

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Randomized controlled trial comparing the effect of Dialectical Behavior Therapy and Transdiagnostic Treatment on binge eating, difficulties in emotion regulation and BMI in obese and overweight patients with binge-eating disorder

Protocol summary

Summary

(1) Objectives: This study aimed to compare the effect of Dialectical Behavior Therapy (DBT) and Trans-diagnostic Treatment on binge eating, difficulties in emotion regulation and BMI in obese and overweight patients with binge-eating disorder at Kashan. (2) Design: General plan of this study is consisted of experimental pre-test and post-test with control group and follow-up period. (3) Setting and conduct: Ninety subjects who met the criteria for binge eating and overweight or obesity were selected by convenient sampling and were randomly assigned in three groups (DBT, Trans-diagnostic Treatment and Control group). After measuring height and weight and calculated BMI of participants, each of the three groups filled out Gormally's Binge Eating Scale and Gratz's Difficulties in Emotion Regulation Scale (DERS) as pre-test and post- test and one month after intervention. The data were analyzed by SPSS-19 using the ANOVA with repeated measure. (4) Inclusion criteria: Binge eating disorder; Overweight or obesity. Exclusion criteria: Obesity associated with physical disease; Diabetes; Pregnancy or lactation; Drug abuse. (5) Interventions: The first intervention is consisted of 10 sessions (each session is 120 minutes) of Dialectical behavior therapy and Advised usual diet for the first experimental group. The second intervention is consisted of 8 sessions (each session is 120 minutes) of Trans-diagnostic therapy and Advised usual diet for the second experimental group. Control group just get Advised usual diet. (6) Main outcome measures variables in this research are binge eating, difficulties in emotion regulation, and BMI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061422709N1**

Registration date: **2015-08-11, 1394/05/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-08-11, 1394/05/20

Registrant information

Name

Maliheh Rahmani

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2305

Email address

rahmani-ma@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial comparing the effect of Dialectical Behavior Therapy and Transdiagnostic Treatment on binge eating, difficulties in emotion regulation and BMI in obese and overweight patients with binge-eating disorder

Public title

comparing the effect of Dialectical Behavior Therapy and Transdiagnostic Treatment on Binge-Eating Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Binge eating disorder; Overweight or obesity; Willingness and able to participate in the research Exclusion criteria: Other early psychiatric diagnoses; Obesity associated with physical disease; Diabetes; Pregnancy or lactation, Drug abuse; Absence more than 3 times; Get a history of psychological interventions during the past month

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Kashan University of Medical Sciences and Health Services

Street address

Ethics committee, Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

City

Kashan

Postal code

8715988141

Approval date

2015-06-24, 1394/04/03

Ethics committee reference number

IR.KAUMS.REC.1394.46

Health conditions studied

1

Description of health condition studied

Binge Eating

ICD-10 code

F50.4

ICD-10 code description

Overeating associated with other psychological disturbances

2

Description of health condition studied

Overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

3

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Binge Eating

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Structured Clinical Interview for DSM Disorders (SCID), Binge Eating Scale (Gormally et al. 1982)

2

Description

Difficulties in Emotion Regulation

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Difficulties in Emotion Regulation Scale (DERS) (Gratz & Roemer 2004)

3

Description

body mass index (BMI)

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Quetelet index (Lambert Adolphe Jacques Quetelet)

Secondary outcomes

empty

Intervention groups

1

Description

dialectical behavior therapy; 10 sessions; 2 hours; Advised usual diet; First intervention group

Category

Behavior

2

Description

Transdiagnostic therapy; 8 sessions; 2 hours; Advised usual diet; First intervention group

Category

Behavior

3

Description

Advised usual diet; Control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Hospital

Full name of responsible person

Maliheh Rahmani

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Maliheh Rahmani

Position

M.Sc Candidate in Clinical Psychology

Other areas of specialty/work

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Position

postgraduate

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty