

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Masoomeh Mahmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7576

Email address

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Haghjoy Shaghayegh

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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

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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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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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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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