Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The Effect of self-care program education on anthropometric indicators in postmenopausal women with metabolic syndrome.

Protocol summary

Summary

Objectives: Determination of the effect of self-care program education on anthropometric indicators in postmenopausal women with metabolic syndrome. Design: This study will be performed in cluster randomized controlled trial in both the experimental and the control groups consisting of 120 postmenopausal women aged 45-60 years old that are presented with metabolic syndrome to the 8 of the 15 healthcare centers in 22 districts of Tehran municipality. The study will be carried out in the second half of 1395. Setting and Conduct: In this study, 8 healthcare centers will be randomly selected and allocated in two experimental and control groups. The sampling will be performed as targeted and accessible after the participants that meet the inclusion criteria give written consent. Data collection will be done through demographic information, anthropometric indicators questionnaire and Orem needs assessment form. Inclusion criteria: Postmenopausal women aged between 45 to 60 years old; Approval of developing metabolic syndrome by physician; Approved mental, emotional and cognitive health by self-reporting; The absence of cardiovascular disease, diabetes, cancer and hypothyroidism; Not being on hormone therapy. Exclusion criteria: Perform a total hysterectomy and oophorectomy during the study; Not attending the entire training sessions. Intervention: The self- care program in this research, will be in the form of an Orem conceptual model that will depend on the training needs of patients participating in the program. Each experimental group, which will contain 5 to 7 participants, will receive a training program that consists of five sessions(45-minutes each) for 5 weeks. Main outcome measures(variables): The anthropometric indicators of (weight, body mass index, waist and hip circumference, waist- to-hip ratio, waist to height ratio and middle arm circumference) in both the intervention and the control groups; will be measured before any intervention and 8 weeks after training.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050333803N1**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Sahab Badizadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5575 0653

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Iran University of Medical Sciences.

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of self-care program education on anthropometric indicators in postmenopausal women with metabolic syndrome.

Public title
The Effect of education on metabolic syndrome.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:Postmenopausal women aged between 45 to 60 years old; Approval of developing metabolic syndrome by physician; Approved mental, emotional and cognitive health by self-reporting; The absence of cardiovascular disease, diabetes, cancer and hypothyroidism; Not being on hormone therapy.
Exclusion criteria: Perform a total hysterectomy and oophorectomy during study; Not attending the entire training sessions.

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomized by colored bullets.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commmittee of Iran University of Medical Science

Street address
Iran University of Medical Science, Hemmat Highway, Tehran.

City
Tehran

Postal code
1449614535

Approval date
2016-09-25, 1395/07/04

Ethics committee reference number
REC.1395.IR.IUMS.9313676006

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E70-E90

ICD-10 code description
Metabolic disorderes

Primary outcomes

1

Description
Weight

Timepoint
Before and 8 weeks after the intervention

Method of measurement
Using a digital scale Seca and with an accuracy of 0.1 kg

2

Description
Body mass index

Timepoint
Before and 8 weeks after the intervention

Method of measurement
Weight by the square of height in metric units

3

Description
Waist circomference

Timepoint
Before and 8 weeks after the intervention

Method of measurement
Using plastic meters and with an accuracy of 0.1 cm

Secondary outcomes

1

Description
Waist-to-hip ratio

Timepoint
Before and 8 weeks after the intervention

Method of measurement
By dividing the waist measurement by the hip measurement unit cm

2

Description
Waist to Height Ratio

Timepoint
Before and 8 weeks after the intervention

Method of measurement
By dividing the waist measurement units cm in height per cm

3

Description
The middle arm circomference
Timepoint
Before and 8 weeks after the intervention
Method of measurement
Using plastic meters per cm

