

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of home base exercise versus supervised exercise therapy on weight loss, fitness and muscle mass in patients undergoing Bariatric surgery

Protocol summary

Summary

The study goal is comparing the effectiveness of home-based aerobic and resistance exercise training versus supervised aerobic or strength training on physical fitness, weight loss and muscle mass in obese patients after Bariatric surgery. This study includes 90 patients who had Bariatric surgery 6 weeks ago. The evaluation includes medical history and physical examination, measurement of weight and height to calculate body mass index. Then patients will undergo the 6-minute walking test to determine physical fitness. We evaluate fatigue and shortness of breath based on Borg Scale questionnaire and muscle strength by Dynamo meter. Then Patients will be randomized to 3 different groups: Group 1 includes 30 patients who will receive conventional therapy including sessions how to do aerobic and resistance exercise, supplemental handbook as a reminder for exercises they are supposed to do as well as a pedometer to keep track of their physical activity. Group 2 includes 30 patients who will receive conventional therapy plus 2 sessions of strength training per week each for an hour under supervision of a Sports Medicine physician. Group 3 Includes 30 patients who will receive 2 hourly sessions of aerobic exercise per week supervised by a sport medicine specialist in addition to conventional therapy. At the end of the 3 months we will re-measure all parameters and compare them to the initial values to find out if our interventions by using supervised training make a difference between the values of 3 different groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111064251N6**
Registration date: **2011-12-29, 1390/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-29, 1390/10/08

Registrant information

Name

Haleh Dadgostar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of home base exercise versus supervised exercise therapy on weight loss, fitness and muscle mass

in patients undergoing Bariatric surgery

Public title

The effect of home base exercise versus supervised exercise therapy on weight loss, fitness and muscle mass in patients undergoing Bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with Bariatric Surgery in 1-3 months ago. Exclusion criteria: 1. Those with heart disease may include: heart valve disease , ischemic heart disease , uncontrolled symptomatic arrhythmia , hypertrophic cardiomyopathy; 2. Patients with high systolic blood pressure ≥ 200 and high diastolic blood pressure ≥ 90 ; 3. Uncontrolled metabolic diseases; 4. Neuromuscular, musculoskeletal and rheumatoid disease that Resonance with exercise; 5. Acute pulmonary embolism; 6. Symptomatic chronic heart failure.

Age

From **15 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ghods street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2011-11-19, 1390/08/28

Ethics committee reference number

130.1764/90/ص

Health conditions studied

1

Description of health condition studied

weight loss in morbid obese patients

ICD-10 code

E66.8

ICD-10 code description

Morbid obesity

Primary outcomes

1

Description

Body mass index

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

$BMI = (Weight \text{ in Kilograms} / (Height \text{ in Meters} \times Height \text{ in Meters}))$

2

Description

physical fitness

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

6-minute walk test

3

Description

Muscle mass

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

Bioelectrical impedance analysis

4

Description

muscle strength

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

hand dynamometer

5

Description

Exertional dyspnea

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

Borg scale questionnaire

Secondary outcomes

1

Description

waist circumference

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

in centimeters by Tape

2

Description

Heart rate

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

Stethoscope

3

Description

weight

Timepoint

6 weeks after bariatric surgery and 4.5 months after surgery

Method of measurement

in kilograms by Balance

Intervention groups

1

Description

Group 1: includes 30 patients who will receive conventional therapy including session of how to do aerobic and resistance exercise, supplemental handbook as a reminder for exercises they are supposed to do as well as a pedometer to keep track of their physical activity.

Category

Lifestyle

2

Description

Group 2: includes 30 patients who will receive conventional therapy plus 2 sessions of strength training per week each for an hour under supervision of a Sports Medicine physician

Category

Lifestyle

3

Description

Group 3: Includes 30 patients who will receive 2 hourly sessions of aerobic exercise per week supervised by a sport medicine specialist in addition to conventional therapy.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity clinic of Rasoul Akram Hospital

Full name of responsible person

Hanieh Adib MD

Street address

Rasoul Akram Hospital, Sattar Khan Ave., Niaiesh St.,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi MD

Street address

Tehran University of Medical Sciences, Keshavarz Boulevard, Ghods St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Haleh Dadgostar MD

Position

Assistant professor

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty