

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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.

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<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.  
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shokoohi@yahoo.com  
**Web page address**  
<https://research.umsha.ac.ir/page-research15081400/fa/6/form/pld3284>

**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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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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**

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**