

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### 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/m<sup>2</sup>, 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3232 4401

**Email address**  
banitalebi@lit.sku.ac.ir

**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/m<sup>2</sup> 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**  
*No information*

**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

**Street address**

Alley 48, Molavi street, Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8817748919

**Phone**

+98 38 3225 3546

**Email**

Banitalebi@lit.sku.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shahrekord University

**Full name of responsible person**

Dr Mohammad Faramarzi

**Street address**

Vice chancellor for research, Shahrekord University,  
Rahbar Blvd, Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۶۴۸۴۵۶

**Phone**

+98 38 3232 4401

**Email**

md.faramarzi@gmail.com

**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

**Full name of responsible person**

Dr Ebrahim Banitalebi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

Rahbar Blvd, Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۶۴۸۴۵۶

**Phone**

+98 38 3232 4401

**Fax**

**Email**

Banitalebi@lit.sku.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahrekord University

**Full name of responsible person**

Dr Mohammad Faramarzi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

Rahbar Blvd, Shahrekord

**City**

shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

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**Phone**

+98 38 3232 4401

**Fax**

**Email**

md.faramarzi@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahrekord University

**Full name of responsible person**

Dr Ebrahim Banitalebi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

Rahbar Blvd, Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۳۳۱۵۶۴۸۴۵۶

**Phone**

+98 38 3232 4401

**Fax**

**Email**

Banitalebi@lit.sku.ac.ir

**Web page address**

**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