

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The Effectiveness of stationary bike combined with attention process training on the positive and negative symptoms and cognitive deficits in schizophrenic patient

Protocol summary

Study aim

Evaluation effect of stationary bike combined with attention process training on the positive and negative symptoms and cognitive deficits in schizophrenic patient

Design

This study is clinical trial and double blind. patients will be divided in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

Patients with schizophrenia in Amirkabir hospital in Arak will enter this study. This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All schizophrenic patients undergoing drug treatment regardless of sex and age
Exclusion criteria: Patients with organic disorder; patients with schizophrenia who are not controlled by drug therapy; bipolar patients

Intervention groups

Intervention group: We will treat 50 patients with schizophrenia by intervention treatment of attention processing training with constant cycling. Control group: We will treat 50 patients with schizophrenia without any intervention.

Main outcome variables

Negative and positive symptoms assessment; continuous attention assessment; focused attention; segmented attention; selective attention; short term memory assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N120**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-10, 1398/06/19**

Update count: **0**

Registration date

2019-09-10, 1398/06/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of stationary bike combined with attention process training on the positive and negative symptoms and cognitive deficits in schizophrenic patient

Public title

The Effectiveness of stationary bike combined with attention process training on the positive and negative symptoms and cognitive deficits in schizophrenic patient

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All schizophrenic patients undergoing drug treatment regardless of sex and age

Exclusion criteria:

Patients with organic disorder
Patients with schizophrenia who are not controlled by drug therapy
Bipolar patients

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.ARAKMU.REC.1398.005

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Negative and positive symptoms assessment

Timepoint

Before intervention and after 24 sessions

Method of measurement

Positive and negative syndrome scale(PANSS)

2

Description

Continuous attention assessment

Timepoint

Before intervention and after 24 sessions

Method of measurement

Continuous Performance Testing

3

Description

Focused attention

Timepoint

Before intervention and after 24 sessions

Method of measurement

Wechsler cryptography sub scale

4

Description

Segmented attention

Timepoint

Before intervention and after 24 sessions

Method of measurement

Subset of a number sequence- Wechsler intelligence test

5

Description

Selective attention

Timepoint

Before intervention and after 24 sessions

Method of measurement

Stroop test

6

Description

Short term memory assessment

Timepoint

Before intervention and after 24 sessions

Method of measurement

Wechsler direct and reverse digit span

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We will treat 50 patients with schizophrenia by intervention treatment of attention processing training with constant cycling. Intervention time is 24 sessions per week for three sessions and intervention time is 3 minutes per session.

Category

Treatment - Other

2

Description

Control group: We will treat 50 patients with schizophrenia without any intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Mostafa Nokani

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Amirkabir hospital, Parastar square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hamidreza Jamilian

Position

Associate professor

Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

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Name of organization / entity
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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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Nokani

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

They have to write letters to the professors and the university

Comments