

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of cognitive rehabilitation based on computer tasks on cognitive dysfunction in patients with Schizophrenia

Protocol summary

Study aim

Effects of cognitive rehabilitation based on computer tasks on cognitive dysfunction in patients with Schizophrenia

Design

Clinical trial with control and parallel groups, randomized and not blinded

Settings and conduct

This study will be performed on 30 patients with schizophrenia referring to Ibn-e-Sina psychiatric Hospital. Patients are randomly assigned one of the two groups of control and intervention. Patients in both groups are prescribed medication and attend psychological skills training session for schizophrenia for 8 weeks. In the intervention group, in addition to medication, patients receive cognitive rehabilitation based on computer tasks. Before and after the interventions in both groups, cognitive assessment tests are performed and the results and the effectiveness of each group are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with schizophrenia between 18 and 60 years; patients must be deficient in several cognitive domains; the patient has no other problem or psychiatric disorder; the patient does not have a record of proven mental disability; the patient has not received Electroconvulsive therapy in the past year; the patient has the ability to read and write. Exclusion criteria: pregnancy and breastfeeding

Intervention groups

In both groups, patients in remission and stabilization phase of the disease receive the medication prescribed by the psychiatrist for eight weeks. Also, psychological skills training for schizophrenia will be done twice a week for 10 minutes in both groups. In the intervention group, cognitive exercises using Captain's Log computer software will be done twice a week for 20 minutes each session and in the control group, 20-minute videos containing images of landscapes will be played each

session.

Main outcome variables

Cognitive functions, memory, attention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N36**

Registration date: **2021-05-05, 1400/02/15**

Registration timing: **prospective**

Last update: **2021-05-05, 1400/02/15**

Update count: **0**

Registration date

2021-05-05, 1400/02/15

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

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+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of cognitive rehabilitation based on computer tasks on cognitive dysfunction in patients with Schizophrenia

Public title
Effects of computer tasks on improvement of cognitive functions in schizophrenic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with schizophrenia between 18 and 60 years
 Patients must be deficient in several cognitive domains.
 The patient has no other problem or psychiatric disorder.
 The patient does not have a record of proven mental disability
 The patient has not received Electroconvulsive therapy in the past year. The patient has the ability to read and write.
Exclusion criteria:
 Pregnancy and breastfeeding.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The envelopes will be prepared by one of the members of the research team and the random numbers generated by the "www.randomization.com" website will be printed and placed in each envelope. The envelopes are sealed and their contents are not visible from outside. At first, purpose of the study is explained for each participants and after filling out the consent form, each participant selects an envelope and opens it and based on its content, the participant will be placed in either control or intervention group.

Blinding (investigator's opinion)
Not 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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.555

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Cognitive functions

Timepoint

At the beginning of the intervention, week 4, week 8 (end on intervention), week 12 & week 20 after the intervention

Method of measurement

Stroop test

2

Description

Memory

Timepoint

At the beginning of the intervention, week 4, week 8 (end on intervention), week 12 & week 20 after the intervention

Method of measurement

Rey auditory verbal learning test and Rey-Osterrieth complex figure test

3

Description

Attention

Timepoint

At the beginning of the intervention, week 4, week 8 (end on intervention), week 12 & week 20 after the intervention

Method of measurement

Digit span test

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: In this group, patients who are in remission and stabilization phase of the disease receive the medication prescribed by the psychiatrist for eight weeks. Also, psycho-educational programs and classes for schizophrenic patients will be held twice a week for 8 weeks. Each session lasts 10 minutes and each week, one of the 8 topics of "introduction to schizophrenia, causes of the disease, treatment, ways to deal with the recurrence of the disease, dealing with hallucinations, problem-solving, cognitive improvement and leisure time" are explained. In addition, a 20-minute video containing images of landscapes will be played each session.

Category

Treatment - Drugs

2**Description**

Intervention group: In this group, patients who are in remission and stabilization phase of the disease receive the medication prescribed by the psychiatrist for eight weeks. Also, psycho-educational programs and classes for schizophrenic patients will be held twice a week for 8 weeks. Each session lasts 10 minutes and each week, one of the 8 topics of "introduction to schizophrenia, causes of the disease, treatment, ways to deal with the recurrence of the disease, dealing with hallucinations, problem-solving, cognitive improvement and leisure time" are explained. In addition, cognitive exercises using Captain's Log computer software will be done twice a week for 20 minutes each session to develop cognitive skills. This software includes training on attention skills using "Drum Signals" and "Musical Pairs" tests and memory skills using "What's Next" and "Match Play" tests.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ibn-e-Sina psychiatric Hospital

Full name of responsible person

Dr. Farhad Faridhoseini

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,boo Ali square

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2**Recruitment center****Name of recruitment center**

Hejazi Psychiatric Hospital

Full name of responsible person

Dr. Farhad Faridhoseini

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Hejazi psychiatric hospital, after Majlesi crossroad, Mashhad, Ebadi Avenue

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Bahareh Hakimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Farhad Faridhoseini

Position

Assistant Pofessor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Farhad Faridhoseini

Position

Assistant Pofessor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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