

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The assessment of effect of cognitive-behavioral counseling on stress , anxiety and depression in menopausal women : A Randomized Controlled Clinical Trial

#### Protocol summary

##### Summary

-The aim of this study is to determine the effect of cognitive-behavioral counseling on stress, anxiety and depression in post-menopausal women. This study is a Randomized, Controlled Clinical Trial. Participants included 90 postmenopausal women who referred to health centers in Tuiserkan city and elected by available sampling method. In this study for implement the random allocation method simple random will be used. This means that 90 consecutive numbers written on paper separately and placed inside a container. Elected even numbers to the group A (control) and elected odd numbers to the group B (intervention) Will be entered. This study was a single blinded, and blinding performance only for data analyst will be implemented. The inclusion criteria: Having a natural menopause (not due to drugs or surgery), age 47 to 57 years with at least 1 and a maximum of 4 years since the last normal menstrual and no chronic disease or acute that limits their participation in the study and exclusion criteria are: Not participating in two or more sessions of counseling and the use of hormone therapy during the study. After random distribution of two groups the measures, including stress, anxiety and depression in both groups by DASS-21 questionnaire carried out. For the control group in addition to routine clinic care, after completing the assessments, a training plan will be held. 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, and a month later measures will be repeated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081624753N2**

Registration date: **2016-09-03, 1395/06/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-03, 1395/06/13

##### 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

Public budget: Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### 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 stress , anxiety and depression in menopausal women : A Randomized Controlled Clinical Trial

**Public title**

The assessment of the effect of cognitive-behavioral counseling on stress , anxiety and depression in menopausal women

**Purpose**

Supportive

**Inclusion/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

**Age**

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

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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 Kermanshah University of Medical Sciences

**Street address**

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

**City**

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**

Depression

**ICD-10 code**

F32

**ICD-10 code description**

Depressive episode

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized anxiety disorder

**3****Description of health condition studied**

Stress

**ICD-10 code**

F43.0

**ICD-10 code description**

Acute stress reaction

**Primary outcomes****1****Description**

Anxiety

**Timepoint**

Before the intervention, after the intervention, and a month later

**Method of measurement**

DASS-21 questionnaire

**2****Description**

Stress

**Timepoint**

Before the intervention, after the intervention, and a month later

**Method of measurement**

DASS-21 questionnaire

**3****Description**

Depression

**Timepoint**

Before the intervention, after the intervention, and a month later

**Method of measurement**

DASS-21 questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention1: In the intervention group 6 one-hour cognitive-behavioral counseling session during 6 weeks will be held.

**Category**

Lifestyle

**2****Description**

Intervention 2: 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

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, 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**

Kermabshah

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**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

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Kermanshah

**City**

Kermanshah

**Postal code****Phone**

+98 83 3827 9899

**Fax****Email**

mrs.marziesoori@yahoo.com

**Web page address****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

**Other areas of specialty/work****Street address**

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mitrakolivand@kums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

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Marzie Soori

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*