

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effectiveness of Compassion-Focused Therapy on Treatment Outcome in Patients With Bipolar Disorder

Protocol summary

Study aim

The effectiveness of compassion-focused therapy on treatment outcome in patients with bipolar disorder

Design

A clinical trial with a control group, with parallel, randomized, phase 2 groups will be performed on 40 patients. The random block method is used.

Settings and conduct

A clinical trial with a control group, with parallel, randomized, phase 2 groups will be performed on 60 patients. The random block method is used. Intervention is a method for people with psychotic disorder to receive 10 sessions of psychotherapy. This study will be performed on patients admitted to Golestan Hospital in Ahvaz. Blinding is not applicable to this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 50 years, Diagnostic Criteria - SCID-5-CV for type 1 and 2 bipolar disorder, Not in the acute phase of the disease, Have a regular medication regimen, Score less than -17 on the Young Mania Test Exclusion criteria: History of brain injury, dementia, and specific neurological disease, Not using any addictive drugs, Severe physical illnesses such as cancer

Intervention groups

Intervention group: in addition to standard drug treatment, receive treatment focused on compassion. Control group: This group will only receive world standard medical treatment and will not receive compassion treatment.

Main outcome variables

Compassion for yourself

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053298N1**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name

Forouzan Behrouzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

abdi.l@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Compassion-Focused Therapy on Treatment Outcome in Patients With Bipolar Disorder

Public title

The effectiveness of compassion-focused therapy on treatment outcome in patients with bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 50 years Diagnostic Criteria - SCID-5-CV for type 1 and 2 bipolar disorder Not in the acute phase of the disease Have a regular medication regimen Score less than -17 on the Young Mania Test

Exclusion criteria:

History of brain injury, dementia and specific neurological disease Not using any addictive drugs Severe physical illnesses such as cancer

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **20**

The sample size for each group will be 20 people.

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning the intervention to individuals is randomly divided into two groups of intervention and control by the method of random permutation blocks with a size of 4 random blocks (using the table related to random permutations). The randomization list is prepared by a statistician. In this method, group A is related to the intervention and group B is considered as the control and is classified into 4 blocks including AABB, ABAB, ABBA, BBAA, BABA, BAAB. To hide the assignment of individuals in the intervention and control groups, 20 even four-digit numbers will be selected as the codes of the participants in the control group and 20 four-digit individuals as the codes of the participants in the intervention group will be selected from a random number table. Then, the numbers of intervention and control groups are placed in sealed envelopes, respectively, and are randomly delivered by one of the personnel to the eligible individuals participating in the study. Random allocation software is also used for randomization. The site <https://www.randomizer.org/> is used for randomization. In the empty fields, the total number of random numbers and the number of random numbers in each group, the range of numbers are entered and the output is received as an excel.

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 Ahvaz Jundishapur University of of Medical Sciences

Street address

Ahvaz Jundishapur University of of Medical Sciences, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Approval date

2021-11-09, 1400/08/18

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.120

Health conditions studied

1

Description of health condition studied

The effectiveness of compassion-focused therapy on treatment outcome in patients with bipolar disorder

ICD-10 code

F31.7

ICD-10 code description

Bipolar disorder, currently in remission

Primary outcomes

1

Description

Self-compassion

Timepoint

Before, after and two months after treatment

Method of measurement

Demographic Characteristics Questionnaire and Structured Clinical Interview, Distress on Bipolar Patients-Short, Self-Critical Rumination Scale

2

Description

external and internal shame

Timepoint

Before, after and two months after treatment

Method of measurement

Shame Scale

3

Description

self-criticism

Timepoint

Before, after and two months after treatment

Method of measurement

Self-Critical Rumination Scale

4

Description

psychological distress

Timepoint

Before, after and two months after treatment

Method of measurement

Distress on Bipolar Patients-Short

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the patients are selected, based on the treatment group, the patients are treated with compassion-focused treatment and after the treatment, the information is re-evaluated. The compassion-focused treatment protocol will be implemented in accordance with the content of the treatment in 10 sessions. The basic principles of compassion-focused therapy point out that external soothing thoughts, factors, images, and behaviors must be internalized, and in this case, the human mind, as it responds to external factors, in the face of this Relax inside. Sessions 1 and 2: Evaluation based on compassion-focused treatment approach, Session 3: Understanding compassion, Session 4: Preparing clients to improve compassionate attention and concentration, Session 5: Illustration of daily compassion, Session 6: Examining the role of self-criticism and shame using the metaphor of two teachers, introducing compassionate self, Session 7: Introducing multiple selves references, exercising multiple selves, Session 8: Compassionate thinking and argument and compassionate behavior, Session 9: Balancing thinking and mind in a compassionate way, Session 10: Writing a letter of compassion jects in the experimental group individually. That is, treatment sessions will be conducted individually and in the presence of the therapist and the patient. That is, 20 people will see the experimental group individually, one session per week, and the questionnaire will be filled out before the first session, after the last session, and two months after the last session, and the results will be analyzed as a group

Category

Treatment - Other

2

Description

Control group: After the patients are selected, based on the treatment group, the patients are treated with world standard medicine and after the treatment, the information is re-evaluated. In this group, no compassion treatment is performed. Medication varies according to the patient's condition and the doctor's prescription.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Forouzan Behrouzian

Street address

Ahvaz Golestan Hospital ,Golestan Blvd,Ahvaz

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4693955599

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behrouzian-f@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Forouzan Behrouzian

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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Forouzan Behrouzian
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Shima Nemati jole karan
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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