

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of education based on health belief model on physical activity and dietary intake in nonalcoholic fatty liver disease patients

Protocol summary

Study aim

Determining the effect of education based on health belief model on physical activity and dietary intake in nonalcoholic fatty liver disease patients

Design

This is clinical trial with intervention and control group, randomized, on 80 patients with nonalcoholic fatty liver disease.

Settings and conduct

Data will be collected before and after the intervention and finally the effect of the intervention program on nutrition and physical activity and structures of the Health Belief Model and liver enzymes of patients with nonalcoholic fatty liver in Isfahan city will be measured

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of non alcoholic fatty liver disease by physician, patients who agree to participate in the study, 20 to 50 years' old, Ability to use smartphones and social media (Whats App) Exclusion criteria : Medical prohibition for physical activity or have special diet, Using alcohol, Pregnancy, lactation and menopause in women, Diagnosis of other diseases, including Liver disease, Biliary disease, Autoimmune disease and Cancers

Intervention groups

Education through social network and based on health belief model with emphasis on empowering patients to have healthy nutrition and increase physical activity will be done for two months in intervention group. Control group receive usual care provided in the Glands and Metabolism research center.

Main outcome variables

dietary intake: physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051546N1**

Registration date: **2021-07-12, 1400/04/21**

Registration timing: **prospective**

Last update: **2021-07-12, 1400/04/21**

Update count: **0**

Registration date

2021-07-12, 1400/04/21

Registrant information

Name

Nafiseh Tamadonpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on health belief model on physical activity and dietary intake in nonalcoholic fatty liver disease patients

Public title

The effect of education based on health belief model on physical activity and dietary intake in nonalcoholic fatty liver disease patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of non alcoholic fatty liver disease by physician
20 to 50 years' old Patients who agree to participate in the study
Ability to use smartphones and social media (Whats App)

Exclusion criteria:

Medical prohibition for physical activity or have special diet
Using alcohol
Diagnosis of other diseases, including Liver disease, Biliary Disease, Autoimmune disease and Cancers
Pregnancy, lactation and menopause in women

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Candidates who were eligible for participation in the study were randomly chosen and were assigned to the groups according to the random number table

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

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Street address

Isfahan University of Medical Sciences, Hezar-Jerib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.108

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver(NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Dietary intake

Timepoint

At the beginning and end of intervention

Method of measurement

3-day food record

2

Description

Physical activity

Timepoint

At the beginning and end of intervention

Method of measurement

The International Physical Activity Questionnaire

Secondary outcomes

1

Description

AST and ALT

Timepoint

At the beginning and end of intervention

Method of measurement

Blood sample

Intervention groups

1

Description

After referral of the patient from the physician, all patients are examined based on criteria for entering the study and are described the goals of the plan to patients. If the patient wishes to participate in plan, the consent form will be given to sign it after the study. Candidates who were eligible for participation in the study were randomly chosen and were assigned to the groups according to the random number table. Health Belief Model questionnaire, International Physical Activity Questionnaire (IPAQ), 3-day food record will be

completed before and after the intervention (2 months after the start of the intervention). also Liver enzymes (ALT, AST) and weight of patients will be measured before and after the intervention. The intervention group will receive messages via Whats App for 2 months, including clips, photos and podcasts about the severity of fatty liver disease, benefits and barriers to regular physical activity and healthy eating, intervention group will receive a self-care book on fatty liver disease, which includes a healthy lifestyle in fatty liver disease and self-assessment tables and the patient will be complete the book tables at the end of each week and send a photo for researcher.

Category

Lifestyle

2

Description

Control group: Control group were follow their routine life for 2 months.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

The Research Center of Glands and Metabolism
Hazrat Sedigheye Tahere

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Hazrat Sedigheh Tahereh Educational, Therapeutic
and Research Complex, After the intersection of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Assistance for Research and Technology, Building No.

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www.research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Nafiseh Tamadonpoor

Position

دانشجوی کارشناسی ارشد

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Study protocol and informed consent form will be shared.

When the data will become available and for how long

The access period starts 12 months after the results are published.

To whom data/document is available

Researchers interested in liver disease , as well as researchers working in academic and scientific institutions, can apply to receive the mentioned data and documents.

Under which criteria data/document could be used

There are no other special conditions for using the mentioned and send able documents.

From where data/document is obtainable

1-email:nafisehtamadonpoor@yahoo.com 2-email:as_pirzadeh@hlth.mui.ac.ir 3-Department of Health Education and Health Promotion, school of Health, Isfahan University of Medical Sciences

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

The applicant for the mentioned documents can receive the requested documents after a few days after submitting his / her application in the ways mentioned in the previous section, such as sending an email .

Comments