Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of intervention based on family-centered empowerment model on preventive lifestyle of cardiovascular risk factors in middle-aged women

Protocol summary

Study aim
Determining the effect of intervention based on family-centered empowerment model on preventive lifestyle risk factors for cardiovascular disease in middle-aged women

Design
The clinical trial includes an intervention and control group that sampling will be done based on the inclusion criteria and randomly (random blocking). The sample size in each group will be 37 people and a total of 74 people.

Settings and conduct
The study site will be comprehensive health service centers in the south of Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age between 40 to 59 years Lack of speech and hearing problems - Literacy - Do not suffer from known mental disorders (self-expression and apple system) - The person is at a moderate and higher risk of cardiovascular disease - Do not have underlying diseases other than diabetes Exclusion criteria: - Absence from more than two sessions of training sessions - Spatial displacement

Intervention groups
After sampling and identification of control and test groups, the intervention based on the family-centered empowerment model will be performed for the test group. Thus, by forming small groups during 6 training sessions, each session will be for half an hour and will be held twice a week, the lifestyle of preventing risk factors for cardiovascular disease using model steps (perceived threat from Through group discussion, promoting self-efficacy through group problem solving, increasing self-esteem (self-confidence) through educational participation) will be taught. In two sessions, a family member will be invited to attend the sessions and participate in training and group discussions. However, in order to comply with ethical considerations, a training session will be held at the end of the intervention for the control group.

Main outcome variables
Improving the preventive lifestyle of risk factors for cardiovascular disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201208049649N1**
Registration date: **2021-01-07, 1399/10/18**
Registration timing: **prospective**

Last update: **2021-01-07, 1399/10/18**
Update count: **0**

Registration date
2021-01-07, 1399/10/18

Registrant information

Name
Fariba Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-19, 1399/10/30

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of intervention based on family-centered empowerment model on preventive lifestyle of cardiovascular risk factors in middle-aged women

Public title
Effect of intervention based on family-centered empowerment model on preventive lifestyle of cardiovascular risk factors in middle-aged women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 40 to 59 years Lack of speech and hearing problems- Literacy Do not suffer from known mental disorders (self-expression and apple system) The person is at a moderate and higher risk of cardiovascular disease Do not have underlying diseases other than diabetes
Exclusion criteria:
Absence from more than two sessions of training sessions Spatial displacement
Age
From **40 years** old to **59 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples were randomly assigned to the experimental and control groups in the form of a random permutation block design with four blocks. Thus, the letter A was considered for the intervention and the letter B was considered for the control group. Then all the permutation compounds of letters A, A and B, B, which were 6 different compounds, were written (AABB for cultivar 1, ABBA for cultivar 2...) and from cultivars 1 to 6, one cultivar was randomly selected by substitution. For example, if the number 2 was selected, it meant that the first person in the intervention group, the next two people in the control group and the fourth person in the intervention group, and we continued this operation until the sample size reached the quorum (37 people in each group).) 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 Tehran University of Medical Sciences
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat Sharghi St., Tohid Sq., Tehran
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2020-10-05, 1399/07/14
Ethics committee reference number
IR.TUMS.FNM.REC.1399.105

Health conditions studied

1

Description of health condition studied
Cardiovascular diseases
ICD-10 code
I50.4
ICD-10 code description
Combined systolic (congestive) and diastolic (congestive) heart failure

Primary outcomes

1

Description
Preventive lifestyle risk factors for cardiovascular disease
Timepoint
Before the intervention, two months after the end of the intervention
Method of measurement
Standard Eating Habits Questionnaire, Metabolic Health Assessment Questionnaire, Baecke Physical Activity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Intervention group: By forming small groups during 6 training sessions, each session will be for half an hour and will be held twice a week, the lifestyle of preventing cardiovascular disease risk factors using the model steps (perceived threat from Through group discussion, promoting self-efficacy through group problem solving, increasing self-esteem (self-confidence) through educational participation) will be taught. In two sessions, a family member will be invited to attend the sessions and participate in training and group discussions. The educational content includes (nutrition, physical activity .....) which will be based on the family self-care guide and will be designed by the esteemed deputy of health and will have a set of practical recommendations for the prevention of cardiovascular disease risk factors. Educational materials are taught according to the model (perceived threat through group discussion, promoting self-efficacy through group problem solving, increasing self-esteem (self-confidence) through educational participation): Step 1 (perceived threat): In this Step by step group discussion will be used to examine the perceived threat. Examining and evaluating the current situation, individual, environmental and behavioral differences and determining the behavioral and environmental factors that affect the change of behavior will be done in this meeting. Group discussion with the research units will be done in two sessions and each session will last for 30 minutes, in which one person will participate alone and in the next session with a family member. During the sessions, discuss their knowledge and potential solutions, then provide educational materials on the importance of self-care and prevention of cardiovascular disease and its dimensions, including care measures to prevent disease. Cardiovascular, communicating with others as a group discussion to achieve codified and effective programs, promoting self-efficacy through group problem solving, increasing self-esteem (self-esteem) through educational participation of research members and families, the nature of the disease Cardiovascular, signs and symptoms of the disease or exposure and issues related to nutrition and physical activity and blood pressure and smoking will be expressed. Step 2 (Improving self-efficacy through group problem solving): For this step, the method of showing educational videos and pamphlets in two sessions for 30 minutes will be used, so that in one of the sessions, family members with the samples studied They will participate in the meeting, and the necessary training and needs assessment in the first session will be provided to the research members through educational videos and pamphlets. Also, in the meeting in which family members also participate, the research members will be asked. To reach possible solutions to the problem and plan to implement it through group discussion with each other and with family members, through the problem solving process. At the end, a program will be prepared based on standard principles and using publicly available materials and methods and will be provided to members. All material presented from scientific sources will be valid and approved by professors. Step 3 (Increase self-esteem through educational participation): In this stage, which will be done in two sessions and each session will be for 30 minutes, the patient is asked Will participate in training their family members and encourage them to help themselves. Step 4 (Final Evaluation): In this stage, which will be eight weeks after the last family-centered empowerment session, invite the research units Will do to answer the research questionnaire as a post-test. After the completion of this process, the written and text file of the trainings presented in the previous sessions will be presented in PDF format along with the pamphlet files related to all research units (both intervention and control groups).

Category

Prevention

2

Description

Control group: The control group will benefit from the usual programs of the center, but in order to observe ethical considerations, a training session will be held for this group at the end of the intervention, in which the training given to the intervention group will be briefly taught. .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in the south of Tehran

Full name of responsible person

Fariba Hosseini

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No. 41, 4th floor, Sadeghi Alley,Farmanieh.

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fariba Hosseini

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No. 41, 4th and 7th floors, Sadeghi Alley, Farmanieh, Tehran

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Other areas of specialty/work
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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data analysis results will be available for use by other experts and researchers after the study

When the data will become available and for how long

One month after data analysis

To whom data/document is available

Researchers, experts and professors in this field, managers, planners and other stakeholders

Under which criteria data/document could be used

There are no special conditions for people to access

From where data/document is obtainable

After publishing the results, they can refer to the site where the results were published

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

After publishing the results in the journal and the site, it is enough to search for the keywords of the research on the internet page, and also to communicate with the researcher, they can contact him through the email published in the article.

Comments