Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women

Protocol summary

Study aim

The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women referred to health centers in mahabad in 2017-218

Design

The present study is a quasi-experimental, pretest-posttest with control group. Sampling in this study was done by selecting the health centers of Mahabad city randomly and selecting samples from each center. A total of 80 women were admitted to menopausal women in two groups (n = 40) and n = 40 (n = 40). The intervention group in this study was women of menopausal age who had criteria for entering the study. Control group In this study, women with menopausal status have criteria for entering the study

Settings and conduct

Firstly, a list of all health centers in Mahabad city was prepared. Subsequently, urban health centers were divided into two levels, 1 and 2, according to the opinion of the health center experts on the basis of cultural and socioeconomic status. At this stage each center's name was written in separate sheets and placed in a bag and selected by random method (simple random) from each center. At each level, a center for the control group and one center for the intervention group were assigned randomly from each node. From each center, 10 menopausal women were selected according to entry criteria.

Participants/Inclusion and exclusion criteria

Inclination to participate in research Iranian nationality Age between 45-55 years Residence in Mahabad city The absence of known physical, psychological and neurological diseases according to the patient No history of ovarian and uterine surgery Failure to develop artificial menopause.En Unwillingness to continue research Missing more than two sessions in counseling sessions The occurrence of any stressful incidents for a patient or first degree family Removal of the ovary and the womb Diagnosis of mental illness and psychiatric disorders during the study.

Intervention groups

Intervention group: The intervention group in this study was women of menopausal age who had inclusion criteria. Intervention for intervention group included self-efficacy counseling components on management of menopausal symptoms, which was performed in 6 sessions of a group of 45-60 minutes with intervals of one week The instruments used in this study were demographic questionnaire and Menopausal Symptom Scale questionnaire which was completed before and after counseling by the samples. Control group: Control group In this study, women were menopausal women who had criteria for entering the study They received routine care and a demographic questionnaire Menopausal scale was a questionnaire completed before and after counseling by samples

Main outcome variables

Independent variables in this research are self-efficacy-based counseling. The dependent variables in this study are menopausal symptoms and women around menopause. The underlying variables are age, the level of education of the wife and wife, the status of the wife and wife, the economic status, the length of the marriage by age, the menstruation, the number of pregnancies, the weight.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038275N1**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Bayaneh Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4233 2958

Email address

bayanrahimi57@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-05-05, 1396/02/15

Actual recruitment end date

2017-07-06, 1396/04/15

Trial completion date

empty

Scientific title

The effects of the counseling Based on self-Efficacy in menopausal symptoms management in peri menopausal women

Public title

The effects of the counseling Based on self-Efficacy in menopausal symptoms management

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclination to participate in research Iranian nationality Age between 45-55 years Residence in Mahabad city The absence of known physical, psychological and neurological diseases according to the patient No history of ovarian and uterine surgery Failure to develop artificial menopause

Exclusion criteria:

Unwillingness to continue research Missing more than two sessions in counseling sessions The occurrence of any stressful incidents for a patient or first degree family Removal of the ovary and the womb Diagnosis of mental illness and psychiatric disorders during the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Not 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 Urmia University of Medical Sciences

Street address

No.26, Ebne Sina Ave

City

Mahabad

Province

West Azarbaijan

Postal code

5914867551

Approval date

2017-03-02, 1395/12/12

Ethics committee reference number

IR.Umsu.rec.1395.391

Health conditions studied

1

Description of health condition studied

Management of menopause symptoms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Management of menopausal symptoms

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Menopause Rating Scale(MRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group in this study was female menopausal women who had inclusion criteria. The intervention for the intervention group included self-efficacy counseling components on management of menopausal symptoms that was held in 6 sessions of a group of 45-60 minutes at intervals of one week. Tools The demographic questionnaire and the Menopausal Symptom Scale questionnaire, completed before and after counseling, were used in this study
Category
Rehabilitation

2

Description
Control group: The control group in this study was female menopausal women who had criteria for entering the study and received routine care. The demographic questionnaire and the menopausal scale scale questionnaire were completed before and after the consultation.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers in Mahabad city
Full name of responsible person
Bayaneh Rahimi
Street address
No. 26, Ebne Sina Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebi
Street address
No. 26, Ebne Sina Ave.
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bayanrahimi57@yahoo.com
Grant name
Grant code / Reference number
7000000
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Bayaneh Rahimi
Position
Student
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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
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Some of the data, such as information on the main outcome, can be shared
When the data will become available and for how long
Get started 6 months after printing results
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
nobody
From where data/document is obtainable
Email address
What processes are involved for a request to access data/document
First, by email, and if not possible by contact number
Comments
Mail for correspondence