Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effects of computer-assisted cognitive rehabilitation on cognitive functions, and mental health of people with schizophrenia

Protocol summary

Study aim

- Investigating the cognitive performance, self-esteem, depression, and quality of life of people with schizophrenia before and after cognitive rehabilitation interventions

Design

A clinical trial with two groups including intervention and control, with a study population of 30 people (15 in the intervention group and 15 in the control group), double-blind, simple randomized using a random number table.

Settings and conduct

Participants will be randomly divided into 2 groups. Patients, and assessors, are blinded to the grouping. In addition to conventional treatments, the intervention group receives 30 sessions of computerized cognitive rehabilitation (using CANTAB software). Interventions are performed at Razi Psychiatric Hospital. The control group, in addition to common treatments, will perform non-cognitive exercises with the computer for the same period of time. Participants will be evaluated before, immediately after, and two months after the interventions with cognitive tools and questionnaires so that the effectiveness of the intervention can be carefully examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age 18 to 55 years, diagnosis of schizophrenia, having mental capacity, and having an MMSE score higher than 18. Exclusion criteria are: suffering from medical problems that hinder sensory and motor function, changing medication during the last month or during the intervention, and suffering from paranoid hallucinations.

Intervention groups

In addition to conventional treatments, the intervention group will receive computerized cognitive rehabilitation in 30 sessions. Each intervention session includes 45 minutes of cognitive rehabilitation. The control group will also have 30 sessions of non-cognitive exercises with the computer.

Main outcome variables

Cognitive functions, Self-esteem, Quality of Life, Depression, Anxiety, Mental well-being

General information

Reason for update

The changes made are due to the conditions and facilities of research centers and research team.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180317039116N2**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**
Update count: **3**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name
Elahe Fathi Azar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3386 1366
Email address
el.fathiazar@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-06-06, 1402/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of computer-assisted cognitive rehabilitation on cognitive functions, and mental health of people with schizophrenia

Public title

The effects of computer-assisted cognitive rehabilitation on cognitive functions, and mental health of people with schizophrenia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Schizophrenia disorder diagnosed based on DSM-V by a psychiatrist Having an MMSE score above 18 Age 18 to 55 years

Exclusion criteria:

Having mental retardation Orthopedic, neurological problems that prevent upper limb function Changing the medication regimen during the last month or during the intervention Having paranoid delusions

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization method using random number tables will be used. for allocation concealment Sequentially numbered, sealed, opaque envelopes will be used for this process: The random numbers are placed in the opaque envelopes and the allocation of these opaque envelopes to groups is done randomly, this allocation is confidential and without informing the executor, patient, and investigators.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients are informed that they consent to participate in a research study. A written consent form will be completed by the participants. Statisticians, assessors , and participants are blinded to grouping.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of social Welfare and Rehabilitation Sciences

Street address

University of social welfare and rehabilitation sciences, Kodakyar Alley, Daneshjo Blv. Evin, Tehran.

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.USWR.REC.1401.199

Health conditions studied

1

Description of health condition studied

Cognitive impairments in Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Visual memory: Visual memory is a type of memory that refers to the ability to recall or remember activities, images, positions of objects or words in the past. Visual memory includes the ability to store and retrieve visual sensations and perceptions previously experienced by the individual.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the intervention period

Method of measurement

PAL, SRM, SWM, and SSP subtests of CANTAB

2

Description

Problem Solving: Problem solving is part of thinking. Problem solving, which is considered the most complex

part of any intellectual operation, is defined as an important cognitive process that requires the integration and control of a series of basic and ordinary skills.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the intervention period

Method of measurement

SOC subtest of CANTAB

3

Description

Self-esteem: Self-esteem is the belief that a person has about her worth and importance.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the intervention period

Method of measurement

Using Cooper-Smith self-esteem inventory (SEI)

4

Description

Mental health is a fundamental and comprehensive factor in the health and life of every person. The World Health Organization (WHO) states:"Health means physical, mental and social well-being and not merely the absence of disease or disability".An important application of this definition is that mental health is more than just the absence of mental disorders or disabilities.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the

Method of measurement

Warwick-Edinburgh Mental Well-Being Scale

5

Description

meaningful activities are related to mental health and well-being

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the

Method of measurement

Engagement in Meaningful Activities Survey (EMAS)

6

Description

Recovery is not just the disappearance of symptoms, but also includes supporting the individual to live a meaningful life.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the

Method of measurement

Recovery Assessment Scale – Domains and Stages (RAS-DS)

7

Description

Basic psychological needs include autonomy, relatedness, and competence.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the

Method of measurement

Basic Needs Satisfaction in General Scale (BPNSG-S)

8

Description

A general mental health assessment is essential to assess the experience of psychiatric problems.

Timepoint

Before the start of the intervention (at the beginning of the study), after receiving the intervention, and three months after the end of the

Method of measurement

General Health Questionnaire (GHQ-12)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving conventional services (doctor, psychologist, and occupational therapist consultation), this group receives computerized cognitive rehabilitation 3 days a week (30 sessions in total). Using the CANTAB cognitive test set, computerized cognitive rehabilitation is performed in 45-minute sessions. This rehabilitation includes the practice of 4 subtests DMS, MTS, OTS, and PRM from CANTAB, which becomes more complex as time passes. For example, as the stage increases, the number of variables and response time changes, and it is expected that the accuracy and speed of the person's action will be affected accordingly. The purpose of DMS, MTS, and PRM exercises is to involve several cognitive processes related to memory and visual-spatial attention. OTS targets planning, problem-solving, and executive functions. All the people in this group are evaluated cognitively and psychologically before, immediately after, and two months after the interventions, in order to evaluate the effectiveness of the intervention in improving the cognitive and mental health of people.

Category

Rehabilitation

2

Description

Control group: Participants in this group will receive

treatment as usual such as psychiatrist, psychologist and occupational therapist visits for 30 sessions of 45 minutes (3 sessions per week).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Elahe Fathi Azar

Street address

Shahid Rastegar Blv., Shahre Rey, Tehran

City

Tehran

Province

Tehran

Postal code

18664

Phone

+98 21 3340 1226

Email

Elahe_fathi91@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hooshang Mirzaei

Street address

university of social welfare and rehabilitation sciences, Daneshjo Blv. Evin

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Email

Elahe_fathi91@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

50

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Hooshang Mirzaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

university of social welfare and rehabilitation sciences

City

تهران

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Email

Elahe_fathi91@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hooshang Mirzaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

university of social welfare and rehabilitation sciences

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Email

Elahe_fathi91@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Elahe Fathi Azar

Position
MSc

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
No.51, Molavi Alley, Abomoslem Ave., Shahak masoudiye, Afsariyeh Junction.

City
Tehran

Province
Tehran

Postal code
1788917341

Phone
+98 21 3386 1366

Fax

Email
elahe_fathi91@yahoo.com

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
Undecided - It is not yet known if there will be 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
Sending all of the data, if the members of the research team agree, a decision will be made based on the applicant's goal.

When the data will become available and for how long
The second half of 1402

To whom data/document is available
First author and corresponding author

Under which criteria data/document could be used
If the members of the research team agree, a decision will be made based on the applicant's goal.

From where data/document is obtainable
Elahe Fathi Azar

What processes are involved for a request to access data/document
Sending an email to Elahe Fathi Azar

Comments