Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Inspiratory Muscle Training Versus Conventional Home-based Breathing Training in Bariatric Surgery Patients at High risk For Obstructive Sleep Apnea: A Single-blind Randomized Clinical Trial.

Protocol summary

Study aim

Evaluating the effectiveness of IMT compared to standard home-based breathing exercises in patients three months after bariatric surgery who are at high risk for obstructive sleep apnea based on the Stop-Bang questionnaire.

Design

Randomized, parallel-group, single-blind, Phase 3 involving 40 patients; block randomization (with a block size of four) and sealed envelopes are used for the randomization process.

Settings and conduct

At the Sports Medicine Department of Sina Hospital, participants will be randomly assigned to two groups and undergo a 12-week intervention, twice weekly: inspiratory muscle training (Group A) or conventional home-based breathing exercises (Group B). Study outcomes will be assessed at baseline, week 6, and week 12, with outcome assessors blinded to group allocation.

Participants/Inclusion and exclusion criteria

Individuals aged 18–65 years who underwent bariatric surgery 3 months prior to study enrollment and were considered at high risk for OSA based on a STOP-Bang score ≥3 will be eligible for inclusion. Individuals with a previously confirmed diagnosis of OSA undertreatment with CPAP, serious postoperative complications, uncontrolled pulmonary and cardiovascular disease and absolute or relative contraindications to MIP testing or IMT will be excluded from the study.

Intervention groups

The intervention is administered twice weekly for 12 weeks in both groups. Patients in Group A undergo inspiratory muscle strength training, while those in Group B perform standard home-based breathing exercises.

Main outcome variables

Maximal inspiratory pressure, Dynamic inspiratory muscle function, Daytime sleepiness, Sleep quality, Physical function and Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260913071032N1**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date

2026-09-17, 1405/06/26

Registrant information

Name

Maryam Eghtesadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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m-eghtesadi@farabi.tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-06, 1405/08/15

Expected recruitment end date

2027-11-06, 1406/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Inspiratory Muscle Training Versus Conventional Home-based Breathing Training in Bariatric Surgery Patients at High risk For Obstructive Sleep Apnea: A Single-blind Randomized Clinical Trial.

Public title

Effectiveness of inspiratory muscle training versus conventional home-based breathing exercises in bariatric surgery patients at high risk for obstructive sleep apnea.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing bariatric surgery (Sleeve Gastrectomy or Gastric Bypass) 3 months prior Pre-operative BMI ≥ 35 kg/m² or ≥ 30 kg/m² with obesity-related comorbidities High risk for OSA based on a STOP-Bang score ≥ 3 Ability to perform breathing exercises and walk independently Written informed consent to participate in the study

Exclusion criteria:

Prior definitive diagnosis of OSA and current use of CPAP or BiPAP, or initiation of CPAP during the study period Serious post-bariatric surgery complications including, Anastomotic leak, Readmission or Severe infection Uncontrolled pulmonary diseases including, Moderate to severe COPD, Uncontrolled asthma or Interstitial lung disease Unstable cardiac disease including, Uncontrolled heart failure, Unstable angina, Pulmonary hypertension, Uncontrolled hypertension (HTN) Neurological or neuromuscular disorders affecting respiration Pregnancy Non-adherence to the training regimen (completing fewer than 70% of training sessions) Absolute and relative contraindications for MIP testing and IMT use, including, Tympanic membrane disorders or a history of tympanic membrane surgery, history of pneumothorax, presence of pulmonary bullae, osteoporosis and high risk of rib fracture during IMT and MIP testing, patients with pacemakers or electronic/magnetic implants, intraocular diseases and disorders (glaucoma, retinal disorders, diabetic retinopathy, etc.), Large abdominal hernia requiring surgical repair, recent abdominal surgery (excluding bariatric surgery performed 3 months prior) Severe orthopedic or neuromuscular diseases or disorders which prevent functional outcome assessment via the 6MWT

