Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of cognitive behavioral therapy based on mindfulness on emotional regulation, metacognitive ability, and cognitive flexibility in patients with mood disorders .

Protocol summary

Study aim

Determining the Effectiveness of Mindfulness-Based Cognitive Therapy on Emotion Regulation, Metacognitive Ability, and Cognitive Flexibility in Patients with Mood Disorders

Design

randomized controlled clinical trial with a parallel-group, pre-test/post-test design conducted on 68 hospitalized patients with mood disorders. Participants are randomly allocated using simple randomization (via SPSS software version 22) into two equal groups . The intervention group receives MBCT in addition to routine treatment, while the control group receives routine treatment only. The outcome assessor and data analyst will be blinded to group allocation.

Settings and conduct

68 patients with mood disorders in the psychiatric ward of Farabi Hospital in Isfahan. The intervention group received 8 sessions of mindfulness-based cognitive-behavioral group therapy in addition to routine treatment, and the control group received only routine treatment.

Participants/Inclusion and exclusion criteria

Inclusion: Age 20-50, hospitalized at Farabi Hospital with mood disorder, literate, consenting, without severe mental illness/substance abuse. Exclusion: Condition exacerbation, withdrawal, or >3 absences.

Intervention groups

Intervention group: This group includes patients with mood disorders (depression or bipolar disorder) of moderate to severe intensity. They receive mindfulness-based cognitive-behavioral therapy (MBCT) in eight group sessions, each lasting 45 minutes. Control group: This group includes patients with mood disorders of moderate to severe intensity who receive only the routine psychiatric care provided by the hospital.

Main outcome variables

Emotion Regulation Cognitive Flexibility Metacognitive Ability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220725055553N1**
Registration date: **2026-02-17, 1404/11/28**
Registration timing: **prospective**

Last update: **2026-02-17, 1404/11/28**
Update count: **0**

Registration date

2026-02-17, 1404/11/28

Registrant information

Name

Fatemeh Lohrasebi Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral therapy based on mindfulness on emotional regulation, metacognitive ability, and cognitive flexibility in patients with mood disorders .

Public title

he Effect of Mindfulness-Based Cognitive Behavioral Therapy on Emotion and Cognitive Function in Patients with Mood Disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum literacy (ability to read and write)... Diagnosis of a mood disorder confirmed by a psychiatrist Hospitalization at Farabi Hospital Age range between 20 and 50 years. Written informed consent to participate in the study

Exclusion criteria:

Severe mental disorders (as diagnosed by a psychiatrist) impeding participation in patient education sessions. history of substance abuse.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **68**

More than 1 sample in each individual

Number of samples in each individual: **34**

Allocation will result in 34 participants in the intervention group and 34 in the control group.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple individual-level randomization will be used. After eligibility is confirmed and the baseline assessment is completed, each participant will be randomly assigned to either the intervention or control group. The random sequence will be generated by an independent statistician using SPSS software, and the allocation list will be kept confidential by the statistician. For allocation concealment, a central allocation method will be used: once the participant’s baseline information is fully recorded, the implementing researcher will contact the statistician to obtain the assigned group. Therefore, the implementer will have no prior knowledge of the participant’s group. Additionally, the person collecting the questionnaires will be blinded to the participants’ group assignments, and the data will be provided to the statistical analyst in a coded form (Groups 1 and 2) to ensure analyses are conducted without knowledge of the intervention type. The codes will only be revealed after the analysis is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

To ensure impartiality, data analysis will be conducted in a single-blind manner. Raw data, after group coding with neutral labels (e.g., Group 1 and Group 2) and without disclosure of the type of intervention, will be provided to the analyst. The analyst will perform all statistical tests based solely on these codes and will remain unaware of the allocation of each group to the intervention or control until the initial analysis is completed. This process prevents bias in the analysis.

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

Hezar Jarib Street, Isfahan University of Medical Sciences

City

Isfahan

Province

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Postal code

81746-73461

Approval date

2026-01-20, 1404/10/30

Ethics committee reference number

IR.MUI.NUREMA.REC.1404.159

Health conditions studied

1

Description of health condition studied

Bipolar affective disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Emotion regulation refers to an individual's ability to recognize, manage, and control their emotions in a way that responses are appropriate to the context, goals, and social situations. This skill includes identifying emotions, modulating their intensity and duration, and selecting suitable strategies to cope with negative emotions or enhance positive ones. Emotion regulation plays a key role in mental health, decision-making, cognitive flexibility, and interpersonal relationships.

