

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison of effectiveness of mindfulness- based eating awareness training (MB-EAT) and its integration with the implementation intentions on weight loss and biological, psychological and behavioral indices in women with obesity

#### Protocol summary

##### Study aim

Comparison of effectiveness of mindfulness- based eating awareness training (MB-EAT) and its integration with the implementation intentions on weight loss and biological, psychological and behavioral indices in women with obesity

##### Design

A clinical trial with two intervention groups and a control group with factorial groups and purposive sampling with random replacement will be performed on at least 45 patients.

##### Settings and conduct

Participants who meet the inclusion criteria are invited to attend a research at the Bahonar Hospital Clinic in Karaj. Participants are then given the opportunity to register for the study if they wish. Group training in Alborz School of Medical Sciences will be performed for experimental and control groups. In pandemic conditions, education will be online. The selection of subjects will be purposeful and will be done in the clinic of Bahonar Hospital in Karaj

##### Participants/Inclusion and exclusion criteria

Inclusion criteria BMI  $\geq$  25 Gender: Female Age : 20 years and older Education: Diploma and higher Exclusion criteria Receive psychotherapy; other regular weight loss; exercise programs at the same time. Use of psychotropic or weight-affecting drugs; hypothyroidism; pregnancy; diabetes

##### Intervention groups

Experimental group 1: Mindfulness- based eating awareness training (MB-EAT) will be held in the form of group training. Experimental group 2: In addition to MB-EAT the behavioral goals will be set for daily meditation, calorie counting, and physical activity. Control group: They will receive information on obesity and overweight, weight loss guidelines and goal setting based on these weight loss guidelines.

##### Main outcome variables

Weight biological indicators ( Chol; TG; HDL; LDL; FBS; waist circumference and BMI Psychological indicators: (life based on weight self-efficacy; eating behavior; conscious mind eating and difficulty in regulating emotion) Behavioral indicators: (Calorie counting; physical activity and healthy eating)

#### General information

##### Reason for update

##### Acronym

MB\_EAT

##### IRCT registration information

IRCT registration number: **IRCT20200919048767N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

##### Registration date

2020-11-18, 1399/08/28

##### Registrant information

##### Name

Mona Jassemi Zergani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2641 9061

##### Email address

mjassemi@yhoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-10-22, 1399/08/01

**Expected recruitment end date**

2020-11-21, 1399/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of effectiveness of mindfulness- based eating awareness training (MB-EAT) and its integration with the implementation intentions on weight loss and biological, psychological and behavioral indices in women with obesity

**Public title**

Effect of mindfulness training on weight loss

**Purpose**

Education/Guidance

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

BMI  $\geq$  25 Gender: Female Age:20 years and older  
Education: Diploma and higher.

**Exclusion criteria:**

Receive concomitant psychotherapy or other regular weight loss and exercise programs Use of psychotropic or weight-affecting drugs. Having a mental disorder Hypothyroidism Pregnancy Diabetes

**Age**

From 20 years old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**

Target sample size: 45

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

1. After equalizing people in weight, age and waist circumference, we put them in three groups. 2. Each intervention is named with the English letters A, B, C. 3. Write the letters A, B, C inside the three envelopes and mix them so that it is not clear what is in each envelope. 4. By asking one person from each category to enter the study, we tell them to take one of the envelopes randomly and according to the letter, that person will be placed in one of the groups. 5. For the fourth to sixth participants, we repeat step 4, and then for the next three people, etc., until the required number of samples is completed in all three groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Factorial

**Other design features**

Implementation intention is integrated with mindfulness-based eating awareness training as a program to implement the goals of change.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the School of Nursing and Midwifery, Karaj Azad University

**Street address**

Faculty of Nursing and Midwifery, Islamic Azad University, Karaj, Rajai Shahr

**City**

Karaj

**Province**

Alborz

**Postal code**

1998669711

**Approval date**

2020-09-16, 1399/06/26

**Ethics committee reference number**

IR.IAU.K.REC.1399.028

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

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

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

Weight

**Timepoint**

Before the study and after that (3 months later) and 3 and 6 months later for follow-up

