

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effect of an educational intervention based on the Health Belief Model on the nutritional behaviors of the older people with non-alcoholic fatty liver disease

Protocol summary

Study aim

Determining the effect of the educational intervention based on the health belief model on the nutritional behaviors of the elderly with non-alcoholic fatty liver in Tehran.

Design

A trial with a control group, with parallel groups, randomized, on 156 patients, rand function of Excel software was used to randomize the groups.

Settings and conduct

After determining the intervention and control groups, the cognitive status questionnaire will be given and if eligible, the main questionnaire will be given. Then, using the compiled educational program, education is provided to the patients. The educational intervention and completing the questionnaire will be done in the mentioned health centers of Shahid Beheshti University of Medical Sciences in Tehran. Finally, the results are analyzed using the software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No cognitive impairment, No history of regular alcohol consumption, Elderly with non-alcoholic fatty liver disease, Minimum education at the sixth elementary level, Elderly covered by designated health centers

Intervention groups

The intervention groups receive training in 5 sessions of 40-60 minutes in a period of 2 months once a week in the form of lectures, questions and answers, and pamphlets. Educational content has been collected from authentic books about this disease and related nutrition. During the intervention, the control group will not receive the training and they will only complete the questionnaire 2 times with a gap of one month, and after completing the training in the intervention group, they will receive the same training content in the form of 1-2 sessions for 30-60 minutes.

Main outcome variables

Mean scores of nutritional behavior, perceived susceptibility, perceived severity, perceived threat, perceived benefits, perceived barriers, self-efficacy, guide to action, awareness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230419057966N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **retrospective**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Fatemeh Ravaghi ardebili

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of an educational intervention based on the Health Belief Model on the nutritional behaviors of the older people with non-alcoholic fatty liver disease

Public title

Investigating the effect of education on the nutritional behaviors of the elderly with non-alcoholic fatty liver disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

No cognitive impairment No history of regular alcohol consumption Elderly with non-alcoholic fatty liver disease Minimum education at the sixth elementary level Elderly covered by designated health centers

Exclusion criteria:**Age**

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of centers to control and intervention groups is done by generating random numbers in Excel. For example, for 4 centers in the first column of Excel, we write 2 zeros to indicate the two control centers and 2 ones to indicate the two intervention centers. In the next column, we generate random numbers with the rand command and then sort the first column based on the generated random numbers column. The order of two zeros and two ones is arranged randomly, for example, as 0, 1, 1, 0. Then the first center is assigned to group 0, the second is intervention center, the third is intervention center and the fourth is control center.

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**

Ethics Committee of Health Faculty and Neuroscience Research Center of Shahid Beheshti University of

Street address

Faculty of Health and Safety, Shahid Beheshti University of Medical Sciences, Daneshju Blvd, Shahid Shahriari Square, Shahid Chamran Highway.

City

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Postal code

1985717444

Approval date

2022-11-29, 1401/09/08

Ethics committee reference number

IR.SBMU.PHNS.REC.1401.105

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**

Mean nutritional behavior scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

2**Description**

knowledge

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

3

Description

Average perceived susceptibility scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

4

Description

Mean perceived intensity scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

5

Description

Mean perceived threat scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

6

Description

Average scores of perceived benefits

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the

effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

7

Description

Mean scores of perceived barriers

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

8

Description

Mean self-efficacy scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

9

Description

Average practice guide scores

Timepoint

before the intervention and one month after the intervention

Method of measurement

Compiled questionnaire (based on the researcher's questionnaire for a thesis entitled "Investigation of the effect of education based on the health belief model on the promotion of nutritional behaviors in elderly women covered by health care centers in Ahvaz in 2013" written by Maryam Erfani mehr)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consists of 5 groups. After completing the questionnaire, the educational intervention will be conducted in the form of 5 educational sessions of 40-60 minutes in a period of 2

months. The intervention will be conducted once a week in the form of lectures, questions and answers, and using pamphlets. The educational content has been collected from authentic books about getting to know the disease, educational programs of the country, ways to improve and prevent the disease from worsening, the role of nutrition in the disease process. From the collected content, 2 educational pamphlets have been prepared, one with the title of healthy nutrition in old age and the other with the title of nutrition and non-alcoholic fatty liver, the content of which is presented in 5 sessions.

