Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of combined foam roller and aerobic exercises versus foam roller exercises alone on cytokine and adipokine levels in sedentary elderly overweight men

Protocol summary

Study aim
Comparison of combined foam roller and aerobic exercises versus foam roller exercises alone on cytokine and adipokine levels in sedentary elderly overweight men

Design
This trial had a control group, with parallel and unblinded groups, conducted using simple randomization on 31 healthy, sedentary, overweight elderly men. A table of random numbers was used for randomization.

Settings and conduct
The study was conducted in an indoor futsal hall in Kerman province, and the study population of this trial was sedentary elderly men between the ages of 60 and 70.

Participants/Inclusion and exclusion criteria
Inclusion criteria: not engaging in regular physical activity throughout the week (at least three days per week for 30 minutes); Overweight older adults aged 60 to 70 years. Exclusion criteria: Presence of specific diseases such as ...(MS, cancer, Parkinson's); undergoing surgery in recent months

Intervention groups
Intervention Group 1; Foam Roller Group: In this group, the subjects performed only foam roller exercises for 3 months, which included upper body and lower body exercises. Intervention Group 2; Foam Roller-Aerobic Group: In this group, the subjects performed fast walking or slow jogging along with foam roller exercises for the lower body muscles for 3 months. Control Group: no type of exercise or intervention was conducted.

Main outcome variables
Irisin; interleukin-6; Adipolin; glycophorin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251029067810N1**
Registration date: **2026-08-16, 1405/05/25**
Registration timing: **retrospective**

Last update: **2026-08-16, 1405/05/25**
Update count: **0**

Registration date
2026-08-16, 1405/05/25

Registrant information

Name
Hamidreza Shakermahani

Name of organization / entity
The University of Tehran

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-30, 1402/03/09

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
2023-07-31, 1402/05/09

Actual recruitment end date
2023-09-01, 1402/06/10

Trial completion date
2024-05-27, 1403/03/07

Scientific title

Comparison of combined foam roller and aerobic exercises versus foam roller exercises alone on cytokine and adipokine levels in sedentary elderly overweight men

Public title

The effects of combining foam roller exercises and aerobic exercises on cytokine and adipokine levels in sedentary overweight elderly men.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

They do not engage in regular physical activity throughout the week (at least three days per week for 30 minutes). Participants should not have a history of smoking or drinking alcoholic beverages. Participants should not have undergone any surgery in the three months prior to the start of the exercise protocol and should not have had any fractures in their limbs. Overweight older adults aged 60 to 70 years were enrolled in the study protocol.

Exclusion criteria:

Presence of specific diseases such as ...(MS, cancer, Parkinson's) History of smoking and alcohol consumption Undergoing specific surgery within 3 months prior to the start of the exercise protocol Presence of fractures in the limbs

Age

From **60 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Using Random Number Table Method. In this method, a table was prepared containing numbers 1 to 31 arranged completely randomly. Each of the 31 subjects was assigned a number. For the starting point and the first desired number, a number was selected randomly by chance. From the starting point, numbers were read row by row, and for each of the 3 groups, numbers were extracted and assigned to the intervention and control groups.

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 and Research Committee of the Faculty of Sports Sciences and Health, University of Tehran

Street address

Opposite the Daneshgah Alley, between 15th and 16th streets, above Jalal Al-Ahmad intersection, North Kargar Street

City

Tehran

Province

Tehran

Postal code

1439813117

Approval date

2023-07-02, 1402/04/11

Ethics committee reference number

IR.UT.SPORT.REC.1402.043

Health conditions studied

1

Description of health condition studied

Overweight in the elderly.

ICD-10 code

E66.3

ICD-10 code description

Overweight

2

Description of health condition studied

physical inactivity in the elderly

ICD-10 code

Z72.3

ICD-10 code description

Lack of physical exercise

Primary outcomes

1

Description

Serum irisin level

Timepoint

Before the start of the intervention and after 3 months at the end of the exercises

Method of measurement

Through the ELISA test.

2

Description

Serum interleukin-6 level

Timepoint

Before the start of the intervention and after 3 months at the end of the exercises

Method of measurement

Through the ELISA test

3

Description

Serum adipolin level

Timepoint

Before the start of the intervention and after 3 months at the end of the exercises

Method of measurement

Through the ELISA test

4

Description

Serum glycophorin level

Timepoint

Before the start of the intervention and after 3 months at the end of the exercises

Method of measurement

Through the ELISA test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Foam Roller Group. The foam roller is a fitness tool used for myofascial release. In this study, 11 participants in the foam roller group performed foam roller exercises for 3 months, three days a week, at a specific time in a gym. The exercises in the foam roller group included upper and lower body workouts, which were conducted with a predetermined structure. The foam roller used in this intervention was manufactured in Taiwan.

Category

Other

2

Description

Intervention group 2: foam roller - aerobic.This group consisted of 11 subjects, and the subjects exercised in a gym three days a week at a specific time for 3 months. The aerobic protocol consisted of 40 minutes of brisk walking or jogging at 50 to 60 percent of maximum heart rate reserve. Foam roller exercises included only lower body exercises.

Category

Other

3

Description

Control group: without any intervention. From the control group, only blood samples, anthropometric measurements, and initial assessments were taken. Measurements and tests were performed once before the start of the training protocol and once 3 months later, after the completion of the intended exercises and interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Neshat’s Pathobiology Laboratory.

Full name of responsible person

Ali Neshat

Street address

Dr. Neshat’s Laboratory, 1st Floor, Atyeh Building, after Imam Jom’ah Crossroads, Jomhoori Eslami Boulevard.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of tehran

Full name of responsible person

Dr.Rahman Soori

Street address

In front of Tehran University Alley, between 15th Street and 16th Street, above the Jalal Al-Ahmad Intersection, North Kargar Street.

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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
The University of tehran
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
The University of tehran
Full name of responsible person
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the data can be shared Data related to the main factors of the article, which include Interleukin-6, Irisin, Adiponectin, and glycophorin.
When the data will become available and for how long
Six months after the results were published

To whom data/document is available

Lecturers and researchers employed by universities

Under which criteria data/document could be used

Keeping the authors of the article informed

From where data/document is obtainable

Hamidreza shakermahani Hamidreza.shaker@ut.ac.ir 09211986959

What processes are involved for a request to access data/document

It will be sent after talking with the author within the appropriate timeframe

Comments