Intervention groups

1

Description
Intervention group: Intervention will be based on a self-care education program. This program will be designed and implemented based on Orem's supportive-educative system; which will include a collection of self-care training programs that assist patients to identify and investigate their needs. This education package will include training the subjects to improve their understanding and awareness of metabolic syndrome and menopause, nutrient regimen, medication regimen, physical activity, and weight loss.This program will be conducted in 5 sessions of 45 minutes duration, of which 30 minutes will include oral presentation and 15 minutes for questions and answers. The program will run over 5 weeks (one session per week), in groups of 5 to 7 people. The training, will start and end at a certain date and will be provided by 5 research assistants. These training programs will be conducted in the morning shift and in the selected healthcare centers of Tehran municipality. The training will contain providing information to the participants regarding metabolic syndrome and its relationship to menopause, complications of the disease, dietary(use of fresh vegetables and fruit, low salt and carbohydrate diet, reduced consumption of saturated fatty acids and their importance and a variety of foods that can be used), medication regimen (the importance of taking them on time, dosage and their effects), weight loss and physical activity (aerobic sports, type of physical activity and its role in health). The training program will also include educating the participants on how to measure their blood pressure, weight and blood sugar levels. At the end of each session, the subjects will be given educational pamphlets of that. The final educational material will be in the form of a booklet with 5 chapters, which will include: metabolic syndrome and menopause(chapter I), diet and metabolic syndrome (chapter II), medication regimen and metabolic syndrome (chapter III), physical activity, weight loss and metabolic syndrome (chapter IV), and how to measure blood pressure, body weight and blood sugar (chapter V). The content of this booklet will be reviewed and approved by 10 medical and surgical scholars. To evaluate the efficiency of training, the participants will be asked two questions at the beginning of each session about the previous session and how they incorporated that at home. It is worth noting that the trainers will be available to answer any questions raised by participants via phone, if needed. At the end of this study the subjects will be rewarded for their participation.
Category
Lifestyle

2

Description
Control group: In this group there, will not be any intervention and they will continue to have their usual lifestyle as before. At the end of this investigation they will be provided with the educational material and also will be rewarded as their other counterparts for their participation in this program.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
District 1 of Tehran Municipality Health Center
Full name of responsible person
Sahab badizadeh, Graduate Student of Medicial & Surgical
Street address
Next to the Gas Station, Bahonar Street, Tajrish Square
City
Tehran

2

Recruitment center
Name of recruitment center
District 3 of Tehran Municipality Health Center
Full name of responsible person
Sahab badizadeh, Graduate Student of Medicial & Surgical
Street address
Before the Hemmat Highway, Lower than Husseinya Ershad, Shariati Street
City
Tehran

3

Recruitment center
Name of recruitment center
District 5 of Tehran Municipality Health Center
Full name of responsible person
Sahab badizadeh, Graduate student of Medicial & Surgical
Street address
Next to Shahid Shali Street, The bigining of the Ashrafi Esfahani Highway, Higher than the Second Square of Sadeghieh
City
Tehran

4

Recruitment center

Name of recruitment center
Disrict 6 of Tehran Municipality Health Center

Full name of responsible person
Sahab badizadeh, Graduate Student of Medicial & Surgical

Street address
NO.19, Shahid Farhang Hosseini Alley, Higher than the Taleghani, Valiasr Street

City
Tehran

5

Recruitment center

Name of recruitment center
Disrict 8 of Tehran Municipality Health Center

Full name of responsible person
Sahab badizadeh, Graduate student of Medicial & Surgical

Street address
NO. 218, Crossroad Kamyab, Dardasht Street, Narmak Street, Resalat Highway

City
Tehran

6

Recruitment center

Name of recruitment center
District 12 of Tehran Municipality Health Center

Full name of responsible person
Sahab badizadeh, Graduate student of Medicial & Surgical

Street address
Estenkafi Alley, Mojahedin Islam Street, Shohada Square

City
Tehran

7

Recruitment center

Name of recruitment center
Disrict 17 of Tehran Municipality Health Center

Full name of responsible person
Sahab badizadeh, Graduate student of Medicial& Surgical

Street address
NO.33, Infront of the shihadaye Gomnam Park, Shahid Firoozi Street, Abozar Street

City
Tehran

8

Recruitment center

Name of recruitment center
Disrict 19 of Tehran Municipality Health Center

Full name of responsible person
Sahab badizadeh, Graduate student of Medicial & Surgical

Street address
NO.240, Corner of 16. Alley, Misag Street, Shahid Latifi Street, Khaniabadno

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research, Iran University of Medical Science

Full name of responsible person
Morteza naserbakht

Street address
Fifh floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway.

City
Tehran

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for research, Iran University of Medical Science

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Daryadokht masror rodsari

Position
The coach, Masteres of Medical Surgical

Other areas of specialty/work

Street address
School of Nursing & Midwifery, Rashid Yasemi Street, Valiasr Street, Tehran

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1996713883

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+98 21 4365 1709

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Daryadokht Masror rodsari

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Other areas of specialty/work

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Web page address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty