

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of telenursing training on the basis of family-center empowerment model on the compliance to regimen treatment rate among patients with type 2 diabetes: a randomized clinical trial

Protocol summary

Study aim

The effect of tele-nursing training on the basis of family-center empowerment model on the compliance to regimen treatment rate among patients with type 2 diabetes: a randomized clinical trial

Design

This study is a non-blinded clinical trial. The study population will be included all patients who referring to the diabetes ward of Al-Zahra hospital of Gilane Gharb city. Sixty eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

Settings and conduct

This study which will be conducted in Al-Zahra hospital of Gilane Gharb city is a nonblinded one. Questionnaire of compliance to regimen treatment will be provided to the patients at the beginning and at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at least six months passed from the diagnosis of type 2 diabetes; age between 30-55 years old; definitive diagnosis of type 2 diabetes by a doctor. Exclusion criteria: severe debilitating complications associated with diabetes.

Intervention groups

The intervention group over 16 sessions (2 times per week for telenursing weeks) for 20 to 30 minutes will receive telenursing training. The control group will not receive any training.

Main outcome variables

Adherence to the regimen treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N115**

Registration date: **2019-03-06, 1397/12/15**

Registration timing: **prospective**

Last update: **2019-03-06, 1397/12/15**

Update count: **0**

Registration date

2019-03-06, 1397/12/15

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of telenursing training on the basis of family-center empowerment model on the compliance to regimen treatment rate among patients with type 2

diabetes: a randomized clinical trial

Public title

The effect of telenursing training on the basis of family-center empowerment model on the compliance to regimen treatment rate among patients with type 2 diabetes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

At least six months passed from the diagnosis of type 2 diabetes Age between 30-55 Definitive diagnosis of type 2 diabetes by doctor The patient lives with the family

Exclusion criteria:

Severe debilitating complications associated with diabetes

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

ir.kums.rec.1397.1010

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Adherence to the regimen treatment

Timepoint

At the beginning and at the end of the study (2 months after the start of the study)

Method of measurement

Using questionnaires of adherence to treatment

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group over 16 sessions (2 times per week for 8 weeks) for 20 to 30 minutes will receive telenursing training.

Category

Lifestyle

2

Description

The control group will not receive any training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital

Full name of responsible person

Negar Shahabi

Street address

Basij Boulevard

City
GilanGharb
Province
Kermanshah
Postal code
6715847141
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+98 83 4322 3502
Email
shahabi.neg@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
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Province
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6715847141
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Email
fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Negar Shahabi
Position
MSc Student Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Dolatabad Blvd, Isar
Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Parvin Abassi

Position

Faculty Member of Kermanshah University of Medical
Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursing education

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p_abasi2003@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Negar Shahabi

Position

MSc Student Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments