# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of eight weeks of high intensity interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and team enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease

## Protocol summary

**Study aim**

Determining the effect of eight weeks of intense interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease.

**Design**

Clinical trial with control group, with parallel groups, randomized, on 60 patients. Randomization by the method of equal blocks (15 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 Hamedan Ba'ath Hospital, eligible people were identified and placed in the intervention groups using equal blocks randomization (15 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements 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**

Entry conditions: suffering from non-alcoholic fatty liver disease Conditions of non-entry: inability to practice

**Intervention groups**

Exercise and supplement group: In the exercise group, the samples are subjected to high-intensity and resistance intermittent exercises, and the supplement group consumes artichoke extract. The control group is not subjected to any intervention.

**Main outcome variables**

Non-alcoholic fatty liver, sirtuin 1, liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221120056548N11**
Registration date: **2023-08-08, 1402/05/17**
Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**
Update count: **0**

**Registration date**

2023-08-08, 1402/05/17

**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**

2023-08-11, 1402/05/20

**Expected recruitment end date**

2023-08-16, 1402/05/25

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of eight weeks of high intensity interval training (HIIT), resistance training and consumption of artichoke extract on the level of sirtuin 1 and team enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in patients with non-alcoholic fatty liver disease

**Public title**
The effect of exercise and artichoke extract on non-alcoholic fatty liver
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Non-alcoholic fatty liver disease being menopausal
**Exclusion criteria:**
History of cardiovascular disease
**Age**
From **50 years** old to **65 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this randomization, the method of equal blocks (15 blocks of 4) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated them to different groups. The method and tool of block random sequence generation has been done using https://www.sealedenvelope.com/simple-randomiser/v1/lists.
**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 Sport Sciences Research Institute
**Street address**
Fifth Alley, Mir Emad Ave., Ostad Motahari Ave
**City**
Tehran
**Province**
Tehran
**Postal code**
1474674646
**Approval date**
2023-06-21, 1402/03/31
**Ethics committee reference number**
IR.SSRC.REC.1402.078

## Health conditions studied

**1**

**Description of health condition studied**
Non-alcoholic fatty liver
**ICD-10 code**
K76.0
**ICD-10 code description**
Fatty (change of) liver, not elsewhere classified

## Primary outcomes

**1**

**Description**
The percentage of people whose liver enzymes have decreased.
**Timepoint**
Before and after interventions
**Method of measurement**
By measuring the liver enzymes in the blood in the laboratory

## Secondary outcomes

**1**

**Description**
The percentage of people in whom the level of sirtuin 1 is increased.
**Timepoint**
Before and after interventions
**Method of measurement**
Using ELISA method and Zelbio kit made in Germany

## Intervention groups

**1**

**Description**
Intervention group: Intense interval training was performed for 8 weeks and four sessions per week and

each session lasted for 60 minutes (15 minutes of warm-up + 30 minutes of interval training + 15 minutes of cooling) with an intensity of 80-85% of the maximum heart rate. They performed high-intensity resistance training of 7 movements 3 times a week. In the first two weeks, they did one maximum repetition and 6 repetitions with 90% intensity, in the third to fifth week with 95% maximum repetition and 4 repetitions, and the last three weeks with 100% ability and two repetitions. The amount of rest between sets was 1 minute and between stations was 2 to 3 minutes. For each subject in each station, which included barbell chest press, front shoulder with barbell, front underarm lat, front arm with cable hand, back arm with cable, front thigh with machine and back thigh with machine, the amount of weight It was found that it is usually able to lift less than 10 times. Artichoke extract is consumed in the following way. The parts of this plant were dried in the shade and crushed with the help of a grinder and turned into powder. The chopped leaves of the dried artichoke plant (fluffy silver leaves) were given to the study subjects in the form of packages in the required number, and they were asked to take them for 45 days, in two occasions (at night before going to bed; that is, two hours after eating dinner and the second time in the morning fasting one hour before breakfast) brew a tablespoon of plant leaves with a glass of boiling water for 20 minutes on indirect heat and at a temperature of 80 degrees Celsius.

**Category**

Treatment - Other

**2**

**Description**

Control group: This group is not subjected to any exercise intervention and supplement consumption.

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Saeid Shamlou Kazemi

**Street address**

Shahid Beheshti Blvd

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice President of Research at Danesh Alborz University

**Full name of responsible person**

Dr. Mohammad Tahernia

**Street address**

Danesh Alborz University, Abyek

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**Province**

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**Phone**

+98 937 125 7977

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tahernia2004@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice President of Research at Danesh Alborz University

**Proportion provided by this source**

10

**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**

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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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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 a written request (one week)
**Comments**