

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effect of 12-week aerobic exercise on glycemic control and lower limb blood flow in type-2 diabetic men with peripheral neuropathy

#### Protocol summary

##### Study aim

To investigate the effect of aerobic exercise on lower limb blood flow in men with type 2 diabetes and peripheral neuropathy.

##### Design

A randomized clinical trial with control group and parallel design, with no blinding and a sample size of 35.

##### Settings and conduct

Three months supervised aerobic training with the intensity of 50% to 70% of one heart rate reserve with the frequency of 3 sessions per week were conducted at the laboratory of sport physiology of Shahrood university of technology. Aerobic training included pedaling on cycle ergometer. The measurements were performed at baseline and 48 hours following the last exercise session in a fasting state. It was impossible to blind the participants and instructor to group allocation but laboratory specialists and data analyst were blinded to the group allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 30-70 years, Diagnosis of Type 2 diabetes for more than 5 years, HbA1c over 6.6%, Sedentary life-style, No restriction for exercise.

##### Intervention groups

Aerobic training group: participants underwent aerobic training on cycle ergometer over 3 months with the frequency of 3 days a week at the intensity of 50 to 70% of heart rate reserve. Control group: they were required to maintain daily physical activity.

##### Main outcome variables

flow mediated dilatation; intima media thickness; mean blood velocity and time to peak diameter of superficial femoral artery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170120032066N3**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **retrospective**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

##### Registration date

2019-05-13, 1398/02/23

##### Registrant information

###### Name

Farhad Gholami

###### Name of organization / entity

Shahrood University of Technology

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41332395900

###### Email address

gholami-fa@shahroodut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-08, 1397/02/18

##### Expected recruitment end date

2018-06-05, 1397/03/15

##### Actual recruitment start date

2018-05-08, 1397/02/18

##### Actual recruitment end date

2018-06-05, 1397/03/15

##### Trial completion date

2018-09-08, 1397/06/17

##### Scientific title

Effect of 12-week aerobic exercise on glycemic control and lower limb blood flow in type-2 diabetic men with peripheral neuropathy

**Public title**

Aerobic exercise and lower limb blood flow in diabetic peripheral neuropathy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age ranges from 30 to 70 years  
Diagnosis of type 2 diabetes for more than 5 years  
HbA1c over 6.6%

Sedentary life-style  
No restriction for exercise

**Exclusion criteria:****Age**

From **30 years** old to **70 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **35**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants were enrolled by one of the research colleagues. A person, blinded to group allocation were provide a random allocation sequence using computer software of SAS prior to the initiation of the study that were used to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 4, 6) were applied to ensure an equal number of participants in each group. Group allocation were concealed in sequentially numbered, opaque, sealed envelopes, and corresponding envelopes were opened after enrolled participants completed all baseline assessments. It was impossible to blind the participants and instructor to group allocation but laboratory specialists assessing the variables and data analyst were blinded to the group allocation.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Sport sciences research institute of Iran

**Street address**

No.3, 5th St., MirEmad St., Motahari Ave., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1587958711

**Approval date**

2019-03-11, 1397/12/20

**Ethics committee reference number**

IR.SSRC.REC.1398.011

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

Type 2 diabetes mellitus with diabetic polyneuropathy

**ICD-10 code**

E11.42

**ICD-10 code description**

Type 2 diabetes mellitus with diabetic polyneuropathy

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

Flow mediated dilation (FMD) in superficial Femoral artery

**Timepoint**

before and after the intervention

**Method of measurement**

Color-Doppler sonography

**2****Description**

Intima media thickenss of superficial Femoral artery

**Timepoint**

before and after the intervention

**Method of measurement**

Color-Doppler sonography

**3****Description**

Mean blood velocity in superficial Femoral artery

**Timepoint**

before and after the intervention

**Method of measurement**

Color-Doppler sonography

**4****Description**

Time to peak diameter of superficial Femoral artery

**Timepoint**

before and after the intervention

**Method of measurement**

Color-Doppler sonography

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: aerobic exercise training on cycle ergometer at the intensity of 50% to 70% of reserved heart rate with the frequency of 3 session per week for 12 weeks.

### Category

Rehabilitation

2

### Description

Control group: no further activity other than daily physical activity

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Pasargad Clinic of Shahrood

#### Full name of responsible person

Farhad Gholami

#### Street address

7-Tir Square., Tehran St.

#### City

Shahrood

#### Province

Semnan

#### Postal code

3619995161

#### Phone

+98 23 3239 5900

#### Email

info@shmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahrood University of Technology

#### Full name of responsible person

Ali Dastfan

#### Street address

7-Tir Square., Tehran St.

#### City

Shahrood

#### Province

Semnan

#### Postal code

3619995161

#### Phone

+98 23 3239 5900

#### Email

info@shahroodut.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shahrood University of Technology

### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shahrood University of Technology

#### Full name of responsible person

Farhad Gholami

#### Position

Assistant professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Exercise physiology

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+93 2332395900

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahrood University of Technology

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Farhad Gholami

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Assistant professor

#### Latest degree

Ph.D.

**Other areas of specialty/work**

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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)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

There is no further information

**When the data will become available and for how long**

There is no further information

**To whom data/document is available**

There is no further information

**Under which criteria data/document could be used**

There is no further information

**From where data/document is obtainable**

There is no further information

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

There is no further information

**Comments**