

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

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

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

City

Arak

Province

Markazi

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

Street address

Vice Chancellor for Education, Amir Kabir Hospital, Arak, Iran

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

m.nokani@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice chancellor for Research, Arak University of Medical Sciences, Basij Square, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

arjmandzadegan@arakmu.ac.ir

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

Street address

Vice Chancellor for Education, Amir Kabir Hospital, Arak, Iran

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

nokani@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mehran Shayeganfard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Vice Chancellor for Education, Amir Kabir Hospital,
Arak, Iran

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

mshayganfard@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Shokouh Sadat Farzaneh Dehkordi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Vice Chancellor for Education, Amir Kabir Hospital,
Arak, Iran

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

amin.medstu@gmail.com

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