

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of educational intervention according family-centered empowerment model (FCEM) on some of the serum hyperglycemia indices, lipid profile, calcium and vitamin D in elderly women : a randomized controlled trial.

Protocol summary

Study aim

to determine the effect of educational intervention according family-centered empowerment model (FCEM) on some of the serum hyperglycemia indices, lipid profile, calcium and vitamin D in elderly women : a randomised controlled trial.

Design

In this single-blind randomized, controlled trial with two parallel arms, 60 elderly eligible women will be randomly assigned into two groups using block randomization with block sizes of 4 and 6, and the ratio of 1: 1, receiving 1) family-center educational intervention, 2) control

Settings and conduct

Eligible women after necessary assessments and receiving written informed consent will be randomized into one of the two groups of education or control. Intervention group will receive education for 10 weeks. Statistical analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 60 years and older, Having a health record in Tabriz's elderly friendly health centers, having reading and writing skills, the ability to do routines independently. Exclusion criteria: Follow a specific diet, prohibition of any sports activity, having neurological disorders and known psychological diseases based on patient's remarks and health records, having acute cardiovascular events based on patient's remarks and health records, having uncontrollable chronic diseases, restrictive musculoskeletal disorders

Intervention groups

The group receiving family-centered education and the group not receiving education

Main outcome variables

Serum levels of glucose (fasting blood glucose and insulin resistance), serum levels of lipid profile

(triglyceride, total cholesterol, HDL, LDL), serum levels of calcium and 25-hydroxyvitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N5**

Registration date: **2018-10-09, 1397/07/17**

Registration timing: **prospective**

Last update: **2018-10-09, 1397/07/17**

Update count: **0**

Registration date

2018-10-09, 1397/07/17

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational intervention according family-centered empowerment model (FCEM) on some of the serum hyperglycemia indices, lipid profile, calcium and vitamin D in elderly women : a randomized controlled trial.

Public title

Effect of educational intervention on some of the serum hyperglycemia indices, lipid profile, calcium and vitamin D in elderly women.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 60 years or older having a health record in the Tabriz Elderly Friendship Centers having read and write literacy ability to do routines independently having a family member to attend educational sessions

Exclusion criteria:

Follow a specific diet (eg vegetarians) Prohibition of any sports activity as directed by the physician Having neurological disorders (stroke - Parkinson's disease and paralysis) and known psychological diseases based on patient's remarks and health records Having acute cardiovascular events (acute myocardial infarction - acute heart failure and uncontrolled hypertension) based on patient's remarks and health records Having uncontrollable chronic diseases (such as advanced diabetes and malignant diseases) Restrictive musculoskeletal disorders

AgeFrom **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Women aged 60 years or older will be randomly assigned into two groups of recipients of training or control using random blocking method and blocks 4 and 6 through Random Allocation Software (RAS) with a 1: 1 assignment ratio by the person not involved in the research. To conceal the allocation, the name of group will be placed inside a consecutively numbered sealed opaque envelopes. Preparation of envelopes and sequence generation will be done by a person not involved in participant recruitment or data collection.

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 Tabriz University of Medical Sciences

Street address

Research Vice-chancellor of Tabriz University of Medical Sciences., End of Gholgasht Ave., Tabriz., Iran.

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East Azarbaijan

Postal code

5166614766

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.TBZMED.REC.1397.396

Health conditions studied**1****Description of health condition studied**

Elderly women aged 60 years or older who are able to do routines independently.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The mean serum level of hyperglycemia indices (fasting blood glucose and insulin resistance) in the studied groups

Timepoint

At baseline, 8 weeks and 6 months after the intervention

Method of measurement

FBS and fasting insulin will be measured by spectrophotometry with Alcyon 300 model using the Pars Test Kit, and ELISA method by ELISA kit, respectively.

2

Description

The mean serum lipid profile (triglyceride, total cholesterol, HDL, LDL) in the studied groups

Timepoint

At baseline, 8 weeks and 6 months after the intervention

Method of measurement

by spectrophotometry with Alcyon 300 model using the Pars Test Kit, and ELISA method by ELISA

3

Description

Mean serum levels of calcium and 25-hydroxy vitamin D in the studied groups

Timepoint

At baseline, 8 weeks and 6 months after the intervention

Method of measurement

Calcium by spectrophotometer with Alcyon 300 and using Pars Test Kit; 25-hydroxy vitamin D by Elisa method using ELISA kit

Secondary outcomes

1

Description

Mean scores of anthropometric characteristics (weight, BMI, waist circumference, waist to hip ratio) in the studied groups

Timepoint

At baseline, 4 weeks, 8 weeks and 6 months after the intervention

Method of measurement

The weight is measured by the Seca scale with a precision of 0.1 kg, height by stadiometer, waist and hip circumference with tape measure, and BMI by dividing the weight (kg) to squared height (meter).

2

Description

The mean systolic and diastolic blood pressure score in the studied groups

Timepoint

At baseline, 4 weeks, 8 weeks and 6 months after the intervention

Method of measurement

The blood pressure will be checked by the German mercury barometer.

Intervention groups

1

Description

Intervention group: Recipient of educational intervention based on family-centered empowerment model in 10 sessions of 45 minutes for 10 weeks. For step-by-step implementation and application of the family-centered empowerment model, four executive stages will be designed for them that are consistent and coherent and

are as follows: Perceived threat, problem solving, educational participation and evaluation.

Category

Lifestyle

2

Description

Control group: During the study, this group will not receive any education, but after completion of the educational program, follow up and completion of the questionnaires, the educational program will be provided in the form of a meeting with the booklet.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Elderly friendly Health Centers

Full name of responsible person

Dr. Mitra Yeghaneh

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Nesfrah Square., Tabriz health center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Requested data will be provided to researchers for

statistical analysis of the submitted proposal (meta-analysis).

When the data will become available and for how long

starting immediately after publication

To whom data/document is available

Data will be available to researchers as well as to journals

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of a proposal to perform meta-analysis

using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journals for checking.

From where data/document is obtainable

Refer to the email address (farshbafa@tbzmed.ac.ir)

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

The requests will be sent by email and data will be available within a week

Comments