

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The Effectiveness of Aerobic Exercise, Computerized Cognitive Rehabilitation, tDCS on Balance, Gait and Cognition among Man Schizophrenia Patients with Depression Disorder

#### Protocol summary

##### Study aim

Investigating the merits of intervention modalities, such as computerized cognitive training, aerobic training, and Trans cranial direct current stimulation on cognition, Gait and Balance in schizophrenia with depression disorder

##### Design

Non-randomized, controlled clinical trial with parallel groups without blinded on 55 male schizophrenia patients with depression disorder

##### Settings and conduct

After obtaining consent from the Arak Welfare Organization and referring to the Schizophrenia Rehabilitation Clinic, 55 patients will be selected based on purpose-based inclusion criteria. Eligible subjects are assigned homogeneously (based on age) to five groups (Trans cranial direct current stimulation group, Aerobic training group, Computerized cognitive training group, Multidimensional training group) after obtaining consent and physician consent. Interventions will be conducted for 12 weeks at the rehabilitation center under the supervision of specialists. Subjects will be evaluated before and after the intervention by the mentioned tests and the results will be compared as pre-test and post-test.

##### Participants/Inclusion and exclusion criteria

Man Schizophrenia Patients with Depression Disorder  
Inclusion criteria: Fulfillment of DSM-IV criteria for schizophrenia The age 18-65 years  
Exclusion criteria: unwillingness to cooperate

##### Intervention groups

Intervention group1: Trans cranial direct current stimulation group  
Intervention group2: Aerobic training group  
Intervention group3: Computerized cognitive training group  
Intervention group4: Multidimensional training group  
Control group

##### Main outcome variables

Static Balance, Dynamic Balance, 10-meter gait speed,

10-meter gait speed under visuo spatial dual-task condition, 10-meter gait speed under motor dual-task condition, Sustain attention, response inhibition, Working Memory

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190908044722N1**

Registration date: **2019-12-24, 1398/10/03**

Registration timing: **retrospective**

Last update: **2019-12-24, 1398/10/03**

Update count: **0**

##### Registration date

2019-12-24, 1398/10/03

##### Registrant information

##### Name

Razieh Khanmohamadi

##### Name of organization / entity

The university of Urmia

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3221 4311

##### Email address

r.khanmohamadi@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-02, 1398/04/11

##### Expected recruitment end date

2019-07-19, 1398/04/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effectiveness of Aerobic Exercise, Computerized Cognitive Rehabilitation, tDCS on Balance, Gait and Cognition among Man Schizophrenia Patients with Depression Disorder

**Public title**

The Effectiveness of Three Interventions on Balance, Gait and Cognition among Man Schizophrenia Patients with Depression Disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Fulfillment of DSM-IV criteria for schizophrenia The age 18-65 years The ability to understand and speak Get a score of 11 or above on the Mini-Mental State Examination Get a score of 11 or above on the Beck Depression Inventory Having physical health, meaning that they have no evidence of cardiovascular, neuromuscular, endocrine or another somatic disorders

**Exclusion criteria:**

Alcohol or substance dependence in the past 3 months Substance dependence with current substance abuse (excluding nicotine) History of head injury Previous seizures Having brain implants, cardiac pacemakers Use of antiepileptic drugs or benzodiazepines > 1 mg Lorazepam equivalent Having severe diabetes and asthma Diagnosis of acute schizophrenia requiring hospitalization, presence of severe schizophrenic symptoms (e.g. persistent withdrawal) that would limit participation in class A history of organic mental disorders (e.g. mental retardation or dementia), presence of physical disabilities Untreated hyper- or hypothyroidism Extreme obesity (BMI  $\geq$  40); Concurrent participation in another study

**Age**

From **18 years** old to **65 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Sport Sciences Research Institute

**Street address**

No. 3, Fifth Alley, Miramad Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1587958711

**Approval date**

2019-07-01, 1398/04/10

**Ethics committee reference number**

IR.SSRC.REC.1398.098

**Health conditions studied****1****Description of health condition studied**

schizophrenia

**ICD-10 code**

F98

**ICD-10 code description**

Other behavioral and emotional disorders with onset usually occurring in childhood and adolescence

