Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Counselling 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 eduacation 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
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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Position
PhD Of Reproductive Health

Latest degree
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Other areas of specialty/work
Reproductive Health

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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
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