Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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The university of Urmia
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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 ≥ 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 been 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 been led by a trainer (Bachelor of Physical Eduation) and will been opened with a10-min trainer-led warm-up (stretching, slow walking) period, will been followed by 45-min AT using the equipment, and will been 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 Hrmax in Week 1, 65% of Hrmax in Week 2, 70% of Hrmax in Week 3, and 75% of Hrmax 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 diffculty level of the task. Participations will been 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 stimulstion 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 been given stimulation of the right hemisphere and in the afternoon will been given stimulation of the left area .The anode electrode will been placed on the motor and pre-motor and the cathode electrode will been 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 been placed over the left DlPFC and the cathode will been 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 been 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 been 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 been given stimulation of the right hemisphere and in the afternoon stimulation of the left area . The anode electrode will been placed on the (M1) motor and pre-motor region and the cathode electrode will been 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 been placed on the left posterior frontal cortex And the cathode electrode will been 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

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

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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

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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

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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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