Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of 12-weeks of interval and continuous training on vaspin, Asymmetric dimethyl-arginine and relationship with flow-mediated dilation in patients with type 2 diabetes

Protocol summary

Study aim

Investigation of high- intensity interval training and continuous intensity moderate training on plasma levels of vaspin, asymmetric dimethyl-arginine, nitric oxide and relation with flow-mediated dilation in patient with type 2 diabetes.

Design

In this study, 75 participants divided into 3 groups 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 University of Azad, research ad science brench and Metabolism and Diabetes Center of Shariati hospital.

Participants/Inclusion and exclusion criteria

Including criteria: included having a history of type 2 diabetes more than two years, glycosylated hemoglobin above 6% (HbA1C >6%), body mass index over 25, pre hypertension or I stage, no history of 6 months of regular exercise to do the study. Exclusion criteria included fasting blood glucose over 400 mg/dl, functional limitations (such as osteoarthritis), 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- intensity interval training that program was including 12 intervals 1.5 minutes at 85-90% HR max that separated by 2 minutes active period at 55- 60% HR max. 2. Continues moderate intensity training consist of 42 minutes at 70% HR max. 3. Control group were encouraged to maintain their daily activities without exercise training.

Main outcome variables

Flow-mediated dilation, Nitrite/ Nitrate, Vaspin, Asymmetric dimethyl-arginine, Resistance insulin, Fasting glucose, VO2peak.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200810048351N1**
Registration date: **2020-11-15, 1399/08/25**
Registration timing: **retrospective**

Last update: **2020-11-15, 1399/08/25**
Update count: **0**

Registration date

2020-11-15, 1399/08/25

Registrant information

Name

mahnaz najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2239 2019

Email address

yazdan.setayesh98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-26, 1398/04/05

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

2019-07-01, 1398/04/10

Actual recruitment end date

2020-01-04, 1398/10/14

Trial completion date

2020-02-09, 1398/11/20

Scientific title

The effect of 12-weeks of interval and continuous training on vaspin, Asymmetric dimethyl-arginine and relationship with flow-mediated dilation in patients with type 2 diabetes

Public title

Effect of interval and continuous training on endothelial function in patients with 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 above 6%(HbA1C >6%) Body mass index over 25 Pre hypertension 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

- Data analyser

Sample size

Target sample size: **75**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by blocking based on gender and age which performed by www.randomizatoin.com. The A code was used for women and B for men. The block size was 3. We used a code for a rage of 10 years. The 1 code included participants that ages was between 40-50 years, 2 code included participants that ages was between 50-60 years and 3 code included participants that ages was between 60-70 years. Therefore, if a person with a male gender and age range was 40 to 50 years, he would be assigned according to the system with A1 code, and if a person with a female gender and age range of 40 to 50 years, she would be assigned with B1 code. According to the 2 sexes of men and women and 3 age groups, combination of 6 types of codes including A1, A2, A3, B1, B2, B3 were placed in one block. In the data entry section, the number of subjects, codes and block size were entered. The output consisted of 12 blocks of 6 people and a block of 3 people, which was provided to us in the form of a table by the site itself. Therefore, each group consisted of 4 blocks and one code.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were aware of the study. 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

Sport Sciences Research Institute of Iran

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street

City

Tehran

Province

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Postal code

1587958711

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.SSRC.REC.1399.042

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Vaspin

Timepoint

Before and after 12-weeks intervention

Method of measurement

ELISA kit

2

Description
Asymmetric dimethy-argenin
Timepoint
Before and after 12-weeks intervention
Method of measurement
ELISA kit

3

Description
Nitrite/nitrate
Timepoint
Before and after 12-weeks intervention
Method of measurement
ELISA kit

4

Description
Flow-mediated dilation
Timepoint
Before and after 12-weeks intervention
Method of measurement
Ultrasound doppler

5

Description
Insuline resistance
Timepoint
Before and after 12-weeks
Method of measurement
HOMA-IR

6

Description
Insulin
Timepoint
Before and after 12-weeks intervention
Method of measurement
ELISA kit

7

Description
Glucose
Timepoint
Before and after 12-weeks intervention
Method of measurement
ELISA kit

8

Description
Peak oxygen consumption
Timepoint
Before and after 12-week intervention
Method of measurement
Gas analyser system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: 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. Exercise training was performed 3 session per week for 12- weeks.
Category
Rehabilitation

2

Description
Intervention group 2: continuous moderate intensity training consists of 42 minutes at 70% HRmax. Exercise training was performed 3 session per week for 12-weeks.
Category
Rehabilitation

3

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mahnaz Najafi

Street address
Faculty of Lecture, Human and Social Science, Islamic Azad University, Science and Research Branch, Daneshgah Blvd, Simon Bolivar Blvd

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Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad 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
Islamic Azad University

Full name of responsible person
Mahnaz Najafi

Position
Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Exercise Physiology

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Person responsible for updating data

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