Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of computer-assisted cognitive remediation on negative symptoms, depression and cognitive functions in Schizophrenic patients

Protocol summary

Study aim

This research aims to investigate computerized cognitive remediation effects on depression and negative symptoms of schizophrenic patients, in order to clarify how these effects take place, and also the effect of this intervention on cognitive abilities of patients.

Design

Two arm parallel groups, one-side blinded and randomized study which will consist of an intervention as well as a control group and 30 participants will be conducted between August and December of 2019.

Settings and conduct

The research will be conducted in several of Tehran rehabilitation centers for chronic mental illness patients. First, Patients who are qualified to be included will take the test supervised by the assessors who are blinded to the study and then participants will be randomly assigned to one of control or intervention groups. At the end of the intervention, again patients will be tested in the same condition.

Participants/Inclusion and exclusion criteria

Inclusion: Diagnosis of schizophrenia 18-59 years old No record of brain damage Not abusing drug or alcohol nor addiction to them No auditory or visual disability No symptom of disorganization Least IQ of 70 Exclusion: Not being consent Disabling medical condition

Intervention groups

Intervention group: 15 sessions of cognitive remediation, each session 35-45 minutes, each week 5 sessions will be delivered to patients. For this purpose, we use BrainHQ pieces of training and treatment schedule. Control group: They will be receiving treatment as usual (TAU)

Main outcome variables

Improvement of cognitive abilities; reduction in patient's score of Calgary Depression Scale for Schizophrenia; reduction in patient's score of Scale for Assessment of Negative Symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190808044478N1**
Registration date: **2019-10-20, 1398/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**
Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name

Alireza Jamaloo

Name of organization / entity

Allameh Tabataba'i University

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 2396

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alirezajamalu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-29, 1398/07/07

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of computer-assisted cognitive remediation on negative symptoms, depression and cognitive functions in Schizophrenic patients

Public title
Effect of cognitive remediation on Schizpohrenia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with Schizophrenia Score of 6 (at least) on Calgary Depression Scale for Schizophrenia No history of brain damage No drug or alcohol abuse No impairment in visual or hearing ability Absence of Disorganized symptoms IQ of 70 at least, based of estimation using WSCI Word Inventory subtest
Exclusion criteria:
Disabling medical condition Not being consent
Age
From **18 years** old to **59 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use Stata 9.0 computer software for simple randomization. Once the difference between groups in important variables (age, gender, IQ, CDSS score, SANS score, cognitive test scores) is not significant; patients will be assigned to either of intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Evaluators who are in charge of doing tests and nurses and other personnel of each clinical center are blinded to Both aim and group allocations. Participants are blinded to the aim of research but are aware of group randomization. Participants are also aware of intervention protocol and the fact that there are two groups in the study, but they are not aware of the aim of study which is enhancing cognitive abilities and improving negative symptoms and depressed mood.
Placebo
Not used
Assignment
Parallel
Other design features
Research will be conducted in multiple clinical centers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Allameh Tabataba'i University
Street address
Dehkadeh Square, Dehkadeh-ye-Olympic, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۸۹۶۸۴۵۱۱
Approval date
2019-07-15, 1398/04/24
Ethics committee reference number
IR.ATU.REC.1398.002

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Score on the Calgary Depression Scale for Schizoprenia
Timepoint
A week before intervention, A week after intervention
Method of measurement
Calgary Depression Scale for Schizophrenia

2

Description
Negative Symptoms
Timepoint
A week before intervention, a week after intervention
Method of measurement
Scale for the Assessment of Negative Symptoms

3

Description
Cognitive Functions
Timepoint
A week before intervention, a week after intervention

Method of measurement
Using following tests: Trail Making Test, Wisconsin Card Sorting Test, Tower of London, Vocabulary and Digit Span subsets of WAIS, Continuous Performance Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Set of cognitive exercises will be delivered to patients via computer. Each session consists of 7 exercises in approximate time of 30-45 minutes, 5 times per week for 3 executive weeks for each patient.
Category
Rehabilitation

2

Description
Control group: Patients in this group will get treatment as usual (TAU) and will not get cognitive intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahebba daily educational and rehablitational center for chronic mental patients
Full name of responsible person
Tayebeh Dehbashi Zadeh
Street address
Tehran Province, Tehran, District 11, Shahid Eskandari
City
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1313773135
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spsahebba@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Allameh Tabataba'i University
Full name of responsible person
Hamidreza Oloumi Yazdi
Street address
Dehkaeh Square, Dehkade-ye-Olympic, Tehran
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+98 21 4473 7510
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oloumi@atu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Allameh Tabataba'i University
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
Allameh Tabataba'i University
Full name of responsible person
Alireza Jamaloo
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Flat 3, No.15, Bahar alley, Habibollah st, Sattarkhan st, Tehran
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
After the data was made anonymous, it will be shared using excel format.
When the data will become available and for how long
Data will be available after publishing final results.
To whom data/document is available
Data will be available for scientific use for researchers and universities in the field of psychology and also schizophrenia treatment centers.
Under which criteria data/document could be used
In order to obtain detailed information on the study and using in meta-analytic and systematic review studies.
From where data/document is obtainable
Farideh Hossein Sabet, Third floor, Psychology and Educational Science faculty, Allameh Tabataba'i University and also alirezajamalu@gmail.com
What processes are involved for a request to access data/document
Each request will be responded after 2-7 days.
Comments