Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of self-care education on severity of symptoms and quality of marital life in menopausal women

Protocol summary

Study aim
Determining the effect of self-care training on the severity of symptoms and quality of marital life in postmenopausal women in two groups of test and control

Design
Collecting samples by dividing the participants into two groups of test and control randomly witness. To be placed

Settings and conduct
The research community will be menopausal women who meet the entry criteria. Research environment, women's clinic of Baqiyatallah hospital will be selected.

Participants/Inclusion and exclusion criteria
Having the age of 65-45 years normal menopause (not with hysterectomy or oophorectomy) Criteria for leaving the study: Absence of more than one session of training sessions Incidents and unfortunate events (death, accident, hospitalization)y

Intervention groups
The researcher will examine the impact of self-care education on the severity of symptoms and the quality of married life in postmenopausal women.

Main outcome variables
Training has the effect of reducing the severity of menopausal symptoms in both test and control groups. Education has an effect on improving the quality of married li

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200624047910N1**
Registration date: **2020-11-10, 1399/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-10, 1399/08/20**
Update count: **0**

Registration date
2020-11-10, 1399/08/20

Registrant information

Name
Leila Karimi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-care education on severity of symptoms and quality of marital life in menopausal women

Public title
The effect of self-care education on severity of symptoms and quality of marital life in menopausal women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having an age of 65-45 years At least 12 months have

passed since the last menstrual period Having a desire to participate in the study Lack of physical and mental problems No smoking Normal menopause (not with hysterectomy or oophorectomy

Exclusion criteria:

Absence of more than one session of training sessions Emergence of adverse events (death, accident, hospitalization Diagnosis of chronic physical and mental problems during the study Distorted questionnaires (with scratches, illegible, more than one Answers to each question) Questionnaires that more than 20% of them have not been answered

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **5**

The study population consisted of postmenopausal women aged 45-45 years, and the criteria for entering the study included women who had at least 12 months since the last menstrual period and had normal menopause without hysterectomy or aforectomy, hormone therapy, and menopause. Do not use tobacco, do not have chronic physical or mental problems, and have a desire to participate in the stud

Randomization (investigator's opinion)

Randomized

Randomization description

(In order to randomly assign to two groups of test and control, block random division method was used with quadruple blocks. In this way, the letter A was assigned to the test group and the letter B was assigned to the control group and in the quadruple blocks with the letters A) And B, the six modes AABB, BBAA, ABAB, BABA, ABBA, BAAB were written on separate sheets and thrown into a container, and randomly took one of these sheets out of the container and wrote the composition written on it. And again "that sheet was thrown into the container. Because the sample size in this study was 80 patients, this operation was repeated twenty times, and each time the composition written on each sheet was written in the sequence of the composition written on the previous sheet. One of the letters of a number from one to eighty was assigned in the order of the letters in a row, and each letter was placed in an envelope and the number was written on the envelope. Each time the disease was selected, one of these envelopes The number written on the envelope was opened in order and it was determined that the patient should be in the test or control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

, Mulla Sadra, Sheikh Baha'i Street

City

tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

1223

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of self-care education on the severity of symptoms and the quality of married life of postmenopausal women

Timepoint

Before training and one month after training

Method of measurement

(Menopause Symptoms Severity Inventory)Revised Dyadic Adjustment Scale

Secondary outcomes

1

Description

The severity of menopausal symptoms and the quality of married life

Timepoint

Measuring the severity of menopausal symptoms and the quality of married life one month after training

Method of measurement
(Menopause Symptoms Severity Inventory)Revised Dyadic Adjustment Scale)

Intervention groups

1

Description
Intervention group: Training the test group in 4-6 sessions of one and a half to two hours and giving educational pamphlets at the end of each session
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's Clinic of Baqiyatallah Hospital
Full name of responsible person
ملیحه مختاری سه قلعه
Street address
Mullah Sadra, Sheikh Baha'i Street
City
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1435916471
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malihemokhtari646@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
malih mokhtaqri
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Mullah Sadra, Sheikh Baha'i Street
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Grant name
Grant code / Reference number
12345
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
malih mokhtari
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Provide a proposal Submit a dissertation
When the data will become available and for how long
Start access 6 months after printing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Scientific use Use in bed
From where data/document is obtainable
Researcher
What processes are involved for a request to access data/document
Contact the researcher
Comments