

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### 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

##### Street address

Amirkabir hospital, Parastar square

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3222 2003

##### Email

m.nokani@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3222 2003

##### Email

arjmandzadegan@arakmu.ac.ir

#### 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**

Psychiatrics

**Street address**

Amirkabir hospital, Parastar square

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

Jamilian@arakmu.ac.ir

**Web page address****Full name of responsible person**

Sirvan Hosseini

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Payambar Azam Complex, Basij Square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3417 3645

**Email**

sirvanhosseiny73@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mostafa Nokani

**Position**

Assistante professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Amirkabir hospital, Parastar square

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 863222003

**Fax**

+98 86 3222 2003

**Email**

nokani@arakmu.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**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**