Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of 8 weeks of high-intensity interval training of two Different protocols with high and low volumes on the glycemic indices and lipids profile in men With type 2 diabetes

Protocol summary

Study aim
The aim of this study was comparison of the effects of two types of low and high volumes of HIIT training on glycemic indices and lipid profile of men with type 2 diabetes.

Design
Clinical trial with control group by using pre-test and post-test

Settings and conduct
subjects were used by patients with type 2 diabetes in the diabetes center of Yazd province who volunteered to participate in this study. All subjects completed the PAR-Q questionnaire and medical assessment. After signing the consent inform and examination by physicians also doing exercise test they enter to study. In order to blindness, in this study, samples and recipients were unaware of the differences between the two groups

Participants/Inclusion and exclusion criteria
Subjects: included 30 non-athlete and non-insulin dependent diabetic patients age range from 29 to 46 years old and BMI 20 to 36. The severity of the disease was 135-300 mg / dl, after 2 hours glucose , 200 to 400 mg, and A1c was above of 6.5%. By referring to the diabetes center of Yazd province, 30 patients with type 2 diabetes mellitus were selected as the subjects and were randomly divided to two groups of exercise (20 subjects) and control (10 people), they were examined for history of cardiovascular, respiratory, orthopedic problems and diabetic neuropathy by physicians before interventions.

Intervention groups
high volume of HIIT group and Low volume of HIIT group

Main outcome variables
fbs; 2hRR; insulin; HOMA-IR; HbA1c: TG; Col

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180827040887N1**
Registration date: **2019-04-26, 1398/02/06**
Registration timing: **retrospective**

Last update: **2019-04-26, 1398/02/06**
Update count: **0**

Registration date
2019-04-26, 1398/02/06

Registrant information

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Name of organization / entity
Yazd University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-26, 1396/07/04

Expected recruitment end date
2017-11-25, 1396/09/04

Actual recruitment start date
2017-09-26, 1396/07/04

Actual recruitment end date
2017-11-25, 1396/09/04

Trial completion date
2018-06-10, 1397/03/20

Scientific title

Comparison of the effect of 8 weeks of high-intensity interval training of two Different protocols with high and low volumes on the glycemic indices and lipids profile in men With type 2 diabetes

Public title
Investigating the effect of different volumes of HIIT training on the health-related indicators of diabetic patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Type II non-athlete diabetic patient The range of glucose is between 126 and 300 mg/l HbA1C above %6
Exclusion criteria:
Cardiovascular disease Diabetic Nephropathy Respiratory diseases orthopedic problems
Age
From **18 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **27**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were matched by BMI, then randomly divided into 3 groups: two groups of training and one control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the two groups of low volume and high volume of training did not aware of intensity and type of intervention and differences between the groups and they only did their protocol. Clinicians and raters were unaware of the two protocols.
Placebo
Not used
Assignment
Parallel
Other design features
Design different HIIT exercises with different volumes. The aim of this study was to obtain the lowest exercise duration for improvement in health indicators of type 2 diabetic patients

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd Shahid Sadoghi University of Medical Sciences
Street address
Bahonar Sq., Yazd
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-08-15, 1396/05/24
Ethics committee reference number
IR.SSU.REC.1396.103

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
percent of people with high blood glucos
Timepoint
before and after intervention
Method of measurement
Biosystems kit

2

Description
The level of glycemic indexes (fasting blood glucose, two-hourly glucose, insulin, insulin resistance, HBa1c) and lipid profile (LDL, HDL, TG, TC)
Timepoint
All indices of this study were measured before the intervention and 48 hours after the last training session at the laboratory.
Method of measurement
1. Stationary bicycle of China Classic model of China 2. Chest sensor 610 i polar made in China to measure heart rate while exercising with clock for monitoring 3- glucometer to measure blood glucose before and during exercise 4-Blood pressure apparatus In order to measure the blood pressure before and after training, the balance and height meter of the Balas model was used to measure the height with a precision of 1 cm and a precision of 0.001 kg, making Iran 6-calipers made in Japan to measure fat thickness Subcutaneous fat percentage to determine the percentage of fat 7-Physical Fitness Preparation Questionnaire (PAR_Q) in order to

investigate the history of the disease and the readiness of Retire in exercise program and medical history. The questionnaire consists of 7 questions that have a yes or no answer and yes, even if a question is answered as a positive one, they are referred to the doctor. 8. Computer for information analysis. 9-meter strip with a precision of 1 mm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1- Low volume HIIT exercises 2. High volume HIIT exercises
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes center of Yazd
Full name of responsible person
Nasim Namiranian
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Sponsors / Funding sources

1

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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
Yazd Diabetes Center
Proportion provided by this source
50
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
Yazd University
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Hamid Abbasi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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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
Not applicable
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