

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Assessment the effectiveness of Telenursing follow-up on treatment adherence in patients with type II diabetes

Protocol summary

Summary

Objectives : The purpose of the present study (single blind for two groups) was to investigate the effect of nurse-led telephone follow-up on adherence to treatment in patients with type 2 diabetes. **Design:** The present quasi-experimental study was conducted on 60 patients with type 2 diabetes, admitted to a diabetes clinic in Aligudarz, Iran. The study population in this quasi-experimental study were patients who suffered diabetes type II and went to the diabetes clinic in Aligudarz, Iran. Samples were selected using the convenience sampling method and randomly divided into 2 groups. In this study, the adherence to the treatment and level of glycosylated hemoglobin were the dependent variables, and nurse-led telephone follow-up was the independent variable. The instruments used for data collection included a data recording sheet for recording the level of glycosylated hemoglobin and a questionnaire containing demographic specifications and questions on the adherence to the treatment. Also will be the single-blind study for researcher and final information analysis. **Setting and conduct:** During the study, the organized form of telephone conversations was used in telephone follow-up of the case group. At baseline, the level of glycosylated hemoglobin was measured and recorded on the data recording sheet, and the questionnaire was completed through a face-to-face interview with all the participants by the peer interviewer. Then, all the participants individually received 3-day training on diabetes self-care. After the training, the participants were randomly divided into two groups, case and control, and the telephone follow-up intervention was performed in the case group for three months. After the intervention, the researcher completed the questionnaire again through face-to-face interviews with the participants and recoded the level of glycosylated hemoglobin in the data recording sheet. It should be noted that the control group did not receive any training program during the study. Participants including major

eligibility criteria: The inclusion criteria were the glycosylated hemoglobin over 7%; minimum educational level of primary school; having a phone line at home; having no difficulty with speaking and hearing; not suffering from advanced form of diseases of vital organs. **Intervention:** the experimental groups had twelve weeks of telephone follow-ups. **main outcome measures:** increase in the mean scores of treatment adherence and reduction in the mean glycosylated hemoglobin levels of the experimental group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052522406N1**

Registration date: **2017-04-12, 1396/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

arezoo shahsavari

Name of organization / entity

Lorestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

This study was derived from a research project approved by Lorestan University of Medical Sciences and

Healthcare Services. The researchers hereby appreciate the Research Deputy of that university and Aligoudarz School of Nursing	
Expected recruitment start date	2012-03-19, 1390/12/29
Expected recruitment end date	2015-03-20, 1393/12/29
Actual recruitment start date	empty
Actual recruitment end date	empty
Trial completion date	empty
Scientific title	Assessment the effectiveness of Telenursing follow-up on treatment adherence in patients with type II diabetes
Public title	Assessment the effectiveness of Telenursing follow-up on treatment adherence in patients with type II diabetes
Purpose	Supportive
Inclusion/Exclusion criteria	The inclusion criteria: the glycosylated hemoglobin over 7%; minimum educational level of primary school; having a phone line at home; having no difficulty with speaking and hearing; not suffering from advanced form of diseases of vital organs. Exclusion criteria : the glycosylated hemoglobin less than 7%; illiterate ; not available a phone line at home; having difficulty with speaking and hearing
Age	From 38 years old to 85 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Lorestan University of Medical Sciences
Street address	3 km Khorramabad - Boroujerd, Lorestan University of Medical Sciences Complex University Campus, Vice Chancellor for research.
City	aligoudarz
Postal code	6814993165
Approval date	2012-06-09, 1391/03/20
Ethics committee reference number	IR.LUMS.REC19/91
Health conditions studied	
<u>1</u>	
Description of health condition studied	diabet type 2
ICD-10 code	E10
ICD-10 code description	diabetes (mellitus)(nonobese)(obese): adult-onset maturity-onset nonketotic stable type II non-insulin-dependent diabetes of the young
Primary outcomes	
<u>1</u>	
Description	Adherence to Treatment
Timepoint	3 month
Method of measurement	Data on the patients' glycosylated hemoglobin and treatment adherence were collected at baseline and again 12 weeks after the intervention.
Secondary outcomes	
<u>1</u>	
Description	HbA1C
Timepoint	3 MONTH
Method of measurement	Data on the patients' glycosylated hemoglobin was collected at baseline and again 12 weeks after the intervention by kalimetry method in same laboratory
Intervention groups	

1

Description

Telenursing follow up The telephone follow-up intervention was performed in the case group for three months. The researcher made telephone contacts with participants for following up the adherence to the treatment ,twice a week in the first and second month and once a week in the third month. The mean duration of each conversation was determined as 20 minutes. The conversations involved the evaluation of the adherence to the diet in participants. In case of any failure to adhere to the treatment, solutions were suggested to the patient for prevention of its reoccurrence besides examining the probable reasons with the help of the patient and answering his questions.

Category

Treatment - Other

2

Description

control group without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Jafar Sadegh hospital Abolfazl Cilinic

Full name of responsible person

Miss Masomeh Sarlak

Street address

Modares street Abolfazl Cilinic Imam Jafar Sadegh Hospital

City

Aligudarz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Lorestan University of Medical Sciences

Full name of responsible person

dr Morovat Taheri Kalani

Street address

3 km Khorramabad - Boroujerd, Lorestan University of Medical Sciences Complex University Campus, Vice Chancellor for research.

City

khoramabad

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 of Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Khodakarami Zahra

Position

Preject Evaluation in Lorestan University of Medical Sciences

Other areas of specialty/work

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Arezoo Shamsavari

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Fax

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Web page address

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