Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the impact of the sleep health educational film on the sleep quality of the elderly over 60 years old

Protocol summary

Study aim
Determining the effect of using sleep hygiene educational videos on the sleep quality of the elderly over 60 years old.

Design
The clinical trial has a control group, randomized, the sample size is 75, the random selection of people in this study will be done using the random number generator software to generate random codes for allocation to the intervention and control groups.

Settings and conduct
All seniors over 60 years old are covered by comprehensive health centers in Tabas city. which will be randomly placed in the intervention and control groups based on the list of random codes in the form of permutation blocks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Age above 60 years, 2- Having good vision, hearing, speech, and cognitive health, 3- Not suffering from depression, cancer, heart failure, severe lung disease, mental and physical disability, chronic pain, and Alzheimer's based on the health records of the elderly, 4- Not using sedatives and hypnotics The ability to use educational videos based on questions from the elderly. Exclusion criteria: 1- illness or hospitalization during the intervention period, 2-Death of relatives and other unexpected events during the intervention period, 3- Failure to respond properly for 2 weeks.

Intervention groups
The intervention will be performed on the members of the intervention group and the control group will receive routine care. Finally, the results of the groups will be compared. In this study, sleep hygiene training videos will be provided for the test group and sleep hygiene training pamphlets will be provided for the control group.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231031059915N1**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **prospective**

Last update: **2023-11-27, 1402/09/06**
Update count: **0**

Registration date
2023-11-27, 1402/09/06

Registrant information

Name
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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the impact of the sleep health educational film on the sleep quality of the elderly over 60 years old

Public title
The effect of the sleep health educational film on the sleep quality of the elderly.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 60 years. Enjoying vision, hearing, speech, and cognitive health (getting a score of 24 or more from the Short Cognitive Status Questionnaire (MMSE) in the literate elderly and getting a score of 7 or more from the Abbreviated Cognitive Status Questionnaire (AMT) in the illiterate elderly literacy). Absence of depression, cancer, heart failure, severe lung disease, mental and physical disability, chronic pain and Alzheimer's based on the health records of the elderly Not using herbal and chemical sedatives and hypnotics. The ability to use educational videos based on questions from the elderly.
Exclusion criteria:
Illness or hospitalization of the elderly during the intervention period. Death of relatives and similar unexpected events during the intervention period. No proper response for 2 weeks.
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
At the beginning of the study, the list of random codes will be prepared with the help of random number generator software in the form of permutation blocks. These codes are for randomly assigning the elderly included in the study to the intervention and control groups. The sampling method in this study is initially based on the goal and the research team will refer to the comprehensive health centers of Tabas city and select the people who meet the inclusion criteria from among the elderly who refer to those centers. In the following, the colleague of the research team will explain to them about the type of study, method and purpose of conducting the study. Then, based on the list of random codes prepared with the help of random number generator software in the form of replacement blocks, the people included in the study will be divided into intervention groups (35 people) and control groups (35 people) in the order specified in the list of random codes. This process will continue until the sample size (70 people) is completed.
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 North Khorasan University of Medical Sciences.
Street address
Research ethics committee, After Imam Ali Hospital, Shahryar St
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Postal code
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Approval date
2023-09-17, 1402/06/26
Ethics committee reference number
IR.NKUMS.REC.1402.073

Health conditions studied

1

Description of health condition studied
sleep quality
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep quality score obtained by completing the Petersburg Sleep Quality Questionnaire
Timepoint
The measurement sections will be done in 2 steps; At the beginning of the intervention and then at the end of the fifth week after the intervention
Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after assigning people to the intervention group, the prepared educational videos will be provided to them. These educational videos will contain the educational axes and objectives as follows: In the first session, gaining knowledge about the importance of sleep in old age and information about the physical characteristics of a suitable room for sleeping. In the second session, gaining knowledge and understanding about the dos and don'ts of a room suitable for sleeping. In the third session, gaining knowledge and understanding about setting a fixed sleep schedule and the necessity of restricting sleep during the day. In the fourth session, gaining knowledge and understanding about the effect of nutrition, activity and consumption of substances such as cigarettes, alcohol and hookah on sleep. Then, since based on a preliminary study that was done experimentally by the researchers, it was found that watching an educational film 4 times is a suitable number for the number of times of watching an educational film among the elderly; Therefore, the elderly will be asked to watch this educational video 4 times. Since at the end of the step-by-step training videos, assignments and tasks corresponding to the materials presented in each session are specified for people, seniors will be asked to do the assignments and tasks presented at the end of each session. Also, the researcher will contact the elderly members of the intervention group 1 or 2 times per week in order to ensure that the elderly use the educational videos, control and follow up on the tasks and assignments and answer the questions. Also, in necessary cases, the researcher will visit the elderly person's place of residence, control and follow up to ensure that the elderly person uses the educational video and carry out the recommendations and assignments. From the beginning of the second week, the elderly who are able to go in person to receive the educational CD will be requested to go to the designated comprehensive health center at the beginning of the second, third and fourth weeks to receive the CD related to the educational video of that week. Also, for the elderly who are not able to go in person to receive educational videos, CDs related to educational videos will be sent every week, and phone follow-up will be done to ensure that the videos reach the elderly. Seniors will also be asked to watch these educational videos in accordance with the recommendations given in the first week and do the assignments and tasks specified in them.

Category

Lifestyle

2

Description

Control group: For people in the control group, routine measures will be provided, which includes the presentation of a pamphlet on the topic of sleep quality in the elderly. In this pamphlet, at first, the importance and changes of sleep during old age are discussed; In the following, 7 health tips for seniors' sleep are provided.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar Comprehensive Health Center

Full name of responsible person

Ruhollah Kosari

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

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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
Bojnourd University of Medical Sciences
Proportion provided by this source
50
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

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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
No - There is not 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