Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparison of the Effects of Eight Weeks of Combined Exercise Training with Two Different Intensities on Attentional Networks, Blood-Brain Barrier-Related Factors, and Explicit Motor Memory in Older Women with Type 2 DiabetesResearch ethics committi of Lourestan univercity

Protocol summary

Study aim

the effectiveness of eight weeks of combined resistance–endurance training at two different intensities on cognitive function and the modulation of biomarkers associated with astrocytic injury, blood–brain barrier dysfunction, and neuroinflammation in older women with type 2 diabetes mellitus

Design

This study is designed as a three-arm, parallel-group randomized controlled trial with pre- and post-intervention assessments to investigate the effects of eight weeks of combined exercise training at different intensities on cognitive function and biomarkers associated with astrocytic injury, blood–brain barrier dysfunction, and neuroinflammation in older women with type 2 diabetes mellitus.

Settings and conduct

this study will be conducted in Chaharmahal and Bakhtiari Province, Iran, at facilities equipped to perform the exercise interventions, cognitive assessments, and laboratory analyses.

Participants/Inclusion and exclusion criteria

Inclusion criteria A confirmed diagnosis of type 2 diabetes mellitus (T2DM) by a physician. HbA1c ≥ 6.5% and fasting blood glucose (FBG) ≥ 126 mg/dL. Current treatment with oral antidiabetic medications. No regular participation in structured exercise during the previous six months. No use of medications known to affect cognitive function or memory. Exclusion criteria included: Musculoskeletal injuries Neurological disorders or chronic inflammatory diseases

Intervention groups

Combined Hypertrophy Resistance Training plus Aerobic Endurance Training group Combined Muscular Endurance Resistance Training plus Aerobic Endurance Training group Active control group

Main outcome variables

Combined aerobic exercise and hypertrophy resistance training (HRT) Combined aerobic exercise and muscular endurance resistance training (ERT) Aerobic exercise (AET)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260714070191N1**
Registration date: **2026-07-27, 1405/05/05**
Registration timing: **prospective**

Last update: **2026-07-27, 1405/05/05**
Update count: **0**

Registration date

2026-07-27, 1405/05/05

Registrant information

Name
Razieh Kooshki
Name of organization / entity
Lorestan University
Country
Iran (Islamic Republic of)
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+98 916 856 8557
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kooshki.r@lu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-02, 1405/06/11

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

A Comparison of the Effects of Eight Weeks of Combined Exercise Training with Two Different Intensities on Attentional Networks, Blood-Brain Barrier-Related Factors, and Explicit Motor Memory in Older Women with Type 2 DiabetesResearch ethics committi of Lourestan univercity

Public title

Effects of Exercise on Cognitive Factors in Elderly Women with Diabetes

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Participants must have a physician-confirmed diagnosis of type 2 diabetes mellitus, HbA1c ≥ 6.5%, fasting blood glucose (FBG) ≥ 126 mg/dL (7.0 mmol/L), and be receiving oral antidiabetic medication.

Exclusion criteria:

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the exercise intervention, blinding of participants and exercise trainers is not feasible. However, outcome assessors (responsible for cognitive, laboratory, and functional measurements) and data analysts will be blinded to participants' group allocation. The group assignment information will be maintained by the principal investigator.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lorestan University Research Ethics Committee

Street address

Golshan 2 Street

City

Khorramabad

Province

Lorestan

Postal code

6814988156

Approval date

2025-11-19, 1404/08/28

Ethics committee reference number

IR.UL.REC.1404.001

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10.4

ICD-10 code description

Type 1 diabetes mellitus with neurological complications

2

Description of health condition studied

Diabetes

ICD-10 code

E10.4

ICD-10 code description

Type 1 diabetes mellitus with neurological complications

Primary outcomes

1

Description

AQP4 (Aquaporin-4)

Timepoint

Study Start and End Dates

Method of measurement

Using specialized laboratory kits

2

Description

Calpain

Timepoint

Study Start and End Dates

Method of measurement

kit

3

Description
GFAP
Timepoint
Study Start and End Dates
Method of measurement
kits

4

Description
S100B
Timepoint
Study Start and End Dates
Method of measurement
kit

Secondary outcomes

empty

Intervention groups

1

Description
Hypertrophy Resistance Training Group
Category
Treatment - Other

2

Description
Intervention group: Endurance Resistance Training Group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
مرکز بهزیستی شهرستان فارسان
Full name of responsible person
زهرا همتی
Street address
No. 1, Alley 4, North Farabi Street, Shahrekord, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Science Foundation of Iran (INSF)
Full name of responsible person
Razieh Kooshki
Street address
Golshan 2 Street
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Khorramabad
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6814988156
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Email
kooshki.razieh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Science Foundation of Iran (INSF)
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
دانشگاه اردکان
Full name of responsible person
Zahra Hemati
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Physiology
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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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

no more information

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

The study results and data will only be published in the form of a scientific article.

When the data will become available and for how long

There is no specific time frame

To whom data/document is available

Researchers

Under which criteria data/document could be used

The data may be made available for research purposes at the discretion of the Principal Investigator.

From where data/document is obtainable

Principal Investigator (PI)

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

The data will be made available for research purposes upon submission of a formal and well-justified request to the Principal Investigator (PI).

Comments