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 months later.

General information

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

Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research, Gonabad University 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 nocturnal wakes up; 9- not having any night shift; 10- not having a habit 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
Postal code
9691793718

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

Ethics committee reference number
90/4/9/5

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 months after intervention

Method of measurement
Pitzburg Questionary

Secondary outcomes

1
Description
Blood glucose, Urea, Creatinine

Timepoint
Before and 3 months 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 University of Medical Sciences

Full name of responsible person
Ali Ekrami

Street address
Next to Asian Road, Gonabad University of Medical Sciences
<table>
<thead>
<tr>
<th>Sciences</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>City</td>
<td>Gonabad</td>
</tr>
</tbody>
</table>

**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 University 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**

empty

**Type of organization providing the funding**

empty

---

### Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Gonabad University Of Medical Sciences

**Full name of responsible person**

Somayyeh Golchin Rahni

**Position**

Bsc. in Nursing- Msc. student in nursing

**Other areas of specialty/work**

**Street address**

No 4, Under Left, The first Two Floors Bulding, 23/1 Saadi Street, Gonabad, Khorasan-e-Razavi

**City**

Gonabad

**Postal code**

9691737958

**Phone**

+98 53 3722 1359

**Fax**

Email

somayyehgolchin@gmail.com

**Web page address**

www.gmu.ac.ir

---

### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Gonabad University of medical sciences

**Full name of responsible person**

Shahla Khosravan Doctor

**Position**

MD of Nursing

**Other areas of specialty/work**

**Street address**

Vice Chancellor for Research, Gonabad University of Medical Sciences, Gonabad

**City**

Gonabad

**Postal code**

9691793718

**Phone**

+98 53 3722 0578

**Fax**

Email

mma_khosravan@yahoo.com

**Web page address**

www.gmu.ac.ir

---

### 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