

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The assessment of aerobic exercise effects on the depression and stress of the chronic schizophrenic patients

Protocol summary

Study aim

The effect of aerobic exercise on anxiety and depression in male patients with chronic schizophrenia

Design

Before after trial without control group and with 30 participants

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.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) Confirmation of the diagnosis of schizophrenia in participating patients by a psychiatrist 2) At least 6 months Presence in the center 3) Ability to participate in regular sports programs. Exclusion criteria: 1) Occurrence of any adverse event such as death, divorce or unemployment of the patient's first degree relatives during the study period 2) Existence of mental retardation or deafness or physical disability 3) Exit and clearance from the center 4) Change the general medication protocol of the patient 5) Drug use 6) Having underlying cardiovascular disease and diabetes, a history of stroke or lung or specific diseases

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). This study is an intervention study of before and after type and has no control group.

Main outcome variables

Depression with the Hamilton Depression questionnaire, Anxiety with the Hamilton Anxiety questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210418051006N2**

Registration date: **2021-09-14, 1400/06/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-14, 1400/06/23**

Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

amirreza khorshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 9111

Email address

khorshidipaji@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

2021-08-11, 1400/05/20

Actual recruitment end date

2022-02-09, 1400/11/20

Trial completion date

2022-02-09, 1400/11/20

Scientific title

The assessment of aerobic exercise effects on the depression and stress of the chronic schizophrenic patients

Public title

The effect of aerobic exercise on anxiety and depression

in patients with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having schizophrenia At least 6 months Presence in Parham rehabilitation and treatment Center

Exclusion criteria:

Occurrence of any adverse event such as death, divorce or unemployment of first-degree relatives

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

Kashan University of Medical Sciences, Parastar Blvd

City

Kashan

Province

Isfahan

Postal code

Approval date

2021-05-11, 1400/02/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.020

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

stress

Timepoint

The beginning of the intervention and the end of the intervention

Method of measurement

Hamilton Anxiety Questionnaire

2

Description

Depression

Timepoint

The beginning of the intervention and the end of the intervention

Method of measurement

Hamilton Depression Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention is aerobic exercise. The exercise performed is similar to warming up before other exercises and morning exercise and does not involve heavy or complex movements that all patients are able to perform. It also involves stretching and strengthening the neck, back, and arms and legs of patients. Movements such as step in place, butterfly movement, step to side, double step to side, forward heel and jump in place, turning the waist and burpees movements and squatting the jack and raising the knee from behind and fluttering, etc.

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

front of Parsian Bank, the beginning of Amir Emad Street, Shahid Rajaei Street, Kashan

City

kashan

Province

Isfahan

Postal code

8715973446

Phone

+98 31 5554 9111

Email

danceandtravelwithme@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Hamidreza Banafsheh

Street address

Deputy Research and technology, end of Parstar Blvd, 5 km from ghotb Ravandi, Kashan

City

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Province

Isfahan

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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

Kargarnejad Hospital, Parstar Blvd, 5 km from Ghotbe Ravandi, Kashan

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8715973446

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+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

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Sara Hamzeh Nezhadi

Position

Psychiatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Kargarnejad Hospital, Parstar Blvd, 5 km from Ghotbe
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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

For 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