

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effect of resistance training and high-intensity interval training (hiit) on metabolic parameters and serum level of sirtuin 1 in postmenopausal women with metabolic syndrome

#### Protocol summary

##### Study aim

Determining the effect of eight weeks of resistance training and high-intensity interval training (hiit) on sirtuin 1 levels in women with metabolic syndrome.

##### Design

Clinical trial with control group, with parallel groups, randomized, on 30 patients. Randomization by the method of equal blocks (8 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

##### Settings and conduct

By referring to Imam Hossein Malayer Hospital and Department of Patients with Metabolic Syndrome, eligible people were identified and placed in the intervention groups using equal blocks randomization (8 blocks of 4). Then people will go to the sports club for exercise intervention and perform exercises for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from metabolic syndrome  
Exclusion criteria: inability to exercise

##### Intervention groups

The group of resistance exercises and Hiit: which are subjected to high-intensity resistance and interval exercises. Control group: which is not under any intervention.

##### Main outcome variables

Investigating the effect of resistance training and high-intensity interval training on sirtuin levels in women with metabolic syndrome

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20221120056548N1**

Registration date: **2022-11-23, 1401/09/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-23, 1401/09/02**

Update count: **0**

#### Registration date

2022-11-23, 1401/09/02

#### Registrant information

##### Name

Saeid Shamlou kazemi

##### Name of organization / entity

Bu-Ali Sina university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 859 7297

##### Email address

saeidshamlou9092@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-11-21, 1401/08/30

#### Expected recruitment end date

2022-12-06, 1401/09/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of resistance training and high-intensity interval

training (hiit) on metabolic parameters and serum level of sirtuin 1 in postmenopausal women with metabolic syndrome

#### Public title

Investigating the effect of resistance training and HIIT on metabolic syndrome

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women with metabolic syndrome Age range between 45-65 years

##### Exclusion criteria:

Inability and inability to do physical activity

#### Age

From **45 years** old to **65 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this randomization, the method of equal blocks (8 blocks of 4 each) is used, in which half of the intervention and half of the intervention people are included in each block. And we assigned resistance training groups, high intensity interval training and control group. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

#### 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

Bu-Ali Sina University

##### Street address

Mahdiyeh Ave

##### City

Hamadan

##### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2022-02-09, 1400/11/20

#### Ethics committee reference number

IR.BASU.REC.1400.046

## Health conditions studied

### 1

#### Description of health condition studied

metabolic syndrome

#### ICD-10 code

E88.81

#### ICD-10 code description

Metabolic syndrome

## Primary outcomes

### 1

#### Description

The percentage of people whose sirtuin level is increased

#### Timepoint

Measurement of sirtuin before and after the intervention

#### Method of measurement

Human Sirtuin 1 (SIRT1)ELISA Kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Sports exercises. The exercise program of the hiit group included 60 seconds of maximum intensity running (85-95% HRR heart rate) followed by 60 seconds of low intensity running (55-60% HRR). Subjects performed the protocol 6 times in the first week, 8 times in the second week, and 10 times in the third to eighth weeks. The training program in the resistance training group included two stages, in the first 4 weeks, the subjects did leg press, front thigh, back thigh, chest press, back lat, side push, back arm pull, front arm and two abdominal leg movements. did the The exercises consisted of 3 sets, eight to ten repetitions maximum, with 60 seconds rest between sets (75% 1RM). After 4 weeks, the training program was performed with 8 repetitions maximum with 90 seconds rest between sets (80% 1RM). The resistance exercises were based on the linear course and the classic model (high volume and lower intensity at the beginning of the exercise, then increasing the intensity and decreasing the volume).

#### Category

Rehabilitation

2

**Description**

Control group: It is not subject to any training program.

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

saeid shamlou kazemi

**Street address**

mahdiyeh Ave

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**Province**

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**Postal code**

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**Phone**

+98 81 3221 0929

**Email**

saeidshamlou9092@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Bu-Ali Sina university

**Full name of responsible person**

Ali heydarianpoor

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mahdiyeh Ave

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+98 81 3838 1601

**Email**

heidarian317@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Bu-Ali Sina university

**Proportion provided by this source**

10

**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**

Bu-Ali Sina University

**Full name of responsible person**

saeid shamlou kazemi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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mahdiyeh AVE

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**Postal code**

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

saeid shamlou kazemi

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bu-Ali Sina University

**Full name of responsible person**

saeid shamlou kazemi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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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**

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**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

It will be available for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

If the intellectual rights are preserved, the data can be sent to the researchers

**From where data/document is obtainable**

Email address:saeidshamlou9092@gmail.com

**What processes are involved for a request to access data/document**

Submission of written request (one week)

**Comments**