

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of Emotion-Focused Group Therapy and Diet Therapy Combined with Exercise on Impulse Control, Night Eating Syndrome and Difficulty in Emotion Regulation in Obese people with Binge Eating Disorder

Protocol summary

Study aim

Determining the difference in the effectiveness of the diet therapy with aerobic exercise and its combined effect with the Emotion Focused Group Therapy on impulse control, Night eating syndrome and Difficulty in emotional regulation of obese people with Binge eating disorder.

Design

The clinical trial has a control group, with parallel groups, a blind strain, randomized, the considered sample size is 54 people. Sampling was done using block method.

Settings and conduct

EFGT consists of 10 sessions that will be implemented for one of the groups. Both intervention groups will receive the intervention diet therapy with exercise, and the place will be performed in the Obesity clinic of Sina Hospital. Single blind and the participants without knowing the type of intervention were divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Entry conditions include: body mass index above 30, no addiction to drugs and alcohol, diagnosis of binge eating disorder, no psychological disorder other than binge eating disorder; Non-entry conditions include: body mass index below 30, not filling informed consent.

Intervention groups

The first group (emotion-focused group intervention and diet therapy combined with exercise): the emotion-focused therapy is based on the intervention provided by Greenberg (2015), the structure of the EFT sessions includes 10 two-hour sessions that are performed weekly. The second group: The intervention is based on diet therapy combined with exercise. The third group (control group) does not receive any intervention.

Main outcome variables

Help to treat obesity with binge eating disorder; impulse

control; improvement of Night eating syndrome; Emotion regulation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220218054053N1**

Registration date: **2022-11-10, 1401/08/19**

Registration timing: **retrospective**

Last update: **2022-11-10, 1401/08/19**

Update count: **0**

Registration date

2022-11-10, 1401/08/19

Registrant information

Name

Mir Javad Chehraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4464 5096

Email address

javi_422@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2022-10-02, 1401/07/10

Actual recruitment start date

2022-09-13, 1401/06/22
Actual recruitment end date
2022-10-04, 1401/07/12
Trial completion date
2023-02-12, 1401/11/23

Scientific title
Comparison of the effectiveness of Emotion-Focused Group Therapy and Diet Therapy Combined with Exercise on Impulse Control, Night Eating Syndrome and Difficulty in Emotion Regulation in Obese people with Binge Eating Disorder

Public title
Effectiveness of Emotion Focused Group Therapy in Obese people with Binge Eating Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent in research Age range 30 to 55 years
Body mass index above 30 Absence of drugs and alcoholic beverages addiction (According to the comments of the participants in the research and their medical records in the Obesity clinic of Sina Hospital
Obtaining a diagnosis of Binge Eating Disorder based on the medical records available in the Obesity clinic of Sina Hospital
No received psychological disorders other than Binge Eating Disorder based on medical records in the Obesity Clinic of Sina Hospital
Exclusion criteria:
Body mass index under 30 People with Bulimia Nervosa

Age
From **30 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample people were assigned in three groups (including two intervention groups and one control group) by block randomization method. Randomization was done using the website <https://www.sealedenvelope.com/>. According to the number of groups (3 groups), the size of the blocks was considered 6 and it is fixed. A total of 9 blocks were obtained. Thus, in each block, 2 people were assigned to the first intervention group, 2 people to the second intervention group, and 2 people to the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Interventions of the intervention and control group are kept blind without the subjects knowing about the

control or intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University of Karaj Branch
Street address
Cross at esteghlal and Moazen Blvd, Rajaii shahr
City
karaj
Province
Tehran
Postal code
3149968111

Approval date
2022-08-31, 1401/06/09

Ethics committee reference number
IR.IAU.K.REC.1401.090

Health conditions studied

1

Description of health condition studied
Obesity with Binge eating disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Obesity, which is calculated by measuring the body mass index; Impulse control by Bart Impulsivity Questionnaire; Night eating syndrome by the Night Eating Questionnaire (NEQ) by Allison et al. (2008); Emotion regulation by the scale of difficulty in emotion regulation (Gertz and Roemer, 2004).

Timepoint
The time periods of measurement are at the beginning of the trial, second time after the completion of the interventions and third time two months after the completion of the interventions.

Method of measurement
Obesity, which is calculated by measuring the body mass index (BMI) using a scale and height measurement tool based on meters, which should be above 30; Impulse control by Bart Impulsivity Questionnaire; Night eating

syndrome by the Night Eating Questionnaire (NEQ) by Allison et al. (2008); Emotion regulation by the scale of difficulty in emotion regulation (Gertz and Roemer, 2004).

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group (group intervention focused on emotion and diet therapy combined with exercise): The intervention focused on emotion in the present study is carried out using the intervention sessions provided by Greenberg (2015) and includes 10 two-hour sessions that are implemented weekly. In short, the sessions include awareness of emotions, emotional experience, and reaching primary maladaptive emotions and changing them to primary adaptive emotions.

Category

Treatment - Other

2

Description

The second intervention group: In this research, it includes diet therapy along with aerobic exercise, the amount of calories needed by all clients in this group and the first group was calculated according to height, age, and gender, and the daily diet was reduced by 500 kilocalories. With the share of 60-65% carbohydrates, 20-25% protein and the rest fat was prescribed, 30-45 minutes of aerobic exercise such as moderate intensity walking was considered daily. Weighing and determination of body mass index were done before and after. Seka scale is used as a standard scale.

Category

Treatment - Other

3

Description

Control group: Control group does not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Maryam Abolhasani

Street address

No. 150, Entrance 14, Block A2, Phase 1, Ekbatan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Hamed Sabet

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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, Karaj Branch

Proportion provided by this source

100

Public or private sector

Private

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
Mir Javad Chehraghi
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Psychology
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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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data on measured variables can be shared after de-identifying individuals.

When the data will become available and for how long

After printing the article

To whom data/document is available

The data will be available to academic and scientific researchers

Under which criteria data/document could be used

Scientific use in improvement and comparison with other research is allowed.

From where data/document is obtainable

Correspond with javadchehraghi@gmail.com.

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

The applicant must send the reason for using the documents by e-mail.

Comments