Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparison of the Effectiveness of Dialectical Behavior Therapy and Mindfulness-Based Cognitive Therapy Packages on Weight-Related Self-Efficacy, Fear of Negative Evaluation, and Psychological Distress in Patients with Obesity.

Protocol summary

Study aim
A Comparison of the Effectiveness of Dialectical Behavior Therapy (DBT) and Mindfulness-Based Cognitive Therapy (MBCT) Packages on Weight-Related Self-Efficacy, Fear of Negative Evaluation, and Psychological Distress in Patients with Obesity

Design
A clinical trial with a control group, parallel groups, unblinded, randomized, on 45 patients

Settings and conduct
The present study will be conducted as a quasi-experimental study among individuals with obesity who refer to medical centers in Tehran. Using purposive sampling method, 45 participants will be selected based on the study's inclusion criteria. They will then be randomly assigned to three groups: experimental group 1, experimental group 2, and a control group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Having literacy skills for reading and writing, not taking any medication, at least 2 years have passed since the diagnosis of obesity, Body Mass Index between 30 and 35, age range between 18 and 45 years. Exclusion Criteria: Substance and alcohol abuse, receiving psychological interventions during the past 6 months, having chronic physical illnesses or psychological disorders.

Intervention groups
Intervention Group 1: DBT 8 weekly 90-min group sessions. Content: Intro, emotional awareness, self-acceptance, craving control, inner/outer wisdom, meditation, mind-body-emotion connection, post-test. Intervention Group 2: MBCT 8 weekly 90-min group sessions. Content: Intro, distress tolerance, mind levels, emotion management, nutrition, chain analysis (binge eating), behavior management, post-test. Control Group No intervention during study; receives treatment post-study (optional).

Main outcome variables
Weight-related self-efficacy, fear of negative evaluation, and psychological distress.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251101067851N1**
Registration date: **2026-03-15, 1404/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-03-15, 1404/12/24**
Update count: **0**

Registration date
2026-03-15, 1404/12/24

Registrant information

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Sahar Saeidiasl
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-01, 1404/12/10

Expected recruitment end date

2026-04-14, 1405/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the Effectiveness of Dialectical Behavior Therapy and Mindfulness-Based Cognitive Therapy Packages on Weight-Related Self-Efficacy, Fear of Negative Evaluation, and Psychological Distress in Patients with Obesity.

Public title

A Comparison of the Effect of Behavioral Therapy Packages on Mindfulness in Patients with Obesity.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having literacy skills for reading and writing Willingness to participate in the study and complete the consent form to receive the therapeutic intervention Not taking any medication At least 2 years have passed since the diagnosis of obesity Body Mass Index (BMI) between 30 and 35 Age range between 18 and 45 years old

Exclusion criteria:

Substance and alcohol abuse. Receiving psychological interventions during the past 6 months. Having chronic physical illnesses or psychological 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: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample of the present study will be selected using purposive sampling. Specifically, from among individuals with obesity who will refer to selected medical centers in Tehran during the study period and who meet the study's inclusion and exclusion criteria, 45 individuals will be selected. The random sequence will be generated using Random Allocation Software by someone outside the research team (a research assistant). The method used will be simple randomization with equal allocation ratio (1:1:1) for the three groups. That is, the software will generate a random list of 45 numbers consisting of 1, 2, and 3 (corresponding to Experimental Group 1, Experimental Group 2, and Control Group, respectively). The process of randomly allocating these 45 participants into three groups of 15 will be carried out as follows: After obtaining informed consent and completing the pre-test, each participant will be assigned a unique identification code. Then, based on the random sequence generated by the software, participants will be placed into one of the three groups in the order they enter the study (from code 1 to 45). All allocation steps will be performed by a research assistant who will not be involved in the subsequent intervention and assessment stages, and the final result will be recorded and stored in sealed envelopes to maintain the principle of allocation concealment. Due to the psychological nature of the interventions, blinding the interventionist and participants will not be possible; however, to reduce measurement bias, the primary outcome assessor (the person collecting the post-test data) will be kept unaware of each participant's group assignment (blinded assessment).

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

The Research Ethics Committee of Islamic Azad University - Tehran North Branch

Street address

5th Floor, Shahid Fakhrizadeh Research and Laboratory Building, Islamic Azad University, Tehran North Branch, Vafadar Boulevard, Shahid Sadoughi Street, Hakimiyeh Exit, Shahid Babaei Highway (Westbound), Tehran, Iran

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Postal code

1651153511

Approval date

2025-09-06, 1404/06/15

Ethics committee reference number

IR.IAU.TNB.REC.1404.241

Health conditions studied

1

Description of health condition studied

Patients with obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description
Weight-related self-efficacy
Timepoint
Before the start of the intervention and at the end of the intervention sessions.
Method of measurement
Weight Self-Efficacy Questionnaire (WSEQ)

2

Description
Fear of negative evaluation
Timepoint
Before the start of the intervention and at the end of the intervention sessions.
Method of measurement
Brief Fear of Negative Evaluation Scale

3

Description
Psychological distress
Timepoint
Before the start of the intervention and at the end of the intervention sessions.
Method of measurement
Depression Anxiety Stress Scales

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group (Dialectical Behavior Therapy): The content of this intervention was extracted using the research synthesis method based on dialectical behavior therapy, and its validity was confirmed by expert professors. This intervention was delivered to participants in eight 90-minute group sessions over 8 weeks (one session per week). Detailed session content: Session 1 (Introduction and Conceptualization): Introduction, motivation building and case conceptualization, creating a safe space and introducing group rules, teaching the psychological model of obesity; Session 2 (Emotional Awareness and Identifying Real Needs): Types of hunger, increasing emotional awareness, and identifying real needs; Session 3 (Teaching the Inner Critic, Cultivating Self-Acceptance): Introducing and identifying mental wandering; Session 4 (Controlling Cravings and Temptations); Session 5 (Teaching Inner and Outer Wisdom); Session 6 (Breathing and Mindful Meditation Exercises); Session 7 (Integrating the Mind-Body-Emotion Connection); Session 8 (Session Summary and Post-test Administration).
Category
Treatment - Other

2

Description
Second Intervention Group: Mindfulness-Based Cognitive Therapy: The content of this intervention was extracted using the research synthesis method based on mindfulness-based cognitive therapy for binge eating and obesity, and its validity was confirmed by expert professors. This intervention was delivered to participants in eight 90-minute group sessions over 8 weeks (one session per week).Detailed session content: Session 1 (Introduction and Conceptualization): Establishing a therapeutic relationship, presenting the dialectical framework (acceptance vs. change), defining weight-related problems in terms of difficulty managing emotions and behaviors, and setting realistic personal goals. Session 2 (Distress Tolerance and Flexibility): Teaching survival skills for distressing situations without resorting to binge eating. Session 3 (Levels of Mind): Increasing awareness of different states of mind and their impact on decision-making and eating behaviors. Session 4 (Emotion Management): Identifying, naming, and modulating problematic emotions instead of suppressing them or acting impulsively. Session 5 (Nutrition and Body Awareness): Providing scientifically-based nutritional information (with a non-restrictive, acceptance-based approach), without imposing strict diets, and fostering a healthy relationship with the body and food. Session 6 (Chain Analysis of Events Contributing to Binge Eating): Precise and personalized identification of triggers, thoughts, emotions, and consequences related to binge eating. Session 7 (Managing Unhealthy Behaviors and Thought Patterns): Modifying dysfunctional beliefs about food, body, and self, reducing weight-related avoidance behaviors, and interpersonal skills training. Session 8 (Session Summary, Mindful Attention, Post-test): Reviewing and integrating skills, assessing progress, and developing a plan to maintain achievements, cope with future challenges, and prevent relapse.
Category
Treatment - Other

3

Description
Control group: does not receive any intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Borna Specialized Rehabilitation Polyclinic

Full name of responsible person
Sahar Saeidiasl
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Kish International 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
Full name of responsible person
Sahar Saeigiasl
Position
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Latest degree
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Email

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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 the participants have been de-identified.

When the data will become available and for how long

Access begins 6 months after final publication.

To whom data/document is available

Eligible applicants include researchers, healthcare professionals (e.g., physicians, psychologists, nutritionists), and postgraduate students (Master’s or Doctoral level) in fields such as psychology, public health, medicine, and related disciplines. Submission of a data access request is permitted following verification of academic credentials and purpose by the Principal Investigator.

Under which criteria data/document could be used

The data and documentation from this study are available for research, educational, and therapeutic development purposes. Access is granted subject to the approval of a formal research proposal by the Principal Investigator and strict adherence to confidentiality protocols, including full data anonymization.

From where data/document is obtainable

Correspondence email: dr.s.saeidi62@gmail.com

What processes are involved for a request to access data/document

Applicants for data who are currently enrolled in a graduate program in one of the fields of psychology, health psychology, therapists and psychology specialists, nutritionists, or physicians can obtain the data file after submitting their documents to the researcher's email address.

Comments