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

**Registrant information**
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**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 University of Medical Sciences
Street address
Next to Asian Road, Gonabad University of Medical Sciences
City
Gonabad
Postal code
9691793718
Approval date
2012-02-25, 1390/12/06
Ethics committee reference number
90/4/9/

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
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Sciences
City
Gonabad

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
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