Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of cognitive-behavioral therapy on the quality of life and psychological capital of patients with bipolar disorder

Protocol summary

Study aim
Determining the effectiveness of cognitive-behavioral therapy on the quality of life and psychological capital of patients with bipolar disorder.

Design
A randomized, controlled, and parallel-group clinical trial on 30 individuals with bipolar disorder used a simple randomization method to randomize participants.

Settings and conduct
The study, conducted at the Empathy Psychology Clinic in Semnan, involves people with bipolar disorder. Participants are randomly assigned to two groups: an experimental group that receives cognitive-behavioral therapy (CBT) and a control group that receives only usual care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of bipolar disorder by a specialist, age between 20 and 50, ability to attend meetings and complete questionnaires, fluency in Persian, and verbal communication. Exclusion criteria: Severe psychiatric disorders (such as schizophrenia or severe personality disorders), severe drug or alcohol dependence, history of suicide attempt in the past six months, and debilitating physical illness that prevents attendance at meetings.

Intervention groups
In this study, the experimental group will participate in 8 90-minute sessions over a period of one month, which are designed based on cognitive-behavioral therapy (CBT). The content of these sessions includes identifying and modifying dysfunctional thoughts, teaching emotion regulation strategies, and strengthening psychological capital. The control group will receive only usual care and no specific therapeutic intervention will be provided to them.

Main outcome variables
Quality of life, psychological capital

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250223064825N1**
Registration date: **2025-03-29, 1404/01/09**
Registration timing: **prospective**

Last update: **2025-03-29, 1404/01/09**
Update count: **0**

Registration date
2025-03-29, 1404/01/09

Registrant information

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Name of organization / entity
Islamic Azad University, Semnan Branch

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-12, 1404/01/23

Expected recruitment end date
2025-05-13, 1404/02/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of cognitive-behavioral therapy on the quality of life and psychological capital of patients with bipolar disorder

Public title
The effectiveness of cognitive-behavioral therapy on the quality of life and psychological capital of patients with bipolar disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of bipolar disorder by a psychiatrist or clinical psychologist. Age range between 20 and 50 years. Ability to participate in therapy sessions, complete questionnaires, and benefit from psychotherapy interventions. Informed consent to participate in the research and the possibility of follow-up after the end of the intervention. Ability to communicate verbally and understand Persian.

Exclusion criteria:
Absence of concomitant psychiatric disorders (such as schizophrenia or severe personality disorders) that would prevent participation in the intervention. Having a substance use disorder or severe dependence on alcohol and drugs Having a history of suicide attempts in the past six months Receiving other similar psychological treatments at the same time (such as cognitive-behavioral therapy or other psychotherapeutic interventions) Having a debilitating physical illness that prevents you from attending therapy sessions Having severe cognitive disability or low IQ that prevents understanding and implementing therapeutic techniques

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 30 people will be randomly divided into two groups: intervention and control. For this purpose, a simple random assignment method will be used. First, each participant will be assigned a number. Then, these numbers will be entered into a random number generation software and based on the generated numbers, the people will be divided into two groups. People whose numbers are randomly assigned to the first group will be entered into the intervention group, and the rest will be assigned to the control group. To ensure the correct implementation of randomization and to prevent any type of bias, the allocation process will be carried out by an independent person who is not involved in the research. This randomization method ensures that each participant has an equal chance of being placed in one of the groups and that the balance in the number of people in each group is maintained.

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 Semnan Azad University

Street address
Islamic Azad University, University Town, Semnan

City
Semnan

Province
Semnan

Postal code
3513137111

Approval date
2024-12-30, 1403/10/10

Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.094

Health conditions studied

1

Description of health condition studied
Bipolar disorder

ICD-10 code
F31

ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
Quality of life

Timepoint
Before the start of the intervention and after completing 8 intervention sessions.

Method of measurement
World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)

2

Description

Psychological capital

Timepoint

Before the start of the intervention and after completing 8 intervention sessions.

Method of measurement

Luthans Psychological Capital Questionnaire (2007)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will undergo a cognitive-behavioral therapy (CBT) intervention, which will be held in 8 weekly 90-minute sessions. This intervention is designed to improve the quality of life and increase the psychological capital of patients with bipolar disorder. Initially, participants will be introduced to the basic concepts of cognitive-behavioral therapy, including the role of thoughts, feelings, and behaviors in everyday experiences. Then, techniques such as identifying and correcting irrational thoughts, cognitive restructuring, and evaluating evidence are taught to change negative thought patterns. In the following stages, participants will practice emotion regulation strategies, problem-solving skills, and effective coping methods to manage their emotional reactions in stressful situations. Also, techniques to increase hope, self-efficacy, and cognitive flexibility are provided to strengthen the psychological capital of patients. Finally, the skills learned to increase quality of life, create emotional balance, prevent relapse, and improve functioning in personal and social areas are reviewed and consolidated.

Category

Treatment - Other

2

Description

Control group: This group does not receive any intervention and serves only as a comparison. Individuals in this group continue with the usual, standard care they would normally receive and do not receive any cognitive-behavioral treatment or intervention during the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamdeli Psychology Clinic

Full name of responsible person

Ali Mohebi

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corner of Azadi 10, Azadi Street, Amirkabir Boulevard.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad University, Semnan branch

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

Islamic Azad University, Semnan Branch

Full name of responsible person

Kiana Emadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after identifying information is removed and ensured to be non-identifiable.
When the data will become available and for how long
Data can be made available one week after the results are published.
To whom data/document is available
Study data and documentation are available to relevant academic and industrial researchers after the request is submitted and approved.
Under which criteria data/document could be used
Data and documents can be used for the purpose of studying or conducting research, provided the source is cited.
From where data/document is obtainable
If you need data, please contact kiana.emadii@gmail.com.
What processes are involved for a request to access data/document
Upon receipt of the request, the principal investigator reviews it. If approved, the data will be sent to the requester within one week, along with a commitment to maintain the privacy of the participants, maintain confidentiality, and not publish the data without mentioning the principal investigator's name.
Comments