Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Feb 2026

Investigating the Effect of Weight Loss through Bariatric Surgery and Exercise on Knee Pain and Function in Women with Sarcopenic Obesity and Knee Osteoarthritis

Protocol summary

Study aim

The aim of this study is to evaluate the effect of weight loss through bariatric surgery combined with exercise programs on knee pain and function in women with sarcopenic obesity and knee osteoarthritis. The study also seeks to compare the effects of different types of exercise on the clinical improvement of these patients.

Design

This is a randomized, single-blind, parallel-group clinical trial conducted on 40 women with sarcopenic obesity and knee osteoarthritis after bariatric surgery. Participants are block-randomized into two exercise groups receiving whey protein: one with aerobic exercise alone and the other with both aerobic and resistance training.

Settings and conduct

This single-blind trial at Sina Hospital sports and exercise medicine ward studies aerobic vs. resistance exercise with whey protein on knee pain and function in sarcopenic obese women post-bariatric surgery. Participants are randomly assigned and blinded to exercise type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with sarcopenic obesity, BMI >40, bariatric surgery candidates with knee osteoarthritis, no recent intra-articular treatment or physiotherapy, and adequate function. Exclusion criteria: arthroplasty history, protein allergy, uncontrolled heart or lung disease, neurological/cognitive disorders, less than 70% exercise adherence post-surgery, or physiotherapy during the study.

Intervention groups

Both groups follow a low-calorie diet with whey protein. The control group does aerobic walking, while the intervention group adds resistance training. Training is supervised then home-based, with intensity monitored. Progress is logged; missing over 30% of sessions leads to exclusion. Acetaminophen up to 1000 mg/day is allowed for pain.

Main outcome variables

Body composition; pain intensity; improvement in muscle function and sarcopenic indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250603066046N1**
Registration date: **2025-06-13, 1404/03/23**
Registration timing: **prospective**

Last update: **2025-06-13, 1404/03/23**
Update count: **0**

Registration date

2025-06-13, 1404/03/23

Registrant information

Name

Farideh karimipour Haddadan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2241 1331

Email address

f-karimip@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Weight Loss through Bariatric Surgery and Exercise on Knee Pain and Function in Women with Sarcopenic Obesity and Knee Osteoarthritis

Public title
The Effect of Weight Loss and Exercise on Knee Pain and Function in Women with Sarcopenic Obesity and Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with a BMI over 40 who are candidates for bariatric surgery and willing to undergo the procedure. Diagnosis of knee osteoarthritis based on the American College of Rheumatology criteria and radiographic evidence according to Kellgren-Lawrence grades 2 to 4. A skeletal muscle mass to height squared ratio of less than 5.7 kg/m², or skeletal muscle mass less than 15 kg. No intra-articular injection, exercise therapy, or physiotherapy within one month prior to enrollment. Walking speed less than 1 meter per second over a 6-meter distance. Grip strength less than 27 kg in men and less than 16 kg in women. Taking more than 15 seconds to perform five chair stands (sit-to-stand test). Timed Up and Go Test result equal to or greater than 20 seconds. 400-meter walk test time equal to or more than 6 minutes.
Exclusion criteria:
History of knee or hip arthroplasty Allergy to protein-based compounds Uncontrolled hypertension Any uncontrolled cardiac or pulmonary disease Neurological or cognitive disorders Failure to complete at least 70% of the post-surgery exercise therapy program Participation in a physiotherapy program during the study period
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization with a fixed block size of 4 was used to allocate participants into two groups: aerobic exercise (A) and resistance training (B), in order to maintain balance between groups over time. All possible combinations of assigning two participants to group A and two to group B within each 4-person block were considered (e.g., AABB, ABAB, ABBA, BAAB, BABA, BBAA). One of these combinations was randomly selected for each block. For instance, if the combination ABBA was randomly chosen, the first and fourth participants would be assigned to group A, and the second and third to group B. The randomization process was conducted using randomization software and carried out by an independent individual to prevent any potential allocation bias.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are informed that they are receiving a type of “standard postoperative exercise program” that includes “various exercises tailored to their physical condition,” without specifying whether the program consists of aerobic or resistance training.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sina Hospital – Tehran University of Medical Sciences (Research Ethics Committee)
Street address
Research Deputy Office, Sina Hospital, before Hassan Abad Square, Imam Khomeini Street
City
Tehran
Province
Tehran
Postal code
4691111367
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.051

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
KOOS Questionnaire Score
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
Completion of KOOS form

2

Description
Knee pain
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
Recording pain intensity on a graded paper (Visual Analogue Scale or VAS)

Secondary outcomes

1

Description
Gait Speed
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
Measurement of distance covered per unit of time

2

Description
Score of Timed up and go test
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
The Timed Up and Go (TUG) test measures functional mobility by timing how long it takes a person to rise from a chair, walk 3 meters, turn around, return, and sit down. The test begins when the person starts to stand and ends once they are seated again.

3

Description
Grip Strength Measurement
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
With Isometric Dynamometer

4

Description
Chair Standing Test Score
Timepoint
Before bariatric surgery, and at 1 month, 3 months
Method of measurement
Measurement of the time it takes to stand up and sit down on a chair five times.

Intervention groups

1

Description
Intervention group: All participants, following bariatric surgery, will be placed on a standardized post-surgical dietary plan consisting of a low-calorie intake (800–1000 kcal/day) supplemented with 30 grams of whey protein (Kaleh Company) daily. This nutritional protocol is intended to support muscle preservation and recovery during the post-operative period and throughout the intervention. In addition to dietary management, participants in the intervention group will engage in a structured physical activity program comprising both aerobic and resistance training components:1. Aerobic Exercise: Participants will perform low- to moderate-intensity walking sessions for 30 minutes per day, five days a week. To increase adherence and reduce fatigue, walking will be broken into three 10-minute sessions distributed throughout the day. The walking intensity will be adjusted to maintain a perceived exertion between 13 and 15 on the Borg Scale, ensuring safe and effective cardiovascular stimulation. 2. Resistance Training: Strength training will be conducted three times per week and will include exercises targeting both upper and lower limbs. Specifically, five exercises for the upper extremities and five for the lower extremities will be performed using TheraBand resistance bands (starting with red bands). The initial training load will consist of one set of 10 repetitions, gradually progressing to three sets of 10 repetitions as tolerated. Intensity will be monitored using the Borg Rate of Perceived Exertion (RPE) scale, and bands will be upgraded to higher resistance levels if the reported exertion falls below the target range of 13–15. The first resistance training session will be conducted under supervision at the clinic, where participants will be instructed on proper techniques and safety protocols. Subsequent sessions will be performed at home, with participants required to record their exercise adherence and progress in a logbook. Participants completing less than 70% of the scheduled exercise sessions will be excluded from the final analysis. 3. Pain Management: Participants will be allowed to consume up to 1000 mg of acetaminophen per day as needed for knee pain. They will be instructed to document the dosage and frequency of usage to monitor the potential influence of analgesics on outcome measures. This combined intervention aims to evaluate the synergistic effects of aerobic activity, resistance training, and protein supplementation on knee pain, physical function, body composition, and sarcopenic indices in women with sarcopenic obesity following bariatric surgery.
Category
Rehabilitation

2

Description
Control group: All participants, following bariatric surgery, will follow a standardized post-operative dietary

plan consisting of a low-calorie intake (800 to 1000 kcal/day) along with 30 grams of whey protein supplementation (Kalleh Co.) per day. This nutritional protocol is designed to preserve muscle mass and support recovery during the post-operative period and throughout the intervention.In addition to dietary management, participants in the control group will engage in a structured exercise program that includes only the aerobic component:1. Aerobic Exercise: Participants will perform low- to moderate-intensity walking sessions for 30 minutes per day, five days a week. To enhance adherence and reduce fatigue, walking will be divided into three 10-minute sessions throughout the day. Walking intensity will be adjusted to maintain a perceived exertion between 13 and 15 on the Borg Scale, ensuring safe and effective cardiovascular stimulation.2. Pain Management: Participants will be allowed to take up to 1000 mg of acetaminophen per day as needed for knee pain. They will be instructed to document the amount and frequency of intake so that the potential impact of analgesics on study outcomes can be evaluated.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital
Full name of responsible person
Farideh Karimipour Haddadan
Street address
Sina Hospital, before Hassan Abad Square, Imam Khomeini Street
City
Tehran
Province
Tehran
Postal code
4691111367
Phone
+98 21 6312 1395
Email
f-karimp@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
6th Floor, Deputy of Research and Technology, Central Administration Building of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology, 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
Farideh Karimipour Haddadan
Position
Resident Physician
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Sina Hospital, before Hassan Abad Square, Imam Khomeini Street
City
Tehran
Province
Tehran
Postal code
4691111367
Phone
+98 21 6634 8587
Email
f-karimip@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Maryam Abolhasani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

Street address
Sina Hospital, before Hassan Abad Square, Imam Khomeini Street

City
Tehran

Province
Tehran

Postal code
46911111367

Phone
+98 21 6634 8587

Email
abolhasani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Farideh Karimi Haddadan

Position
Resident Physician

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

Street address
Sina Hospital, before Hassan Abad Square, Imam Khomeini Street

City
Tehran

Province
Tehran

Postal code
4691111367

Phone
+98 21 6634 8587

Email
f-karimip@razi.tums.ac.ir

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
No - There is not 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
This research has been registered as a thesis proposal for the Sports Medicine Residency Program. The resulting thesis will include participant data (all data), the study protocol, statistical analysis, and a full report of the study (including all variables), and will be submitted to Tehran University of Medical Sciences and the Department of Sports Medicine. It is noteworthy that, upon approval of the thesis, a comprehensive article covering all the aforementioned aspects will be published in a journal relevant to the subject. Access to raw data not included in the final report or published article requires direct contact with the principal investigator.

When the data will become available and for how long
The present study started on 22 June 2025 (01/04/1404 in the Iranian calendar) and is expected to last for two years until its completion as a thesis. The data obtained from this research will be submitted for publication after the thesis is approved (at the end of the two-year period). Access to raw data not included in the final report or published article will be possible after publication by contacting the study’s corresponding researcher.

To whom data/document is available
The data obtained from this study will be available to all interested individuals without any restrictions.

Under which criteria data/document could be used
There are no restrictions on the use, publication, or processing of this study’s data, provided that prior communication is made with the principal investigator via email or other means, and the necessary permission is obtained from the principal investigator.

From where data/document is obtainable
To access information about this study, the applicant can contact the principal investigator via email or phone.

What processes are involved for a request to access data/document
Permission to use the information will be granted to the applicant as soon as their email is received or a phone call is made. The requested information will then be promptly sent to the applicant via their email.

Comments