

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of nurses telephone follow-up (Telenursing) on the self-efficacy of dietary behavior and physical activity in patients with nonalcoholic fatty liver disease referred to subspecialty gastrointestinal Clinics of Shiraz

Protocol summary

Summary

This study examines the impact of nurse telephone follow-up on the self-efficacy of nutritional behavior and physical activity in patients with nonalcoholic fatty liver disease (NAFLD). Inclusion criteria included capability to perform moderate physical activity; confirmed by medical professionals; accessibility to a telephone at home, while, exclusion criteria included a history of chronic liver disease; hyperthyroidism or hypothyroidism; diabetes mellitus; alcohol consumption; drug abuse. In this interventional study, we enrolled 60 patients (30 patients in control groups and 30 patients in case groups) with NAFLD. Selective sampling was used to randomize the participants into case and control groups. The patients received dietary advice from a nutritionist individually and were trained to perform physical activity. Telephone intervention in the case group lasted for 12 weeks; while, the control group did not receive any follow-ups by the researcher and were only followed up as usual by a specialist. Before and after intervention, Questionnaires related to the self-efficacy of dietary behavior and physical activity were completed by study participants and also measurements (height, weight and BMI) was done by the researcher and all the patients were referred to assess blood test and to determine the liver size by ultrasound. Finally, the impact of nurse telephone follow-up on the self-efficacy of nutritional behavior and physical activity in patients with nonalcoholic fatty liver disease was examined by using the Statistics test.

General information

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT2015040411691N5**

Registration date: **2015-06-21, 1394/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-21, 1394/03/31

Registrant information

Name

Fariba Ghodsbin Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4250

Email address

ghodsbin@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of nurses telephone follow-up (Telenursing) on the self-efficacy of dietary behavior and physical activity in patients with nonalcoholic fatty liver disease referred to subspecialty gastrointestinal Clinics of Shiraz

Public title

The Effect of nurses telephone follow-up on the self-efficacy of dietary behavior and physical activity in patients with nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 19 years and over; the incidence of overweight or obesity; capability to perform moderate physical activity confirmed by medical professionals; accessibility to a telephone at home; lack of any speech and hearing problems. Exclusion criteria: history of chronic liver disease such as viral or drug hepatitis; confirmed diagnosis of Wilson diseases; primary hemochromatosis; hyperthyroidism or hypothyroidism; bile duct cancer; diabetes mellitus; obesity due to excessive use of corticosteroid; Cushing's syndrome; Addison syndrome; chronic infections such as tuberculosis; use of hepatotoxic drugs within the past 6 months; incidence of gall stones in the gallbladder having exposure to petrochemicals; alcohol consumption; drug abuse; genetic diseases related to lipid disorders.

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

14336 - 71348

Approval date

2010-04-21, 1389/02/01

Ethics committee reference number

ct-92-9262-6602

Health conditions studied

1

Description of health condition studied

Nonalcoholic Fatty Liver

ICD-10 code

k75.8

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

dietary behavior self efficacy

Timepoint

Before and three months after intervention

Method of measurement

dietary behavior self-efficacy Questionnaire (Sherer & Madox)

2

Description

Physical activity self-efficacy

Timepoint

Before and three months after intervention

Method of measurement

Exercise Self-Efficacy Questionnaire (Pender)

Secondary outcomes

1

Description

weight average

Timepoint

Before and three months after intervention.

Method of measurement

scale

2

Description

lipid average

Timepoint

Before and three months after intervention

Method of measurement

Blood test

3

Description

Liver Enzymes Average

Timepoint

Before and three months after intervention

Method of measurement

Blood test

4

Description

liver size average

Timepoint

Before and three months after intervention

Method of measurement

Ultrasound

Intervention groups

1

Description

Intervention group : Before and after intervention, Questionnaires related to the self-efficacy of dietary behavior and physical activity were completed by study participants .The patients received dietary advice from a nutritionist individually and were trained to perform physical activity. Telephone intervention in the Intervention group lasted for 12 weeks for following up the recommended diet and physical activity. Before and after intervention, measurements of weight, height and BMI of the patients was done by the researcher and all the patients to assess serum levels of AST, ALT, TG, LDL, HDL, Cholesterol and FBS and to determine the size of the liver by ultrasound were referred.

Category

Lifestyle

2

Description

Control group : Before and after intervention, Questionnaires related to the self-efficacy of dietary behavior and physical activity were completed by study participants .The patients received dietary advice from a nutritionist individually and were trained to perform physical activity. the case group did not receive any intervention by the researcher and were only followed up as usual by a specialist. Before and after intervention, measurements of weight, height and BMI of the patients was done by the researcher and all the patients to assess serum levels of AST, ALT, TG, LDL, HDL, Cholesterol and FBS and to determine the size of the liver by ultrasound were referred.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Sorur Javanmardi Fard

Street address

Namazi Hospital, Namazi Square, Zand Street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Masoom Masoom Pur

Street address

Central Building of Shiraz University of Medical Sciences, Infront of the Felestin Street, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fariba Ghodsbin

Position

Faculty Member and Instructor/Master degree

Other areas of specialty/work

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty