Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Continuous Care Model on the Elderly's Sleep Quality

Protocol summary

Study aim
determine the effect of Continuous care model on elderly's sleep quality.
Design
Semi-experimental study with control group
Settings and conduct
This semi-experimental study was conducted in two groups of control and intervention on the elderlies referred to the senior-citizen center of Zirab, Mazandaran province in 2017
Participants/Inclusion and exclusion criteria
the membership in the senior-citizen center of Zirab, the willingness to cooperate, the age of 60-80 years, and no participation in other self-care programs affecting the quality of sleep simultaneously with the present study
Intervention groups
The continuous care model was implemented in the intervention group, which consists of four stages of orientation, sensitization, control and evaluation.Considering the barriers to elderly sleep in orientation and sensitivity of the elderly to this , intervention was carried out. In the control stage, the intervention was reviewed and corrected if necessary. The control group did not receive any intervention and was followed up during this period, but after effective in the intervention group, the control group also performed
Main outcome variables
the quality of sleep in the elderly

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180303038931N1**
Registration date: **2018-05-29, 1397/03/08**
Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**
Update count: **0**

Registration date
2018-05-29, 1397/03/08

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-05-10, 1396/02/20
Expected recruitment end date
2017-08-06, 1396/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Continuous Care Model on the Elderly's Sleep Quality

Public title
The Effect of Continuous Care Model on the Elderly's Sleep Quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
the membership in the senior-citizen center of Zirab the willingness to cooperate the age of 60-80 years no

participation in other self-care programs affecting the quality of sleep simultaneously with the present study
Exclusion criteria:
Unwillingness to cooperate Having an acute illness that is undergoing hospitalization

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: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Faculty of Medical Sciences, Tarbiat Modares University

Street address
Bridge nasr- Jalal Al-e Ahmad -Tehran

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Province
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Postal code
14115-111

Approval date
2017-01-09, 1395/10/20

Ethics committee reference number
IR-TMU-REC-1395.460

Health conditions studied

1

Description of health condition studied
Elderly sleep quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
sleep quality

Timepoint
Before the intervention, one month and two months after the intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Continuous care model was implemented in four phases in their .Considering the barriers to elderly sleep in the stage of orientation and sensitivity of the elderly to this, intervention was carried out. In the control stage, the intervention was reviewed and corrected if necessary. Between 5-8 sessions with the presence of the elderly family on modifying the sleep pattern, including fluid restriction, sleep acceleration techniques, relaxation methods, and so on. The intervention lasted 6 weeks.

Category
Lifestyle

2

Description
Control group: The control group did not receive additional intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
The Association of Retirees of the Zirab City in Mazandaran Province

Full name of responsible person
Lotf Ali Faraj Nejad

Street address
The main square of the city - beside the mosque

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Mazandaran

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Sponsors / Funding sources

1

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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
Tarbiat Modares University
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

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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
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable