

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 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**

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)

###### Phone

+98 53 3722 1359

###### Email address

golchin.s@gmu.ac.ir

##### 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 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 University of Medical Sciences

**Full name of responsible person**

Ali Ekrami

**Street address**

Next to Asian Road, Gonabad University of Medical 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

**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**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Shahla Khosravan Doctor

**Position**

MD of Nursing

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Somayyeh Golchin Rahni

**Position**

MS student of MA nursing

**Other areas of specialty/work****Street address**

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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*