

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

befor 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of kashan university of medical
science

Full name of responsible person

Gholamali Hamidi

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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

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

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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