

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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 exclusion : 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

East Azarbaijan

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 scientific inquiries

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Person responsible for updating data

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Phone

009833331633

Email

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 طرف یک ماه امکان پذیر است

Comments