

# 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; 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: **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)

##### Phone

+98 51 3621 1916

##### 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 hospital

**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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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**

Dr Foad Seidi

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North Kargar

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infosport@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**  
Vice president of of Research of Tehran University  
**Full name of responsible person**  
Ramin Salehi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiology  
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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 observation in Email Adress

**Comments**