Category

Behavior

2

Description

The control group, which consists of 4 groups, did not receive any intervention during the intervention and only completed the questionnaire twice with a time interval of one month, without receiving training. After completing the training in the intervention group, training will be provided to them. The training will be conducted by lectures, questions and answers and by using pamphlets. The educational content has been collected from authentic books about getting to know the disease, educational programs of the country, ways to improve and prevent the disease from worsening, the role of nutrition in the disease process. From the collected content, 2 educational pamphlets, one with the title of healthy nutrition in old age and the other with the title of nutrition and non-alcoholic fatty liver, have been prepared and will be presented to the elderly in a compact form of 1-2 sessions lasting 30-60 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Nader comprehensive health service center

Full name of responsible person

Fatemeh Ravaghi

Street address

Esfandani St, Jashnvareh St, The second square of Tehranpars, Javadieh neighborhood.

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2

Recruitment center

Name of recruitment center

Salavati Comprehensive Health Service Center

Full name of responsible person

Fatemeh Ravaghi

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No. 59, corner of 1/24 St, 1st Nirou Havaie St, Pirouzi St, Pirouzi neighborhood.

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3

Recruitment center

Name of recruitment center

Mohammadian Comprehensive Health Services Center

Full name of responsible person

Fatemeh Ravaghi

Street address

south side of Lozi square, Nirou Havaie St, Hafeziieh neighborhood.

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4

Recruitment center

Name of recruitment center

Chizer comprehensive health service center

Full name of responsible person

Fatemeh Ravaghi

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No. 4, Neda Square, Andarzgo (Chizar), Chizar neighborhood.

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Phone

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5

Recruitment center

Name of recruitment center

Jafarian Comprehensive Health Service Center

Full name of responsible person

Fatemeh Ravaghi

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corner of 19th Square, Ghaffari Alley, Rudbari St, Resalat Highway.

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6

Recruitment center

Name of recruitment center

Kadus comprehensive health service center

Full name of responsible person

Fatemeh Ravaghi

Street address

Sojdei St, Jashnvaresh St, second floor of Tehranpars, West Tehranpars neighborhood.

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7

Recruitment center

Name of recruitment center

Jafari Comprehensive Health Service Center

Full name of responsible person

Fatemeh Ravaghi

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next to the fire department, Pishahang Station, Hefdah Shahrivar St.

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8

Recruitment center

Name of recruitment center

Niko comprehensive health service center

Full name of responsible person

Fatemeh Ravaghi

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No. 24, next to the Tejarat Bank, at the beginning of the Dezashib St, Bahonar St.

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9

Recruitment center

Name of recruitment center

Imamzadeh Ghasem comprehensive health service center

Full name of responsible person

Fatemeh Ravaghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Arabi St, Daneshjou Blvd, Velenjak.

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zarghi@sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fatemeh Ravaghi Ardebili

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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No. 2, Rahimi Alley, after Chaman park, South Homayunshahr St, Soroush 1st St, Deriano St, Sattarkhan St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Ramezankhani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Publishable data from this study include: age, sex,

marital status, education, occupation, educational intervention based on the health belief model, mean scores (nutritional behavior, perceived susceptibility, perceived severity, perceived threat, perceived benefits , perceived barriers, self-efficacy, guide to action), awareness.

When the data will become available and for how long

After completing the research and obtaining the necessary results, it will be possible to access the mentioned data.

To whom data/document is available

The data obtained from the research will be available to researchers who intend to design a similar study.

Under which criteria data/document could be used

It is possible to use the data to evaluate the impact of training and also perform analyzes that compare the average of the variables.

From where data/document is obtainable

Researchers can contact the study registrar via email f77.ravaghi@gmail.com to receive data.

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

The applicant must send the proposal file or code of ethics to the research registrar and after review by the research team, the relevant data will be sent to them within one month.

Comments