

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effects of cognitive rehabilitation based on computer tasks on cognitive dysfunction in remitted patients with bipolar disorder

Protocol summary

Study aim

The effectiveness of computer-based cognitive rehabilitation on the improvement of cognitive deficits in patients with bipolar disorder

Design

The clinical trial has three intervention control groups, three groups of thirty are prepared for randomization with the help of Randomize.com, with parallel groups, double-blind, randomized,

Settings and conduct

Clinic of Ibn Sina Hospital, Mashhad. Assessment tests are taken to enter the study

Participants/Inclusion and exclusion criteria

People with bipolar disorder, ranging in age from 18 to 40, both men and women. The patient has no other psychiatric disorder or problem. The patient has an intelligence score above 90. The patient has not received shock therapy in the past year. Exclusion criteria: The emergence of serious physiological or psychiatric problems. Cancel the continuation of the plan. Pregnancy and lactation. Creating thoughts of active suicide or episodes of psychotic depression while studying

Intervention groups

After the psychiatric specialist's approval to diagnose the patient in the euthymic phase, and conduct cognitive-behavioral assessment tests to confirm the entry criteria, the patients are placed in 3 groups of 30 people using available sampling and after obtaining consent. In the control group, only drug treatment is performed. In addition to drug treatment, the other two groups are treated with computer-based cognitive rehabilitation. Before and after interventions in all three groups, cognitive evaluation tests were performed, the results and effectiveness of each are compared. Also, quantitative electroencephalography (qEEG) will be performed in an improved form of EEG before and after treatment. In order to compare and evaluate QEEG and Cognitive Test series, 30 matched healthy people will also participate.

Main outcome variables

Patients' cognitive deficits

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N59**

Registration date: **2022-10-15, 1401/07/23**

Registration timing: **prospective**

Last update: **2022-10-15, 1401/07/23**

Update count: **0**

Registration date

2022-10-15, 1401/07/23

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

2022-10-23, 1401/08/01

Expected recruitment end date

2023-01-21, 1401/11/01

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 remitted patients with bipolar disorder

Public title

Effects of cognitive rehabilitation on the improvement of cognitive deficits

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with bipolar disorder Age range 18 to 40 years Of both sexes The patient has no other psychiatric disorder or problem The patient has an intelligence score above 90 The patient has not received shock therapy in the past year

Exclusion criteria:

Emergence of serious physiological or psychiatric problems that are effective in the intervention. Cancel the continuation of the plan Creating thoughts of active suicide or episodes of psychotic depression while studying

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

This is how random numbers are prepared with the help of Randomaize.com. As per the sample size of the research, a number of envelopes with envelopes Aluminum (in the sense of the lack of clarity of the contents of the envelopes), preparation and each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to preserve the random sequence, on the outer surface of the envelopes. Numbering is done in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes is opened in order, the envelopes containing the odd number of the control group and the envelopes containing the even number of the 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 Science

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9117699199

Approval date

2019-05-23, 1398/03/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.032

Health conditions studied**1****Description of health condition studied**

Bipolar disorder

ICD-10 code

F30.3

ICD-10 code description

Manic episode in partial remission

Primary outcomes**1****Description**

Patients' cognitive deficits

Timepoint

One week before and one week after interventions

Method of measurement

Cognitive assessment tests

Secondary outcomes

empty

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

Intervention group: they are subjected to computer-

based cognitive rehabilitation therapy. Exercises with computer programs are scheduled for an average of 2 to 3 months. The rehabilitation sessions are 2 months or eight weeks, two sessions a week and each session is 60 minutes with Captain Lagast software. Psychological and compensatory training programs are involved in these interventions. Before and after the interventions, cognitive evaluation tests will be performed.

Category

Treatment - Other

2**Description**

Control group: In the control group, only drug treatment is done. Cognitive evaluation tests will be done before and after the interventions.

Category

Treatment - Other

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

Ibn Sina Psychiatric Hospital

Full name of responsible person

Ali Talaei

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Mashhad, Bu Ali Square, Ibn Sina Psychiatric Hospital

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

Mashhad University of Medical Sciences

Full name of responsible person

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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

ali Talaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

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Person responsible for updating data

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Name of organization / entity

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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

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

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

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