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; VO2peak; 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

Applin

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

Malondealdehid

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 haspital

Full name of responsible person
Ensieh Nasli Esfahani MD

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

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Tehran

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Tehran

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1411713135

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+98 21 0218 4901

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shariatihosp@tums.ac.ir

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.

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1439956141

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+98 21 8835 1740

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

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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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
Alireza Ghardashi Afousi
Position
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Latest degree
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Other areas of specialty/work
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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
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