

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of Aerobic Training and Calorie Restriction on Hormonal and Metabolic Factors Related to Fatty Liver in Postmenopausal Women with NAFLD

Protocol summary

Study aim

Effect of Aerobic Training, Calorie Restriction and Combination of Aerobic Training and Calorie Restriction on Hormonal and Metabolic Factors Related to Fatty Liver in Postmenopausal Women with NAFLD

Design

Randomised, parallel group trial with blinded outcome assessment.

Settings and conduct

The study will be carried out on patients of Gastroenterologist clinic and blindness in participants

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Overweight Postmenopausal Women with NAFLD Exclusion Criteria : 1. Weight Changing over 2 kg over the past 6 months; 2. Smoking; 3. Alcohol consumption more than 30 grams per day; 4. Use of supplementary pills and special dietary ; 5. Cardiovascular disease And respiratory diseases; 6. orthopedic problems; 7. prohibition of participation in sports activities; and 8. regular exercise in the past year (at least 3 days a week).

Intervention groups

Aerobic Training - Calorie Restriction - Aerobic Training with Calorie Restriction

Main outcome variables

Estrogen Levels , Glucose Levels , Insulin Levels, Liver Enzymes, Fetuin A Levels, Lipid profile and Hepatic Fat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190408043203N1**
Registration date: **2019-04-30, 1398/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

Registration date

2019-04-30, 1398/02/10

Registrant information

Name

Elham Akbarzadeh

Name of organization / entity

The University of Guilan

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0485

Email address

akbarzadeh.elham@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aerobic Training and Calorie Restriction on Hormonal and Metabolic Factors Related to Fatty Liver in Postmenopausal Women with NAFLD

Public title

Effect of Aerobic Training and Calorie Restriction on Hormonal and Metabolic Factors Related to Fatty Liver in

Postmenopausal Women with NAFLD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Overweight Postmenopausal Women with NAFLD
Exclusion criteria:
 Weight Changing over 2 kg over the past 6 months
 Smoking Alcohol consumption more than 30 grams per day
 Use of supplementary pills and special dietary
 Cardiovascular disease And respiratory diseases
 Orthopedic problems Prohibition of participation in sports activities
 Regular exercise in the past year (at least 3 days a week)

Age
From **45 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly assigned with random number table in one of the three groups and will receive intervention of the same group

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 Guilan University of Medical Sciences
Street address
 Rasht, Namjoo St, Shahid Siadati Avenue, in front of the 17th Shahrivar Hospital, vice chancellery for research and technology
City
 Rasht
Province
 Guilan
Postal code
 4188794755
Approval date

2019-03-09, 1397/12/18
Ethics committee reference number
 IR.GUMS.REC.1397.482

Health conditions studied

1

Description of health condition studied
 Non-Alcoholic Fatty Liver Disease
ICD-10 code
 K75.81
ICD-10 code description
 Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
 Estrogen Levels
Timepoint
 Before and after intervention
Method of measurement
 Blood Sample Analysis

2

Description
 Insulin Resistance Index
Timepoint
 Before and after intervention
Method of measurement
 Insulin Resistance Index Formula with Insulin and Glucose Levels

3

Description
 Hepatic Fat
Timepoint
 Before and after intervention
Method of measurement
 elastography

4

Description
 Glucose Levels
Timepoint
 Before and after intervention
Method of measurement
 Blood Sample Analysis

5

Description
 Insulin Levels
Timepoint
 Before and after intervention
Method of measurement
 Blood Sample Analysis

6

Description

Liver Enzymes

Timepoint

Before and after intervention

Method of measurement

Blood Sample Analysis

7

Description

Fetuin A Levels

Timepoint

Before and after intervention

Method of measurement

Blood Sample Analysis

8

Description

Lipid profile

Timepoint

Before and after intervention

Method of measurement

Blood Sample Analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1st: moderate intensity Aerobic Training (running on treadmill with 65% of HRmax), 4 days per week - 12 weeks

Category

Treatment - Other

2

Description

Intervention group 2nd: Calorie Restriction (25 % reduction of daily energy requirement), 4 days per week - 12 weeks

Category

Treatment - Other

3

Description

Intervention group 3rd: Aerobic Training with Calorie Restriction - 4 days per week - 12 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterologist Clinic

Full name of responsible person

Afshin Shafaghi

Street address

Rasht - Golsar crossroad - in front of boostan Park - Dr.Afshin Shafaghi Clinic

City

Rasht

Province

Guilan

Postal code

۴۱۹۹۶۱۳۷۷۶

Phone

+98 13 3373 6122

Email

Drafshinshafaghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of University of Guilan

Full name of responsible person

Seyyed Ziaeddin Mirhosseini

Street address

Rasht, Khalij Pars Highway(5th Kilometer of Ghazvin Road), University of Guilan, Faculty of Exercise Science

City

Rasht

Province

Guilan

Postal code

4199613776

Phone

+98 13 3369 0338

Email

szmirhoseini@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for Research of University of Guilan

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

The University of Guilan

Full name of responsible person

Elham Akbarzadeh

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Sport Physiology

Street address

Rasht, Khalij Pars Highway(5th Kilometer of Ghazvin Road), University of Guilan, Faculty of Exercise Science

City

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

The University of Guilan

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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 of measured variables can be shared without identifying subjects

When the data will become available and for how long

Starting at March 2020

To whom data/document is available

Researchers

Under which criteria data/document could be used

Scientific use in improving and comparing with other researches is allowed

From where data/document is obtainable

The applicant must contact the researcher's email address (Elham Akbarzadeh) Email: akbarzadeh.elham@gmail.com

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

Applicants must send the reasons for requesting the documentation to the researcher's e-mail address. The researcher, after examining the reasons and, if the reasons are sufficient, will send the documents for

applicant up to 4 work days.

Comments