Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluting the Effect of Self-Care Application on Lifestyle and Laboratory Indicators of client with Non-Alcoholic Fatty Liver disease

Protocol summary

Study aim
Determining the effect of Self-Care App on Lifestyle and Laboratory Indicators in patients with NAFLD

Design
This is clinical trial with intervention and control group and randomization with lottery method to allocate odd and couple days to groups and 70 patients are participating from july to march.

Settings and conduct
The content is prepared and the app is designed and verified by experts. With available sampling method is sampling from patients referring to gastroenterology clinic of Imam Khomeini Hospital in Tehran. Both control and intervention groups are examined for inclusion criteria and the purpose of plan are described to patients. If the patient is tend to participate in the project , a consent form is provided to the patient for study and signature.

Participants/Inclusion and exclusion criteria
Entry conditions: diagnosis by specialist physician; BMI more than 25; capability to work with it; lack of chronicl iver diseases , hyper or hypothyroidism, diabetes, Cushing's syndrome, Adisone disease, TB, lipid disorder; not using hepatotoxic drugs in the past 6 months; non-exposure to petrochemicals; not using alcohol and opiate. Exit conditions: unwilling to participate; no use of the app for one month.

Intervention groups
Control group: life style education and pamphlet is provided. First, one, two and three months later, the LSQ questionnaire is completed by patient and height, weight , BMI and ALT, AST, TG, Chol, HDL, LDL and FBS, Alb, Alp, CBC, HOMA are evaluated first and 12 weeks later. Weight and adherence is followed up with call phon (the first month is on a weekly, second and third month every two weeks). Intervention group: in addition to the control group actions, the app is installed for patient and how to use the app is taught. Motivational message are send via app daily and the WhatsApp group is formed.

Main outcome variables
Lifestyle; Laboratory Indicators

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190518043614N1**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **prospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date
2019-06-15, 1398/03/25

Registrant information
Name
Roya Rahmani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3522 6264
Email address
r-rahmani@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-06-21, 1398/03/31
Expected recruitment end date
2020-03-18, 1398/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluting the Effect of Self-Care Application on Lifestyle and Laboratory Indicators of client with Non-Alcoholic Fatty Liver disease

Public title
Effect of Self-Care Application on Lifestyle and Laboratory Indices

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis by specialist physician BMI greater than 25 capability to moderate physical activity Age between 19to 60 years Access to smart phones under the Android capability to work it Informed consent and interest in participating in the study Lack of liver disease such as viral ,autoimmune or medication hepatitis Lack of Wilson, hemochromatosis, hyper or hypothyroidism, diabetes, Addison Lack of gallstone, bile cancer, corticosteroid obesity, Cushing's syndrome Lack of tuberculosis, lipid disorders, alcohol and drug abuse Not using hepatotoxic drugs in the last 6 months, Non-exposure to petrochemicals

Exclusion criteria:
Unwillingness to participate in the study Not using self-care app for one month Failure to answer the phone for follow up and no presence in the clinic for two consecutive months

Age
From **19 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization done for days of the week with lottery method between the control group (card A) and the intervention group (card B) and available sampling according to entry conditions.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Nursing and Midwifery and Rehabilitation

Street address
Mailbox: 6459(East Nusrat)Dr. Mirkhani Street,Tawhid Square

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2018-09-02, 1397/06/11

Ethics committee reference number
IR.TUMS.FNM.REC.1397.104

Health conditions studied

1

Description of health condition studied
Non-Alcoholic Fatty Liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified
Nonalcoholic fatty liver disease [NAFLD]

Primary outcomes

1

Description
Lifestyle score is in the Lifestyle Questionnaire

Timepoint
Before intervention and one and two and three months after the intervention.

Method of measurement
Measurement is done with life style questionnaire which has 32 questions in the Likert spectrum and are scored. always (3), usually (2) or sometimes (1) and never (0) and It has dimensions of physical health and disease prevention, sports and health, weight control and nutrition, psychological health, social health, and the prevention of drugs and drugs.

2

Description
Fasting blood glucose

Timepoint
Before and 12 weeks after the intervention

Method of measurement
Examination of blood patient in laboratory

3

Description
Blood triglyceride
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

4

Description
blood cholesterol
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

5

Description
Blood Alanin aminotransferase
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

6

Description
Blood Aspartate aminotransferase
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

7

Description
Blood Albumin
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

8

Description
Homeostasis model assessment Insulin resistance)
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Measurement of fasting serum insulin in the laboratory and it is calculated as fasting insulin (micronutrile bromolitre), multiplied by fasting blood glucose (mgol / liter) divided by 22.5.

