

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of sleep health education program with follow-up care method on elderly sleeps quality

#### Protocol summary

##### Study aim

This study determines the effect of sleep health education with follow care pattern on elderly sleep quality that they are covered by the Gonabad health centers in 1398.

##### Design

This study is a randomized clinical trail in two parallel group.

##### Settings and conduct

Samples will select By systematic random method among the elderlies referring to Gonabad health centers. And with Blocked by random allocation method (Fourth block) will divide in to two groups: A) intervention, B) control. The main questionnaire (pre-test) is provided to the elderly by the researcher prior to the assignment of the subjects to the two groups. After the intervention, the post-test questionnaire is completed by someone other than him who is not aware of the group. Also, information analysis from the group will not be known.

##### Participants/Inclusion and exclusion criteria

older than 60, hearing and speaking health, cognitive health, the possibility to call with client. Also if the elderly man had depression, cancer, heart failure, severe lung disease, physical disability, chronic pain, Alzheimer, use another interventions to improve sleep quality, hospitalization during intervention, Unexpected event such as Close Death; he will exclude from the study.

##### Intervention groups

. After that for group A, a One-hour meeting will be held in health center and issues such as the importance of sleep in elderly's life, changes of sleep during aging, sleep health and effective factors on it Will be taught. Then In order to follow up, A phone call will be taken, twice a weak in the first month and once a weak in second month. For group B there won't be any intervention.

##### Main outcome variables

Elderly sleep quality improvement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190622043968N1**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **retrospective**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

##### Registration date

2019-07-06, 1398/04/15

##### Registrant information

##### Name

Maryam Moradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5652 5792

##### Email address

moradi.mf69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-08, 1397/11/19

##### Expected recruitment end date

2019-02-18, 1397/11/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of sleep health education program with follow-up care method on elderly sleeps quality

**Public title**

The effect of sleep health education program on elderly sleeps quality

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

older than 60 hearing and speaking health cognitive health the possibility to call with client

**Exclusion criteria:**

the elderly man had depression, cancer, heart failure, severe lung disease, physical disability, chronic pain, Alzheimer use another interventions to improve sleep quality hospitalization during intervention Unexpected event such as Close Death

**Age**

From 60 years old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: 120

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will select By systematic random method among the elderlies referring to Gonabad health centers. And with Blocked by random allocation method (Fourth block) will divide in to two groups: A) intervention, B) control

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

1- The random allocation sequence is obtained by the methodologist with the software. 2- Experts appointed in the Gonabad Triple Centers register the elderly. The researcher will make a central list 3. An individual outside the team collects the codes and assigns them to the intervention and control groups based on the assignment sequence.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shahroud University of Medical Sciences

**Street address**

University of Medical Sciences and Services, Seventh Tir Square, Shahroud

**City**

Shahroud

**Province**

Semnan

**Postal code**

۳۶۱۴۷-۷۳۹۴۷

**Approval date**

2019-02-05, 1397/11/16

**Ethics committee reference number**

IR.SHMU.REC.1397.192

**Health conditions studied****1****Description of health condition studied**

sleep quality

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sleep quality score based on Pittsburgh Sleep Inventory

**Timepoint**

Before the intervention begins 2 months after intervention

**Method of measurement**

Pittsburgh Sleep Quality Index

**Secondary outcomes**

empty

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

Intervention group: . After that for group A, a One-hour meeting will be held in health center and issues such as the importance of sleep in elderly's life, changes of sleep during aging, sleep health and effective factors on it Will be taught. Then In order to follow up, A phone call will be taken, twice a weak in the first month and once a weak in second month.

**Category**

Treatment - Other

**2****Description**

Control group: For group B there won't be any intervention. Only routine health care will be provided

**Category**

N/A

**Phone**

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**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

centerl Health Fayyazbakhsh

**Full name of responsible person**

Maryam Moradi

**Street address**

Imam Khomeini Street, Gonabad

**City**

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**Province**

Razavi Khorasan

**Postal code**

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**2**

**Recruitment center**

**Name of recruitment center**

Health Center No. 2

**Full name of responsible person**

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**3**

**Recruitment center**

**Name of recruitment center**

Health Center No. 3

**Full name of responsible person**

Maryam Moradi

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**Postal code**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy of Research and Technology of Shahrood

University of Science

**Full name of responsible person**

Dr. Mohammad Hassan Emamian

**Street address**

University of Medical Sciences and Services, Seventh

Tir Square, Shahrood

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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**

Deputy of Research and Technology of Shahrood

University of Science

**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**

Shahrood University of Medical Sciences

**Full name of responsible person**

Maryam Moradi

**Position**

Student Nursing Masters

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mahboubeh Khajeh

**Position**

Ph.D. Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Maryam Moradi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data will be released after unidentifiable people

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

Immediately after completing the plan

**To whom data/document is available**

All the researchers

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

covered by the Gonabad health centers

**From where data/document is obtainable**

moradi.mf69@gmail.com Maryam Moradi

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

Initially, an application is submitted via email, then after the email is read, if possible, the data will be provided

**Comments**