

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 lemraskey

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.ir/>

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