

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Self-Esteem educational intervention on weight loss in obese patients.

Protocol summary

Study aim

Determining the effect of Self-Esteem educational intervention on weight loss in obese patients.

Design

A Randomized Clinical Trial with a control group with a parallel design without blinding was performed on 40 patients who were divided into two groups (20 in each group) via block randomization

Settings and conduct

This was a quasi-experimental study that was performed in 2021 in Farshchian Heart Hospital in Hamadan on obese patients (BMI equal to or greater than 30). Before and at the end of the study (2 months after educational sessions), body mass index was measured and Cooper-Smith self-esteem Inventory (CSEI) was completed for both groups.

Participants/Inclusion and exclusion criteria

The participants who had BMI greater than or equal to 30, aged over 18 years, not being pregnant, and had no history of hypothyroidism, diabetes, cancer or mental disorders such as depression and bulimia nervosa enrolled in the study.

Intervention groups

In the control group, common recommendations such as lifestyle changes, diet, and medication were prescribed if necessary. In the intervention group, in addition to the control group's actions, four consecutive sessions of self-esteem training programs were performed by a psychologist focusing on increasing self-esteem. These educational programs were performed every other week and each session lasts about 2 hours.

Main outcome variables

Weight Loss; Increase Self-Esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220924056026N1**

Registration date: **2023-02-20, 1401/12/01**

Registration timing: **retrospective**

Last update: **2023-02-20, 1401/12/01**

Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Mohamadali Seifrabiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0583

Email address

seifrabie@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

2021-06-22, 1400/04/01

Actual recruitment end date

2021-09-06, 1400/06/15

Trial completion date

2022-02-08, 1400/11/19

Scientific title

The effect of Self-Esteem educational intervention on weight loss in obese patients.

Public title

The effect of Self-Esteem educational intervention on

weight loss in obese patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Obesity (BMI equal or greater than 30) Age over 18 years
Exclusion criteria:
Not being pregnant Had no history of hypothyroidism, diabetes, cancer or mental disorders such as depression and bulimia nervosa

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization (4-digit blocks)

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 Hamadan University of Medical Sciences
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838736
Approval date
2020-02-08, 1398/11/19
Ethics committee reference number
IR.UMSHA.REC.1398.984

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
At the beginning and at the end (2 months after starting the intervention)
Method of measurement
Calculating BMI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Conducting an educational intervention including education on self-esteem and ways to increase it in 4 training sessions for 2 months by a psychiatrist.
Category
Behavior

2

Description
Control Group: All routine weight loss programs are similar to the intervention group, including diet, physical activity, etc., without self-esteem training in the intervention group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Preventive Clinic, Farshchian Heart center, Hamadan
Full name of responsible person
Elham Meidanchi
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan

Postal code
6517838736
Phone
+98 81 3838 1741
Email
seifrabiei@yahoo.com
Web page address
<https://hcvc.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3131 4058
Email
shokoohi@yahoo.com
Web page address
<https://research.umsha.ac.ir/page-research15081400/fa/6/form/pId3284>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mohamadali Seifrabiei
Position
Associate professor
Latest degree

Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0462
Email
seifrabiei@yahoo.com
Web page address
<https://medschool.umsha.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohamadali Seifrabiei
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0462
Email
seifrabiei@yahoo.com
Web page address
<https://medschool.umsha.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohamadali Seifrabiei
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0462

Email

seifrabiei@yahoo.com

Web page address

<https://medschool.umsha.ac.ir/>

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

All of the data are sharable after being anonymous

When the data will become available and for how long

Start of access one year after publishing the results

To whom data/document is available

Employees in Medical Universities

Under which criteria data/document could be used

No limitation

From where data/document is obtainable

Dr. Mohamadali Seifrabiei seifrabiei@yahoo.com

What processes are involved for a request to access data/document

Utmost 2 weeks after the request

Comments