

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of a short term computer-based cognitive remediation program on cognitive performance in people with bipolar disorder: A randomized controlled study

Protocol summary

Study aim

Efficacy of a short term computer-based cognitive remediation program on cognitive performance in people with bipolar disorder

Design

Controlled randomized clinical trial

Settings and conduct

In this study, target population includes people with bipolar mood disorder and study population is a subset of them, who are in complete or partial remission and receive services from Roozbeh Hospital. Study sample will be chosen from this population based on inclusion and exclusion criteria. Subjects will randomly be assigned to intervention or control group. Cognitive remediation which is going to be done in day center of Roozbeh Hospital using COGPACK software, is the intervention in order to improve different domains of cognition. Cognitive state will be assessed before and after intervention to assess its efficacy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.People with bipolar mood disorder in partial or complete remission 2.Aged 18 through 55 years 3.Education level higher than 8th grade 4.IQ level above 70 Exclusion criteria: 1.A history of substance abuse (except nicotine & caffeine) within the past month 2.A history of electroconvulsive therapy within the six weeks prior to the study 3.A history of head trauma followed by loss of consciousness 4.Comorbidity of a major neurological disorder 5.Acute episode of the disease which requires immediate intervention

Intervention groups

The intervention group, in addition to treatment as usual (TAU) which is the 1st intervention, will receive second intervention which consists of twelve 90-minute personal sessions of cognitive remediation, using COGPACK software tasks to improve cognitive status.The control group will receive only TAU (1st intervention). TAU

includes medication treatment and psychoeducation.

Main outcome variables

Attention, memory, executive function, quality of life, function, clinical impression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200213046485N1**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **prospective**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

mehrnoosh vahidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

vahidi-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-02, 1399/02/13

Expected recruitment end date

2021-05-03, 1400/02/13

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of a short term computer-based cognitive remediation program on cognitive performance in people with bipolar disorder: A randomized controlled study

Public title
Cognitive remediation in people with bipolar disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 people with bipolar disorder in partial or complete remission (Young Mania Rating Scale (Y-MRS) score less than 8 and Hamiltone Depression Rating Scale (HDRS) score less than 8) Education level higher than 8th grade IQ level above 70 based on Wechsler intelligence scale
Exclusion criteria:
 A history of substance abuse (except nicotine and caffeine) within the past month A history of Electroconvulsive therapy within the six weeks prior to the study A history of head trauma followed by loss of consciousness Comorbidity of major neurological disorders including epilepsy, Parkinson's disease, dementia etc. Acute episode or active phase of the disease which requires immediate intervention

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be randomly assigned into intervention or control group via Blocked randomization method (Permuted block randomization). To create a randomized sequence the following website will be used: <http://www.sealedenvelope.com>. To conceal allocations, a randomized sequence is provided only for an specific individual. Then based on the sequence of subjects entering the program, the researcher asks that individual about the group in which each subject must be included. For every intervention according to the randomized sequence a number is assigned to each case.

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 School of Medicine, Tehran University of Medical Sciences

Street address

Roozbeh hospital, South Kargar Ave., Tehran

City

Tehran

Province

Tehran

Postal code

13337159140

Approval date

2020-02-10, 1398/11/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.883

Health conditions studied

1

Description of health condition studied

Bipolar mood disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Executive function score

Timepoint

before and after intervention

Method of measurement

Stockings of Cambridge test of CANTAB battery tests

2

Description

Visual memory score

Timepoint

before and after intervention

Method of measurement

Delayed matching to sample test of CANTAB battery tests

3

Description

Spatial working Memory score

Timepoint

before and after study

Method of measurement

Spatial working memory test of CANTAB battery tests

4

Description

Attention score no.1

Timepoint

before and after study

Method of measurement

Choice Reaction time test of CANTAB battery tests

5

Description

Attention score no.2

Timepoint

Before and after intervention

Method of measurement

Rapid visual information processing test of CANTAB battery tests

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before and after intervention

Method of measurement

Michalak Quality of Life in Bipolar Disorder scale

2

Description

Clinical global impression score

Timepoint

Before and after intervention

Method of measurement

Clinical global impression scale

3

Description

Global function score

Timepoint

before and after intervention

Method of measurement

Global Assessment of Functioning scale

4

Description

Hamilton depression rating scale score

Timepoint

before and after intervention

Method of measurement

Hamilton depression rating scale

5

Description

Young mania rating scale score

Timepoint

before and after intervention

Method of measurement

Young mania rating scale

Intervention groups

1

Description

Intervention group: In the present study, the intervention group, in addition to usual standard treatment, will receive the intervention which consists of 12 personal sessions of ninety-minute computer-based training for cognitive remediation, twice or three times a week, using the Cogpack software. Cogpack is a software composed of many exercises and tasks for improvement of different domains of cognition, like attention, memory, language, planning, etc. In this study we aim to use some of these exercises to improve attention, memory and executive function. All of the sessions are going to be conducted by an occupational therapist in day center of Roozbeh Hospital. Usual standard treatment will include medication treatment and patient and family psychoeducation.

Category

Treatment - Other

2

Description

Control group: The control group will only receive usual standard treatment including medication treatment and patient and family psychoeducation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Mehrnoosh Vahidi

Street address

Roozbeh hospital, South Kargar Ave.

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 2222

Email

mehrnoosh.vahidi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahre Mirsepasi

Street address

Roozbeh hospital, South Kargar Ave., Tehran

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9151

Email

mirsepassizahra@gmail.com

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

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**

Tehran University of Medical Sciences

Full name of responsible person

Mehrnoosh vahidi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital, South Kargar Ave.

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 2222

Email

mehrnoosh.vahidi@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepasi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital, South Kargar Ave.

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 2222

Email

z-mirsepassi@sina.tums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mehrnoosh Vahidi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh hospital, South Kargar Ave.

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 2222

Email

mehrnoosh.vahidi@gmail.com

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