Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of high-intensity functional training on the expression of miR-637, CRP and lipid profile levels in overweight/obese women

Protocol summary

Study aim

Determining the effect of high-intensity functional training on the expression of miR-637, CRP, RBP HuR and lipid profile levels in overweight/obese women

Design

The clinical trial will consist of two groups. Twenty-four overweight and obese women aged 35 to 45 years (voluntarily) will be divided into two groups of intervention (Functional training) and control (without intervention) with random arrangement (simple randomization). The present design will be a semi-experimental and single blind.

Settings and conduct

In a quasi-experimental research project, 24 overweight and obese women aged 35 to 45 years were considered as a research sample. Subjects will be randomly divided into 2 groups of 12: control and High Intensity Functional Training (HIFT). The training protocol is performed 3-4 days a week for eight weeks. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session. All measurements and exercises will be measured in the Tabriz Technical and Vocational University.

Participants/Inclusion and exclusion criteria

inclusion criteria: overweight and obese women aged 35 to 45 years, without cardiorespiratory problems, body mass index (BMI) 25 to 35, inactive (less than 90 minutes of regular exercise per week), without blood pressure ; The non-use of drugs and anabolic, anti-inflammatory and antioxidant supplements. exclusion criteria: Chronic diseases (such as cardiovascular disease, cancer or respiratory diseases), smoking and BMI<25.

Intervention groups

Two groups: 1- High Intensity Interval Functional (HIFT) and 2- Control Group (will do nothing)

Main outcome variables

miR-637، C-reactive protein (CRP)، Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220128053844N2**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **retrospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

hamid reza zolfi

Name of organization / entity

Technical and vocational university

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 9011

Email address

hzolfi@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-19, 1402/01/30

Expected recruitment end date

2023-05-13, 1402/02/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of high-intensity functional training on the expression of miR-637, CRP and lipid profile levels in overweight/obese women

Public title
Effect of exercise training on obese women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 35 to 45 years Body mass index 25 to 35

Exclusion criteria:
Smoking Taking certain medications to control body weight and blood pressure during the last three months Diastolic and systolic pressures greater than 100 and 140 mm Hg, respectively having neuromuscular diseases as well as cardio-respiratory diseases. Having cardiorespiratory diseases

Age
From **35 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Assigning samples using simple random-lottery method. In this method, first the list of names of all members is obtained. It is then assigned a number to each. It is placed inside the box. The papers are then selected and removed individually until the desired sample size is complete.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study is performed in a single blind manner and the only researchers knows how to assign individuals to different groups.In general, all participants in this project are unaware of what kind of sports group they are said to be, and the researchers will individually give the exercise to individuals and will not be explained to people about the type and name of the exercise. Also, the data analyst, clinical caregiver, outcome assessor, as well as the safety committee and data monitoring will not know how to assign exercise.

Placebo
Not used

Assignment
Parallel

Other design features
In the present study, participants were randomly assigned to two training and control groups. The control group does not receive any intervention (exercise or supplement). Blood samples are taken from the control group only in two time periods.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Research Institute of Movement Sciences

Street address
KhU, No. 43. South Mofatteh Ave., Tehran.

City
Tehran

Province
Tehran

Postal code
1571914911

Approval date
2023-05-02, 1402/02/12

Ethics committee reference number
IR-KHU.KRC.1000.160

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
The level of micro RNA 637 (miR-637)

Timepoint
Before and after starting eight weeks of HIFT training

Method of measurement
Real-Time PCR and using PCR mic

2

Description
The level of C-Reactive Protein (CRP)

Timepoint
Before and after starting eight weeks of HIFT training

Method of measurement
It will be measured by Elisa Reader method with high sensitivity.

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before and after the start of research

Method of measurement

Using the kit of Pars Azmoun company and with the sensitivity of the kit, 5 mg/dl will be measured.

Intervention groups

1

Description

Intervention group: Eight weeks of high-intensity interval training (HIFT). Subjects will participate in high-intensity functional training (HIFT) 3-4 days a week for 8 weeks. Blood samples are taken at rest 48 hours before the start of training and 48 hours after the last training session. The duration of the study period will be 2 months (equal to 8 weeks).

Category

Prevention

2

Description

Control group: Control group: In this group, we will not have any exercise or drug intervention. Blood samples will be taken from the subjects in two stages (48 hours before the start of the research study and 48 hours after the last day of the research period). The duration of the study period will be 2 months (equal to 8 weeks).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Technical and vocational university

Full name of responsible person

Hamidreza Zolfi

Street address

Manzariyeh Ave

City

Tabriz

Province

East Azarbaijan

Postal code

51749-13136

Phone

+98 41 3477 9011

Fax

+98 41 3477 9065

Email

Hamidreza.zolfi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research and Technology, Technical and Vocational University

Full name of responsible person

Javad Saghaei Saeidi

Street address

Manzariyeh Ave

City

Tabriz

Province

East Azarbaijan

Postal code

51749-13136

Phone

+98 41 3477 9011

Fax

+98 41 3477 9065

Email

javadsaidi_2007@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Technical and Vocational University

Proportion provided by this source

5

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

East Azarbaijan Technical and Vocational University

Full name of responsible person

Hamidreza zolfi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Technical and Vocational University. Manzariyeh,Tabriz,East Azerbaijan Province.

City

Tabriz

Province

East Azarbaijan

Postal code

۵۱۷۴۹۱۳۱۳۶

Phone
+98 41 3477 9011
Fax
+98 41 3477 9065
Email
Hamidreza.zolfi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Technical and Vocational University
Full name of responsible person
Hamid Reza Zolfi
Position
Assistant Professor of Exercise Physiology
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Technical and Vocational University of East Azarbaijan, Manzariyeh, Tabriz, East Azarbaijan
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۷۴۹۱۳۱۳۶
Phone
+98 41 3477 9011
Fax
Email
hzolfi@tabrizu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
East Azarbaijan Technical and Vocational University.
Full name of responsible person
Hamid Reza Zolfi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise Physiology
Street address
Technical and Vocational University.
Manzariyeh,Tabriz, East Azerbaijan Province.
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۷۴۹۱۳۱۳۶
Phone
041 - ۳۴۷۷۹۰۱۱ -12- 291 داخلی
Email
Hamidreza.zolfi@yahoo.com

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
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
In the meetings that will be held with the participants before and after the study, all the data and their analysis, consent and trial and study protocol will be explained to them.
When the data will become available and for how long
Depending on the variable, the data of some variables will be accessed before the start of the research and others after the end of the research.
To whom data/document is available
Project participants, researchers and university professors
Under which criteria data/document could be used
Other researchers will be allowed to access the data in order to use and assist other researchers and to commit not to misuse the data.
From where data/document is obtainable
Email - In-person visit
What processes are involved for a request to access data/document
Provide identification documents and research resume and provide commitment in order not to misuse the data
Comments