Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of a computerized cognitive remediation program on cognitive functioning of patients with schizophrenic disorders: A randomized controlled study

Protocol summary

Summary

This study aims to investigate the effect of cognitive remediation on cognitive functioning in patients with schizophrenic disorders. Sixty two patients with schizophrenia or schizoaffective disorder aged 18 to 55 will be enrolled from Roozbeh Hospital. Participants will be allocated randomly to a treatment and a control group using random blocks (size=4) with concealed allocation. The raters will be blind to the allocated groups. Subjects in the intervention group will receive cognitive remediation as well as treatment as usual that usually include antipsychotic medications, and the control group will receive only treatment as usual. The cognitive remediation protocol consists of 10 one-hour sessions of computerized training using the Cog-pack software. Positive and Negative Syndrome Scale (PANSS) will be used to investigate psychotic symptoms. Clinical Global Impression scale (CGI) will be used for clinical evaluation of the patients in terms of illness severity upon entering the study. The Global Assessment of Functioning (GAF) and the Quality of Life questionnaire will be employed to assess global functioning and quality of life of patients. Five subscales of the adult Wechsler Test will be used to measure the baseline intelligence quotient (IQ) of the patients. Furthermore, illness and treatment history will be obtained using chart reviews as well as interviews with patients and their relatives. The CANTAB software (Cambridge Neuropsychological Test Automated Battery) will be employed to assess the cognitive functioning before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011810782N2**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Vandad Sharifi

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

vsharifi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of a computerized cognitive remediation program on cognitive functioning of patients with schizophrenic disorders: A randomized controlled study

Public title
Effectiveness of cognitive remediation in schizophrenia
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria: Patients with DSM-IV schizophrenia or schizoaffective disorder, aged 18 to 55 years and with education not less than 3rd grade in guidance school. Patients will be clinically stable and not acutely psychotic (Clinical Global Impression scale score less than 4, and Positive and Negative Syndrome Scale score less than 50). The dosage and the type of antipsychotic medications patients will receive at least during the three weeks prior to the study will be unchanged. At least 12 hours before the intervention, patients will receive their last dose of a benzodiazepine (if any) but no antihistamine medication will be administered. Exclusion criteria: Receiving electroconvulsive therapy (ECT) within six weeks prior to the study, mental retardation, uncorrected visual impairment, concurrent consumption of substances with the exception of nicotine and caffeine, a history of head trauma followed by loss of consciousness, suffering from a major neurological disorder (including epilepsy, Parkinson's disease, dementia, multiple sclerosis, or any motor disability), severe worsening of illness during study requiring a change in medical treatments.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Tehran University of Medical Sciences
Street address
Ghods Avenue, Keshavarz Boulevard
City
Tehran
Postal code
Approval date
2016-02-08, 1394/11/19
Ethics committee reference number
IR.TUMS.REC.1394.1898

Health conditions studied

1

Description of health condition studied
Schizoaffective Disorder
ICD-10 code
F25
ICD-10 code description
Schizoaffective disorder

2

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

Primary outcomes

1

Description
Executive function
Timepoint
Before and after the intervention
Method of measurement
CANTAB Battery

2

Description
Attention
Timepoint
Before and after the intervention
Method of measurement
CANTAB Battery

3

Description
Memory
Timepoint
Before and after the intervention
Method of measurement
CANTAB Battery

Secondary outcomes

1

Description
Global Function
Timepoint
Before and after the intervention
Method of measurement
Global Assessment of Functioning

2

Description
Quality of life
Timepoint
Before and after the intervention
Method of measurement
Quality of life questionnaire

3

Description
Severity of illness
Timepoint
Before and after the intervention
Method of measurement
Positive and Negative Syndrome Scale, and Clinical global impression

Intervention groups

1

Description
Computer assisted cognitive remediation that consists of 10 training sessions using tasks in Cogpack software for improvement of memory, attention and executive functions. Sessions are delivered in 2-3 per week frequency.
Category
Rehabilitation

2

Description
Treatment-as-usual that usually consists of antipsychotic medications in standard maintenance dosage prescribed by a physician and accompanied by patient education.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Azadeh Sedighnia
Street address
South Kargar Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice chancellor for research and technology,Tehran University of Medical Sciences
Street address
Ghods Avenue, Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Roozbeh Hospital
Full name of responsible person
Azadeh Sedighnia
Position
Psychiatrist
Other areas of specialty/work
Street address
South Kargar Avenue
City
Tehran
Postal code
Phone
+98 21 5541 9151
Fax
Email
Azadehsedighnia@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Roozbeh Hospital
Full name of responsible person

Vandad Sharifi

Position

Psychiatrist/Professor

Other areas of specialty/work

Street address

South Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 5541 9151

Fax

Email

Vsharifi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Roozbeh Hospital

Full name of responsible person

Azadeh Sedighnia

Position

Psychiatrist

Other areas of specialty/work

Street address

South Kargar Avenue

City

Tehran

Postal code

Phone

+98 21 5541 9151

Fax

Email

Azadehsedighina@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty