Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effects of two training methods: electrical muscle stimulation (EMS) and high-intensity functional training (HIFT) on FTO gene expression and metabolic functions in obese men

Protocol summary

Study aim

To investigate the effects of two training methods — electrical muscle stimulation (EMS) and high-intensity functional training (HIFT) — on FTO gene expression and metabolic functions (including fasting glucose, serum insulin, serum leptin, and insulin resistance) in obese men.

Design

A semi-experimental, three-arm, randomized controlled trial with a control group. The target population will be randomly allocated into three groups: (1) electrical muscle stimulation, (2) high-intensity functional training, and (3) control.

Settings and conduct

The study will be conducted in Shiraz, Iran. The exercise intervention will be implemented over 8 weeks, with a frequency of three sessions per week, under the direct supervision of the researcher. Fasting blood samples will be collected from the brachial vein of participants before the intervention and 24 hours after the final training session.

Participants/Inclusion and exclusion criteria

The study population comprises sedentary obese men in Shiraz with a mean age of 30–40 years and a body mass index (BMI) of 30–35 kg/m². Forty-five eligible participants will be selected through convenience sampling. Inclusion criteria include the absence of cardiovascular, renal, hepatic, or respiratory (asthma) disease; no musculoskeletal abnormalities; no history of surgery; no use of supplements or medications; no regular exercise participation within the past 6 months; and no use of tobacco or alcohol.

Intervention groups

Group 1: Electrical muscle stimulation (EMS) — 8 weeks, 3 sessions/week, 20 minutes per session Group 2: High-intensity functional training (HIFT) — 8 weeks, 3 sessions/week Group 3: Control (no intervention)

Main outcome variables

FTO gene expression (measured via quantitative real-time PCR), fasting glucose, fasting serum insulin, serum leptin, and insulin resistance (HOMA-IR).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191210045690N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date

2026-08-31, 1405/06/09

Registrant information

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Homa Sheikhani Shahin
Name of organization / entity
Zand Institute of Higher Education
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-21, 1405/04/30

Expected recruitment end date

2026-09-21, 1405/06/30

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

Scientific title
Studying the effects of two training methods: electrical muscle stimulation (EMS) and high-intensity functional training (HIFT) on FTO gene expression and metabolic functions in obese men

Public title
The Effects of EMS and HIFT on FTO gene expression and metabolic functions
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Body Mass Index between 30 and 35 kg/m², No history of cardiovascular disease, renal failure, liver failure, or asthma, No musculoskeletal abnormalities, No history of surgery, No use of any supplements or medications, No history of regular participation in exercise training for at least 6 months prior to the start of the study, No tobacco use or alcohol consumption
Exclusion criteria:
Age
From **30 years** old to **40 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization
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 Shiraz University
Street address
Republic of Islamic Boulevard
City
Shiraz
Province
Fars
Postal code
۸۴۳۳۴ - ۷۱۹۴۶
Approval date
2026-07-21, 1405/04/30
Ethics committee reference number
IR.US.PSYEDU.REC.1405.083

Health conditions studied

1

Description of health condition studied
FTO gene expression and metabolic functions
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
FTO gene expression
Timepoint
Before starting the intervention and eight weeks after performing electrical muscle stimulation an high-intensity functional training
Method of measurement
Real Time-PCR

2

Description
Serum Leptin
Timepoint
Before starting the intervention and eight weeks after performing electrical muscle stimulation an high-intensity functional training
Method of measurement
ELISA (Enzyme-Linked Immunosorbent Assay)

3

Description
Fasting Plasma Glucose
Timepoint
Before starting the intervention and eight weeks after performing electrical muscle stimulation an high-intensity functional training
Method of measurement
Glucose oxidase enzymatic method

4

Description
Serum Insulin
Timepoint

Before starting the intervention and eight weeks after performing electrical muscle stimulation an high-intensity functional training

Method of measurement

Radioimmunoassay

5

Description

Insulin Resistance

Timepoint

Before starting the intervention and eight weeks after performing electrical muscle stimulation an high-intensity functional training

Method of measurement

Homeostatic model assessment of insulin resistance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Behavior

2

Description

Control group:

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bitaran laboratory

Full name of responsible person

Iman Jamhiri

Street address

No. 52, Alley 11, Haft Tanan Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zand Institute of Higher Education

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Zand Institute of Higher Education

Full name of responsible person

Homa Sheikhani Shahin

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared due to the need to protect participants' confidentiality and privacy and to prevent potential identification of individual participants. Sharing individual-level data may also be inconsistent with ethical requirements and the scope of informed consent obtained from the participants. The study results will be reported and published in an aggregated form without any identifiable participant information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
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
Individual participant data include demographic information, laboratory findings, FTO gene expression, and other metabolic indicators. Individual-level data will not be publicly released or made openly accessible, and the study findings will be reported in an aggregated and non-identifiable form.

When the data will become available and for how long
Individual participant data will not be made publicly accessible after completion of the study.

To whom data/document is available
Individual participant data will be accessible only to authorized members of the research team and solely for research purposes.

Under which criteria data/document could be used
Individual participant data will not be publicly shared. If access is scientifically justified, data may only be used subject to protection of participants' confidentiality, ethical requirements, and the necessary approvals.

From where data/document is obtainable
In case of a justified scientific request, the request should be submitted to the principal investigator of the study.

What processes are involved for a request to access data/document
An access request should be formally submitted and reviewed for scientific and ethical considerations. If approved and the necessary permissions are obtained, only the required non-identifiable data will be provided to the requester.

Comments
To protect participants' privacy and confidentiality, identifiable individual-level data will not be publicly released. The study findings will be reported in the master's thesis and submitted for publication in a scientific journal.