Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

City

Tehran

Province

Tehran

Postal code

3319118651

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
Zahra Kiasalari

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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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Position
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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