

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of mobile-based self-management intervention on liver function in overweight patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Study aim

The effect of a mobile-based self-management intervention for non-alcoholic fatty liver patients with obesity

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 140 patients. Random numbers inside the envelope are used for randomization

Settings and conduct

The location is performed in the private office of the physician and the patients of Mashhad Cohort Center or Persian Cohort that is located in Imam Reza Hospital - next to the multi-storey car park. Facing Ibn Sina 5, are used and the patients are divided into control and intervention groups blindly and randomly using random numbers inside the envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-People aged 18 and over. 2- Diagnosis of non-alcoholic fatty liver for the patient. 3- Ability to access the patient. 4- Having a smart phone 5-literacy. 6- Informed satisfaction and interest in participating in the study. 7-Not having comorbidity
Exclusion criteria : Grade 4 liver

Intervention groups

To evaluate the effect of the designed intervention, patients are randomly divided into two groups of control and intervention. Educational content is given to both control and intervention groups. It is also given to the mobile app intervention group. The two groups of control and intervention are evaluated for 3 months in terms of ALT(alanine aminotransferase) , AST(aspartate aminotransferase) and patients' level of knowledge and adherence to diet protocol and physical activity in a clinical trial study.

Main outcome variables

1- Liver enzymes: ALT(alanine aminotransferase) and AST(aspartate aminotransferase) 2- Weight 3-Abdomen circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051627N1**

Registration date: **2021-08-27, 1400/06/05**

Registration timing: **retrospective**

Last update: **2021-08-27, 1400/06/05**

Update count: **0**

Registration date

2021-08-27, 1400/06/05

Registrant information

Name

Azam Kheirdoust

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 1393

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kheirdousta971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-07-25, 1400/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mobile-based self-management intervention on liver function in overweight patients with Non-Alcoholic Fatty Liver Disease

Public title

Effect of mobile-based self-management intervention on liver function in overweight patients with Non-Alcoholic Fatty Liver Disease

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Not having Comorbidity Diagnosis of non-alcoholic fatty liver for the patient Having a cell phone Adults up to 65 years Patient informed consent and interest in participating in the study Access to patients Literacy

Exclusion criteria:

Grade 4 liver

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Researcher after preparing a list of non-alcoholic fatty liver patients whose condition The research is divided into two groups of experimental and control by simple random sampling method. Randomization unit is individual. As in this Study of 140 people randomly selected (sealed envelopes in Inside the envelopes are written the letters C (meaning control and I (intervention)) and in two groups of intervention and The controls are divided and assigned a code to each participant It will be given .

Blinding (investigator's opinion)

Double blinded

Blinding description

1- Non-alcoholic fatty liver patients who meet the research conditions are divided into two groups of experimental and control by simple random sampling method. Randomization unit is individual. In this study, 140 people were randomly selected (sealed envelopes inside the envelopes are written the letters C means control and M means intervention) and are divided into two groups of intervention and control and each Participants are assigned a code. 2- Outcome assessor who evaluates the occurrence or non-occurrence of outcome in participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No 237, Seydrazi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188753431

Approval date

2021-06-28, 1400/04/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.152

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver enzymes : ALT(alanine aminotransferase) and AST(aspartate aminotransferase)

Timepoint

At the beginning of the study and then 3 months after the intervention according to expert opinion

Method of measurement

Blood test

Secondary outcomes

1

Description

Weight

Timepoint

Weekly

Method of measurement

Ordinary weight measuring device

Intervention groups

1

Description

Intervention group: Motivational messages in the categories of nutrition, physical activity and knowledge to increase the patient's knowledge of his disease and fully personalized messages according to the score that the patient gives each week to adhere to his diet and physical activity and Also, the weight changes that he reports every week, which are based on two theories of behavior change and cognitive therapy, due to the low motivation of patients and their lack of follow-up, result in increasing patient adherence to diet and physical activity recommendations. Finally, improve the patient's condition. According to the questionnaire that has been designed and evaluated, the patient is classified into two categories: low motivation and high motivation. According to the documents, for a group with low motivation, 4 summary shorter messages, and for a group with a higher motivation, 3 longer complete messages are presented.

Category

Treatment - Other

2

Description

Control group: Receive a diet plan and routine physical activity recommendations on paper base

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Cohort Center or Persian Cohort

Full name of responsible person

Dr. Saeed Eslami

Street address

Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Eslami

Position

Supervisor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Eslami

Position

Supervisor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Mashhad cohort policies

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable