Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Email address
kheirdoustha971@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

City
Mashhad

Province
Razavi Khorasan

Postal code
9188753431

Phone
+98 51 3180 6812

Email
kheirdoustha@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Saeed Eslami

Street address
Park Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9188753431

Phone
+98 51 3602 9000

Email
EslamiS@mums.ac.ir

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
Medical Informatics

Street address
MELLAT Park Square

City
Mashhad

Province
Razavi Khorasan

Postal code
918875331

Phone
+98 51 3800 2429

Email
EslamiS@mums.ac.ir

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
Medical Informatics

Street address
Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9188753431

Phone
+98 51 3800 2429

Email
EslamiS@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Azam Kheirdoust

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Seyd Razi Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9188753431

Phone
+98 51 3605 1393

Email
kheirdoustha971@mums.ac.ir

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