Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Prevalence of sleep disorder in type 2 Diabetics and effect of implementing continuous care model on sleep quality and disease control in 2012.

Protocol summary

Summary

Counseling and education of continuous self-care is one of controller factors of diabetes, as implementing this model have had positive effects on sleep quality of hemodialysis patients and chemical warfare victims with bronchiolitis obliterans. We decided to assess the effect of implementing continuous care model on sleep quality of patients with type 2 diabetes in Gonabad. Material and method: in this clinical trial 80 patients with type 2 diabetes who have sleep disturbances and other inclusion criteria will enter the study and randomly assigned to two intervention and control groups. The continuous care model will be implemented for the intervention group and the sleep quality will be assessed after 3 mounths later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202269140N1**
Registration date: **2012-04-11, 1391/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-11, 1391/01/23

Registrant information

Name

Somayyeh Golchin Rahni

Name of organization / entity

Gonabad university of medical sciences

Country

Iran (Islamic Republic of)

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+98 53 3722 1359

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Gonabad Univesity of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevalence of sleep disorder in type 2 Diabetics and effect of implementing continuous care model on sleep quality and disease control in 2012.

Public title

Prevalence of sleep disorder in type 2 Diabetics and effect of implementing continuous care model on sleep quality and disease control .

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- patients with type 2 diabetes; 2- having sleep disorders; 3- having no acute complications and able to response to questionnaire; 4- having no psychological disease; 5- not taking sedatives; 6- having willingness to participate in the study; 7- having no known effective disease on sleep; 8- not having a neonate or any person which is needing frequent

noctural wakes up; 9- not having any night shift; 10- not having a habbit of day sleeping; 11- not having frequent trips which effect on normal sleeping; 12- not pregnant; 13- ages between 50-70 years old; 14- have diploma up to BA degree. Exclusion criteria: 1- no willingness to continue the study, 2- researcher found the exchange of educated information between two intervention and control groups, 3- change in activity, dietary habits and medications.

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Gonabad Univesity of Medical Sciences

Street address
Next to Asian Road, Gonabad Univesity of Medical Sciences

City
Gonabad

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9691793718

Approval date
2012-02-25, 1390/12/06

Ethics committee reference number
90/4/9/ک

Health conditions studied

1

Description of health condition studied
diabetes

ICD-10 code
e10-e14

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Sleep quality

Timepoint
Before and 3 mounths after intervention

Method of measurement
Pitzburg Questionary

Secondary outcomes

1

Description
Blood glucose, Urea, Creatinine

Timepoint
Before and 3 mounths after intervention

Method of measurement
Pitzburg Questionary,Clinical tests

Intervention groups

1

Description
In control group: measuring blood glucose and urea and creatinine and at the end of intervention assessment for sleep quality.

Category
N/A

2

Description
In intervention group: measuring blood glucose and urea and creatinine and then implementing continuous care model for 6 weeks.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Gonabad Health Center

Full name of responsible person
Mrs Zohreh Ahrari

Street address
22 Bahman Hospital, Naser khosro Street

City
Gonabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Gonabad Univesity of Medical Sciences
Full name of responsible person
Ali Ekrami
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Next to Asian Road, Gonabad Univesity of Medical Sciences
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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
Vice Chancellor for Research, Gonabad Univesity of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty