

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

froughi@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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719936646

**Phone**

+98 83 3835 5349

**Email**

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

**City**

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**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3836 0014

**Email**

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

**Street address**

School of Health, Dolatabad Blvd, Isar Square

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719851351

**Phone**

+98 988338264165

**Email**

n414yavari@yahoo.com

### Person responsible for scientific inquiries

##### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Behrooz Hamzeh

**Position**

Faculty Member of Kermanshah University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health promotion

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

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Masters student in health education and 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**