

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effects of nurse-led telephone follow-up (tele nursing) versus no follow-up on self-efficacy and quality of life in diabetic patients: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of nurse-led telephone follow-up (tele nursing) versus no follow-up on self-efficacy and quality of life in diabetic patients

Design

This is a randomized clinical trial, phase II, in which 58 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible diabetic patients who will refer to telenursing Diabetes Center of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Diabetes; Access to telephone at home; Residence of Hamadan City
Exclusion criteria: Hearing problem

Intervention groups

Intervention group: Routine care and phone contact and training the patient for 5 to 10 minutes twice a week in the first month and then once a week in the second and third month
Control group: Just routine care

Main outcome variables

Primary outcome: Assessing self-efficacy
Assessing the quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N249**
Registration date: **2018-11-18, 1397/08/27**
Registration timing: **prospective**

Last update: **2018-11-18, 1397/08/27**

Update count: **0**

Registration date

2018-11-18, 1397/08/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of nurse-led telephone follow-up (tele nursing) versus no follow-up on self-efficacy and quality of life in diabetic patients: a randomized clinical trial

Public title

The effects of nurse-led telephone follow-up (tele nursing) versus no follow-up on self-efficacy and quality of life in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 65 years; Diabetes; Access to telephone at home; Residence of Hamadan City

Exclusion criteria:
Hearing problem

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)
Not 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 Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2018-09-22, 1397/06/31

Ethics committee reference number
IR.UMSHA.REC.1397.439

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E11.9

ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
Assessing self-efficacy

Timepoint
In the first, second and third months of follow-up

Method of measurement
Using standard questionnaire

2

Description
Assessing quality of life

Timepoint
In the first, second and third months of follow-up

Method of measurement
Using standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care and phone contact and training the patient for 5 to 10 minutes twice a week in the first month and then once a week in the second and third month

Category
N/A

2

Description
Control group: Just routine care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Center of Hamadan City

Full name of responsible person
Soheila Shadi

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Ave.

City

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Province

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Soheila Shadi

Position

Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Shamsizadeh

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available