Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 toinvestigate 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 on60 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 Aligoudarz, 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 theexperimental 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 schoo; 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 availablea 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

1

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
aligudarz
Postal code
6814993165
Approval date
2012-06-09, 1391/03/20
Ethics committee reference number
IR.LUMS.REC19/91

Health conditions studied

1

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

1

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

1

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 kalimetery method in same labratory

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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Contact

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Full name of responsible person
Saeid Foroghi

Position
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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
Arezoo Shahsavari

Position
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Other areas of specialty/work

Street address
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Aligudarz

Postal code

Phone
00

Fax

Email

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