

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of dialectical behavioral therapy on executive function, affective control and severity of symptoms in patients with bipolar disorder type I.

Protocol summary

Study aim

Determine the effectiveness of dialectical behavioral therapy on executive function, emotional control and severity of symptoms in patients with bipolar disorder type I.

Design

This study is a randomized controlled clinical trial with 50 patients randomly divided into two groups of 25.

Settings and conduct

After obtaining informed consent, patients who are referred to Khorshid Hospital and are diagnosed to be affected by bipolar disorder by psychiatrist and are eligible to enter the study will be included. Before the start of treatment, all patients will be screened, and then the intervention group will participate in psychotherapy sessions. After treatment, all the patients will be subjected to do a post-test to compare their results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being in the maintenance phase of bipolar I; being at the age of 20 to 45 years; education level of at least grade 3 of guidance school. exclusion criteria: personality disorders, using alcohol and drugs , organic problems in patients, receiving other psychiatric interventions during previous 6 months , using simultaneous psychotherapy and having psychotic symptoms.

Intervention groups

The intervention group will receive dialectical behavioral therapy during 12 sessions (once a week), which will be held by psychiatrists and psychologists, and the control group won't receive any intervention.

Main outcome variables

The severity of the symptoms of depression and mania, Executive function score, Affective control score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040974N1**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-19, 1397/09/28**

Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Fatemeh Zargar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

f.zargar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-01-04, 1397/10/14

Actual recruitment start date

2018-10-06, 1397/07/14

Actual recruitment end date

2019-03-05, 1397/12/14

Trial completion date

2019-05-04, 1398/02/14

Scientific title

Effectiveness of dialectical behavioral therapy on executive function, affective control and severity of symptoms in patients with bipolar disorder type I.

Public title

Effectiveness of dialectical behavioral therapy in the treatment of patients with bipolar disorder type I.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with bipolar type I, which are in the phase of maintenance Being at the age of 20 to 45 years old
Minimum 8 classes education

Exclusion criteria:

Having a simultaneous personality disorder Drinking alcohol and drug use Physical problems such as seizure in patients Receive any other psychotherapy, simultaneously or during last 6 months The presence of psychotic symptoms Presence a concurrent course of mania in patients

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible subjects are randomly assigned to either intervention or control group through stratified block randomization.

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 Isfahan University of Medical Sciences

Street address

Khorshid Hospital, Hashtbehesht Ave, Corner of the

Ostandari's Street

City

Isfahan

Province

Isfahan

Postal code

8199888945

Approval date

2018-05-08, 1397/02/18

Ethics committee reference number

IR.MUI.MED.REC.1397.045

Health conditions studied

1

Description of health condition studied

bipolar disorder type I

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

depression score

Timepoint

At the beginning of study(before the intervention begins) and after the intervention(3 months later)

Method of measurement

Beck Depression Inventory

2

Description

Executive function score

Timepoint

At the beginning of study(before the intervention begins) and after the intervention(3 months later)

Method of measurement

Color Trails Test

3

Description

Affective control score

Timepoint

At the beginning of study(before the intervention begins) and after the intervention(3 months later)

Method of measurement

Affective Control Scale

4

Description

The severity of Young mania

Timepoint

At the beginning of study(before the intervention begins) and after the intervention(3 months later)

Method of measurement

Young Mania Inventory

Secondary outcomes

empty

Intervention groups1**Description**

Intervention group: The intervention group will receive dialectical behavioral therapy during 12 sessions (once a week), which will be held by psychiatrists and psychologists.

Category

Behavior

2**Description**

Control group: The control group won't receive any intervention.

Category

Behavior

Recruitment centers1**Recruitment center****Name of recruitment center**

Khorshid hospital

Full name of responsible person

Naimeh Haghshenas

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No. 8, intersection of Hashtbehesht Street, Ostandari Avenue

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Doctor Mansour Siavash

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https://mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Naimeh Haghshenas

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Web page address**Person responsible for scientific**

inquiries

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Name of organization / entity

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available