

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect of energy-matched continuous vs high-intensity interval training with weight-loss diet on metabolic indices and arterial stiffness in patients with type-2 diabetes

Protocol summary

Study aim

Comparison of the effect of energy-matched continuous vs high intensity interval training with weight-loss diet on metabolic indices and arterial stiffness in patients with type-2 diabetes

Design

A clinical trial including 2 experimental and a control group with parallel design and without blinding in which participants will be randomly assigned to study groups.

Settings and conduct

This study will be conducted by joint cooperation of Shahrood University of Technology and Shahrood University of Medical Sciences, in which diabetic patients with medical records will participate and receive relevant interventions for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of type-2 diabetes over 5 years, glycosylated hemoglobin (Hb1Ac) over 6.5%, fasting blood glucose over 126 mg/dl, inactive lifestyle and body mass index over 25 kg/m². Exclusion criteria: having weight-loss diet, severe diabetic complications like foot ulcer, not permitted for exercise.

Intervention groups

Experimental group 1, continuous training on treadmill for 12 weeks, 3 session pre week and 36 sessions in total and experimental group 2, interval training on treadmill for 12 weeks, 3 session pre week and 36 sessions in total.

Main outcome variables

Glycosylated hemoglobin (HbA1c); systolic blood pressure; Cardio-ankle vascular index (CAVI); Weight; body fat percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170120032066N5**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Farhad Gholami

Name of organization / entity

Shahrood University of Technology

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of energy-matched continuous

	vs high-intensity interval training with weight-loss diet on metabolic indices and arterial stiffness in patients with type-2 diabetes
Public title	Effect of energy-matched continuous vs interval training in type-2 diabetes
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: History of type-2 diabetes over 5 years Glycosylated hemoglobin (Hb1Ac) over 6.5% Fasting blood glucose over 126 mg/dl Inactive lifestyle Body mass index over 25 kg/m2 Exclusion criteria: Having weight-loss diet Severe diabetic complications like foot ulcer Not permitted for exercise
Age	From 18 years old to 55 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 58
Randomization (investigator's opinion)	Randomized
Randomization description	Participants will be allocated to continuous exercise, interval exercise and control groups with 1:1:1 ratio. Participants will be classified based on BMI and HbA1c level to ensure inter-group homogeneity and stratified blocked randomization with block size of 4-6 will be applied. Sequencing using table of random numbers will be generated by a blind assistant to ensure allocation concealment.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committer of Shahrood University of Technology
Street address	Shahrood University of Technology, 7-Tir Square

City	Shahrood
Province	Semnan
Postal code	3619995161
Approval date	2023-05-13, 1402/02/23
Ethics committee reference number	IR.SHAHROODUT.REC.1402.002
Health conditions studied	
<u>1</u>	
Description of health condition studied	Type-2 diabetes
ICD-10 code	E11
ICD-10 code description	Type 2 diabetes mellitus
Primary outcomes	
<u>1</u>	
Description	Glycosylated hemoglobin (HbA1c)
Timepoint	Measurement of glycosylated hemoglobin (HbA1c) before and after 12 weeks intervention
Method of measurement	Using a commercial kit through enzymatic method
<u>2</u>	
Description	systolic blood pressure
Timepoint	Measurement of systolic blood pressure before and after 12 weeks intervention
Method of measurement	Digital sphygmomanometer
<u>3</u>	
Description	Cardio-ankle vascular index (CAVI)
Timepoint	Measurement of Cardio-ankle vascular index (CAVI) before and after 12 weeks intervention
Method of measurement	Arterial stiffness assessment device VaSera VS-2000 (Fukuda Denshi, Japan)
<u>4</u>	
Description	Weight
Timepoint	Measurement of weight before and after 12 weeks intervention

Method of measurement

Using digital scale

5**Description**

Body fat percentage

Timepoint

Measurement of body fat percentage before and after 12 weeks intervention

Method of measurement

Bioimpedance method by body composition analyzer InBody230

Secondary outcomes**1****Description**

Fasting blood glucose

Timepoint

Measurement of fasting blood glucose before and after 12 weeks intervention

Method of measurement

Enzymatic calorimetry

2**Description**

2 hours postprandial glucose

Timepoint

Measurement of 2 hours postprandial glucose before and after 12 weeks intervention

Method of measurement

Enzymatic calorimetry

3**Description**

Ankle-brachial index (ABI)

Timepoint

Measurement of ankle-brachial index before and after 12 weeks intervention

Method of measurement

Arterial stiffness assessment device VaSera VS-2000 (Fukuda Denshi, Japan)

Intervention groups**1****Description**

Intervention group: continuous exercise training and calorie restriction over 12 weeks

Category

Treatment - Other

2**Description**

Intervention group: interval exercise training and calorie restriction over 12 weeks

Category

Treatment - Other

3**Description**

Control group: habitual daily routine

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

پلی کلینیک تخصصی و فوق تخصصی دانشگاه علوم پزشکی شاهرود

Full name of responsible person

خانم علیزاده

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrood University of Technology

Full name of responsible person

Dr. Hamid Hasanpour

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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

Shahrood University of Technology

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

Shahrood University of Technology

Full name of responsible person

Farhad Gholami

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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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

Not applicable

Data Dictionary

Not applicable