

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The Effectiveness of Emotion-Focused Therapy On Anxiety, Depression and Difficulty in Emotion Regulation in Binge Eating Disorder

#### Protocol summary

depression, anxiety, and difficulty in emotion regulation and binge eating disorder

#### Study aim

The purpose of this study was to investigate the effectiveness of emotion-focused therapy on depression, anxiety, and difficulty in emotion regulation in women with binge eating disorder.

#### Design

The study was a quasi-experimental clinical trial with a pre- post-test design and 6 weeks of follow up with control group. After identifying Binge eating disorder and determining the criteria for Inclusion and exclusion criteria and selecting 40 patients and randomly assigning coins to the experimental (n = 20) and control (n = 20) groups, the research tools were pretest, posttest and follow up on the two groups. Was executed.

#### Settings and conduct

After selecting the sample and randomly assigning them to the experimental and control groups, both groups were administered a pretest (Emotion Regulation Difficulty Questionnaire and Beck Depression Anxiety Inventory). After pre-test group program with emotion-centered treatment approach was performed in 10 90-minute sessions weekly for experimental group in a weight loss clinic. The control group also received placebo during this period. The treatment program was performed in eight stages.

#### Participants/Inclusion and exclusion criteria

Participants' inclusion criteria: 1- Over 18 years of age 2- Being female 3- Not participating in other treatment programs during the study. Exclusion criteria: 1- Imminent suicide risk 2- Any substance abuse or dependence To Materials and Alcohol 3 - Body Mass Index (IBM = Weight in kg divided by the square of height in cm) above 40.

#### Intervention groups

The experimental group received EFT treatment (emotion-centered treatment approach) in 10 90-minute sessions weekly. The control group also received placebo during this period.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200222046583N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **retrospective**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

##### Registration date

2020-03-11, 1398/12/21

##### Registrant information

##### Name

yousef asmaribardezard

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8899 4742

##### Email address

asmariyousef@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-31, 1398/06/09

##### Expected recruitment end date

2020-02-29, 1398/12/10

##### Actual recruitment start date

2019-08-31, 1398/06/09

##### Actual recruitment end date

2020-01-30, 1398/11/10

**Trial completion date**

2020-01-31, 1398/11/11

**Scientific title**

The Effectiveness of Emotion-Focused Therapy On Anxiety, Depression and Difficulty in Emotion Regulation in Binge Eating Disorder

**Public title**

The Effectiveness of Emotion-Focused Therapy On Anxiety, Depression and Difficulty in Emotion Regulation in Binge Eating Disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

women with overeating disorder, overeating disorder diagnosed by a clinical specialist (non-therapist) based on the Structured Clinical Interview for DSM-5 (SCID-5), and a cut-off point of the questionnaire (above 16).

**Exclusion criteria:**

Imminent suicide risk Any substance abuse or dependence on alcohol & alcohol Body mass index (BMI = Weight in kg divided by square of height in cm) above 40.

**Age**

From **18 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Forty patients were selected after being interviewed and filtered by inclusion and exclusion criteria. Members of the control group and the experimental group were chosen through the toss of coin. Coin was tossed as many times as need to complete the number of control and experimental groups.

**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**

IR.USWR.REC :

**Street address**

University of Social Welfare and Rehabilitation Sciences, kodakyar Ave., Daneshjo Blvd.,Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713871

**Approval date**

2017-07-25, 1396/05/03

**Ethics committee reference number**

IR.USWR.REC.1397.78

**Health conditions studied****1****Description of health condition studied**

Binge eating disorder

**ICD-10 code**

F50.81

**ICD-10 code description**

ICD-10 Code: F50.81.

**Primary outcomes****1****Description**

Overeating intensity courses

**Timepoint**

Before intervention (pre-test), after intervention (one week after intervention as post-test), 1 month later (Follow-up)

**Method of measurement**

Research tools included Beck Depression and Anxiety Inventory, Difficulty in Emotion Regulation and Gormal Eating Intensity Scale.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The group-based program of emotion-focused treatment was performed in 10 weight sessions weekly for the experimental group in a weight loss clinic.

**Category**

Behavior

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sina Hospital Obesity Center

**Full name of responsible person**

Sajad Khanjani

**Street address**

Sina Hospital, Hassan Abad Square, Imam Khomeini Ave, Tehran, Iran

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hosp\_sina@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Fateme Amiri

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Evin, boulevard student, Dead-end babysitting

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yo.asmari@uswr.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Research Support

**Proportion provided by this source**

30

**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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Usef Asmari Bardezdard

**Position**

Student

**Latest degree**

Ph.D.

**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)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

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