

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of differential exercise training on endothelial function of type 2 diabetes and relation with inflammatory cytokines

#### Protocol summary

##### Study aim

Investigation of low-volume high- intensity interval training, high- volume high- intensity interval training and continuous intensity moderate training on endothelial function of type 2 diabetes and relation with mechanisms involved in endothelial function.

##### Design

In this study, 70 participants divided into 4 groups low- volume high- intensity interval training, high- volume high- intensity interval training, continuous intensity moderate training and control. Randomization was performed by block randomization with a block size of 4. Randomised clinical trial with single-blind and parallel groups.

##### Settings and conduct

This study was performed in physical education of University of Tehran and Metabolism and Diabetes Center of Shariati hospital. Participants, outcome assessor and statistic specialist was blinded. They did not know which group they were in because they were assigned in groups based on randomization and the codes they provided. The specialists of assessment and statistical analysis were unaware of the study because the groups were sent to him based on coding.

##### Participants/Inclusion and exclusion criteria

Including criteria: included having a history of type 2 diabetes more than two years, glycosylated hemoglobin <6% (HbA1C <6%), body mass index over 25, hypertension uncontrolled pre or I stage, no history of 6 months of regular exercise (more than one day a week) to do the study. Exclusion criteria included fasting blood glucose over 400 mg/dl, functional limitations (such as osteoarthritis), liver or kidney failure, history of myocardial infarction or coronary artery bypass surgery or angioplasty, chronic heart failure, cardiac arrhythmias, smoking, insulin therapy and HbA1C > 10%.

##### Intervention groups

1. High- volume high- intensity interval training that program was including 6 intervals 4 minutes at 85-90%

HRmax that separated by 3 minutes active period at 45-50% HRmax. 2. Low- volume high- intensity interval training that program was including 12 intervals 1.5 minutes at 85-90% HRmax that separated by 2 minutes active period at 55- 60% HRmax. 3. Continues moderate intensity training consist of 42 minutes at 70% HRmax. 4. Control group that maintenance daily activities and no have regular exercise.

##### Main outcome variables

Flow-mediated dilation; Diameter at baseline; Diameter at peak; Antegrade shear rate; Retrograde shear rate; Oscillatory shear index; Nitrite/ Nitrate; Endothelin-1; Apelin; Arterial stiffness; Superoxide dismutase; Malondialdehyde; Carotid intima-media thickness; Resistance insulin; Lipid profile; VO<sub>2</sub>peak; exercise time; Resting and maximal heart rate; Resting diastolic blood pressure; Resting systolic blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100423002N2**

Registration date: **2016-03-04, 1394/12/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-06, 1396/11/17**

Update count: **1**

##### Registration date

2016-03-04, 1394/12/14

##### Registrant information

##### Name

Alireza Ghardashi Afousi

##### Name of organization / entity

University of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8201 5031

**Email address**

ghardashi.a@ut.ac.ir

**Recruitment status**

Recruitment complete

**Funding source**

Investigator

**Expected recruitment start date**

2015-03-20, 1393/12/29

**Expected recruitment end date**

2016-03-20, 1395/01/01

**Actual recruitment start date**

2015-05-05, 1394/02/15

**Actual recruitment end date**

2016-04-24, 1395/02/05

**Trial completion date**

empty

**Scientific title**

Effect of differential exercise training on endothelial function of type 2 diabetes and relation with inflammatory cytokines

**Public title**

Effect of exercise training on endothelial function of type 2 diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

History of type 2 diabetes more than 2 years No history of 6 months of regular exercise Glycosylated hemoglobin <6%(HbA1C <6%) Body mass index over 25 Hypertension uncontrolled pre or I stage

**Exclusion criteria:**

HbA1c over 10% Fasting blood glucose more than 400 mg/dl Functional limitations (such as osteoarthritis) Liver and kidney disease Myocardial infarction Coronary artery bypass surgery or angioplasty Chronic heart failure Cardiac arrhythmia's Smoking Uncontrolled BP (BP < 170/100 mmHg) Insulin therapy

