

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of guided imagery on quality of sleep and general health among older adults with sleep disorders

Protocol summary

Study aim

Determining the effect of guided imagery on sleep quality and general health of the elderly with sleep problems

Design

Clinical trial with a control group, randomized, with a sample size of 75 people. Randomization by random number table method.

Settings and conduct

or sampling, by referring to one of the health centers of Ardabil city, 70 elderly people will be selected by the available method to enter the study. Then samples will be randomly divided into two groups of 35 people (intervention and control).

Participants/Inclusion and exclusion criteria

- Men and women 60 years and older - A score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire - Lack of history of using mental relaxation methods 0 Appropriate Mental Cognitive Ability According to Abbreviated Mental Test (AMT) - Lack of chronic pain affecting sleep quality - Do not have hearing problems diagnosed by a medicine. - Non-smoking - Access to audio file playback technology (CD player or smartphone) - Consent to participate in research

Intervention groups

The intervention group will receive a guided imagery audio file.

Main outcome variables

guided imagery, sleep quality, general health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210925052570N1**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Registrant information

Name

mahdieh heidarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3378 0723

Email address

mahdieh.heidarian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-03, 1400/11/14

Expected recruitment end date

2022-04-03, 1401/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of guided imagery on quality of sleep and general health among older adults with sleep disorders

Public title

Effect of guided imagery on quality of sleep and general health among older adults with sleep disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women 60 years and older
A score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire
No history of using mental relaxation methods
Appropriate mental-cognitive ability according to Abbreviated Mental Test (AMT)
Do not have hearing problems diagnosed by a MD
Do not take new sleeping medicine during the study
Lack of chronic pain affecting sleep quality

Exclusion criteria:

Hospitalization during the study period
Reluctance of the participant to continue participating in the research

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting 70 elderly people referring to health centers based on the inclusion criteria and the available method, randomization will be done randomly using the random number table method and intervention and control groups will be assigned to two groups of 35 people. For this purpose, from 01 to 70 codes will be assigned to each of the studied samples. Then a row and column of the table are randomly selected. The intersection point of the selected row and column is the starting point of sampling. From this point, a plus or a cross is drawn. All numbers placed on this plus or a cross are selected as sample members.

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 University of social welfare and rehabilitation

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

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Province

Tehran

Postal code

1985713871

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.USWR.REC.1400.239

Health conditions studied

1

Description of health condition studied

sleep problems

ICD-10 code

Z72.82

ICD-10 code description

Problems related to sleep

Primary outcomes

1

Description

Percentage of people with a Pittsburgh Sleep Quality Questionnaire score less than 5.

Timepoint

Measure sleep quality score before and after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Members of the intervention group will receive a guided imagery audio file. This file contains 10 minutes of guided imagery. The audio in the form of a CD or MP3 file will be provided to the members of the intervention group. Everyone in the intervention group will listen to the CD at home for 10 minutes, once a day at a set time, for four weeks. On a daily basis, by making a phone call, the process will be reviewed, people will be encouraged to perform it regularly, and the participants' questions will be answered.

Category

Lifestyle

2

Description

Control group: The control group will receive only routine care. This group will also complete the questionnaires in parallel with the intervention group before, after and one month after the intervention.

Category

N/A

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Javid Mohseni Health Centre

Full name of responsible person

Mahdieh Heidarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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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

University of social welfare and rehabilitation 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

Person responsible for general inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Mahdieh Heidarian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

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

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