

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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

Shahrood 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

7091739931

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

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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

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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

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Ashayer Ave., Isar Blv., School of Nursing and
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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

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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

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