

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sleep health education on improving sleep quality in the elderly with diabetes

Protocol summary

Study aim

The results of this study can be predicted and used in the geriatric care system and increase the sleep quality of the elderly and teach methods to improve sleep quality and control insomnia in the elderly.

Design

A clinical trial with a control group, a blind strain, with entry and exit criteria and randomized is performed on 64 patients.

Settings and conduct

diabetes clinic in Gorgan city

Participants/Inclusion and exclusion criteria

Age over 65 years; Literacy for reading and writing; Ability to communicate; Patients with diabetes referred to Deziani Specialized Clinic in Gorgan, who have had at least one year of diagnosis and history of drug treatment and have an active case file in the clinic; Not having known progressive chronic diseases such as cancer and lupus; Obtaining low and medium scores from the sleep quality questionnaire; Willingness to participate in the study; Absence of psychiatric problems based on the file and self report

Intervention groups

Diabetic patients referred to diabetes clinic in Gorgan city

Main outcome variables

The effectiveness of the intervention of using education and continuous care on the sleep quality of patients with diabetes

General information

Reason for update

Acronym

TSDE

IRCT registration information

IRCT registration number: **IRCT20220411054493N1**

Registration date: **2022-07-30, 1401/05/08**

Registration timing: **retrospective**

Last update: **2022-07-30, 1401/05/08**

Update count: **0**

Registration date

2022-07-30, 1401/05/08

Registrant information

Name

ghazale mazraie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 727 0160

Email address

ghazallmazraie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-10, 1401/03/20

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sleep health education on improving sleep quality in the elderly with diabetes

Public title

The effect of sleep health education on diabetic elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 65 years Being literate Ability to communicate

Exclusion criteria:

The death of the elderly Not attending the class for more than one session Elder moving to another city or country absence of the elder due to illness that leads to hospitalization Withdrawal of the patient to continue participation in the study

Age

From **65 years old**

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that at the beginning of the study, the quality of sleep of the elderly is measured as a criterion for inclusion in the study, the score obtained from the questionnaire is arranged from small to large and placed in 2 blocks (one letter A and one letter B) and allocated as Classified will be executed. First, we will form a random sequence of 64 letters in double blocks as follows: BA-AB-AB-BA-AB-BA-AB-AB-BA-AB-BA-AB-AB-BA-AB-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB-BA-AB In this random sequence, there will be 32 of each letter A and B. According to the above block, 64 envelopes will be prepared and in each envelope, the letter A or B will be placed and will be numbered from 1 to 64. The person delivering the envelopes to the patients does not know what is inside. The production of a random sequence is done by a statistics and methodology consultant who does not have access to patients and only he knows what is in each envelope. Patients who received the letter A will be in the intervention group and patients who received the letter B will be in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst does not know the names of the patients and how to complete the questionnaire and the scores of the people.

Placebo

Not used

Assignment

Parallel

Other design features

empty

1

Name of ethics committee

Golestan university of medical science

Street address

Shastkola Street

City

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Province

Golestan

Postal code

4918936316

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.GOUMS.REC.1401.066

1

Description of health condition studied

diabet

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

1

Description

The effectiveness of the intervention of using education and continuous care on the sleep quality of patients with diabetes

Timepoint

one month and tow months after intervention

Method of measurement

Petersburg questionnaire

empty

1

Description

Intervention group: 32 elderly people who meet the entry criteria will be given a sleep health training program during 3 sessions. Then one month and two months after the intervention, sleep quality is measured.

Category

Lifestyle

2

Description

Control group: We select 32 elderly people who meet the entry criteria as a control group. Then one month and two months later, we measure the quality of sleep.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan Diabetes Clinic

Full name of responsible person

Fateme maghsoudloo

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Shahid beheshti street

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Sponsors / Funding sources

1

Sponsor

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Gorgan University of Medical 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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Ghazale Mazraie

Position

Master sudent if nursing

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

Yes - There is 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

Title and more details about the data/document

"No more information"

When the data will become available and for how long

"No more information"

To whom data/document is available

"No more information"

Under which criteria data/document could be used

"No more information"

From where data/document is obtainable

"No more information"

What processes are involved for a request to access data/document

"No more information"

Comments