Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Determining the effect of attention bias correction in overweight or obese people

Protocol summary

Study aim
Determining the effect of attention bias modification in overweight or obese people

Design
In this clinical trial study with parallel groups, 40 patients aged 18-60 years with BMI> 25 were randomly divided into intervention and control groups. In the intervention group, patients received metformin 2000 mg/day with correction of bias and the control group received metformin 2000 mg/day alone.

Settings and conduct
This is a clinical trial study with parallel groups. In this study, 40 patients aged 18-60 years with BMI> 25 were randomly divided into intervention and control groups. In the intervention group, patients received metformin 2000 mg/day with bias correction, and in the control group, metformin 2000 mg/day was given alone. Then the two groups are evaluated for attention bias, BMI, and food cravings at the beginning of the study at intervals of 12 and 24 weeks.

Participants/Inclusion and exclusion criteria
inclusion criteria: Age 18-60 years, BMI over 25 Non-entry criteria: concomitant medical disorder, use of medication during the course, decreased level of consciousness

Intervention groups
The intervention group received metformin 2000 mg daily (metformin becomes tolerable for a period of 3 weeks to 2 grams per day) and the correction of attention bias was obtained by point search software and the control group received metformin 2000 mg daily.

Main outcome variables
Attention bias, BMI, food cravings

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191104045328N5**
Registration date: **2021-03-04, 1399/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-04, 1399/12/14**
Update count: **0**

Registration date
2021-03-04, 1399/12/14

Registrant information
Name
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-03-04, 1399/12/14
Expected recruitment end date
2022-02-20, 1400/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of attention bias correction in overweight or obese people

Public title
Investigating the effect of attention bias correction on

weight loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years BMI > 25

Exclusion criteria:

History of liver disease or kidney failure Use of medication during the course Loss of consciousness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

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

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Province

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Postal code

3848176941

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.ARAKMU.REC.1399.038

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Attention bias

Timepoint

Beginning of the study - End of the study

Method of measurement

Dot-probe test

2

Description

Food cravings

Timepoint

Beginning of the study - 12th week - 24th week

Method of measurement

using Fcod Craving Questionnaire-Trait

3

Description

Bone Mass Index

Timepoint

Beginning of the study - 12th week - 24th week

Method of measurement

Tape meter and scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients received metformin 2000 mg/day with correction of bias . Attention bias correction includes ten 30-minute sessions that are performed three times a week. Each session includes exercises for paying attention to neutral images. For this purpose, 100 pairs of emotional and neutral images are used.Each pair of images is presented to the subject for 500 milliseconds, then the images disappear immediately and a cross appears instead of a neutral image on the screen, and the subject must press a key in the same direction as the neutral image.This action causes the subject to pay attention to neutral images and to turn his attention away from obsessive emotional images as a result of repeating the exercise.

Category
Treatment - Devices

2

Description
Control group: Patients are given metformin 2000 mg daily

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Amirkabir hospital

Full name of responsible person
Dr Mostafa Nokani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr Mostafa Nokani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
When the article was out of print.

When the data will become available and for how long
After publishing the article

To whom data/document is available
University researchers

Under which criteria data/document could be used
If there are any further questions

From where data/document is obtainable
Dr Mostafa Nokani

What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.

Comments