

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

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Recruitment centers

1

Recruitment center

Name of recruitment center

centerl Health Fayyazbakhsh

Full name of responsible person

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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

Street address

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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

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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

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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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