Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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
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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
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4199613776
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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

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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