Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 comitte 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 in Kilograms / (Height in Meters x Height 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 daynamo meter

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 Boulvard, 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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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