Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of Continuous Moderate-Intensity Training and High-Intensity Interval Training on Vasodilators And Cardiac Function in Type 2 Diabetes

Protocol summary

Study aim

Comparison of continuous moderate-intensity training and high-intensity interval training on vasodilators and cardiac function in type 2 diabetes.

Design

In this study, 47 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 15. 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

Entrance Criteria: Type 2 Diabetes According to Defined by American Diabetes Association fasting blood sugar (FBS) more than 7 mmol/L. Haemoglobin Glycosylated (HbA1c) above 6%. Pre- or stage I hypertension, or treated hypertension (systolic blood pressure 120–159 mmHg. Diastolic blood pressure 80–99 mmHg. No exercise training in the previous 6 months. Non-Entry Criteria: Patients with FBS more than 22 mmol/L. HbA1c above 10%. Functional limitations (such as osteoarthritis), liver or kidney Disease, and Smoking.

Intervention groups

Intervention Group 1: Continuous Moderate-Intensity Training on Stationary Bike Intervention Group 2: High-Intensity Interval Training on Stationary Bike Control Group: No Training

Main outcome variables

Adropin; Nitric Oxide; Resistance insulin; Fasting Glucose; 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: **IRCT20181219042056N1**
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

Ramin Salehi

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

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Email address

salehi.1371@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-02-24, 1396/12/05

Actual recruitment start date

2017-12-16, 1396/09/25

Actual recruitment end date

2018-06-26, 1397/04/05

Trial completion date

2018-12-16, 1397/09/25

Scientific title

Comparison of Continuous Moderate-Intensity Training and High-Intensity Interval Training on Vasodilators And Cardiac Function in Type 2 Diabetes

Public title

Comparison of Continuous Moderate-Intensity Training and High-Intensity Interval Training on Vasodilators And Cardiac Function in Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 to 60 years. According to Defined by American Diabetes Association 2015, fasting blood sugar (FBS) more than 7 mmol/L. Glycosylated Haemoglobin (HbA1c) above 6%. Type 2 Diabetes. Pre- or stage I hypertension, or treated hypertension (systolic blood pressure 120–159 mmHg, diastolic blood pressure 80–99 mmHg). Patients with history of Type 2 Diabetes for at least 2 years. No exercise training in the previous 6 months.

Exclusion criteria:

Patients with FBS more than 22 mmol/L. HbA1c above 10%. Myocardial infarction, coronary artery bypass surgery or angioplasty, chronic heart failure, cardiac arrhythmia, functional limitations (such as osteoarthritis), liver or kidney disease, and smoking. Hypertension, or treated hypertension (systolic blood pressure 170 mmHg, diastolic blood pressure 100 mmHg).

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **47**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized to Intervention And Control Groups. 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 15 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 Faculty of Physical Education and Sport Sciences - University of Tehran

Street address

Tehran Province, Tehran, North Kargar

City

Tehran

Province

Tehran

Postal code

14398-13117

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.UT.SPORT.REC.1397.010

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

Adropin Factor

Timepoint

Before and After from 12 week exercise

Method of measurement

Using the Laboratory Elisa Kit

2

Description

Nitrite/Nitrate plasma

Timepoint

Before and After from 12 week exercise

Method of measurement

Using the Laboratory Elisa Kit

3

Description

HOMA-IR

Timepoint

Before and After from 12 week exercise

Method of measurement

HOMA-IR

4

Description

Glucose

Timepoint

Before and After from 12 week exercise

Method of measurement

Enzymatic

5

Description

peak consumption oxygen

Timepoint

Before and After from 12 week exercise

Method of measurement

Gas analyser system

6

Description

Diastolic and systolic blood pressure

Timepoint

Before and After from 12 week exercise

Method of measurement

oscillometric device

7

Description

Heart rate rest

Timepoint

Before and After from 12 week exercise

Method of measurement

Cornometer/ numbere

8

Description

Insulin

Timepoint

Before and After from 12 week exercise

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Doing 12 weeks continuous moderate-intensity training (70 % Heart Rate max) on cycle , every week 3 times and every time 1 hour pedal

Category

Rehabilitation

2

Description

Intervention group 2: Doing 12 weeks High-Intensity Interval Training (85-90% Heart Rate max) on cycle , every week 3 times and every time 1 hour pedal

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

Maryam pour abbas

Street address

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

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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

Dr Foad Seidi

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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
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
Vice president of of Research of Tehran University
Full name of responsible person
Ramin Salehi
Position
Student
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Bachelor
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Person responsible for updating data

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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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document

Some of data

When the data will become available and for how long

1 year after publish

To whom data/document is available

All of people

Under which criteria data/document could be used

For scientific study

From where data/document is obtainable

Salehi.1371@ut.ac.ir

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

In First Time After observetion in Email Adress

Comments