**Method of measurement**

weight of digital scales

**Secondary outcomes****1****Description**

Cholesterol

## **Timepoint**

Before the intervention and 3 and 6 months after the intervention

## **Method of measurement**

Blood samples after 12 hours of fasting using laboratory kits

## **2**

### **Description**

Triglycerid

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Blood samples after 12 hours of fasting using laboratory kits

## **3**

### **Description**

High density lipoprotein(HDL)

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Blood samples after 12 hours of fasting using laboratory kits

## **4**

### **Description**

low density lipoprotein(LDL)

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Blood samples after 12 hours of fasting using laboratory kits

## **5**

### **Description**

Fasting blood sugar(FBS)

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Blood samples after 12 hours of fasting using laboratory kits

## **6**

### **Description**

Waist circumference

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

The narrowest waist area with tape measure (accuracy 0.5 cm)

## **7**

### **Description**

self-efficacy

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

weight efficacy lifestyle questionnaire

## **8**

### **Description**

Eating behavior

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Three Factor Eating Questionnaire

## **9**

### **Description**

Mindful eating

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Mindful Eating Questionnaire

## **10**

### **Description**

Emotional eating

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

Difficulties in Emotion Regulation Scale( DERS)

## **11**

### **Description**

Calorie counting

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

check list

## **12**

### **Description**

physical activity

### **Timepoint**

Before the intervention and 3 and 6 months after the intervention

### **Method of measurement**

check list

## **13**

### **Description**

Healthy diet

## Timepoint

Before the intervention and 3 and 6 months after the intervention

## Method of measurement

check list

## Intervention groups

### 1

#### Description

Intervention group 1: Mindful based eating awareness training will be done for 12 sessions, one session per week and each session for 2 and a half hours according to the training instructions. Participants will be introduced to the concepts of inner wisdom and outer wisdom. Inner wisdom, wise use of: Awareness of physical hunger and fullness, eating triggers, emotions and thoughts/ Self-acceptance. Outer Wisdom: wise use of nutrition and calories/activity-exercise Information. At the end of each session, group participants are asked to practice the trained techniques to turn this knowledge into a wisdom and become a lifestyle.

#### Category

Lifestyle

### 2

#### Description

Intervention group 2: This group, just like experimental group 1 receives mindfulness-based eating awareness training. At the end of each session, they are asked to do the practices and techniques they have learned to become a lifestyle, according to implementation Intention, the therapist will write a practical plan for how to count calories, healthy eating and physical activity, and asks them to have a high commitment to performing these three components on a daily basis and to report their practice virtually.

#### Category

Lifestyle

### 3

#### Description

Control group: Simultaneously with the experimental groups, they will receive information about obesity and overweight. After the end of the intervention and follow-up; to observe the treatment ethics, the intervention will be performed for this group.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bahonar hospital

##### Full name of responsible person

Habibeh Taghavi

## Street address

No. 30, 24 metri Ave., Saadat Abad.,Tehran

## City

Karaj

## Province

Alborz

## Postal code

1998669711

## Phone

+98 21 2641 9061

## Fax

## Email

mjassemi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Mohammad Reza Seirafi

##### Street address

No. 30, 24 metri Ave., Saadat Abad., Tehran

##### City

Karaj

##### Province

Alborz

##### Postal code

1998669711

##### Phone

+98 21 2641 9061

##### Email

mjassemi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### 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

Mona Jassemi Zergani

##### Position

Student of health psychology (Phd)

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

NO. 30, Mohammadali Keshaverz Ave; Saadat Abad.

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mjassemi@yhoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mona Jassemi Zergani

**Position**

Student of health psychology (Phd)

**Latest degree**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mona Jassemi Zergani

**Position**

Student of health psychology (Phd)

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

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**Email**

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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**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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