Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of lifestyle modification on the recovery of non-alcoholic fatty liver (NAFLD) of health insurance staff in Tabriz

Protocol summary

Study aim

The effect of lifestyle modification on the recovery of non-alcoholic fatty liver disease (NAFLD) in health insurance employees in Tabriz

Design

A concealed, randomized, clinical trial with a parallel group design of 50 patients

Settings and conduct

The study population consisted of Tabriz Health Insurance employees who were randomly divided into two groups of intervention (receiving diet + exercise) and control group (without receiving diet and exercise). Division of individuals between the two groups is done using random attribution (Random-Allocation) and allocation consilment. Participants are invited separately to complete the questionnaire and in the intervention group, in addition to completing the questionnaire, provide diet and standard activity recommendations. Physically done. The low-calorie diet for the intervention group will be 6 kcal less than the calculated daily energy and will contain 2% carbohydrates, 5% fat and 2% protein. The intervention group, in addition to diet, will participate in aerobic exercise for 3 weeks and three sessions per week. Liver (AST and ALT), liver ultrasound is measured to determine the fatty liver grade and BMI index is measured before and after 4 weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion: non-alcoholic fatty liver Patients of both sexes in the age range of 20-55 years exclution : Cardiovascular, thyroid, renal, inflammatory, autoimmune patients, hepatitis B and Alcoholics.

Intervention groups

This study includes two intervention groups (diet recipient with aerobic exercise) (n=25) and control group (without diet and physical activity) (n=25)

Main outcome variables

The level of disease recovery is measured by measuring liver enzymes (AST and ALT), liver ultrasound to determine the grade of fatty liver and BMI index before and after 4 weeks of intervention.

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20210808052106N1**
Registration date: **2022-02-28, 1400/12/09**
Registration timing: **retrospective**

Last update: **2022-02-28, 1400/12/09**
Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

leila javadi

Name of organization / entity

Health Insurance Organization

Country

Iran (Islamic Republic of)

Phone

+98 41 5104 0223

Email address

javadi.l@ihio.gov.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of lifestyle modification on the recovery of non-alcoholic fatty liver (NAFLD) of health insurance staff in Tabriz

Public title
The effect of Diet and Exercise on Fatty Liver Disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-alcoholic fatty liverdisease
Exclusion criteria:
Cardiovascular, thyroid, renal, inflammatory, autoimmune, hepatitis B and C, hereditary hemochromatosis, Wilson Alcohol consumers
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomly divided into two groups of intervention and control using random blocking method using 4 and 6 blocks by RAS (Random Allocation Software) and 1: 1 allocation ratio. In order to hide the assignment of the groups based on the random sequence of allocation by the person not involved in the research, the number was written on paper and sealed in a matte envelope. So that the researcher and the analyst will not know about the allocation concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, after randomly assigning the individual to the study group, blinding the researcher and the participant in terms of nutrition counseling will not be possible, but the outcome researcher and statistical analyst will be blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
NO.35, Roshdie Alley, Saadi Ave, valiasr
City
Tabriz
Province
East Azarbaijan
Postal code
5157936534
Approval date
2021-06-21, 1400/03/31
Ethics committee reference number
IR.TBZMED.REC.1400.303

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease (NAFLD)
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Aspartate trans amylase
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometric method

2

Description
Alanine amino transferase
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometric method

3

Description
Body Mass index
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement

Divide weight by height squared

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group receiving diet and physical activity
Category
Prevention

2

Description
Control group: Group without diet and physical activity
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Insurance Organization
Full name of responsible person
leila javadi
Street address
General Health Insurance, Office Golha St, Ail Goli
City
Tabriz
Province
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Postal code
5167858525
Phone
+98 41 5104 0100
Email
info.as@ihio.gov.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Health Insurance Organization
Full name of responsible person
Ali Shojaee
Street address
No.1, North Flamack Street, Ivanak Blvd, Gods town
City
Tehran
Province
Tehran
Postal code
1467863433
Phone
+98 21 9688 1000
Email
info@ihio.gov.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Health Insurance Organization
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Health Insurance Organization
Full name of responsible person
leila javadi
Position
Health Services Evaluation Expert
Latest degree
Ph.D.
Other areas of specialty/work
Responsible for the health committee
Street address
No.35, rushdieh alley, saadi st., valiasr
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Person responsible for updating data

Contact

Name of organization / entity

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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

Part of the data, such as information about the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Research using our study from another dimension

From where data/document is obtainable

Ms. Soraya Moradi Analyst of the study
Tel:009851040444 moradi.s@ihio.gov.ir

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

ایمیل از طرف محقق علمی دانشگاهی و با احراز هویت محقق ظرف یک ماه امکان پذیر است

Comments