

# 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  $60 \pm 5.07$  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 (Kudrete 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

#### Street address

Khatami Blvd

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#### Province

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#### Postal code

8951895491

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+98 35 3224 3027

#### Fax

#### Email

azramohammadpanah@ardakan.ac.ir

## Person responsible for scientific inquiries

### Contact

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

Ardakan University

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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**