**Age**

From 40 years old to 70 years old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 70

Actual sample size reached: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization work by randomizing participants within blocks such that an equal number are assigned to

each intervention groups. Given a block size in this study was 4 assign participants to a block.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participants were aware of the study. However, they did not know assigned to which groups, because they were assigned in groups based on randomization and the codes. The evaluators are specialists who were unaware of the grouping and the purpose of the study. Statistical analysis was performed by statisticians who were unaware of the study because the groups were sent to him based on coding.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of University of Tehran

**Street address**

16th Azar Street, Enghelab Square, Central Organization of University of Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۶۶۱۹-۱۴۱۵۵

**Approval date**

2016-07-31, 1395/05/10

**Ethics committee reference number**

IR.UT.Rec.1395002

**Health conditions studied**

**1**

**Description of health condition studied**

type 2diabetes

**ICD-10 code**

E 11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

**Primary outcomes**

**1**

**Description**

Nitrite/Nitrate plasma

**Timepoint**

Before and after 12 week intervention  
**Method of measurement**  
ELISA kit

## 2

### **Description**

Endothelin-1

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

ELISA kit

## 3

### **Description**

Flow mediated dilation

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

Ultrasound doppler

## 4

### **Description**

Carotid intima-media thickness

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

Ultrasound doppler

## 5

### **Description**

Insulin resistance

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

HOMA-IR

## 6

### **Description**

Glucose

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

Enzymatic

## 7

### **Description**

Apelin

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

ELISA kit

## 8

### **Description**

peak consumption oxygen

### **Timepoint**

Before and after 12 week intervention

## **Method of measurement**

Gas analyser system

## 9

### **Description**

Diastolic and systolic blood pressure

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

oscillometric device

## 10

### **Description**

Heart rate rest

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

Cornometer/ numbere

## 11

### **Description**

Lipid profile

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

Enzymatic

## 12

### **Description**

Malondealdehyd

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

ELISA kit

## 13

### **Description**

Glutathion proxidase

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

ELISA kit

## 14

### **Description**

Insulin

### **Timepoint**

Before and after 12 week intervention

### **Method of measurement**

ELISA kit

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### Description

Intervention group 1: High- volume high- intensity interval training that consists of 6 intervals 4 minutes at 85- 90% HRmax which separated by 3 minutes at 45-50% HRmax.

### Category

Rehabilitation

## 2

### Description

Intervention group 2: High- volume high- intensity interval training that consists of 12 intervals 1.5 minutes at 85- 90% HRmax which separated by 2 minutes at 55-60% HRmax.

### Category

Rehabilitation

## 3

### Description

Intervention group3: continuous moderate intensity training consists of 42 minutes at 70% HRmax.

### Category

Rehabilitation

## 4

### Description

Control group: normal condition without any exercise

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

diabetes and metabolic disease institute of Shariati hospital

#### Full name of responsible person

Ensieh Nasli Esfahani MD

#### Street address

Metabolism and Diabetes Center of Shariati hospital, North Kargar Street, Enghelab Square

#### City

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice president of of Research of Tehran University

#### Full name of responsible person

Alireza Ghardashi Afousi

#### Street address

Faculty of Physical Education and Sport Science, above the intersection Jalal Al-e Ahmad, North Kargar Avenue, Islamic Revolution Square.

#### City

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#### Province

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#### Postal code

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#### Phone

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#### Email

Ghardashi.a@ut.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice president of of Research of Tehran University

### 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

University of Tehran

#### Full name of responsible person

Alireza Ghardashi Afousi

#### Position

PhD

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Exercise Science, Exercise Physiology

#### Street address

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
University of Tehran

**Full name of responsible person**  
Alireza Ghardashi Afousi  
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**Latest degree**  
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**Web page address**

## 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

There is no further information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available