Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of sleep hygiene education on sleep quality of older women.

Protocol summary

Summary

Objective: Defining the effects of sleep hygiene on sleep quality among old women. Design: it is a clinical trial study including an intervention and a control group without blinding. Sample volume: Adopting the limited random approach, 35 persons will be chosen for both the intervention and the control groups. Implementation: The intervention will take place in Jahandidegan center (Gorgan, Golestan). Educational content will be instructed by a researcher in 5 weeks. Using Pittsburg questionnaire, there will be an area test at the very beginning of the course and a post-test at the end of the fifth session. Major Inclusion criteria: Aged 60-74, resident of Gorgan, able to support oneself, and obtaining a score higher than 7 in the Epworth questionnaire. Major Exclusion criteria: Women who have experienced recent unpleasant events such as a relative's death during the previous year, and those who have not participated in hygienic educational sessions. Interventions: The educational content of the first to the fifth session will last 45, 50, 40, 40 and 30 minutes, respectively. The interval between sessions is exactly one week. These trainings include avoiding factors that disturb sleep, preparing a proper sleep environment, the role of diet and exercise in improvement of sleep quality, effects of smoking on sleep, educating behavioral interventions including deep breathing, relaxation techniques, imaginary drawing and muscle relaxation. For the control group, the Pittsburg questionnaire is only filled out twice in the interval of one month. The variable of main outcome is sleep quality.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016090429694N1**
Registration date: **2017-06-02, 1396/03/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

mehrnaz montazeri lemrasky

Name of organization / entity

Babol University of Medical Sciences, Faculty of Nursing Ramsar

Country

Iran (Islamic Republic of)

Phone

+98 11 5522 1584

Email address

info@moubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-07-22, 1396/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sleep hygiene education on sleep quality of older women.

Public title

Studying the effect of Sleep Hygiene Education on sleep quality of adult women with comparing two groups of control & intervention.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: include, age between 60-74 years old, living in Gorgan city, being able to support oneself using ADL instrument and not having cognitive disorders with obtaining the score higher than 6 with the scale of MAT and obtaining the score higher than 7 based on Epworth sleep instrument and having a tendency for participating in this research. Exclusion criteria include: Those women who have had an unpleasant event such as: their relative's death during previous year, using specific diet (hydro therapy, vegetarian, raw veganism) , not participating in educational sessions of sleep hygiene, doing Yoga sport at the time of doing this research

Age

From **60 years** old to **73 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Limited randomized will be based on random specific method. After determining whole sample volume, the names of persons will be put in lottery container. Then the names of 35 persons in the first step will be taken out that belong to intervention group and the rest belong to control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Science, Ganjafrooz Ave

City

Babol

Postal code

4717647745

Approval date

2016-07-10, 1395/04/20

Ethics committee reference number

MUBABOL.REC.1395.102

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

G47

ICD-10 code description

Sleep disorder

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention, End of fifth session Intervention

Method of measurement

Pittsburg questionnaire sleep quality Index

Secondary outcomes

1

Description

Subjective quality of sleep

Timepoint

Sleep quality one time before intervention and the second time at the end of last session

Method of measurement

Questionnaire

2

Description

Sleep latency

Timepoint

Sleep quality one time before intervention and the second time at the end of last session

Method of measurement

Questionnaire

3

Description

Habitual sleep efficiency

Timepoint

Sleep quality one time before intervention and the second time at the end of last session

Method of measurement

Questionnaire

4

Description
Sleep duration
Timepoint
Sleep quality one time before intervention and the second time at the end of last session
Method of measurement
Questionnaire

5

Description
Use of sleeping medication
Timepoint
Sleep quality one time before intervention and the second time at the end of last session
Method of measurement
Questionnaire

6

Description
Sleep disturbances
Timepoint
Sleep quality one time before intervention and the second time at the end of last session
Method of measurement
Questionnaire

7

Description
Daytime dysfunction
Timepoint
Sleep quality one time before intervention and the second time at the end of last session
Method of measurement
Questionnaire

Intervention groups

1

Description
Interventions: The educational content of the first to the fifth session will last 45, 50, 40, 40 and 30 minutes, respectively. The interval between sessions is exactly one week. These trainings include avoiding factors that disturb sleep, preparing a proper sleep environment, the role of diet and exercise in improvement of sleep quality, effects of smoking on sleep, educating behavioral interventions including deep breathing, relaxation techniques, imaginary drawing and muscle relaxation
Category
Behavior

2

Description
Control group: The Pittsburg questionnaire is only filled out twice in the interval of one month.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan Jahandidegan center
Full name of responsible person
Maryam Beygom Ghoreishi
Street address
Gorgan Jahandidegan center, Edalat 2, ValiAsr Square
City
Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Babol University of Medical Sciences
Full name of responsible person
Dr.Ali BIJANI
Street address
Babol University of Medical Science, Ganjafrooz Ave
City
Babol
Grant name
9542422
Grant code / Reference number
3701
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Babol 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
Babol University of Medical Science,Ramsar Fatemeh Zahra(SA) School Of Nursing and Midwifery
Full name of responsible person
Mehrnaz Montazeri Lemrasky
Position
Master Student in Geriatric Nursing

Other areas of specialty/work
Street address
School of Nursing and Midwifery Fatemeh Zahra (SA), Imam Sajjad Hospital, Enghelab Square
City
Ramsar
Postal code
4691714141
Phone
+98 11 5522 6393
Fax
-
Email
montazeri3000@yahoo.com
Web page address
http://ramsar.mubabol.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Abbas Shamsalinia
Position
Assistant Professor
Other areas of specialty/work
Street address
Ramsar Fatemeh Zahra (SA) School of Nursing and Midwifery, Imam Sajjad Hospital, Enghelab Square
City
Ramsar
Postal code
4691714141
Phone
+98 115225151
Fax
+98 115226413
Email
a.shamsalinia@mubabol.ac.ir; abbasshamsalinia@yahoo.com
Web page address
http://ramsar.mubabol.ac.irl

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Science, Ramsar Fatemeh Zahra(SA) School Of Nursing and Midwifery
Full name of responsible person
Mehrnaz Montazeri Lemrasky
Position
Master Student in Geriatric Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery Fatemeh Zahra (SA), Imam Sajjad Hospital, Enghelab Square
City
Ramsar
Postal code
4691714141
Phone
+98 115226413
Fax
+98 11 5222 6413
Email
montazeri3000@yahoo.com
Web page address
http://ramsar.mubabol.ac.ir/

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