

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

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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

Roazbeh 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

Roazbeh Hospital

Full name of responsible person

Azadeh Sedighnia

Position

Psychiatrist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Roazbeh Hospital

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Other areas of specialty/work

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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