

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the effects of sleep Health education based on a mobile application on the sleep quality of the older adults

Protocol summary

Study aim

Determining the effects of sleep Health education based on a mobile application on sleep quality of the older adults covered by Rasht state pension fund, 2021.

Design

A semi-experimental study with a control group, parallel groups, randomized, on 96 patients. The sealed Envelope online service was used for randomization.

Settings and conduct

This research is carried out in two stages. The first phase of it is a cross-sectional study with the aim of determining the quality of sleep of 330 people among the elderly referring to the national pension fund of Rasht city. The second phase is a semi-experimental clinical trial that will be implemented with the aim of determining the effect of the educational application on the sleep quality of the elderly on 48 people in two intervention and control groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are: age 60 years or older, not suffering from substance abuse disorder, membership in the Rasht National Pensioners Fund, having minimum reading and writing literacy, willingness to participate in research, ability to use a smartphone, not having memory disorders and cognitive, and having sleep disorders

Intervention groups

Using the random block method, elderly people are divided into two intervention groups under training with the application and a control group. Intervention group: Face-to-face sessions will be held for one week and two sessions for the intervention group. Then, the elderly people will implement its programs every day for 4 weeks. Control group: At the end of the study, the research samples in the control group receive all the training in the form of booklets, face-to-face training, and mobile applications.

Main outcome variables

Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220926056042N1**

Registration date: **2022-12-06, 1401/09/15**

Registration timing: **retrospective**

Last update: **2022-12-06, 1401/09/15**

Update count: **0**

Registration date

2022-12-06, 1401/09/15

Registrant information

Name

Hannaneh Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3377 8110

Email address

rahimihannaneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of sleep Health education based on a mobile application on the sleep quality of the older adults

Public title
sleep Health education based on mobile application on sleep quality of the older adults

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Consent of the elderly to participate in the study Age 60 years and older Not having a substance abuse disorder Membership in the national pension fund of Rasht city Having at least reading and writing literacy Ability to communicate visually and verbally Ability to use a smartphone Having a sleep disorder Absence of memory and cognitive disorders
Exclusion criteria:
 Taking sleeping pills Simultaneously participating in other educational programs and clinical trials and using similar applications

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible people will be divided into two intervention and control groups using the block randomization method with the size of 4 blocks. To generate the randomization list from the online randomization service of Sealed Envelope Ltd. 2019 will be used. (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). In general, the sampling method of the first phase and at the end of the samples in the second phase will be done by simple random and random allocation based on the software.

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 Guilan University of Medical Sciences
Street address
 University Research and Technology Vice-Chancellor- in front of 17 Shahrivar Hospital- Shahid Siadati St. - Namjo St.
City
 Rasht
Province
 Guilan
Postal code
 41937-13194
Approval date
 2022-09-21, 1401/06/30
Ethics committee reference number
 IR.GUMS.REC.1401.322

Health conditions studied

1

Description of health condition studied
 Sleep disorders
ICD-10 code
 G47
ICD-10 code description
 Sleep disorders

Primary outcomes

1

Description
 sleep quality
Timepoint
 Before the start of the intervention, 5 weeks after the intervention
Method of measurement
 Pittsburgh sleep quality index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
 Intervention group: an in-person meeting will be held in small groups. Face-to-face intervention sessions will be held in the training class of the pension fund, which has sufficient capacity to comply with health protocols during the 2019 coronavirus epidemic. Face-to-face sessions will be held for one week and two sessions. In the first and second sessions, while getting to know the elderly, and mentioning the study's objectives, the pre-intervention questionnaire will be filled out by the elderly. On the

other hand, the intervention group will be taught how to use a mobile-based sleep health educational application. Then, the elderly will run its programs every day for 4 weeks. If they have questions about using the application, they will contact the researcher by phone and receive the necessary instructions. The researcher will follow up by phone twice a week. Also, an educational booklet related to the application is prepared and provided to them.

Category

Behavior

2

Description

Control group: at the end of the study, all educational materials will be implemented for this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

State Pension Fund

Full name of responsible person

Sajjad Mohammadian

Street address

No. 153, Hafez Blvd

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41937-13194

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+98 13 3333 2610

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

Street address

Shahid Siyadati St, Namjo St.

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Guilan

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41937-13111

Phone

+98 13 3333 5821

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research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Hanana Rahimi

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shahla Asiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Shahla Asiri

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Latest degree

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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 is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in multicenter studies with the approval of the author team

From where data/document is obtainable

E-mail

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

After the request and approval of the authors, the data will be sent within a week.

Comments