

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of the effect of aerobic training time (morning and evening) on the cognitive and physiological characteristics of the elderly with type 2 diabetes

Protocol summary

Study aim

Investigating the effect of 12 weeks of aerobic exercise in morning and evening on cognitive function and the predictor axis of Alzheimer's disease in elderly people with type 2 diabetes

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 45 patients.

Settings and conduct

All subjects will complete the written consent form and cooperation in the research before entering the study. Before and after the training session, physical fitness tests, anthropometry, cognitive performance and blood tests are taken from all participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having type 2 diabetes for more than five years, age range of 60-65 years, not suffering from a specific disease that interferes with doing sports, not suffering from severe depression due to the effect of mood changes and depression. In the memory tests, for the same reason, the depression test (Beck) will be taken from the subjects, and people with a score higher than 13 will not be included in the study (a score higher than 13 is a sign of depression). Also, a sedentary lifestyle and the ability to perform sports movements. Exclusion criteria will include injury and inability to perform exercise programs.

Intervention groups

The statistical population will include all women with type 2 diabetes with an average age of 60 ± 5.07 years who have a medical file in Shahrekord Diabetes Association. Sampling will be done based on a call from eligible women with type 2 diabetes and will be selected based on the available population.

Main outcome variables

Investigating the difference in the effect of aerobic activity in morning and evening on short-term memory in

elderly people with type 2 diabetes Investigating the difference in the effect of aerobic activity in morning and evening on executive performance in elderly people with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181212041935N1**

Registration date: **2024-02-18, 1402/11/29**

Registration timing: **retrospective**

Last update: **2024-02-18, 1402/11/29**

Update count: **0**

Registration date

2024-02-18, 1402/11/29

Registrant information

Name

Azra Mohammadpanah Ardakan

Name of organization / entity

Ardakan University

Country

Iran (Islamic Republic of)

Phone

+98 35 3224 3027

Email address

azramohammadpanah@ardakan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-19, 1402/09/28

Expected recruitment end date

2024-02-17, 1402/11/28

Actual recruitment start date

2023-12-19, 1402/09/28

Actual recruitment end date

2024-02-17, 1402/11/28

Trial completion date

2024-02-17, 1402/11/28

Scientific title

Comparison of the effect of aerobic training time (morning and evening) on the cognitive and physiological characteristics of the elderly with type 2 diabetes

Public title

Comparison of the effect of aerobic training time (morning and evening) on the cognitive and physiological characteristics of the elderly with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria include having type 2 diabetes for more than five years, age range of 60-65 years, not suffering from a specific disease that interferes with doing sports, not suffering from severe depression due to the effect of mood changes and depression. In the memory tests, for the same reason, the depression test (Beck) will be taken from the subjects, and people with a score higher than 13 will not be included in the study (a score higher than 13 is a sign of depression (Kudretil et al., 2022)). Also, a sedentary lifestyle and the ability to perform sports movements.

Exclusion criteria:

Exclusion criteria will include injury and inability to perform exercise programs.

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

blocked randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Yazd University Research Ethics Committee

Street address

Ardakan University, Ardakan

City

Ardakan

Province

Yazd

Postal code

9549189518

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.YAZD.REC.1402.044

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Having type 2 diabetes for more than five years, not suffering from severe depression

Timepoint

before the start of the intervention and 12 weeks after the start of the intervention

Method of measurement

Before and after the training session, physical fitness tests, anthropometry, cognitive performance and blood tests are taken from all participants.

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group: aerobic exercise in the morning

Category

Treatment - Other

2

Description

The second intervention group: aerobic exercise in the evening

Category

Treatment - Other

3

Description

Control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Diabetes Association

Full name of responsible person

Alireza Badri - security officer

Street address

Shahrekord Medical University

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

Phone

+98 38 3333 0061

Email

azramohammadpanah@ardakan.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Iran National Science Foundation (INSF)

Full name of responsible person

President

Street address

No. 33, No. 33, 5th St., above Jalal Al Ahmad Intersection, North Kargar St., Tehran

City

Tehran

Province

Tehran

Postal code

1439634665

Phone

+98 21 8216 1000

Email

info@insf.org

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The Iran National Science Foundation (INSF)

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardakan University

Full name of responsible person

Azra Mohammadpanah Ardakan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

The information and part of the data from the main outcome will be published in the form of articles extracted from the trial.

When the data will become available and for how long

After printing the results as an article

To whom data/document is available

For researchers working in academic and scientific institutions and people who are also engaged in industry

Under which criteria data/document could be used

In organizations with similar intervention work, they can get guidance from the results and process of this research and experiment.

From where data/document is obtainable

Researcher azramohammadpanah@ardakan.ac.ir

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

After reviewing the request and going through the legal procedures of publishing information

Comments