Timepoint

pre and post intervention

Method of measurement

Gross & John's Cognitive Emotion Regulation Questionnaire

2

Description

Metacognitive ability refers to an individual's skill in awareness, monitoring, and control of their own cognitive processes. This ability includes recognizing one's thoughts and beliefs, understanding cognitive strengths and limitations, and managing strategies for problem-solving and decision-making. Metacognition plays a key role in learning, cognitive flexibility, self-regulation, and mental health enhancement.

Timepoint

pre and post intervention

Method of measurement

Wells' Metacognitions Questionnaire

3

Description

Cognitive flexibility refers to an individual's ability to adapt their thoughts, attitudes, and behaviors according to new or unexpected situations. This skill includes the capacity to view problems from different perspectives, select alternative strategies, and adjust to environmental changes, playing a key role in problem-solving, decision-making, and stress management.

Timepoint

pre and post intervention

Method of measurement

Dennis & Vander Wal's Cognitive Flexibility Scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention for the experimental group consists of a structured psychological protocol that combines cognitive-behavioral therapy (CBT) and mindfulness exercises (Mindfulness-Based Cognitive Therapy, MBCT). The primary goal of this intervention is to help patients with mood disorders (depression or bipolar disorder) increase awareness of their present-moment thoughts and feelings without judgment or automatic reactions. The intervention is delivered in the form of 8 in-person group sessions, each lasting 45 minutes, following the standard MBCT protocol, with sessions held three times per week. The total duration of the intervention is approximately three weeks. Sessions are led by a clinical psychologist trained in MBCT and include theoretical instruction, practical exercises, group discussions, and homework assignments. The session content includes the following:• Introduction to the concept of mindfulness and its importance in mood and emotion regulation• Body scan exercises and breathing practices• Identifying and observing thoughts and feelings as transient phenomena• Mindfulness practice in daily activities• Developing a non-judgmental attitude and acceptance without automatic reaction special equipment is required for the intervention other than a group therapy room, chairs, and the ability to play audio files (for some guided meditations). It should be noted that all participants are simultaneously receiving routine psychiatric care at the hospital, and the MBCT intervention is provided as an adjunctive therapy.

Category

Lifestyle

2

Description

Control Group: Participants in this group do not receive any structured mindfulness-based cognitive-behavioral therapy sessions. Their intervention consists of standard routine psychiatric care provided by the hospital. This care includes regular follow-up by the treating psychiatrist for medication management, administration of prescribed psychiatric medications (with names, doses, and frequency according to the physician's prescription), and routine nursing and environmental care on the ward. No educational programs, structured group therapy sessions, or other specific psychological interventions will be provided to this group during the study period. Like other hospitalized patients, members of this group receive only medical supervision and treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital, Isfahan University of Medical Sciences, Isfahan, Iran

Full name of responsible person

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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
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
Fatemeh Lohrasebi Nejad

Position
Assistant professor

Latest degree
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Nursery

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Person responsible for updating data

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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
Key data include: scores from the Cognitive Emotion Regulation Questionnaire (CERQ), metacognitive ability (Wells Questionnaire), cognitive flexibility (Dennis & Vanderwal), and baseline/demographic data such as age, sex, marital status, and hospitalization history.

When the data will become available and for how long
The access to de-identified participant data and related documents will begin **6 months after the publication of the study results** and will remain available for **5 years**.

To whom data/document is available
Academic Researchers

Under which criteria data/document could be used
The de-identified participant data and related documents may be used only for scientific research purposes and secondary analyses related to the study topic. Requests for access to the data must be submitted by independent researchers with a clear research proposal and, upon approval by the ethics committee or the responsible research team, the data will be provided to the requester. Any publication of secondary results must cite the original study, and commercial use of the data is not permitted. Additionally, the requester is required to maintain data confidentiality and must refrain from any attempt to identify study participants.

From where data/document is obtainable
Fatemeh Lohrasebi Flohrasebi@nm.mui.ac.ir

What processes are involved for a request to access data/document
After submitting a request for access to the data and documents along with a research proposal, the request will be reviewed by the study team and the ethics committee. Once approved, the de-identified data and documents will be provided to the requester through a secure method. This process typically takes 4 to 8 weeks.

Comments