

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of an intervention, based on Health Action Process Approach, on obesity surgery outcomes in patients undergone bariatric surgery after one year

Protocol summary

Study aim

Effect of an intervention, based on Health Action Process Approach, on obesity surgery outcomes in patients undergone bariatric surgery after one year

Design

The study had a control group, with parallel groups, arranged in blocks on 90 patients

Settings and conduct

It was in Tehran Obesity Treatment Cohort Center that the educational intervention was done virtually and the control group received routine care in the center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent and one year after bariatric surgery Non-entry conditions: Participant's pregnancy

Intervention groups

Educational interventions aimed at influencing the results of bariatric surgery were carried out on the intervention group using the structures of the health action process approach in the form of lectures, slide shows, sending pamphlets, sending educational and motivational text messages, and the control group received the usual care at the center.

Main outcome variables

Structures of the health action process model for self-management of appropriate diet, physical activity, self-management, blood chemistry parameters, food recall questionnaire, international physical activity questionnaire, BMI, body weight loss percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230722058887N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Maryam Maghsoodlo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3230 2275

Email address

maryam.maghsoodlo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-16, 1402/06/25

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an intervention, based on Health Action Process Approach, on obesity surgery outcomes in patients undergone bariatric surgery after one year

Public title

Comparison of intervention after bariatric surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

One year after surgery Consent to participate

Exclusion criteria:

Pregnancy of participating women

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation: with a computer program, by randomizing alternative blocks with the length of random variable blocks of 2, 4 and 6 And the ratio is 1:1

Consecutive sampling method, 90 people are selected from the center and entered into the sample from among the people who had the conditions to enter the study and did not have the conditions to leave the study.

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 Tehran University of Medical Sciences

Street address

Porsina Alley, Shanzdeh Azar St

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.TUMS.SPH.REC.1400.230

Health conditions studied

1

Description of health condition studied

Bariatric surgery patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-management

Timepoint

4 months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

reminder questionnaire

Timepoint

4 months

Method of measurement

questionnaire

2

Description

Healthy diet with health action process approach model constructs

Timepoint

4 months

Method of measurement

questionnaire

3

Description

Physical activity with the structures of the health action process approach model

Timepoint

4 months

Method of measurement

questionnaire

4

Description

International Physical Activity Questionnaire

Timepoint

4 months

Method of measurement

questionnaire

5

Description

Bariatric surgery self-management behaviors

Timepoint

4 months

Method of measurement
questionnaire

6

Description

Blood chemical parameters Fe

Timepoint

4 months

Method of measurement

Hitachi autoanalyzer

7

Description

Hemoglobin blood chemical parameters

Timepoint

4 months

Method of measurement

Hitachi autoanalyzer

8

Description

Hematocrit blood chemical parameters

Timepoint

4 months

Method of measurement

Cell counter machine

9

Description

BMI

Timepoint

4 months

Method of measurement

Calculate the weight divided by the square of the height

Intervention groups

1

Description

Intervention group: Intervention group: For only the intervention group, we sent a training class, pamphlets and educational SMS

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Obesity Treatment Cohort (Hakim Clinic) درمان (چافی تهران) کلینیک حکیم

Full name of responsible person

Dr. Alireza Khalaj

Street address

Number 49, Manzar Nejad Alley, Shariati St

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5133072100

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+98 21 2664 4853

Email

khalaj.totc@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoume Doreghi

Street address

Porsina Alley, Shanzheda Azar St

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Phone

+98 21 4293 3333

Fax

Email

sph@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

34

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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Maghsoodlo

Position

Student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available