Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

The assessment of effect of cognitive-behavioral counseling on menopausal symptoms and quality of life in menopausal women : A Randomized Controlled Clinical Trial

Protocol summary

Study aim
Determine the effect of cognitive-behavioral counseling on menopausal symptoms and quality of life in menopausal women

Design
In this research, 90 postmenopausal women referring to Health Centers who are eligible for inclusion in the study are chosen . The participants are non- randomly divided into intervention and control groups.

Settings and conduct
In this study participants are elected by available sampling method from those referred to health centers in Tuiserkan city. after two groups distribution, the measures, including menopausal symptoms and quality of life in both groups by Greene Climacteric Scale and the World Health Organization's Quality of Life Questionnaire are carried out. For the intervention group, counseling process in the form of groups of 12-11 people with cognitive-behavioral approach, during a six- one hour meeting in the conference hall of Tuiserkan city health center will be held . After the intervention, measures will be repeated.

Participants/Inclusion and exclusion criteria
The inclusion criteria include: Having a natural menopause (not due to drugs or surgery); The age of 47 to 57 years; Minimum 1 and maximum 4 years of their last normal menstrual have passed; Without any chronic or acute disease in the past 12 months with an intensity that person could not attend meetings; Not using hormone therapy to reduce menopausal symptoms; Exclusion criteria include: Not participating in two or more sessions of counseling; The use of hormone therapy during the study

Intervention groups
In the intervention group 6 one-hour cognitive-behavioral counseling session during 6 weeks will be held. in the control group, after the end of the assessments, a one-hour training session will be held.

Main outcome variables
Quality of life; Menopausal symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151028024753N3**
Registration date: **2018-01-11, 1396/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**
Update count: **0**

Registration date
2018-01-11, 1396/10/21

Registrant information

Name
Mitra Kolivand

Name of organization / entity
Shahroud University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 3835 9980

Email address
mitrakolivand@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of effect of cognitive-behavioral counseling on menopausal symptoms and quality of life in menopausal women : A Randomized Controlled Clinical Trial

Public title

The assessment of effect of cognitive-behavioral counseling on menopausal symptoms and quality of life in menopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria include: Having a natural menopause (not due to drugs or surgery) The age of 47 to 57 years Minimum 1 and maximum 4 years of their last normal menstrual have passed Without any chronic or acute disease in the past 12 months with an intensity that person could not attend meetings Not using hormone therapy to reduce menopausal symptoms

Exclusion criteria:

Exclusion criteria include: Not participating in two or more sessions of counseling The use of hormone therapy during the study

Age

From **47 years** old to **57 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **75**

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 Kermanshah University of Medical Sciences

Street address

Building No. 2 of Kermanshah University of Medical Sciences, Shaheid Beheshti Blvd. Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2016-07-23, 1395/05/02

Ethics committee reference number

IR.KUMS.REC.1395.327

Health conditions studied

1

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states. Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Quality of life

Timepoint

Before the intervention, after the intervention

Method of measurement

World Health Organization's Quality of Life Questionnaire

2

Description

Menopausal symptoms

Timepoint

Before the intervention, after the intervention

Method of measurement

Greene Climacteric Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group 6 one-hour cognitive-behavioral counseling session during 6 weeks will be held.
Category
Lifestyle

2

Description
Control group: In the control group, after the end of the assessments, a one-hour training session will be held.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Clinic
Full name of responsible person
Marzie Soori
Street address
17 Shahrivar Clinic, Enghelab Ave.Tuiserkan
City
Tuiserkan
Province
Hamadan
Postal code
٦٥٩١٦٣٩٩٣١
Phone
+98 83 3827 9899
Email
mrs.marziesoori@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Kourosh Hamzehee
Street address
Building No. 2 of Kermanshah University of Medical Sciences, Shaheid Beheshti Blvd. Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3827 9899
Email
hamzehee@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Marzie Soori
Position
Master Student of Counselling in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Ashayer Ave., Isar Blv., School of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3827 9899
Email
mrs.marziesoori@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mitra Kolivand
Position
Student of Reproductive Health-PHD Degree-Faculty member

Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Ashayer Ave., Isar Blv., School of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3827 9899
Email
mitrakolivand@kums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Marzie Soori
Position
Master Student of Counselling in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Ashayer Ave., Isar Blv., School of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3827 9899
Email
mrs.marziesoori@yahoo.com

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
Not applicable
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
All data is Shared after being unidentifiable.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific centers
Under which criteria data/document could be used
For use in other scientific researches after obtaining the consent of the responsible author
From where data/document is obtainable
mrs.marziesoori@yahoo.com
What processes are involved for a request to access data/document
Send an email to person responsible for scientific inquiries.After receiving the email,If you have conditions, the information will be sent to the requester.
Comments