

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

Email address

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 Schizopohrenia

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 substest

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 Schizophrenia

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 rehabilitational 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

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Dehkaeh Square, Dehkade-ye-Olympic, Tehran

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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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Person responsible for scientific inquiries

Contact

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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**Person responsible for updating data****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

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