Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Comparison the Effect of Interval, Continuous and combined Aerobic Exercise on Liver Enzymes, IGF-1 and Insulin Hormone and Metabolic Syndrome in Overweight Type 2 Diabetic Patients with Nonalcoholic Fatty Liver

Protocol summary

Study aim

The aim of current study was to investigate and compare the effects of interval, continuous and combined aerobic exercise training on liver enzymes in type 2 diabetic patients with non-alcoholic fatty liver disease.

Design

A clinical trial with a control group, available as a sample and then randomized grouping

Settings and conduct

The research method was quasi-experimental with four control groups, interval aerobic training group, continuous aerobic training group and combined group (combination of interval and continuous aerobic training) with pretest and post test. Subjects were 48 type 2 diabetic women with fatty liver who had filed a case in the office of Dr. Fatemeh Razvan Madani. After reviewing the patients' files, about 60 eligible subjects were selected and after contacting patients, 48 of them were invited to start the study.

Participants/Inclusion and exclusion criteria

Entry criteria: All subjects were overweight according to BMI. The subjects were 40-55 years old. They were non-insulin dependent and used oral medications. The maximum glycosylated hemoglobin in these patients was 11. Exclusion criteria: Retinopathy, severe nephropathy, and neuropathy, a history of cardiovascular disease, neuromuscular and severe musculoskeletal problems that limit physical activity.

Intervention groups

Interval aerobic exercise group, with intensity of 75 to 80 percent of maximum heart rate Continuous aerobic exercise group, with intensity of 60 to 75 percent of maximal heart rate Combined aerobic training group, one interval session and one continuous session Control group, without regular exercise

Main outcome variables

Alanine amino transferase, aspartate amino transferase, alkaline phosphatase, glycosylated hemoglobin, fasting blood glucose, cholesterol, LDL cholesterol, HDL cholesterol, triglyceride, waist circumference, blood pressure, IGF-1 hormone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110527006611N3**
Registration date: **2019-11-12, 1398/08/21**
Registration timing: **retrospective**

Last update: **2019-11-12, 1398/08/21**
Update count: **0**

Registration date

2019-11-12, 1398/08/21

Registrant information

Name
Zahra Bayat
Name of organization / entity
The University of Tehran
Country
Iran (Islamic Republic of)
Phone
+98 83 3822 9422
Email address
zahra_bayat2008@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-01-21, 1397/11/01

Trial completion date

2019-01-30, 1397/11/10

Scientific title

Comparison the Effect of Interval, Continuous and combined Aerobic Exercise on Liver Enzymes, IGF-1 and Insulin Hormone and Metabolic Syndrome in Overweight Type 2 Diabetic Patients with Nonalcoholic Fatty Liver

Public title

Comparison the Effect of Interval, Continuous and combined Aerobic Exercise on Liver Enzymes and Metabolic Syndrome in Overweight Type 2 Diabetic Patients with Nonalcoholic Fatty Liver

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects are type 2 diabetic women with non-alcoholic fatty liver. They are non-insulin-dependent They use oral medications for treatment (glibenclamide and metformin and sulfonylurease). The maximum blood glycosylated hemoglobin is 11%. The minimum history of diabetes is 1 year and the maximum history of diabetes is 15 years

Exclusion criteria:

Patients have retinopathy, nephropathy and severe neuropathy. Have a history of cardiovascular disease and musculoskeletal disorders Severe musculoskeletal problems that restrict physical activity

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were classified according to fatty liver grade and then randomly divided into 4 groups.

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 Sport Sciences Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street,

City

tehran

Province

Tehran

Postal code

1587958711

Approval date

2018-10-08, 1397/07/16

Ethics committee reference number

IR.SSRI.REC.1397.332

Health conditions studied

1

Description of health condition studied

Type 2 diabetes- Non-alcoholic fatty liver disease

ICD-10 code

E11-K76.0

ICD-10 code description

K76.0: Nonalcoholic fatty liver disease [NAFLD]-E11: Type 2 diabetes mellitus

Primary outcomes

1

Description

Alanine Aminotransferase enzyme

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

2

Description

Aspartate Aminotransferase enzyme

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

3

Description

Alkaline phosphatase enzyme

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

4

Description

Glycosylated hemoglobin

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with Pishtaz Teb kit

5

Description

HDL Cholesterol

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

6

Description

LDL Cholesterol

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

7

Description

Cholesterol

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

8

Description

triglyceride

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

9

Description

Waist circumference

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Standard tape meter

10

Description

Blood Pressure

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

brachial digital blood pressure monitor

11

Description

Fasting blood glucose

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

12

Description

IGF-1 Hormone

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with DiaSorin kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: interval aerobic exercise - The interval aerobic exercise group performed exercise on a stationary bike for two months, three days a week, with an intensity of 75 to 80 percent of maximum heart rate.

Category

Lifestyle

2

Description

Intervention group: Continuous aerobic exercise - The Continuous aerobic exercise group performed exercise on a stationary bike for two months, three days a week, with an intensity of 60 to 75 percent of maximum heart rate.

Category

Lifestyle

3

Description
Intervention group: Combined aerobic exercise - The combined aerobic exercise group performed exercise on a stationary bike for two months, three days a week, and in between sessions (continuous aerobic exercise and periodic aerobic exercise).
Category
Lifestyle

4

Description
Control group: No regular exercise
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Fatemeh Rezvan Madani office
Full name of responsible person
Fatemeh Rezvan Madani
Street address
the office of Dr. Rezvan Madani, Ground Floor, Negin Golestan Apartment, Chahardah Metri-ye-Shariat Street, Emami Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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The Office of Dr. Rezvan Madani, Ground Floor, Negin Golestan Apartment, Chahardah Metri-ye- Shariat Street, Emami Blvd
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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
University of Tehran
Proportion provided by this source
1
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
The University of Tehran
Full name of responsible person
Zahra Bayat
Position
PhD Candidate
Latest degree
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Other areas of specialty/work
Exercise Biochemistry and Metabolism
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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The informed consent form will be available to others without mentioning the names of the participants. Details of the study process are also provided in detail in the file format.

When the data will become available and for how long
Start of the 8 month period after the research

To whom data/document is available
For university students and students in research related fields

Under which criteria data/document could be used
There are no specific conditions to provide such information.

From where data/document is obtainable
Zahra Bayat

What processes are involved for a request to access data/document
Send message to the person responsible for providing the data

Comments