# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effect of eight weeks of independent combined training with coffee consumption on blood lipid profile of middle-aged men with non-alcoholic fatty liver in Covid-19 condition

## Protocol summary

**Study aim**

Evaluation of the independent and combined effects of combined training with the approach of ultimate preparation and coffee consumption on blood characteristics of middle-aged men with non-alcoholic fatty liver

**Design**

The clinical trial has three experimental groups and the control group is divided into four groups of 11 randomly, without blinding.

**Settings and conduct**

The method of the present study is quasi-experimental and is performed with a pre-test-post-test design in three experimental groups (combined exercise group, combined exercise-coffee consumption, coffee consumption) and control group. The statistical population is middle-aged men 30-60 with non-alcoholic fatty liver with ultrasound grades 1, 2 and 3, and enzymes (ALT) and (AST) and lipid profile above normal, in Borkhar city of Isfahan. The training protocol is done 3 times a week for 60 minutes. Each session consists of 3 5-part practice sections. Consumption of coffee on a daily basis between 9 am and 11 am and in the afternoon between 3 pm and 5 pm One cup (180 cc) of Robusta coffee is consumed in the form of Turkish coffee.

**Participants/Inclusion and exclusion criteria**

Middle-aged men 30 to 60 Year and conditions of entry: Grade 1, 2 and 3 liver disease, people with high blood lipid profile, people without cardiovascular disease and people without physical disabilities Conditions of non-entry: People with grade 4 fatty liver disease, People with physical disabilities, People with heart failure, People with lung disease

**Intervention groups**

The first intervention, combined exercise, the second intervention of coffee consumption, which received three experimental groups of intervention and the control group did not receive any intervention..

**Main outcome variables**

Decreased liver grade, enzymes (AST) and (ALT) and blood lipid profile, index (BMI) and increased functional skills

## General information

**Reason for update**

**Acronym**

_____

**IRCT registration information**

IRCT registration number: **IRCT20210521051357N1**
Registration date: **2021-07-22, 1400/04/31**
Registration timing: **retrospective**

Last update: **2021-07-22, 1400/04/31**
Update count: **0**

**Registration date**

2021-07-22, 1400/04/31

**Registrant information**

**Name**

Alireza Taheri dolatabadi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-06-16, 1400/03/26

**Expected recruitment end date**

2021-06-18, 1400/03/28

**Actual recruitment start date**

2021-07-01, 1400/04/10

**Actual recruitment end date**

2021-07-03, 1400/04/12

**Trial completion date**

2021-08-01, 1400/05/10

**Scientific title**

The effect of eight weeks of independent combined training with coffee consumption on blood lipid profile of middle-aged men with non-alcoholic fatty liver in Covid-19 condition

**Public title**

The effect of combined exercises with the approach of extreme readiness and coffee consumption on liver enzymes and motor function of middle-aged men with non-alcoholic fatty liver

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Middle-aged men 30 to 60 years Grade 1, 2 and 3 liver disease People with high blood lipid profiles People without cardiovascular disease People without physical disabilities

**Exclusion criteria:**

Men over 60 years old People with fatty liver disease grade 4 People with physical disabilities People with heart failure People with lung disease

**Age**

From **30 years** old to **60 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

Actual sample size reached: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Describe how to randomize Random assignment to intervention and control groups In this study, we used the restricted randomization method for all study groups with sample size. We will use the same type of random allocation rule. This method represents a large block for the total sample size, which means that the balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, the sample size (44 people) will be determined first. Then we randomly assign their set to groups A, B and C to the intervention groups (11 people in each group). And group D is for control (11 people). 11 balls (or lottery cards) for each group And we consider a total of 44 numbers.We throw the balls (sheets) into a container and then randomly, the balls (sheets) are taken out of the container without replacement, and the created sequence is recorded. The randomization process is performed by someone outside the study researchers to reduce possible bias.Community Verified icon

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics of Shahed University of Tehran

**Street address**

No,1,in front of the Imam Khomeini Shrine ,The free end of the Persian Gulf road, Shahed University

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**Province**

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**Approval date**

2020-10-27, 1399/08/06

**Ethics committee reference number**

IR.SHAHED.REC.1399.116

## Health conditions studied

### 1

**Description of health condition studied**

Non-alcoholic fatty liver disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

## Primary outcomes

### 1

**Description**

Serum levels of hepatic alanine transaminase and aspartate transaminase enzymes

**Timepoint**

Measurement three days before the start of the study intervention

**Method of measurement**

Blood test to determine the serum levels of alanine transaminase and aspartate transaminase liver enzymes is performed by BT 2500 analyzer and 3000 rpm centrifuge for 5 minutes with Behdad device made in Iran

and standard kits of Par Azmoon company.

### 2

**Description**
Liver grade
**Timepoint**
Measurement three days before the start of the study intervention
**Method of measurement**
Liver grade with ultrasound device from Samsung Korea WS80A model.

