Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Effects of an 8-Week Combined Aerobic Exercise and Vitamin D Supplementation Program on Metabolic Variables, Oxidative Stress, Health-Related Quality of Life (HRQoL), and Psychological Disorders (Depression, Anxiety, and Sleep Disorders) in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD) Across Different Grades

Protocol summary

Study aim

The aim of this study was to investigate the effect of an 8-week combined intervention of aerobic exercise and vitamin D supplementation on metabolic variables and oxidative stress, health-related quality of life (HRQoL), and psychological disorders in patients with non-alcoholic fatty liver disease (NAFLD) of different grades.

Design

A randomized, controlled, single-blind, parallel-group clinical trial on the diet of women with nonalcoholic fatty liver disease of different grades.

Settings and conduct

This research will be conducted in the city of Tuyserkan. First, the research variables will be measured. Then, 6 groups of participants in the research will receive the desired interventions. After the interventions are completed, the research variables will be measured again. In this research, participants will be blinded. Tablets similar to vitamin D tablets will be used as placebo.

Participants/Inclusion and exclusion criteria

Women with non-alcoholic fatty liver disease (NAFLD) between the ages of 45 and 65, confirmed diagnosis of NAFLD based on ultrasound findings, no significant weight loss or gain (more than 5% of body weight) in the last three months, no other liver disease, no bariatric surgery

Intervention groups

Group 1: Patients with grade 1 fatty liver + aerobic exercise + vitamin D supplementation Group 2: Patients with grade 2 fatty liver + aerobic exercise + vitamin D supplementation Group 3: Patients with grade 3 fatty liver + aerobic exercise + vitamin D supplementation Control group: Patients with fatty liver (grade 1) without exercise and receiving placebo Control group: Patients with fatty liver (grade 2) without exercise and receiving placebo Control group: Patients with fatty liver (grade 3) without exercise and receiving placebo

Main outcome variables

liver enzymes, lipid profile, inflammation, oxidation .improvement in quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251127068131N1**
Registration date: **2025-12-05, 1404/09/14**
Registration timing: **prospective**

Last update: **2025-12-05, 1404/09/14**
Update count: **0**

Registration date

2025-12-05, 1404/09/14

Registrant information

Name

Maryamalsadat Emami

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

Phone

+98 81 3492 3139

Email address

maryam.s.emami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-01-05, 1404/10/15
Expected recruitment end date
2026-03-06, 1404/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effects of an 8-Week Combined Aerobic Exercise and Vitamin D Supplementation Program on Metabolic Variables, Oxidative Stress, Health-Related Quality of Life (HRQoL), and Psychological Disorders (Depression, Anxiety, and Sleep Disorders) in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD) Across Different Grades

Public title
Investigating the Effects of an 8-Week Combined Aerobic Exercise and Vitamin D Supplementation in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD) Across Different Grades
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Gender and Age: Participants must be women with non-alcoholic fatty liver disease (NAFLD) between the ages of 45 and 65. Diagnosis: The diagnosis of NAFLD must be confirmed based on ultrasound findings and patients are categorized into three grades (1, 2, and 3)
Exclusion criteria:
No alcohol consumption: Participants should have no history of alcohol consumption (alcohol consumption less than 20 grams per day for women). Weight stability: Participants should not have had significant weight loss or gain (more than 5% of body weight) in the last three months. No other liver disease: Patients should not have viral hepatitis (such as hepatitis B and C), autoimmune hepatitis, hemochromatosis, drug-induced liver disease, Wilson's disease, or celiac disease. No bariatric surgery: Participants should not have a history of bariatric surgery (such as gastric bypass)
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method will be used through the website www.randomization.com. For this purpose, each subject is first assigned a number as a unique identification code and a 48-digit sequence (equal to the sample size) is created. Then, the names of the intervention groups, including 1) Group 1: Patients with Grade 1 fatty liver + aerobic exercise + vitamin D supplementation, 2) Group 2: Patients with Grade 2 fatty liver + aerobic exercise + vitamin D supplementation, 3) Group 3: Patients with Grade 3 fatty liver + aerobic exercise + vitamin D supplementation, 4) Control group: Patients with fatty liver (Grade 1) without exercise and receiving placebo, 5) Control group: Patients with fatty liver (Grade 2) without exercise and receiving placebo, and 6) Control group: Patients with fatty liver (Grade 3) without exercise and receiving placebo; will be defined in the relevant section on the website. After defining the groups and in order to prevent potential problems caused by blocking with fixed-sized blocks, a random selection method of blocks of different sizes will be used for blocking. In this case, given the sample size, the block sizes will be unequal and a multiple of the number of intervention groups (e.g., 4 or 8). The website has the ability to randomly generate sequences of blocks of different sizes. In the final step, by executing the Generate Plan command on the website, using the number (code) assigned to each subject and examining the blocks, the group of each subject will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study will be conducted in a single-blinded manner and participants will be kept blind to the vitamin D or placebo intake, while due to the nature of exercise training, blinding will not be done in this case (exercise intervention). In order to blind the three groups that do not receive vitamin D tablets, tablets similar to vitamin D tablets in terms of appearance, smell, taste and color will be used as placebo. For this purpose, both vitamin D and placebo will be placed inside capsules with completely identical appearance. Information regarding vitamin D and placebo intake will be kept secret from the subjects.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Razi University
Street address
Razi University, University Avenue, Taq-e Bostan
City

kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2025-11-12, 1404/08/21

Ethics committee reference number

IR.RAZI.REC.1404.039

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver in different grades

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver enzymes (ALP, AST, ALT)