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to either Group A or Group B using block randomization (block size of four) and sealed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessment of patient outcomes conducted before, during, and at the end of the intervention is performed by a trained assessor, while the other stages of the intervention are carried out by the researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences, Sina Hospital

Street address

School of Medicine of Tehran University of Medical Sciences, Poursina Street, Qods Street, Enghelab Street

City

Tehran

Province

Tehran

Postal code

1461884513

Approval date

2026-09-06, 1405/06/15

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1405.081

Health conditions studied

1

Description of health condition studied

Bariatric surgery, Obesity, Obstructive sleep apnea, Inspiratory muscle training

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before intervention, 6 and 12 weeks after the start of the

intervention

Method of measurement

Pitsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description

Daytime Sleepiness

Timepoint

Before the intervention, six and twelve weeks after the intervention

Method of measurement

Epworth Sleepiness Scale

2

Description

Submaximal functional performance

Timepoint

Before the intervention, six and twelve weeks after the intervention

Method of measurement

6 Minutes Walk Test

3

Description

Quality Of Life

Timepoint

Before the intervention, six and twelve weeks after the intervention

Method of measurement

Short Form Survey-36

4

Description

Maximal Inspiratory Pressure

Timepoint

Before the intervention, six and twelve weeks after the intervention

Method of measurement

Power Breathe Device K5

5

Description

Dynamic inspiratory muscle function

Timepoint

Before the intervention, six and twelve weeks after the intervention

Method of measurement

S-index

Intervention groups

1

Description

Intervention group: In addition to standard post-bariatric surgery care, patients will undergo inspiratory muscle training using the PowerBreathe K5 device for 12 weeks. Training will commence at an intensity of 30% of Maximum Inspiratory Pressure (MIP) and—depending on the patient's condition and tolerance—will be increased to 40–60% of MIP over the course of 2 to 4 weeks. The sessions will consist of 30 breaths, organized into six sets of five breaths with a one-minute rest interval between sets; training will be conducted twice weekly under the supervision of a researcher in the sports medicine department.

Category

Rehabilitation

2

Description

Intervention group: In addition to standard post-operative care, patients will perform routine home-based breathing exercises, including diaphragmatic breathing, deep controlled breathing, and the use of an incentive spirometer for a period of 12 weeks. These exercises will be conducted twice weekly; patients will receive in-person instruction on the correct technique and will be provided with an instructional video and a logbook to record their practice. To monitor adherence, patients will be contacted by phone every 10 days.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Eghtesadi
Position
Sports medicine specialist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol, research findings, and data analysis will be published as scientific articles upon completion of the study. Other study-related data and documentation will be made available to interested parties upon request—subject to feasibility—by contacting the principal investigator via email. Access to the data will be granted in compliance with principles of confidentiality and the protection of participants' information.
When the data will become available and for how long
Following the publication of the article, access to the mentioned data will be possible under the specified conditions.
To whom data/document is available
The data will be available to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
Requests for access to de-identified individual-level data or other study documentation must be submitted via email to the principal investigator. Applicants must clearly state the purpose and intended use of the data or documentation in their request. Use of the provided data is permitted solely for scientific and research purposes, and any attempt to re-identify participants is prohibited. Statistical analyses and research activities aligned with the study's scientific objectives are permitted, provided that data confidentiality and research ethics principles are upheld. Furthermore, the publication or presentation of results derived from the data analysis must be conducted in a manner that precludes the identification of participants. Requests will be reviewed by the principal investigator, and upon approval, the requested data or documentation will be made available to the applicant.
From where data/document is obtainable
Principal investigator of the study; requests for data or documentation can be made by emailing the principal investigator.
What processes are involved for a request to access data/document
The applicant's request is submitted via email to the principal investigator and must include the applicant's details, the purpose of obtaining the data or documentation, and the specific type of data or documentation required. The request is reviewed by the principal investigator, and upon approval, the requested de-identified data or documentation is provided to the applicant. Prior to the release of the data, the importance of maintaining confidentiality and refraining from any attempt to re-identify participants is emphasized.
Comments