

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Country

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

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+98 21 8882 2222

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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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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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

nurs

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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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