Timepoint

During the pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Blood sampling, Use of ultrasound

2

Description

Lipid profile (total cholesterol, triglycerides, HDL, LDL)

Timepoint

During the pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Blood sampling

3

Description

Inflammatory index (TNFα)

Timepoint

During pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Blood sampling. ELISA method

4

Description

Antioxidant index (SOD and MDA)

Timepoint

During pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Blood sampling. ELISA method

Secondary outcomes

1

Description

Health-related quality of life

Timepoint

In the pre-test and post-test phase (48 hours after the last practice session)

Method of measurement

using the SF-36 questionnaire

2

Description

Depression

Timepoint

In the pre-test and post-test phase (48 hours after the last training session)

Method of measurement

From the Beck Depression Inventory (BDI)

3

Description

Anxiety

Timepoint

In the pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Beck Anxiety Inventory (BAI)

4

Description

Sleep disorders

Timepoint

In the pre-test and post-test phase (48 hours after the last training session)

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

Intervention groups

1

Description

Intervention group: In this group, people with grade 1 fatty liver will receive an aerobic exercise program consisting of 45-60 minute sessions at an intensity of 60-75% of maximum heart rate (MHR), three sessions per week for 8 weeks. This group will also receive 50,000 international units of vitamin D once a week.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, people with grade 2 fatty liver will receive an aerobic exercise program consisting of 45-60 minute sessions at an intensity of 60-75% of maximum heart rate (MHR), three sessions

per week for 8 weeks. This group will also receive 50,000 international units of vitamin D once a week.

Category

Treatment - Drugs

3

Description

Intervention group: In this group, people with grade 3 fatty liver will receive an aerobic exercise program consisting of 45-60 minute sessions at an intensity of 60-75% of maximum heart rate (MHR), three sessions per week for 8 weeks. This group will also receive 50,000 international units of vitamin D once a week.

Category

Treatment - Drugs

4

Description

Control group: In this group, people with grade 1 fatty liver will receive placebo pills, which are completely similar to vitamin D pills, daily for 8 weeks and will not do any exercise.

Category

Placebo

5

Description

Control group: In this group, people with grade 2 fatty liver will receive placebo pills, which are completely similar to vitamin D pills, daily for 8 weeks and will not do any exercise.

Category

Placebo

6

Description

Control group: In this group, people with grade 3 fatty liver will receive placebo pills, which are completely similar to vitamin D pills, daily for 8 weeks and will not do any exercise.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Vermaghani Ultrasound Clinic

Full name of responsible person

Maryamsadat Emami

Street address

Mahdieh Alley,Bahonar Street

City

Tuyserkan

Province

Hamadan

Postal code

6581855632

Phone

+98 81 3492 3139

Email

maryam.s.emami@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

keyvan Amini

Street address

Razi University, University Avenue, Taq Bostan

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 4515

Email

kamini@razi.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi University

Proportion provided by this source

100

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

Razi University

Full name of responsible person

Rastegar Hosseini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Room 49, Faculty of Sport Sciences, Razi University,

University Avenue, Taq-e Bostan

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3845 8428

Email
rastegar.hoseini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Razi University

Full name of responsible person
Rastegar Hosseini

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Room 49. Faculty of Sport Sciences, Razi University, University Avenue, Taq-e Bostan

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3845 8428

Email
rastegar.hoseini@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Razi University

Full name of responsible person
Rastegar Hosseini

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
Room 49. Faculty of Sports sciences, Razi University, University Avenue, Taq-e Bostan

City
Kermanshah

Province
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Postal code
6714414971

Phone
+98 83 3845 8428

Email
rastegar.hoseini@gmail.com

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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared after de-identifying the subjects

When the data will become available and for how long
6 9 months after results are published

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
All data can be used for citation

From where data/document is obtainable
If you need to receive documents, please send an email to Rastegar Hoseini, Head of the Research Team, at the email address: rastegar.hoseini@gmail.com and Maryam Al-Sadat Emami, executive researcher, at the email address: maryam.s.emami@gmail.com

What processes are involved for a request to access data/document
In case of formal request, stating the relevant reasons and providing full details, the data will be sent via email after 72 hours

Comments