### 3

**Description**
Blood lipid profile
**Timepoint**
Measurement three days before the start of the study intervention
**Method of measurement**
Blood test to determine the amount of blood lipid profile is measured by BT 2500 analyzer and 3000 rpm centrifuge in 5 minutes with Behdad device made in Iran and standard kits of Par Azmoon company.

### 4

**Description**
Motor function
**Timepoint**
Measurement three days before the start of the study intervention
**Method of measurement**
Motor function is performed by fitness tests (sit-ups, steps, stork balance, quadratic agility, and Welsh flexibility).

## Secondary outcomes

### 1

**Description**
Decreased hepatic alanine transaminase and aspartate transaminase enzymes
**Timepoint**
Measurement three days after the end of the study
**Method of measurement**
Blood test is done to determine the serum levels of the liver enzymes alanine transaminase and aspartate transaminase.

### 2

**Description**
Decreased liver grade
**Timepoint**
Measurement three days after the end of the study
**Method of measurement**
Liver grade with ultrasound device from Samsung Korea WS80A model.

### 3

**Description**
Decreased blood lipid profile
**Timepoint**
Measurement three days after the end of the study
**Method of measurement**
Blood sample to determine the amount of blood lipid profile by BT 2500 analyzer and 3000 rpm centrifuge in 5 minutes with Behdad machine made in Iran and standard kits of Pars Azmoon company.

### 4

**Description**
Increase motor performance
**Timepoint**
Measurement three days after the end of the study
**Method of measurement**
Motor function is performed by physical fitness tests (sitting position, step test, quadratic agility, stork balance and flexibility).

## Intervention groups

### 1

**Description**
Intervention group: Intervention group 1: Combined exercise, training intervention will be done 3 sessions per week for 60 minutes. Each session consists of 3 parts of practice, 5 parts. Start the training program by warming up for 10 to 15 minutes. Then the training sections are performed as follows three times without rest: 1- Balance movement for 15 to 20 seconds 2- Aerobic movement for 20 to 30 seconds and with an intensity of 55 to 65% of the maximum heart rate. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Becomes.Subjects rest for 1 to 2 minutes before the start of the next part. Subsequent parts will be performed according to the same procedure and with various movements on other parts of the body. After finishing 3 parts, cooling is done for 5 minutes.
**Category**
N/A

### 2

**Description**
Intervention group: Intervention group 2 combined exercises with coffee consumption, combined exercise intervention 3 sessions per week for 60 minutes. Each session consists of 3 parts of practice, 5 parts. Start the training program by warming up for 10 to 15 minutes. Then the training sections are performed in the following way three times without rest: 1- Balance movement for 15 to 20 seconds 2- Aerobic movement for 20 to 30 seconds and with an intensity of 55 to 65% of the maximum heart rate. Pilates largely avoids high impact,

high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Becomes.Subjects rest for 1 to 2 minutes before the start of the next part. Subsequent parts will be performed according to the same procedure and with various movements on other parts of the body. After finishing 3 parts, cooling is done for 5 minutes. And the coffee consumption intervention coincides with the days of the training intervention (once an hour before the training intervention) in the morning between 9 and 11 o'clock and in the afternoon between 15 and 17 o'clock a cup (180 c) C) Indonesian robusta coffee is consumed in the form of cherry and Java and medium roast with a degree of softness of / 5 in the form of Turkish coffee. The required dose of coffee is 10 grams per serving (the amount of caffeine in the sample is between 215 to 235 mg per serving is 180 cc).

**Category**

N/A

### 3

**Description**

Intervention group: Intervention group 3 Coffee consumption, Coffee consumption intervention on a daily basis and in coordination with intervention days Training between 9 am and 11 am and in the afternoon between 3 pm and 5 pm Medium degree of softness of 5 / is consumed in the form of Turkish coffee. The required dose of coffee is 10 grams per serving. (The amount of caffeine in the sample is between 215 to 235 mg per serving of 180 cc)

**Category**

N/A

### 4

**Description**

Control group: Intervention group 4 Controls do not receive any intervention

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Reza Hospital

**Full name of responsible person**
Mohmmad Moini

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No,1، Imam Reza StreetTaleghani Boulevard

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Shahed University

**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Shahed University

**Proportion provided by this source**
100

**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**
Shahed University

**Full name of responsible person**
Alireza Taheri Dilatabadi

**Position**
Student

**Latest degree**
Master

**Other areas of specialty/work**
Physiology

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## Person responsible for scientific inquiries

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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**
Not applicable

**Analytic Code**
Not applicable

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

**Title and more details about the data/document**
Information on the main outcomes studied Possibility of subscription Has a transition.

**When the data will become available and for how long**
The data are available after the publication of all the results obtained Will take Community Verified icon

**To whom data/document is available**
Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
The study or proposal protocol should be submitted by the Ethics Committee of the institution or university To be approved. The rights of authors and their sponsors must be protected Be

**From where data/document is obtainable**
Talireza099@gmail.com or alireza.taheri@shahed.ac.ir

**What processes are involved for a request to access data/document**
This request must be addressed to the Vice Chancellor for Research and Technology of Shahed University of Tehran and will be done with the information of the project manager

**Comments**