

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of an educational intervention on reducing the consumption of high-fat foods in women referred to the health houses in Tehran

Protocol summary

Study aim

Determine the effect of an educational intervention on reducing the consumption of high-fat foods in women referred to the health houses in Tehran

Design

In total, Tehran has 354 health homes (affiliated to Tehran municipal). From each of the four districts of Tehran city (including north, south, east and west), one health home will be randomly selected by simple sampling methods. Then, 23 female referring to each health homes will be selected and randomly assigned to the control and the intervention group.

Settings and conduct

Setting: Health Houses of Tehran (affiliated to Tehran municipal). Conduct: Ninety two female referring to 4 health homes will be selected and randomly assigned to the control and the intervention group. The two groups completed the questionnaires. Educational intervention will be developed based on the pretest results. By face to face meetings, participants in the intervention group will be received education intervention. Educational media such as pamphlets will be given the participants. Two months after the intervention, the two groups will be followed and completed the questionnaires again. Finally, the data will be analyzed by SPSS software .

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Literacy $\geq$ 5 grade - Being female
Exclusion criteria: - History of diseases that limit lipid consumption (such as diabetes, cardiovascular, blood pressure, kidney, fatty liver) - History of consumption of lipid lowering medications

Intervention groups

Intervention group: Face to face education in the field of high fat foods and reducing it consumption during 4 weeks was provided. Also, educational media such as pamphlets, posters, etc was given to the participants.
Control group: No intervention

Main outcome variables

Reducing high-fat foods consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110727007132N19**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **retrospective**

Last update: **2019-11-03, 1398/08/12**

Update count: **0**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

Tahereh Dehdari

Name of organization / entity

Iran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 2188779118263

Email address

t-dehdari@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2020-02-20, 1398/12/01

Scientific title

The effect of an educational intervention on reducing the consumption of high-fat foods in women referred to the health houses in Tehran

Public title

The effect of an educational intervention on reducing the consumption of high-fat foods in women referred to the health houses in Tehran

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy $\geq$ 5 grade Being female

Exclusion criteria:

History of diseases that limit high-fat foods consumption (such as diabetes, cardiovascular, blood pressure, kidney, fatty liver)- History of consumption of lipid lowering medications History of consumption of blood lipid lowering medications

Age

From **19 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Actual sample size reached: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The list of 354 Health Houses (affiliated to Municipal of Tehran) in the 4 regions including north, south, east and west of Tehran city at the moment of the study is available to the researchers. One Health Home will be randomly selected by simple sampling methods (Lottery method) from each region. Then, among female referred during a day to each health home, 23 female will be selected by simple sampling. The first person to visit of the Health House will be randomly assigned to the intervention group. The second person will be randomly assigned to the control group. The third person will be assigned to the intervention group. Similarly, the allocation of the remaining subjects will be continued in two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

There is no special characteristic in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences and Health Services Ethics ComCommittee of Ir

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1397.1177

Health conditions studied

1

Description of health condition studied

high-fat diet

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Consumption of high-fat foods

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reducing high- fat foods consumption

Timepoint

Before and two months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving educational intervention including three face- to- face sessions during 3 weeks (in terms of awareness of type of lipids, the methods of

reducing the rate of lipid of foods, attitude toward less high-fat foods consumption and less use of high-fat foods daily) and educational media such as booklet

Category

Lifestyle

2**Description**

Control group: Not received any educational intervention

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health Houses in Tehran

Full name of responsible person

Zainab Nasiri

Street address

The Intersection of the Martyred Freeway, Kurdistan Highway

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1438614151

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<http://farhangi.tehran.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Abbas Motevalian

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

No

Title of funding source

Person (Miss Fatemeh Zeinalzadeh Bruji)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Tahereh Dehdari

Position

Ph.D in Health Education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Contact

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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 results only will be published in the article

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable