Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of education based on Orem self care model on self care behavior and quality of life in menopausal women: a randomized controlled trial

Protocol summary

Summary

Target: evaluate the effect of education on self-care, based on Orem self-care model on self-care behaviors and quality of life menopausal women. Designing: randomized clinical trial. How do: in health centers of Saghez will be done. 130 of menopausal women aged 45 to 55 with blocks 4 and 6 with allocation ratio of 1: 1 Placed into two groups Intervention and control. A member of the research team uninvolved in the selection of samples, random allocation sequence using a computer program will determine.Participants using a randomized. Sealed opaque envelope numbered sequentially allocation will be used for concealment of allocation. Inclusion criteria: natural menopasue; lack of participation in sijmilar studies; access to cell phone; no Known history of mental illness. Exclusion criteria: implemention of hormone replacment therapy; giving any type of education in menopausal area and need for surgical intervention. Intervention: in the intervention group; four one-hour group training session on the basis of Orem self-care and the results of the self-care questionnaire completed in the first session.one personal training session will be conducted based on specific needs. The main educational content determined according to the Ministry of Health booklets and reference books. In the control group after the end of the study and completing the questionnaires, pamphlets will be taught. The main outcome variables: Self-care behavior scores before and 4 weeks after intervention and individual outcomes: quality of life before and 4 weeks after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020221917N6**
Registration date: **2016-06-10, 1395/03/21**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name
Sevil Hakimi
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 3479 6770
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hakimis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences-Faculty of Nursing and Midwifery

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education based on Orem self care model on self care behavior and quality of life in menopausal women: a randomized controlled trial

Public title

Effect of education based on Orem self care model on self care behavior and quality of life in menopausal

women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: menopaual women aged rane between 45- 55; Passing one year from the last date of menstruation;natural menopasue; lack of participation in sijmilar studies; access to cell phone; no Known history of mental illness. Exclusion criteria: implemention of hormone replacment therapy; not wanting to continue the study; impossibility of attending a training class; giving any type of education in menopausal area; mental disorders; surgical intervention.

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Number 2 central building, third floor, research and technology department, Golgasht street, Azadi avenue, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2016-01-24, 1394/11/04

Ethics committee reference number

tbzmed.rec.1394.971

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

2

Description of health condition studied

Self care in menopause

ICD-10 code

N95.8

ICD-10 code description

Other specified menopausal and perimenopausal disorders

3

Description of health condition studied

Quality of life

ICD-10 code

Z73.9

ICD-10 code description

Problem related to life-management difficulty, unspecified

Primary outcomes

1

Description

Self-care behavior

Timepoint

Baseline, forth weeks after intervention

Method of measurement

Orem self care questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Baseline, forth weeks after intervention

Method of measurement

12-Item short form health survey

Intervention groups

1

Description

In the control group; after the end of the study and completing the questionnaires, pamphlets will be taught.

Category

N/A

2

Description
In The intervention group; group and individual training will be done.four one-hour group training session on the basis of Orem self-care and the results of the self-care questionnaire completed in the first session.one personal training session will be conducted based on specific needs.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Urban health center

Full name of responsible person
Somayeh Rahimi

Street address
11th Shahab alley, Shahid Montazeri Street, Saghez

City
Saghez

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person
Rashidi Mohammad Reza

Street address
Number 2 central building, third floor, research and technology department, Golgasht street, Azadi avenue, Tabriz University of Medical Sciences

City
Tabriz

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, Tabriz University of Medical Sciences

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
Tabriz University of Medical Sciences

Full name of responsible person
Sevil Hakimi

Position
PhD of reproductive health

Other areas of specialty/work

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Person responsible for updating data

Contact

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Web page address

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