

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effectiveness of dialectical behavior therapy on executive function and emotion regulation in bipolar spectrum disorders patients

#### Protocol summary

##### Summary

Objectives: Bipolar Disorder (BD) is one of the most common psychological disorders. Considering to the role of executive function and emotion regulation in psychological disorders such as bipolar, this study aimed to assess the effectiveness of dialectical behavior therapy (main variable) on executive function and emotion regulation (dependent variables) among referred patients to Kargarnejad hospital in Kashan city. Main variable: Dialectical behavior therapy, Dependent variables: executive function and emotion regulation. Design: This clinical trial designed as pre-test, post-test and three month follow-up. Participants: The population of this clinical trial including all bipolar patients who had referred to the Kashan Kargarnejad hospital from April to January 2016 and were selected by available sampling method. The inclusion criteria were receiving Bipolar diagnosis in Yang Mania Rating Scale (YMRS) and Clinical Interview and the exclusion criteria included another psychotherapy, mania and psychotic episode and another psychiatry disorders during this project. Setting and conduct: 50 participants were divided randomly to experimental and control group, equally. The tools of this study were Yang Mania Rating Scale (YMRS), Difficulties of Emotion Regulation Scale (DERS), Beck Depression Inventory-II (BDI-II), Wisconsin Card Sorting Task (WCST) and Tower of London Task (TOL). Interventions: Dialectical behavior therapy in 12 group sessions, once a week.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017031233023N1**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-17, 1396/08/26

##### Registrant information

###### Name

Behrooz Afshari

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5558 1833

###### Email address

behrooz.afshari71@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research Kashan University of Medical Sciences and Health Services

##### Expected recruitment start date

2017-03-15, 1395/12/25

##### Expected recruitment end date

2017-09-16, 1396/06/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of dialectical behavior therapy on executive function and emotion regulation in bipolar spectrum disorders patients

##### Public title

The effectiveness of dialectical behavior therapy on executive function and emotion regulation

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Having an age of 18 til 45 years; Having a degree in secondary education or higher; Bipolar spectrum disorders based on DSM-5 diagnostic criteria. exclusion criteria: Entrance to mania phase; Having a history of psychotic disorders; Receiving psychotherapy during past six months; Unwillingness to continue participating in the study; Failing to participate in more than two sessions of the study intervention; Had a history of substance abuse disorders.

## Age

From **18 years** old to **45 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

From all participation's that meets inclusion criteria, 50 people randomly enter the study and then 25 participants for each group selected by Random assignment will be done, that by the use of computer-generated random numbers.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan university of medical science

##### Street address

Ethics committee of kashan university of medical science, Qotb ravandi blv, Kashan

##### City

Kashan

##### Postal code

8713781147

#### Approval date

2017-02-08, 1395/11/20

#### Ethics committee reference number

IR.KAUMS.REC.1395.129

## Health conditions studied

### 1

#### Description of health condition studied

Bipolar disorder

#### ICD-10 code

F31

#### ICD-10 code description

Bipolar affective disorder

## Primary outcomes

### 1

#### Description

Emotion regulation

#### Timepoint

Before intervention, After intervention, three month after intervention

#### Method of measurement

Difficulties in emotion regulation scale

### 2

#### Description

executive function

#### Timepoint

Before intervention, After intervention, three month after intervention

#### Method of measurement

wisconsin card sorting task and tower of london task

### 3

#### Description

planning

#### Timepoint

Before intervention, After intervention, three month after intervention

#### Method of measurement

Tower of london task

### 4

#### Description

problem-solving

#### Timepoint

Before intervention, After intervention, three month after intervention

#### Method of measurement

wisconsin card sorting task

### 5

#### Description

cognitive flexibility

#### Timepoint

Before intervention, After intervention, three month after intervention

#### Method of measurement

wisconsin card sorting task

## Secondary outcomes

1

### Description

depression

### Timepoint

before of intervention, after of information, three month after intervention

### Method of measurement

Beck depression inventory

## Intervention groups

1

### Description

Intervention group: This treatment is during the twelve 90-minute sessions for three months.

### Category

Behavior

2

### Description

Control group : control group include of medication depend on psychiatrist diagnosis .

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Kargarnejad psychiatric hospital

#### Full name of responsible person

Ghoreishi PHD

#### Street address

kashan university of medical science, ghotbe ravandi blv, Kashan, Esfahan

#### City

Kashan

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Research Deputy of kashan university of medical science

#### Full name of responsible person

Gholamali Hamidi

#### Street address

kashan university of medical science, ghotbe ravandi blv, Kashan

#### City

Kashan

#### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Research Deputy of kashan university of medical science

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Kashan university of medical science

#### Full name of responsible person

Behrooz afshari golshekanani

#### Position

MSc student of clinical psychology

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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blv, Kashan

**City**

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**Postal code**

8715988141

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*