

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of the program on improving eating behavior and body image on psychological well-being of obese and overweight women

#### Protocol summary

##### Study aim

Determining the effect of eating and body image improvement program on psychological well-being of obese and overweight women referring to hypertension clinic

##### Design

Clinical trials with control group, with parallel groups, randomized, Sample size 72 people

##### Settings and conduct

By holding 8 sessions on the program for improving eating behavior and body image on psychological well-being of overweight and obese women referred to the hypertension clinic at the Chamran Heart Rehabilitation Center

##### Participants/Inclusion and exclusion criteria

Entry requirements: Having a medical record at the center of the Chamran heart research center, willingness to participate in the study, ability to read and write, and people of the informed form have filled in; Conditions of absence: no overweight and obesity

##### Intervention groups

n intervention group: Eight 90 minute sessions on eating and body image improvement programs on psychological well-being of obese and overweight women In control group: holding two sessions on common topics

##### Main outcome variables

Psychological well-being

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180818040826N1**

Registration date: **2018-11-09, 1397/08/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-09, 1397/08/18**

Update count: **0**

##### Registration date

2018-11-09, 1397/08/18

##### Registrant information

###### Name

Masoomah Mahmoudi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7576

###### Email address

masoomah.mahmoudi61@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the program on improving eating behavior and body image on psychological well-being of obese and overweight women

##### Public title

Evaluating the effect of improving eating habits in obese women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Have a medical record at Chamran Heart Center The desire to participate in the study People have filled in the form Ability to read and write

**Exclusion criteria:**

The presence of chronic diseases

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 72

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, the samples will be selected using the random number table method, so that all individuals who come to the Chamran Heart Rehabilitation Center who will accept acceptable conditions for entering the research will be selected according to a random number table. And are randomly assigned to two groups of test and control.

**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 Isfahan University of Medical Sciences

**Street address**

A thousand jeribs, Isfahan University of Medical Sciences

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-02-24, 1396/12/05

**Ethics committee reference number**

IR.MUI.REC.1396.3.842

**Health conditions studied**

1

**Description of health condition studied**

Psychological well-being

**ICD-10 code**

F54

**ICD-10 code description**

Psychological and behavioural factors associated with disorders or diseases classified elsewhere

**Primary outcomes**

1

**Description**

Psychological well-being

**Timepoint**

Before the intervention, immediately after the intervention and one month after the intervention

**Method of measurement**

Reef Psychological Well-Being Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

The researcher already develops the content of the training based on the texts, books and articles available and according to the approval of the experts in this field. Eating behavior improvement program in 8 sessions of 90 minutes over a period of 8 weeks (one week each week) in groups of 17 to 18, using lecture, group discussion and role play in the educational class of the Chamran Heart Institute The training program will begin with a briefing session in order to acquaint the members with each other, how to hold meetings, how to participate in the research process, to be accountable and to be active in the group, and the importance of research. The content of the sessions is the same for all groups and all study groups provide an educational pamphlet based on the subject of each session, and they are asked to practice the homework daily until the next session, and at the beginning of the next meeting, the discussion They will be posted

**Category**

Behavior

2

**Description**

Holding two sessions on topics such as the recent lifestyle program,

**Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Chamran Heart Rehab center

**Full name of responsible person**

Masoumeh Sadeghi

**Street address**

Postcode: Isfahan, Mashhagh Third, after the city bridge, next to Shahid Chamran Heart Center, Shahid Rahmani Alley, Isfahan Cardiovascular Research Center

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**Province**

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sadeghimasoumeh@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Haghjoy Shaghayegh

**Street address**

A thousand Jebra, Isfahan University of Medical Sciences, Nursing and Midwifery Faculty

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taleghani@nm.mui.ac.ir

**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**

zahra ghazavi/masoomah mahmoudi

**Position**

Faculty Member of Isfahan University of Medical Sciences / MSc

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

A thousand Jebra, Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery, Psychiatric Nursing

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masoomah.mahmoudi61@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ghazavi Zahra

**Position**

Instrutor, Accademic Member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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zahra\_ghazavi@nm.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Masoomah Mamoudi

**Position**

Master of Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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8179614894

**Phone**

+98 31 3778 2599

**Email**

masoomah.mahmoudi61@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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Thesis

**When the data will become available and for how long**

"Starting the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia and academia will be available

**Under which criteria data/document could be used**

Impact on psychological well-being

**From where data/document is obtainable**

Zahra Ghazavi / Masoomah Mahmoudi Faculty Member of  
Isfahan University of Medical Sciences / MSc MA Nursing  
Department of Psychiatric Nursing, Isfahan University of  
Medical Sciences, Isfahan, Iran 8174673461

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

Email or SMS

**Comments**