

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### effect of mindfulness-based stress management therapy on the emotion regulation ,anxiety ,depression and food addiction in obese people

#### Protocol summary

##### Study aim

Determining the effect of Mindfulness-Based Stress Management Therapy on the Emotion regulation, Anxiety, Depression and Food Addiction in Obese People

##### Design

Sample: Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

The researcher will refer to the health centers and specialized clinics related to weight management with letter from Kashan University of Medical Sciences and select eligible people and call them and invites candidates participates in intervention sessions.

##### Participants/Inclusion and exclusion criteria

BMI> 30, A score above 5 on the Food Addiction Scale, Minimum Cycle Education Exclusion criteria:, Participate in a regular exercise program, Absence in treatment sessions more than 2 times, Having a drug addiction, Use of diet. Medical problems such as diabetes and endocrine disorders, hypothyroidism or hyperthyroidism

##### Intervention groups

Intervention Group: Mindfulness-Based Stress Reduction is an eight-session, 90-minute intervention that teaches participants to communicate with their inner and outer world in the present moment, without judgment, with full awareness and awareness. This approach is based on the treatment protocol of Kabat Zain (2013). Control group: Includes eight one-hour sessions on topics such as: Referrals and meeting group members-General psychology topics that lack emotion regulation topics:Examples: types of conditioning and learning, types of memory, theory of forgetfulness, social psychology, various aspects of adult development.

##### Main outcome variables

emotions regulation, anxiety, depression, food addiction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190804044436N1**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **retrospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

##### Registration date

2020-02-06, 1398/11/17

##### Registrant information

##### Name

hanieh kebriti

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5545 1898

##### Email address

m.kebriti20@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-21, 1398/06/30

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

effect of mindfulness-based stress management therapy on the emotion regulation ,anxiety ,depression and food addiction in obese people

#### Public title

effect of mindfulness-based stress management therapy on the emotion regulation ,anxiety ,depression and food addiction in obese people

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

BMI>30 Ages 18 to 50 Score higher than 5 on the Food Addiction Scale A score above 7 on the DASS-21 Depression Scale A score above 6 on the DASS-21 Anxiety Scale Minimum Cycle Education

##### Exclusion criteria:

Acute psychiatric disorders such as psychosis and bipolar disorder and body dysmorphic disorder Participate in a regular exercise program Taking supplements for weight loss Absence of more than two sessions of treatment Substance abuse Simultaneous psychological treatment

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization will be based on the random numbers table and hiding with the help of sealed envelopes kept by the clinic manager, whereby individuals will be placed in one of the MBSR and control groups.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, evaluators and data analyzers will not be aware of the allocation of individuals to MBSR and control groups.

#### Placebo

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

##### Street address

Kashan University of Medical Sciences Ethics Committee, Ravandi Boulevard , Kahan

##### City

kashan

##### Province

Isfahan

##### Postal code

3713979671

#### Approval date

2019-02-18, 1397/11/29

#### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.111

### Health conditions studied

### 1

#### Description of health condition studied

Overweight and obesity

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

### Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before the intervention, after the intervention, three months after the intervention

#### Method of measurement

DASS\_21 Depression Anxiety Inventory

### 2

#### Description

Depression

#### Timepoint

Before the intervention, after the intervention, three months after the intervention

#### Method of measurement

DASS\_21 Depression Anxiety Inventory

### 3

#### Description

food addiction

#### Timepoint

Before the intervention, after the intervention, three months after the intervention

#### Method of measurement

Food Addiction Questionnaire (YFAS)

## Secondary outcomes

1

### Description

Emotion Regulation

### Timepoint

Before intervention, After intervention , three month after intervention

### Method of measurement

Difficulty adjusting the excitement (DERS)

## Intervention groups

1

### Description

Intervention group: Mindfulness-Based Stress Reduction is an eight-session, 90-minute intervention that teaches participants to communicate with their inner and outer world in the present moment, without judgment, with full awareness and awareness. . This approach is based on the treatment protocol of Kabat Zain (2013).

### Category

Treatment - Other

2

### Description

Control group: Includes eight one-hour sessions once a week with topics in general psychology and no emotion-related training including: types of conditioning, types of memory, types of learning, theory of forgetfulness, social psychology, adult developmental theories, Personality Types, Review of Tutorials.

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Health Centers

#### Full name of responsible person

Hanieh Kebriti

#### Street address

Kashan University of Medical Sciences., GHotb Ravandi Blvd.,Kashan Town

#### City

kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5545 1898

#### Email

m.kebriti20@gmail.om

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Dr. Hamid Reza Banafsheh

#### Street address

Kashan University of Medical Sciences, Ravandi Boulevard , Kashan Town

#### City

kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5554 2999

#### Email

medicine@kaums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kashan University of Medical Sciences

### 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

Kashan University of Medical Sciences

#### Full name of responsible person

Hanieh Kebriti

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Psychology

#### Street address

Kashan University of Medical Sciences., GHotb Ravandi Blvd.,Kashan Town

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Hanieh Kebriti

**Position**

Student

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Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

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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