

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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**

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##### **Province**

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##### **Postal code**

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##### **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**

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##### **Phone**

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##### **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

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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

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## 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

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**Email**

majd\_nilofar@yahoo.com

## 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