Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aerobic and resistance and combined exercise on the expression of mir-15a, muscular strength and endurance in women with type 2 diabetes.

Protocol summary

Study aim

1- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on miRNA-15a expression in women with type 2 diabetes 2- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on insulin resistance levels in women with type 2 diabetes 3- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on muscle strength and endurance in women with type 2 diabetes 4- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on insulin in women with type 2 diabetes 5- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on cardiorespiratory endurance in women with type 2 diabetes 6- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on body fat percentage in women with type 2 diabetes 7- Determining the effect of 8 weeks of selected aerobic, resistance and combined training on glycosylated hemoglobin levels in women with type 2 diabetes

Design

Control group: having a normal lifestyle, aerobic, resistance and combined exercise (simultaneous aerobic and resistance exercise intervention)

Settings and conduct

These exercises are performed under the supervision of a sports specialist at the Sedighe Tahereh Endocrinology and Metabolism Research Center.

Participants/Inclusion and exclusion criteria

Type 2 diabetes, failure to participate in regular physical activities over the past year, normal diabetic foot , no chest pain , no history of hospitalization, normal foot pulse, no history of diabetic foot ulcers, no history of retinal hemorrhage and Avastin injection

Intervention groups

Aerobic exercises, resistance exercises, combined exercises, control

Main outcome variables

Improve strength, endurance, disease status, cardiorespiratory endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240721062487N2**
Registration date: **2025-02-27, 1403/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-27, 1403/12/09**
Update count: **0**

Registration date

2025-02-27, 1403/12/09

Registrant information

Name

Sahar Ghasemi pour

Name of organization / entity

The universiy of Isfahan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-03-21, 1404/01/01

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

Scientific title
The effect of aerobic and resistance and combined exercise on the expression of mir-15a, muscular strength and endurance in women with type 2 diabetes.

Public title
Exercise training and type 2 diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Gender: Female Aged between 30-60 years Not participating in regular physical activity Not using drugs Not using insulin injections Normal examination of the diabetic foot Not chest pain or heaviness or history of hospitalization for heart disease Not history of retinal bleeding and Avastin injection(No history of Proliferative retinopathy) No other underlying disease
Exclusion criteria:
Voluntary withdrawal of participants from continuing the study Having a specific illness that prevents physical activity Occurrence of physical injury Absence of more than three session in sports interventions Pregnancy
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Initially, participants are evaluated and ranked according to factors such as muscle strength or endurance and cardiovascular endurance, and subsequently categorized into two groups based on their preferences for specific types of exercise.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants dose not know of their group assignment. The researcher does not know which group each individual is in. The clinical monitor does not know each participant's group assignment.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences - Alzahra Research Centers Complex
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town
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Approval date
2025-02-19, 1403/12/01
Ethics committee reference number
IR.ARI.MUI.REC.1403.244

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
miRNA-15a, FBS, HDL, LDL, CREATININE, Muscle endurance and strength
Timepoint
48 hours before intervention, after intervention for 2 months
Method of measurement
Blood sampling, Dynamometer, Fitness tests

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Having a normal life routine within 8 weeks

Category
Lifestyle

2

Description
Intervention group: Performing aerobic exercise

Category
Lifestyle

3

Description
Intervention group: Performing endurance exercise

Category
Lifestyle

4

Description
Intervention group: Performing combined exercise

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Sedigheh Tahereh Education, Therapeutic and Research Complex

Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan University of Medical Sciences

Proportion provided by this source
10

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 Isfahan

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Position
PhD student

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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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
It can be available upon request from academic researchers, in coordination with the university's Vice President for Research.

When the data will become available and for how long
Three months after publication, the article can be made available at the discretion of the corresponding author and the university's vice president for research.

To whom data/document is available
Only academic researchers can access this information.

Under which criteria data/document could be used
The use of data for statistical analysis and inferential statistics is not permitted.

From where data/document is obtainable
First, coordination must be made with the university's vice president for research and then with the corresponding author.

What processes are involved for a request to access data/document
Official request to the Vice President for Research of the university, administrative correspondence from the Vice President for Research to the corresponding author

Comments