**Primary outcomes****1****Description**

Static balance

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

The test of standing on dominant foot with open and closed eyes

**2****Description**

Dynamic Balance

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

The Test of Timed up and Go

### 3

**Description**

10-meter gait speed

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

The Test of 10-meter gait speed

### 4

**Description**

of 10-meter gait speed under visuospatial dual-task condition

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

The Test of 10-meter gait speed under visuospatial dual-task condition

### 5

**Description**

of 10-meter gait speed under motor dual-task condition

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

The Test of 10-meter gait speed under motor dual-task condition

### 6

**Description**

Sustain attention

**Timepoint**

One month before intervention and two weeks after intervention

**Method of measurement**

Continuous Performance Test

### 7

**Description**

Response Inhibition

**Timepoint**

One month before intervention and two weeks after intervention

**Method of measurement**

Stroop Test

### 8

**Description**

Working Memory

**Timepoint**

One month before intervention and two weeks after intervention

**Method of measurement**

N-back Test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group 1: Aerobic training group: Participants will be enrolled in AT will undergo a 12-week, 3 sessions per week, 1-h AT training program informed by the American College of Sports Medicine and federal guidelines which recommend 150 min of moderate-intensity AT per week. The AT sessions will be led by a trainer (Bachelor of Physical Education) and will be opened with a 10-min trainer-led warm-up (stretching, slow walking) period, will be followed by 45-min AT using the equipment, and will be ended with a 5-min cooldown period. The AT equipment will include two stationary bike, a treadmill machine. The trainer will be present during the AT sessions for guidance and support. AT intensity will be set to 60% of H<sub>max</sub> in Week 1, 65% of H<sub>max</sub> in Week 2, 70% of H<sub>max</sub> in Week 3, and 75% of H<sub>max</sub> in Weeks 4-12

**Category**

Rehabilitation

### 2

**Description**

Intervention group 2: computerized cognitive training group : Cognitive rehabilitation was carried out using a cognitive rehabilitation program called the Attentive Rehabilitation of Attention and Memory (ARAM). This program is a kind of software designed to enhance the cognitive abilities created by Nejati and in some reports, its effectiveness was shown on executive functions. The program included a group of organized hierarchical tasks that enhanced the various dimensions of attention (selective, sustained, shifting, and divided) and working memory. These practices are hierarchical. This means that the therapist records the information obtained from the evaluation of the sessions, including the percentage of the correct responses of the client and task completion speed. If the client masters a task, the therapist increases the difficulty level of the task. Participations will be enrolled in CCT will attend in the computerized cognitive training session for 45-60 minutes three times weekly for 12 weeks (36 total sessions).

**Category**

Rehabilitation

### 3

**Description**

Intervention group 3: a-tDCS group: The anode stimulation group will receive on the motor and pre-motor region for 24 sessions, two times weekly over 12 weeks. That way, in the morning will be given stimulation of the right hemisphere and in the afternoon will be given stimulation of the left area. The anode electrode will be placed on the motor and pre-motor and the cathode electrode will be placed in the center of the forehead. Also, the a-tDCS group, will receive stimulation on F3 for 24 sessions, two times weekly over

12 weeks. The anode will be placed over the left DIPFC and the cathode will be placed on the contralateral deltoid muscle. The maximum current intensity will be 2 mA.

#### Category

Treatment - Devices

#### 4

##### Description

Intervention group4: multidimensional training group : The multidimensional training consist of aerobic training, cognitive training, and direct electrical stimulation of the brain. Participations will be enrolled in MT will attend in the computerized cognitive training session for 10 minutes 3 times weekly for 12 weeks (36 total sessions). Also, They will undergo a 8 weeks, 2 sessions per week, 1-h AT training program. Minimal AT intensity will be set to 60% of Hrmax in Week 1, 65% of Hrmax in Week 2, 70% of Hrmax in Week 3, and 75% of Hrmax in Weeks 4-12. During the exercise sessions, heart rate will be monitored using a Beurer PM 15 Heart Monitor. Participants will receive stimulation at the motor and pre-motor point in the right and left hemispheres from 9th to 12 th week. In the morning area will be given stimulation of the right hemisphere and in the afternoon stimulation of the left area . The anode electrode will be placed on the (M1) motor and pre-motor region and the cathode electrode will be placed in the center of the forehead. Also Participants will receive stimulation on F3 for 12 sessions during 4 weeks (3 times per week). Electrode anode will be placed on the left posterior frontal cortex And the cathode electrode will be placed on the opposite side of the deltoid muscle

#### Category

Rehabilitation

#### 5

##### Description

control group: Routine care

#### Category

Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shaiestegan Rehabilitation Center

###### Full name of responsible person

Reza Parivar

###### Street address

Behind Gerdoo Hospital, Razavi Twon, Arak city, Markazi Province, Iran

###### City

Arak

###### Province

Markazi

###### Postal code

3819164765

#### Phone

+98 86 3277 2141

#### Email

parivar.reza@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Faculty of Physical Education and Sport Sciences, University of Tehran, Tehran, Iran

###### Full name of responsible person

Foad Seidi

###### Street address

Between Fifteenth and Sixteenth St, Amirabad St, Tehran, Iran

###### City

Tehran

###### Province

Tehran

###### Postal code

14398-13117

###### Phone

+98 21 8835 1730

###### Email

foadseidi@ut.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Faculty of Physical Education and Sport Sciences, University of Tehran, Tehran, Iran

##### Proportion provided by this source

100

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Other

### Person responsible for general inquiries

##### Contact

###### Name of organization / entity

University of Tehran

###### Full name of responsible person

Razieh Khanmohammadi

###### Position

PHD student

###### Latest degree

Ph.D.

###### Other areas of specialty/work

Motor Development

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Latest degree**

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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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

The analysis of information obtained from the results of the interventions on balance and gait speed can be published

**When the data will become available and for how long**

From the time the article was published until a year later

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Provided Someone wants to do a similar research project

**From where data/document is obtainable**

r.khanmohamadi65@yahoo.com

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

Send request by email

**Comments**