

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of mindfulness-based group counseling on sleep quality in postmenopausal women

#### Protocol summary

##### Study aim

The effect of group counseling based on Mindfulness on sleep quality in postmenopausal women Referring to Zanjan Health Center

##### Design

Clinical trial with control group, parallel design, randomized

##### Settings and conduct

Counseling sessions will be held in the assistant's room at the Center for Comprehensive Health Services in the city and will be supervised by a consultant's professor. Questionnaires will be completed before, at the end of the last counselling and eight weeks after the last counseling session in both intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Sleep Disturbance Based on Pittsburgh Sleep Quality Questionnaire in Women With Natural Menopause between 45-60 Years 2) Lack of mental illness (having stress, anxiety and depression based on DASS-21 questionnaire) and lack of chronic physical disease 3) No use of hormonal drugs, radiotherapy and chemotherapy, and medications that affect menstruation over the past six months 4) Having at least guidance school level of education 5) Residence in Zanjan

##### Intervention groups

Intervention group: The intervention group will be 28 people who will participate in eight 90-minute counseling sessions based on the Mindfulness Approach, under the supervision of a consultant's professor and according to the protocol by the researcher. Control group: The control group will have 28 people who will not receive any counseling.

##### Main outcome variables

The quality of sleep in postmenopausal women

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160608028352N7**

Registration date: **2019-04-22, 1398/02/02**

Registration timing: **retrospective**

Last update: **2019-04-22, 1398/02/02**

Update count: **0**

##### Registration date

2019-04-22, 1398/02/02

##### Registrant information

##### Name

Roghieh Kharaghani

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3314 8144

##### Email address

r.kharaghani@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-20, 1397/10/30

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of mindfulness-based group counseling on sleep quality in postmenopausal women

## Public title

The effect of mindfulness-based group counseling on sleep quality in postmenopausal women

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Sleep disturbance based on Pittsburgh Sleep Quality Questionnaire in women with natural menopause between 45-60 Years Having at least a guidance school level of education Residence in Zanjan

### Exclusion criteria:

Having mental illness (having stress, anxiety and depression based on DASS-21 questionnaire) and chronic physical disease Use of hormonal medicines, radiotherapy, and chemotherapy, and medications that affect menstruation over the past six months

## Age

From **45 years** old to **60 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **56**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will assigned into two groups of intervention and control using blocked randomization method. Blocks of four-dimensional size will be created, and in each block, half of the participants will be in the intervention group and the other half will be in the control group, randomly. All possible clip of the participants in the blocks will predicted and the blocks number will selected from random table numbers. Selection of the blocks will continue to reach the determined sample size of 28 people in the intervention group and 28 in the control group.

## 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 Zanjan University of Medical Sciences

#### Street address

North side Azadi Boulevard Zanjan

#### City

Zanjan

#### Province

Zanjan

#### Postal code

4515613191

#### Approval date

2018-12-19, 1397/09/28

#### Ethics committee reference number

IR.ZUMS.REC.1397.276

## Health conditions studied

## 1

### Description of health condition studied

Sleep quality

### ICD-10 code

G47.9

### ICD-10 code description

Sleep disorder, unspecified

## Primary outcomes

## 1

### Description

The sleep quality

### Timepoint

Before intervention , immediately after intervention, and two months after intervention

### Method of measurement

Pittsburgh Sleep Quality Questionnaire

## Secondary outcomes

## 1

### Description

Quality of life in the postmenopausal women

### Timepoint

Before intervention , after intervention and two months after intervention

### Method of measurement

Questionnaire of the quality of life of postmenopausal women

## Intervention groups

## 1

### Description

28 participants in the control groups who will not receive any counseling.

**Category**

N/A

**2****Description**

Individuals in the intervention group will given eight sessions of one and a half hours based on mindfulness group counseling, all of which will be provided by the researcher. The number of sessions was determined according to the studies that were conducted using a similar counseling approach to the intervention of the researcher. Counselling sessions will organized in the assistant's room under the supervision of the assistant professor. The counselling protocol will be based on the mindfulness approach on the sleep quality.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Urban comprehensive health center in Zanjan City

**Full name of responsible person**

Sima Kakavand

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Urban comprehensive health center in Zanjan City

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Shaghli

**Street address**

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North side Boulevard Azadi, zanjan

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r.kharaghani@zums.ac.ir

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

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Sima Kakavand

**Position**

student Masters Midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Roghieh Kharaghani

**Position**

PhD Of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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8%B6%D8%A7-%DA%AF%D8%B1%D9%88%D9%87-  
%D8%A2%D9%85%D9%88%D8%B2%D8%B4%DB%8  
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**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Roghieh Kharaghani

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**Other areas of specialty/work**

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**Web page address**

<http://zums.ac.ir/content/34415/%D8%A7%D8%B9%D>

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

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

A Portion of the data associated with the original outcome is shared

**When the data will become available and for how long**

Starting the access period from 1399

**To whom data/document is available**

Information will be available for scholars working in academic and academic institutions.

**Under which criteria data/document could be used**

Apply this type of advice to another target group

**From where data/document is obtainable**

By e-mail address

**What processes are involved for a request to access data/document**

It will be answered by email and immediately after ensuring the plan is used.

**Comments**