Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Dec 2019

Effects of sprint interval versus combined aerobic and resistance training on adipokines, myokines and metabolic outcomes in overweight women with type 2 diabetes

Protocol summary

Study aim

The main purpose of this study is to investigate the effects of sprint interval versus combined aerobic and resistance training on adipokines, myokines and metabolic outcomes in overweight women with type 2 diabetes.

Design

this study is an interventional and not blinded research.

Settings and conduct

Fifty two overweight women with type 2 diabetes (aged 45-60 years, body mass index >30 kg/m2, HbA1C ≥ 6.5%) selection and randomly (Based on random blocks) will be divided into three groups: SIT (n = 17), combined training (aerobic + resistance) (n = 17) and control (n = 17). The training sessions will be 3 sessions per week and each session will be 50 minutes for 10 weeks. The location of the exercises will be the Center for correctional movements, sport rehabilitation and massage of Pars. Aerobic training program Include a cycle ergo-meter or Treadmill, resistance training program Include several upper and lower body workout and SIT training program is performed on cycle ergo-meter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female 45 - 60 years old with type 2 diabetes; BMI>30; HbA1C ≥ 6.5%; fasting blood glucose ≥ 126 mg/dL; sedentary Exclusion criteria: blood pressure ≥ 160/100 mmHg; fasting triglyceride ≥ 500 mg/dL; a history of cardiovascular diseases, thyroid disorder, cancer, hormonal disorder, kidney and liver diseases; smoking, use of opioids, alcohol; doing regular exercise more than one year

Intervention groups

Intervention group 1: The SIT training group dose an exercise program on an cycle ergometers for 10 weeks. Each session consisted of a 5-minute warm-up, 4 × 30 seconds maximum intensity intervals at breaking wattage of the individual, then followed by 2 minutes of recovery and in the last cool down 4 minutes. Intervention group 2: The combined training (aerobic + resistance) do a training program for 10 weeks. Aerobic training progressed from 20 min/session at 50% maximum heart rate (HR) in week 1-2 to 30 min/session at 70% Max HR in week 3-10 on a treadmill or bike ergometer. Resistance training program includes several upper and lower body exercises using special devices. Control group: The control group do not any regular physical activity in daily life.

Main outcome variables

Primary outcome: IL-15, SPARC, Irisin, FGF-21 and ANGPTL4 will be evaluated 24 hours before and 48 hours after training program.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141118019995N10**
Registration date: **2017-12-04, 1396/09/13**
Registration timing: **retrospective**

Last update: **2017-12-04, 1396/09/13**
Update count: **0**

Registration date

2017-12-04, 1396/09/13

Registrant information

Name
Zahra Mardanpour Shahrekordi
Name of organization / entity
Shahrekord University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-05-23, 1394/03/02

Actual recruitment start date

2015-04-21, 1394/02/01

Actual recruitment end date

2015-05-31, 1394/03/10

Trial completion date

empty

Scientific title

Effects of sprint interval versus combined aerobic and resistance training on adipokines, myokines and metabolic outcomes in overweight women with type 2 diabetes

Public title

Effects of sprint interval versus combined aerobic and resistance training in overweight women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female 45 - 60 years old with type 2 diabetes BMI>30 kg/m2 HbA1C ≥ 6.5% Fasting blood glucose ≥ 126 mg/dL Sedentary

Exclusion criteria:

Blood pressure ≥ 160/100 mmHg Fasting triglyceride ≥ 500 mg/dL A history of cardiovascular diseases, thyroid disorder, cancer, hormonal disorder, kidney and liver diseases Smoking, use of opioids, alcohol Doing regular exercise more than one year

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

None

Sample size

Target sample size: **60**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using statistical software and block method, and the individual randomization unit.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord university

Street address

Rahbar Blvd, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۶۴۸۴۵۶

Approval date

2014-12-23, 1393/10/02

Ethics committee reference number

140.3326

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

IL-15

Timepoint

Before and after 10 weeks of intervention

Method of measurement

ELISA kit for IL-15

2

Description

SPARC

Timepoint

Before and after 10 weeks of intervention

Method of measurement

ELISA kit for SPARC

3

Description

Irisin

Timepoint

Before and after 10 weeks of intervention

Method of measurement

ELISA kit for Irisin

4

Description
FGF-21
Timepoint
Before and after 10 weeks of intervention
Method of measurement
ELISA kit for FGF-21

5

Description
ANGPTL4
Timepoint
Before and after 10 weeks of intervention
Method of measurement
ELISA kit for ANGPTL4

Secondary outcomes

1

Description
Weight
Timepoint
Before and after 10 weeks of intervention
Method of measurement
digital scale

2

Description
Body fat percent
Timepoint
Before and after 10 weeks of intervention
Method of measurement
Caliper

3

Description
Body Mass Index (BMI)
Timepoint
Before and after 10 weeks of intervention
Method of measurement
Weight divided by height squared

4

Description
Fasting blood glucose
Timepoint
Before and after 10 weeks of intervention
Method of measurement
ELISA kit

5

Description
Ansulin
Timepoint
Before and after 10 weeks of intervention
Method of measurement
ELISA kit

6

Description
Insulin resistance
Timepoint
Before and after 10 weeks of intervention
Method of measurement
The insulin resistance index by the (HOMA-IR) formula.

Intervention groups

1

Description
Intervention group 1: The SIT training group dose an exercise program on an cycle ergometers for 10 weeks. Each session consisted of a 5-minute warm-up, 4 × 30 seconds maximum intensity intervals at breaking wattage of the individual, then followed by 2 minutes of recovery and in the last cool down 4 minutes.
Category
Other

2

Description
Intervention group 2: The combined training (aerobic + resistance) do a training program for 10 weeks. Aerobic training progressed from 20 min/session at 50% maximum heart rate (HR) in week 1-2 to 30 min/session at 70% Max HR in week 3-10 on a treadmill or bike ergometer. Resistance training program includes several upper and lower body exercises using special devices.
Category
Other

3

Description
Control group: The control group do not any regular physical activity in daily life.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for correctional movements, sport rehabilitation and massage of Pars
Full name of responsible person
Dr Ebrahim Banitalebi
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Alley 48, Molavi street, Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahrekord University
Full name of responsible person
Dr Mohammad Faramarzi
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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 chancellor for research, Shahrekord University
Proportion provided by this source
70
Public or private sector
Private
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
Shahrekord University
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Dr Ebrahim Banitalebi
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable