phone**

+98 31 5554 2999

**Email**

banafshe57@hotmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

dr. afshin ahmadvand

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kashan - 5 km from Ravandi pole - end of Parstar Boulevard - Kargarnejad Hospital

**City**

kashan

**Province**

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**Postal code**

8715973446

**Phone**

+98 31 5554 9111

**Email**

afshin.ahmadvand@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

dr. afshin ahmadvand

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

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7815973446

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+98 31 5554 9111

**Email**

afshin.ahmadvand@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

aliakbar atae

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kashan - 5 km from Ravandi pole - end of Parstar

Boulevard - Kargarnejad Hospital

**City**

kashan

**Province**

Isfahan

**Postal code**

8715973446

**Phone**

+98 31 5554 9111

**Email**

ataei@kaums.ac.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**

Because of moral considerations

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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