9

Description
High density lipoprotein
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

10

Description
Low density lipoprotein
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

11

Description
Count blood cell
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

12

Description
Alkaline Phosphatase
Timepoint
Before and 12 weeks after the intervention
Method of measurement
Examination of blood patient in laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Control group: After referral of the patient from the gastroenterologist, both the control and intervention groups 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. The LSQ Lifestyle Questionnaire is completed the first referral, one , two and three months later by the patient.The educational needs of patients in the field of lifestyle modification are identified, according to the patient's responses to the lifestyle questionnaire and the patient is trained in this cases.Height and weight and body mass index are measured. Patients are referred for testing for ALT, AST, TG, Cholesterol, HDL, LDL, and FBS, Alb, ALKph, CBC, and HOMA indicators before the intervention and 12 weeks after it begins.Educational pamphlet of illness and self-care of non-alcoholic fatty liver is delivered to the patient. Weight and adherence to treatment are assessed on the basis of patients' willingness to attend (clinic) or telephone (first month, weekly, second and third month every two weeks) for 12 weeks.
Category
Lifestyle

2

Description

Intervention group: In addition to the control group actions,The fatty liver self-care application is installed on the patient's phon at first day of the visit which has these parts:1.guide to app 2. Familiarity with non-alcoholic liver disease 3. Self-care assessment and lifestyle education 4. To measure my BMI and calculate BMI. 5. My goal.6. Calories record 7. My weight control 8. My progress 9.contact us. The method of working with the app is taught to the patient. In order to ensure learning, the patient responds to questions by directing the researcher on the self-assessment page. Based on patient responses in every aspect of self care assessment, the app gives the patient an educational feedback. The patient will be asked to read the messages and the lifestyle chart with the color guide is explained to the patient on the app's first page. The patient is asked to focus on his weaknesses in lifestyle modification .The patient enters his height, weight and age on the record page and app is calculated BMI and gives feedback the patient about his weight range.On mygoal page, the patient sets the target weight loss and daily physical activity for one month .The app calculates the patient's daily calorie intake based on the weight loss target in the month.The patient is asked to record on calories page,eaten foods and exercises performed hypothetically.The app gives feedback the patient about the amount of residual daily calorie .Daily allowed , residual, extra and My weight control , My progress and contact us are explained to the patient. To ensure learning is fallowed up with call to patient one, three, and six days after installing the app and the patient is asked to take a photo from the home and calorie record page and send it via WhatsApp.The duration of the intervention is 12 weeks. The patient determines the goal for each month and records daily calories via app and measure the weight weekly and records on my weight control page and sends this page photo via WhatsApp. The first and last day of the targeting, app displays a reminder message on the home page and sends a reminder message every day at 22:00 to record calories. Two motivational messages are sent daily to the patient via the app.An interactive group is formed by WhatsApp messenger between patients and researcher with the aim of sharing questions and experiences of patients and self-care educational materials related to lifestyle modification for improving fatty liver are sent to interactive group for patients daily. The names of the first to fifth individuals in terms of access to the objective of weight loss will be announced in this interactive group to patient motivation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex affiliated to Tehran University of Medical Sciences

Full name of responsible person

Roya Rahmani

Street address

Imam Khomeini Hospital Complex,Dr. Gharib Street,End of Farmer Blvd,Tehran Town

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6110

Fax

+98 21 6658 1615

Email

Imamhospital@tums.ac.ir

Web page address

http://ikhc.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

Sixth floor of research and technology deputy,Central Organization of Tehran University of Medical Sciences,Corner of Quds Street,Keshavarz Blvd,Tehran Town

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3623

Email

rmo@tums.ac.ir

Web page address

http://rmo.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Roya Rahmani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No994,Nargess Ave37,Qafari street,Takestan Town

City

Takestan

Province

Qazvin

Postal code

3481797994

Phone

+98 28 3522 6264

Fax

Email

r-rahmani@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

roya rahmani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No994,Nargess Alley37,Qafari Street,Takestan Town

City

Takeastan

Province

Qazvin

Postal code

3481797994

Phone

+98 21 3522 6264

Email

r-rahmani@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

roya rahmani

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No994,Nargess Alley37,Qafari Street,Takestan Town

City

Takestan

Province

Qazvin

Postal code

3481797994

Phone

+98 21 3522 6264

Email

royanrahmani@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Lifestyle and results of laboratory indicators are shared.

When the data will become available and for how long

Starting the access period from 2020

To whom data/document is available

Data will be available for scholars from academic and Scientific institutions and people who are involved in the industry and the general public can take action to get them.

Under which criteria data/document could be used

The results of data analysis, such as article and posters, for presentation at seminars and lectures and also these results and application can be used by physicians and healthcare providers and the general public.

From where data/document is obtainable

Applicants can be contacted by Roya Rahmani(researcher) Address:No994,Nargess Alley37,Qafari Street,Takestan Town,Postal code:3481797994 email:royanrahmani@gmail.com Mobile Phone Number:0098 9127886560 phone number:0098 28 35226264

What processes are involved for a request to access

data/document

The applicant can apply for article or application by sending an email or telephone call with researcher. The paper is sent to him for a week .The application is sent to applicant before being commercialized by researcher and the applicant must announce the 6-digit code to the researcher,then the app install code is sent by the researcher to the applicant .After the commercialization of the app, access to the app will be possible to pay the money for researcher.

Comments