

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effectiveness of an educational intervention based on self-help for sleep hygiene promotion on employees of Qazvin University of Medical Sciences

Protocol summary

Study aim

Determining The effectiveness of an educational intervention based on self-help for sleep hygiene promotion on employees of Qazvin University of Medical Sciences

Design

Controlled, double-blind, randomized trials Randomized with parallel groups and Blind Evaluation of results, systematic randomization using an external site

Settings and conduct

This plan will be implemented on the staff of the Qazvin University of Medical Sciences. The Insomnia Severity Index questionnaire will be used to screen for insomnia and low sleep health. This questionnaire is provided online to the staff through communication channels such as telegrams to help people who are interested in participating in this research. Individuals who scored more than 8 were randomly assigned to intervention and control groups and completed the Insomnia Index Index. The intervention group will then receive an educational app designed to improve sleep hygiene. Control group: Participants in the control group perform routine activities. The intervention and control group will fill out the relevant questionnaire one and three and six months after the completion of the training to assess the impact of the intervention online.

Participants/Inclusion and exclusion criteria

Inclusion criteria: staff of the Qazvin University of Medical Sciences; having a laptop or smartphone; Internet access; being literate; getting a score of 8 to the top of the ISI questionnaire. Non-compliance criteria: Non-participation in the study; With chronic disease; Severe psychological problems; Pregnancy ;current insomnia treatment ;having a child under two years of age

Intervention groups

Intervention group: Participants in the intervention group will receive an educational app designed to improve

sleep hygiene. Control group: Participants in the control group perform routine activities

Main outcome variables

sleep hygiene behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180131038582N1**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **retrospective**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

Registration date

2018-09-01, 1397/06/10

Registrant information

Name

nilofar rajabimajd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3562 2276

Email address

majd_nilofar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of an educational intervention based on self-help for sleep hygiene promotion on employees of Qazvin University of Medical Sciences

Public title
The effectiveness of an educational intervention based on self-help for sleep hygiene promotion

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
A staff member of the Qazvin University of Medical Sciences having a laptop or computer or smartphone
Internet access being literate (for reading and using the educational app getting a score of 8 to the top on ISI questionnaire)
Exclusion criteria:
Pregnancy current insomnia treatment having a child under two years of age Non-participation in the study
Suffering from chronic illness Severe psychological problems

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **308**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the Insomnia Severity Index (ISI) questionnaire to screen for insomnia and low sleep hygiene, people with a higher score of 8 will be selected and randomly selected using a randomized software. It is worth noting that the random unit Individuals will be individualized, and people will be placed in two groups of intervention and control.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants are unaware of the allocation of study groups. The outcome evaluator did not know how to randomize the disease And examine the data related to the outcome variables, regardless of the groups of individuals. After collecting the data, the groups are named in alphabetical order so that the analyst from the intervention and control group is not informed.

Placebo
Not used

Assignment
Parallel

Other design features
This study is done online.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.QUMS.REC.1396.455

Health conditions studied

1

Description of health condition studied

insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Sleep Quality

Timepoint

changes in PSQI baseline , 1 month, 3 months and 6 months follow-up

Method of measurement

The Pittsburgh Sleep Quality Index includes seven components of subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, the use of sleep medications and day time dysfunctions provide a total score of these seven components that allows us to better understand the quality and quantity of one's sleep. The Pittsburgh Sleep Quality Index is a self-reporting instrument consisting of nine questions designed to measure the quality of sleep disorders in a period of one month. The scale scores range from 0 to

21, with higher scores indicating poor quality of sleep and scores less than 5 considered as high quality of sleep

2

Description

sleep hygiene behavior

Timepoint

changes in sleep hygiene behavior baseline , 1 month, 3 months and 6 months follow-up

Method of measurement

Sleep hygiene behaviour will use three items to measure how many days the participants had good sleep hygiene behaviour

Secondary outcomes

1

Description

Anxiety and depression score

Timepoint

Before the intervention, one month , three & Six months after the intervention, the questionnaire is completed.

Method of measurement

Hospital Anxiety and Depression Inventory

2

Description

Psychological predictors of sleep hygiene behavior(beliefs, intention, planning, Perceived cues,Habit)

Timepoint

Before the intervention, one month , three & Six months after the intervention, the questionnaire is completed.

Method of measurement

psychological predictors of sleep hygiene behavior will be assessed using a using a self-reported measure. All items are rated on a Likert-type scale, ranging from 1 to 5.

Intervention groups

1

Description

Intervention group: They will receive an educational app designed to improve sleep, and will receive self-help training in a six-week training package.

Category

Behavior

2

Description

Control group: Participants in the control group perform routine activities

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Amir Pakpour Haji Agha

Street address

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

pakpour_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

Street address

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

sdh@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

+98 28 3333 6001

Email

pakpour_amir@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Nilofar Rajabimajd

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

No.1426, Imam Khomeini Ave., Saidi Alley, Ziaabad Town

City

Qazvin

Province

Qazvin

Postal code

3485156955

Phone

+98 28 3562 2276

Fax

Email

majd_nilofar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Nilofar Rajabimajd

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

No.1426, Imam Khomeini Ave., Saidi Alley, Ziaabad Town

City

Qazvin

Province

Qazvin

Postal code

3485156955

Phone

+98 28 3562 2276

Fax

Email

majd_nilofar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Pakpour Haji Agha

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Qazvin University of Medical Sciences., Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available