

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effectiveness of lifestyle modification by micro learning method on the amount of non-alcoholic fatty liver

Protocol summary

Study aim

Determining the effect of lifestyle education by micro learning method on non-alcoholic fatty liver

Design

This study is a two-group, parallel and randomized clinical trial on 120 patients with non-alcoholic fatty liver disease. Random selection (APRI Score 0.5-1.5) and then random allocation.

Settings and conduct

Data will be collected using a questionnaire including demographic variables, HPLP2 and APRI Score. The intervention of the present study includes the effect of educational clips produced for 8 sequential weeks on patients with non-alcoholic fatty liver referred to the gastroenterology and liver clinic of Baqiyatallah Hospital (Tehran).

Participants/Inclusion and exclusion criteria

Enrollment: Having non-alcoholic fatty liver confirmed by a doctor and APRI Score between 0.5 and 1.5. Not having underlying problems such as diabetes and digestive problems. Having and knowing how to use a smart phone. Adult patients over 18 years old. Consent to participate in the study. Failure to enter: Patients who do not answer the questionnaires completely for any reason or can't do exercising.

Intervention groups

Training through educational clips based on health-promoting lifestyle dimensions, with an emphasis on empowering patients to have healthy nutrition, increasing physical activity along with other lifestyle dimensions through social networks, for a period of 8 weeks will be done in the test group and the control group will receive the usual recommendations and treatments in the gastroenterology and liver clinic.

Main outcome variables

Severity of fatty liver, amount of APRI Score, Quality of Life (HPLP2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221231056997N1**

Registration date: **2023-10-04, 1402/07/12**

Registration timing: **prospective**

Last update: **2023-10-04, 1402/07/12**

Update count: **0**

Registration date

2023-10-04, 1402/07/12

Registrant information

Name

Rasoul Davoudi Rahaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 5724

Email address

davoudir25@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-06, 1402/07/14

Expected recruitment end date

2023-12-05, 1402/09/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of lifestyle modification by micro learning method on the amount of non-alcoholic fatty liver		Vanak Square, Mollasadra St., South Sheikh Bahai St., Baqiyatullah University of Medical Sciences (Aj).	
Public title	Investigating the effectiveness of lifestyle modification by micro learning method on the amount of non-alcoholic fatty liver	City	Tehran
		Province	Tehran
Purpose	Education/Guidance	Postal code	1435916471
		Approval date	2023-08-14, 1402/05/23
Ethics committee reference number			
IR.BMSU.BAQ.REC.1402.044			
Health conditions studied			
1			
Description of health condition studied			
ICD-10 code	Non-alcoholic fatty liver		
		K76.0	
ICD-10 code description		Fatty (change of) liver, not elsewhere classified	
Primary outcomes			
1			
Description		diet	
Timepoint		The beginning of the study (before the intervention) and 4 weeks after the end of the intervention.	
Method of measurement		Health promotion lifestyle questionnaire.	
2			
Description		physical activity	
Timepoint		The beginning of the study (before the intervention) and 4 weeks after the end of the intervention.	
Method of measurement		Health promotion lifestyle questionnaire.	
Secondary outcomes			
empty			
Intervention groups			
1			
Description		Intervention group: After the patient is referred by the gastroenterologist and the entry criteria are met, the goals of the plan are explained to the patient. If desired, the consent form is given to the patient to sign after the study. Then the samples are randomly allocated. They will be allocated between the groups using blocks of 4. The HPLP2 questionnaire and blood tests including	

aspartate aminotransferase and platelets will be completed before and 4 weeks after the end of the intervention. The test group will receive at least 12 educational clips for 8 weeks through social media messages. Regarding the severity and severity of fatty liver disease, they will receive the benefits and barriers of diet and physical activity based on HPLP2, which also includes other dimensions, and to stabilize the training, a 2-week linear training of the important points of the clips sent the same week. will be placed in the group.

Category

Lifestyle

2

Description

Control group: They are trained and treated by a gastroenterology specialist according to the normal routine.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah Hospital (Aj), Gastroenterology and Liver Clinic.

Full name of responsible person

Rasoul Davoudi Rahaqi

Street address

Vanak Square, Mulla Sadra Street, after Sheikh Bahai, Baqiyatullah Hospital (Aj), Gastroenterology and Liver Clinic.

City

Tehran

Province

Tehran

Postal code

141556437

Phone

+98 21 81261

Email

bag@bmsu.ac.ir

Web page address

https://baq.bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Gholamhossein Alishiri

Street address

Mulla Sadra St., South Sheikh Bahai St., Baqiyatullah University of Medical Sciences (Aj).

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8804 0060

Email

unv@bmsu.ac.ir

Web page address

https://www.bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Rasoul Davoudi Rahaqi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Majid Haddadadal St., plate 87

City

Tehran

Province

Tehran

Postal code

1178865911

Phone

+98 21 3344 1123

Email

Davoudir25@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Fakhruddin Faizi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Molla Sadra St., South Sheikh Bahai St., Baqiyatullah
University of Medical Sciences (Aj)

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8804 0060

Email

f_f_1346@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Rasoul Davoudi Rahaqi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Majid Haddadadal St., plate 87

City

Tehran

Province

Tehran

Postal code

1178865911

Phone

+98 21 3344 1123

Email

davoudir25@gmail.com

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

The personal information of the participants will be kept confidential.

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

The study protocol and informed consent form will be shared.

When the data will become available and for how long

12 months after the results are published.

To whom data/document is available

Researchers interested in liver diseases, as well as researchers working in academic and scientific institutions, can send a request to receive the mentioned data and documents.

Under which criteria data/document could be used

There are no other special conditions for the use of the mentioned and sendable documents.

From where data/document is obtainable

davoudir25@gmail. com f_f_1346@yahoo.com and Baqiyatullah 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 submitting her request using the methods mentioned in the previous section, such as sending an email after a few days.

Comments