Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two training methods including face to face and a short message for modification the nutrition, physical activity and cholesterol levels in women with high blood cholesterol

Protocol summary

Study aim

Comparison of two training methods including face to face and a short message for modification the nutrition, physical activity and cholesterol levels in women with high blood cholesterol

Design

This study is a non-blinded clinical trial. The study population will be included all women with high blood cholesterol who will refer to comprehensive health care center of Kermanshah city.165 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups and one control group.

Settings and conduct

This study that will be conducted in a comprehensive health care center of Kermanshah city, is non-blinded one. At the beginning of the study, nutritional status and physical activity will be measured using a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cholesterol levels above 200; Having a mobile phone and the ability to read text messages
Exclusion criteria: People with cardiovascular disease, diabetes, and high blood pressure; Taking statin medications; already get training before the start of the study

Intervention groups

The first intervention group will receive the modification of nutrition and physical activity (educational content based on educational packages of the Ministry of Health) via texting as 2 weekly text messages for 12 weeks. The second intervention group will receive the modification of nutrition and physical activity (educational content based on educational packages of the Ministry of Health) face-to-face, monthly for a period of three months. The control group will not receive any intervention.

Main outcome variables

Cholesterol level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N114**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **prospective**

Last update: **2019-02-27, 1397/12/08**
Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-06-15, 1398/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of two training methods including face to face and a short message for modification the nutrition, physical activity and cholesterol levels in women with high blood cholesterol

Public title
Comparison of two training methods including face to face and a short message for modification the nutrition, physical activity and cholesterol levels in women with high blood cholesterol

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Cholesterol levels above 200 Having a mobile phone and the ability to read text messages Minimum age 30 years

Exclusion criteria:
People with cardiovascular disease, diabetes and high blood pressure Taking Statin medications already get training before the start of the study

Age
From **30 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **165**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly Individually by random number table via code receipt

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 Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2018-11-14, 1397/08/23

Ethics committee reference number
ir.kums.rec.1397.576

Health conditions studied

1

Description of health condition studied
Hypercholesterolemia

ICD-10 code
E78.0

ICD-10 code description
Pure hypercholesterolemia

Primary outcomes

1

Description
Cholesterol level

Timepoint
The beginning and end of the study

Method of measurement
Using blood tests

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive the modification of nutrition and physical activity (educational content based on educational packages of the Ministry of Health) via texting as 2 weekly text messages for 12 weeks

Category
Treatment - Other

2

Description
The second intervention group will receive the modification of nutrition and physical activity (educational content based on educational packages of the Ministry of Health) face-to-face monthly for a period of three months

Category
Treatment - Other

3

Description
The control group will not receive any intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Center
Full name of responsible person
Neda Yavari
Street address
Ellahyah, Taleghani Street
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6719936646
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n414yavari@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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+98 83 3836 0014
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Neda Yavari
Position
Masters student in health education and health promotion
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
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School of Health, Dolatabad Blvd, Isar Square
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Masters student in health education and health promotion

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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6719851351

Phone
+98 83 3826 4165

Email
n414yavari@yahoo.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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared.

When the data will become available and for how long
6 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable
To receive the documentation, email send for update manager

What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail

Comments