

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

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##### 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**

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**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**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**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

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University of social welfare and rehabilitation sciences

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## 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**

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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**

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**