Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the diaphragmatic relaxation training and cognitive-behavioral therapy on sleep quality of the elderly

Protocol summary

Study aim
Comparison of diaphragmatic relaxation training and cognitive-behavioral therapy on sleep quality of the elderly referred to comprehensive health centers in Rafsanjan in 1400-1401

Design
75 eligible seniors will be divided into 3 groups (two intervention groups and one control group) using a simple random division method using a random number table, and the type of intervention will be determined again by random division.

Settings and conduct
On the elderly with sleep disorders referred to health centers in Rafsanjan, cognitive therapy intervention is performed in groups in the School of Nursing and diaphragmatic breathing is performed in groups for one session in the faculty and the project is continued in the elderly home.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having an age above 60 years 2- Having a suitable level of cognitive function 3- Having the ability to read and write 4- Complete mastery of Persian language 5- Having written consent to participate in research 6- Having sleep disorders based on getting a score higher than 5 in the questionnaire Pittsburgh Exclusion criteria: 1 - unwillingness to continue cooperation 2 - deterioration of the patient's physical condition so that he can not cooperate

Intervention groups
Cognitive-behavioral therapy intervention is provided for 4 weeks (2 sessions of 60 minutes per week) under the supervision of a qualified instructor. Diaphragmatic breathing intervention group is invited to the faculty to practice a session in person and they are given practice. And the implementation of the plan is done by them at home. The control group will be explained in the Whats App group for 4 weeks about the problems that will be created in the aging process. The sleep quality of all participants in the study will be measured before, immediately and one month after the intervention.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N26**
Registration date: **2022-11-13, 1401/08/22**
Registration timing: **retrospective**

Last update: **2022-11-13, 1401/08/22**
Update count: **0**

Registration date
2022-11-13, 1401/08/22

Registrant information

Name
Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-07, 1400/12/16

Expected recruitment end date
2022-05-06, 1401/02/16

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the diaphragmatic relaxation training and cognitive-behavioral therapy on sleep quality of the elderly

Public title
Comparing the diaphragmatic relaxation training and cognitive-behavioral therapy on sleep quality of the elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being over 60 years old Having an appropriate level of cognitive function (minimum score of 8 in the shortened cognitive test) Having the ability to read and write Complete mastery of Persian language Having the written consent to participate in the research Sleep disturbance based on getting a score higher than 5 in the Pittsburgh questionnaire
Exclusion criteria:
Not wanting to continue cooperation Deterioration of the patient's physical condition so that he is unable to cooperate Start taking sleeping pills Performing exercises and other interventions that affect the quality of sleep Foot of the patient
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining the framework of the samples, the data will be divided between 3 blocks A, B, C with the help of block randomization based on gender and age, in such a way that the first data in one of the 3 groups will be divided by a simple random method and using the software "Random allocation software" are selected and in the next 2 groups, the data is allocated in the same way based on the software. After equal allocation of data to 3 groups, treatment methods were written on 3 separate sheets and one method was assigned to each of the groups by lottery.
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
Research Ethics Committee of Rafsanjan University of Medical Sciences
Street address
School of Nursing and Midwifery, Nurse Avenue, Rafsanjan
City
rafsanjan
Province
Kerman
Postal code
7718796755
Approval date
2022-02-23, 1400/12/04
Ethics committee reference number
IR.RUMS.REC.1400.252

Health conditions studied

1

Description of health condition studied
sleep quality
ICD-10 code
F51
ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Sleep quality score of PSQI questionnaire
Timepoint
Before, immediately and one month after the intervention
Method of measurement
Elderly Sleep Quality Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive-behavioral therapy

intervention according to the instructions of Morin CM, Espie CA booklet for 4 weeks (2 sessions of 60 minutes per week) under the supervision of a qualified instructor (having work experience in psychological interventions with the elderly, including cognitive-behavioral therapy) A group is presented in the classroom to ensure the correct implementation of the work method. Meetings are performed with individual assignments (checklist for intervention at home) and the last 10 minutes of each session are spent reviewing reports related to these assignments and answering questions.

Category

Treatment - Other

2

Description

Diaphragmatic breathing intervention group is invited to the faculty to practice a session in person and is practiced by the student (who has received the necessary permission to perform this intervention) through oral training, educational clips and pamphlets. After the end of the first session, the student will be evaluated one by one to ensure the correct implementation, and the implementation of the plan will be continued by them at home for 30 days and the student will be followed by a daily phone call to perform the procedure correctly and continuously. According to the LEE study, patients are advised to sit comfortably in a chair 30 minutes before bedtime, with one hand on the chest and the other on the abdomen with the knees bent and the shoulders relaxed. They are then asked to breathe slowly through their nose so that their abdomen moves up in front of their hands. The hand on the chest should be as stable as possible. During the exhalation phase, the patient should tighten the abdominal muscles and exhale slowly through the pursed lips. This exercise should be performed for 20 minutes every night before bed.

Category

Treatment - Other

3

Description

Control group: The control group will be formed by the Whats App group for 4 weeks by the researcher and will explain the problems that will occur in the aging process and will answer their medical questions and problems.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers in Rafsanjan

Full name of responsible person

Dr.Tayebeh Mirzaei

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Faculty of Nursing, Nurse blvd., Jomhury street, Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Reza Vazirinejad

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Grant name

Grant code / Reference number

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

No

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Tayebeh Mirzaei

Position

Associate Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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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