

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

Name

Mahsa Kamali

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

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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

City

Tehran

Province

Tehran

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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Zirab

Province

Mazandaran

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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
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

Contact

Name of organization / entity
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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