Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness-Based Cognitive Therapy on Depression, Dysfunctional Beliefs, and Self-Esteem in Mothers of Children with Intellectual Disabilities

Protocol summary

Study aim
Investigating the Effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) on Depression, Dysfunctional Beliefs, and Self-Esteem in Mothers of Children with Intellectual Disabilities

Design
This study is applied in terms of purpose and uses a pretest–posttest design with a non-randomized control group.

Settings and conduct
The study will be conducted at a rehabilitation center in Mashhad. Twenty-four mothers will be assigned to experimental and control groups. Both groups will complete the study questionnaires before and after the intervention, and the experimental group will receive MBCT.

Participants/Inclusion and exclusion criteria
Inclusion Criteria 1. Having a child with an intellectual disability with a confirmed diagnosis provided by a specialist physician or rehabilitation center. 2. Having at least basic literacy skills (reading and writing) to understand the session materials and complete the research instruments. 3. No severe psychiatric disorders, based on self-report and treatment history. 4. Not receiving other similar psychological interventions or specific pharmacological treatment for depression concurrently during the study. ### Exclusion Criteria 1. Absence from more than two intervention sessions. 2. Failure to cooperate in completing the questionnaires or withdrawal from participation at any stage of the study. 3. The occurrence of new medical or psychological conditions that interfere with the intervention process. 4. Diagnosis of a severe psychiatric disorder during the study, based on clinical assessment and medical records.

Intervention groups
Mothers who receive Mindfulness-Based Cognitive Therapy (MBCT)

Main outcome variables
Depression, Dysfunctional Beliefs, Self-Esteem

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250523065853N6**
Registration date: **2026-09-07, 1405/06/16**
Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**
Update count: **0**

Registration date
2026-09-07, 1405/06/16

Registrant information

Name
zahra saedi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3377 6842

Email address
darya2674@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-12, 1405/07/20

Expected recruitment end date
2027-03-11, 1405/12/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mindfulness-Based Cognitive Therapy on Depression, Dysfunctional Beliefs, and Self-Esteem in Mothers of Children with Intellectual Disabilities

Public title

Mindfulness-Based Cognitive Therapy for Mothers of Children with Intellectual Disabilities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a child with an intellectual disability with a confirmed diagnosis provided by a specialist physician or rehabilitation center. Having at least basic literacy skills (reading and writing) to understand the session materials and complete the research instruments. No severe psychiatric disorders, based on self-report and treatment history. Not receiving other similar psychological interventions or specific pharmacological treatment for depression concurrently during the study.

Exclusion criteria:

Absence from more than two intervention sessions. Failure to cooperate in completing the questionnaires or withdrawal from participation at any stage of the study. The occurrence of new medical or psychological conditions that interfere with the intervention process. Diagnosis of a severe psychiatric disorder during the study, based on clinical assessment and medical records.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad university of medical science

Street address

Bahar 2, Baharestan Dormitory, Hejab Boulevard, Mashhad University of Medical Sciences, End of Bahonar Boulevard, Mashhad, Iran

City

Masshad

Province

Razavi Khorasan

Postal code

9177948974

Approval date

2025-09-02, 1404/06/11

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.336

Health conditions studied

1

Description of health condition studied

Depression, dysfunctional beliefs, and self-esteem in mothers of children with intellectual disabilities, without a specific clinical diagnosis.

ICD-10 code

F30-F39

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Depression, Dysfunctional Beliefs , Self-Esteem

Timepoint

Pretest: Before the intervention and Posttest: Immediately after the intervention

Method of measurement

Depression will be assessed using the Beck Depression Inventory (BDI), self-esteem using the Coopersmith Self-Esteem Inventory (CSEI), and dysfunctional beliefs using the Dysfunctional Attitude Scale (DAS). The questionnaires will be administered to both groups at pretest and posttest.

Secondary outcomes

empty

Intervention groups

1

Description
Mothers of children with intellectual disabilities who receive Mindfulness-Based Cognitive Therapy (MBCT) will participate in nine weekly two-hour sessions. The intervention includes training in mindfulness skills, techniques for managing negative thoughts, and practicing nonjudgmental acceptance.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Saedi

Street address
Research Affairs Office, Central Building of the University, Vakilabad Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۴

Phone
+98 916 604 6877

Email
darya2674@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Central Building, Vakilabad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۴

Phone
+98 916 604 6877

Email
darya2674@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra saedi

Position
Independent researcher

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۴

Phone
+98 916 604 6877

Email
darya2674@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mehdi Amiri

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Psychology

Street address
Research Administration, Central Building, Vakilabad Boulevard, Mashhad University of Medical Sciences, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۸۹۵۴
Phone
+98 915 914 1563
Email
amirime@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
fatemeh joneydiepour
Position
independent researcher
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No. 21, Milad 3, Kermani Street, Varamin, Iran
City
varamin
Province
Tehran
Postal code
3371949174
Phone
+98 996 537 9811
Email
fatemehjoneydie@gmail.com

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
Not applicable
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
De-identified Participant Data: An anonymized dataset including participant codes, demographic information, and pretest and posttest scores for depression, dysfunctional beliefs, and self-esteem. Study Protocol:The study protocol including the research objectives, methodology, inclusion and exclusion criteria, description of the Mindfulness-Based Cognitive Therapy (MBCT) intervention, and outcome measures. Statistical Analysis Plan:A statistical analysis plan describing the methods used to analyze the data and compare the experimental and control groups at the pretest and posttest stages. Informed Consent Form:The participant information sheet and informed consent form used in the study (Persian version). Analytical Codes: SPSS syntax files used for data entry, cleaning, management, and statistical analysis. Data Dictionary: A data dictionary defining the variables included in the anonymized dataset, including variable names, definitions, data types, and coding schemes.
When the data will become available and for how long
The data and documents will become publicly available upon acceptance for publication of the primary results manuscript. They will be stored with no end date for access.
To whom data/document is available
Available to researchers, students, and meta-analysts in the scientific community worldwide.
Under which criteria data/document could be used
Data and documents may be used for non-commercial, scientific purposes such as validation, meta-analysis, methodological research, or educational purposes. Any proposed use must be approved by an independent scientific review committee and must comply with ethical standards.
From where data/document is obtainable
The documents (Protocol, SAP, Consent Form) will be attached to the trial registration on the Iranian Registry of Clinical Trials (IRCT). The final, shareable versions of all items will be deposited in a public, open-access repository such as Mendeley Data, Figshare, or Zenodo. A direct link (DOI) will be provided in the published manuscript and updated in this registry entry.
What processes are involved for a request to access data/document
For the deidentified IPD: A managed access process is required. Requestors must submit a brief proposal outlining their intended use, analysis plan, and ethical approval to the Corresponding Author (Dr. Mehdi Amiri) via email. Requests will be reviewed by the study's principal investigator within 4 weeks. Approved requestors will be granted access via the repository with a unique token or will receive the data directly.
Comments