

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Investigating and comparing the effectiveness of a mindfulness-based intervention along with standard treatment compared to standard treatment alone on the food craving trait in overweight and obese individuals with mild to moderate anxiety and/or depression: a randomized controlled trial.

Protocol summary

Study aim

Investigating the effectiveness of a mindfulness-based intervention on the food craving trait in overweight and obese individuals with mild to moderate anxiety and/or depression

Design

Two arm parallel group randomized trial including 60 patients in total. The list created by the random allocation software will be used for randomization.

Settings and conduct

This study will be in the form of a randomized controlled trial. The study will be conducted on overweight and obese people referred to the special nutrition clinic of Al-Zahra Hospital, Isfahan. Individuals, after obtaining written informed consent, will be randomly assigned to one of the control or intervention groups. All will receive the standard treatment. In addition to the standard treatment, the participants in the intervention group will receive the audio course. There is no possibility of blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI ≥ 25 , mild to moderate anxiety or depression
Exclusion criteria: Candidates for bariatric surgery, previous regular use of mindfulness-based techniques

Intervention groups

Control group: Receives the standard treatment, which includes a normal caloric restriction diet tailored to the person, which is determined by a nutritionist, based on factors such as the person's nutritional status, the amount of overweight and obesity, and underlying diseases.
Intervention group: In addition to the standard treatment, participants in the intervention group will receive a 14-day training course including audio files of

maximum 10-15 minutes on mindfulness and mindful eating.

Main outcome variables

The main result will be the amount of food craving trait

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210507051204N2**

Registration date: **2024-01-09, 1402/10/19**

Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**

Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Sayed Amirhossein Allameh

Name of organization / entity

Country

Iran (Islamic Republic of)

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sahallameh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2024-12-20, 1403/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the effectiveness of a mindfulness-based intervention along with standard treatment compared to standard treatment alone on the food craving trait in overweight and obese individuals with mild to moderate anxiety and/or depression: a randomized controlled trial.

Public title

Investigating the effectiveness of mindfulness on the food craving trait

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

BMI $\geq$ 25 Mild to moderate anxiety or depression: according to the DASS-21 questionnaire, a score of 7 to 12 in men and 9 to 14 in women for the depression subscale, or a score of 6 to 11 in men and 8 to 12 in women for the anxiety subscale Access to a smart phone and the ability to use it to receive and use the files related to study Having sufficient literacy (reading and writing) to complete forms and questionnaires Living in Isfahan city or nearby towns and villages Willingness to participate in the study

Exclusion criteria:

Being a candidate for bariatric surgery History of bariatric surgery in the last 18 months Age less than 18 or more than 65 years Having mental disabilities, blindness or deafness Being treated in other centers or participating in other similar studies Having a history of acute psychological diseases such as major depression, bulimia, anorexia, suicide or suicidal thoughts, schizophrenia, acute personality disorders, severe anxiety and depression, panic disorder and drug addiction. History of hospitalization due to psychological diseases History of diseases affecting appetite and weight gain/loss such as hypo/hyperthyroidism, liver cirrhosis, uncontrolled metabolic diseases, immune diseases and malignancy Taking drugs that have a significant effect on metabolism or appetite, such as corticosteroids, psychiatric drugs, and hormonal drugs Previous familiarity with and regular use of mindfulness-based techniques (more than or equal to three times a week, each time 10 minutes or more) Pregnant or lactating women Not willing to participate in the study or withdrawing from cooperation at any stage of the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization will be done in blocks with blocks of 4, where the strata are obesity and overweight. The order of assigning people to groups will be determined based on the list generated by "Random Allocation" software, and people will be assigned to one of two intervention or control groups based on this list. The main interventionist is not aware of the order created by this list, and after the decision to enter a person into the study, the list is checked by another researcher, who then informs the main researcher of the individual's group.

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**

Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Sciences

Street address

Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Ave.

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اصفهان

Province

Isfahan

Postal code

8174673461

Approval date

2024-01-03, 1402/10/13

Ethics committee reference number

IR.MUI.PHANUT.REC.1402.055

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

Food craving-trait score from FCQ-T-r questionnaire

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

FCQ-T-r questionnaire

Secondary outcomes

1

Description

binge eating

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

Binge eating scale questionnaire

2

Description

anxiety level

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

Anxiety subscale of 21 question version of depression-anxiety-stress scale questionnaire

3

Description

depression level

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

Depression subscale of 21 question version of depression-anxiety-stress scale questionnaire

4

Description

Mindful eating level

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

Mindful-Eating questionnaire

5

Description

Mindfulness level

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

Philadelphia mindfulness scale questionnaire

6

Description

satisfaction level regarding the therapy

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

visual analogue scale

7

Description

body mass index

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

weight in kilograms divided by height in meters squared

8

Description

weight

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

body analyzer

9

Description

body composition

Timepoint

The beginning of the study (before the start of the intervention), 2, 6, 10 and 14 weeks after starting to use the audio files.

Method of measurement

body analyzer

Intervention groups

1

Description

Control group: will receive standard treatment, which

includes a normal caloric restriction diet tailored to the individual, which is determined by a nutritionist based on factors such as the individual's nutritional status, degree of overweight and obesity, and underlying diseases.

Category

Treatment - Other

2**Description**

Intervention group: In addition to the standard treatment, will receive a 14-day course including audio files of maximum 10-15 minutes including training related to mindfulness and mindful eating. Participants will be asked to listen to these files daily and apply the skills taught throughout the day. The educational topics will include a concept section and a mindful eating section. Topics in the concepts section include Mindfulness-introduction, Present moment awareness, Acceptance and non-judgment, Body scan, Decentralization, Beginner's mind, Gratitude and Self-acceptance. Topics in the Mindful Eating section include Mindful Eating-Introduction, Mindful snack, Connection to Food, Types of Hunger, Satiety Cues, and Coping with Food Cravings.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Gholamreza Askari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Amirhossein Allameh

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact**

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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
Undecided - It is not yet known if there will be a plan to
make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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 is potentially shareable after individuals were
unidentified
**When the data will become available and for how
long**
After results publication
To whom data/document is available
Everyone
Under which criteria data/document could be used
For further studies
From where data/document is obtainable
Dr. Zeinab Mokhtari, Assistant Professor of Nutritional
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**What processes are involved for a request to access
data/document**
Contacting Dr. Zeinab Mokhtari via email
Comments