

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Benson Relaxation Technique on Sleep Quality among the Elderly at Health Center of Qazvin

Protocol summary

2016-11-30, 1395/09/10

Summary

Considering the common complaint of Older people with Insomnia, Sleeping Pills side effects and adverse impact that sleep deprivation affects the Physical Health of the Elderly Later, where this method is much less Expensive and Require Specialized personnel and equipment and no special tools and the Elderly can use this method anywhere in the world, This study aimed to determine the effect of Benson Relaxation will be done on sleep Quality in the Elderly. This study is a clinical trial that among all Health Centers in Qazvin 10 centers will be selected randomly. The sample size was estimated 80 people. Seniors eligible for the study available and in the two Intervention groups (n = 40) and Control (n = 40), and will be followed up. Inclusion criteria included an age over 60 years, a sleep disorder on a scale of Pittsburgh Sleep and exclusion criteria of the study in unwillingness to participate in the study, a disease with mental disorders (Schizophrenia, Dementia, Anxiety and Depression), having intellectual disabilities and Chronic diseases including Cancer, taking tranquilizers to sleep and doing drugs are given relaxation training program is incomplete. Benson relaxation in the test group for 20 minutes twice a day for 4 weeks will be done. Sleep disorders in both groups at baseline and 4 weeks will be evaluated using a questionnaire Pittsburgh.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071228891N1**

Registration date: **2016-11-30, 1395/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

mitra habibollahpour

Name of organization / entity

Qazvin University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 33696824

Email address

fmohammadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Benson Relaxation Technique on Sleep Quality among the Elderly at Health Center of Qazvin

Public title

The Effect of Benson Relaxation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having Over 60 Years Old, Having a Sleep Disorder based on the Pittsburgh Sleep Scale,

Interest in Participating in the Study, Having full Consciousness, Ability Speech and hearing, Having the tools necessary to use the Instruction file, Resident Qazvin City Exclusion criteria: Unwillingness to Participate in the Study, Having a Mental Illness, Having Intellectual Disabilities and Chronic Diseases, Use Sedatives Except Sleep Aids, Incomplete Carried Taught Relaxation Program, Elder Died or was Admitted to the Hospital During the Study

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University Of Medical Sciences

Street address

bahonar Blvd, Integrated campus University of Medical Sciences, Qazvin, Iran

City

Qazvin

Postal code

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.QUMS.REC.1395.114

Health conditions studied

1

Description of health condition studied

Sleep Disorder

ICD-10 code

G47.2

ICD-10 code description

Disorders of the Sleep-Wake Schedule

Primary outcomes

1

Description

Sleep Disorder

Timepoint

the first day and a month later

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Sleep Disorder

Timepoint

the first day and a month later

Method of measurement

Pittsburgh Sleep Quality Index

Intervention groups

1

Description

Control Group: The control group received no intervention will not cross.

Category

Behavior

2

Description

In the Intervention group relaxation Techniques for 20 minutes twice daily for 4 weeks will. Benson relaxation instructions will be trained in the following way. 1. Sit in a comfortable position. 2. Close their eyes. 3. Relax all their muscles beginning from the soles of the feet, moving forward up, and relax all parts of their body. 4. Breath through their nose, pay attention to the sound of their breathing and say the word one quietly to themselves when the breath was out. 5. Continue for 20 min. The patients were instructed to check the time by opening their eyes. However using an alarm was prohibited.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers in Qazvin

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mitra Habibollahpour

Street address

Bahonar Blvd, Qazvin University of Medical Sciences,
Qazvin, Iran

City

Qazvin

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mitra Habibollahpour

Position

Masters Student Geriatric Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Fatemeh Mohammadi

Position

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Other areas of specialty/work

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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 Geriatric Nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty