Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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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
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Province
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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
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Basij Boulevard

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Sponsors / Funding sources

1

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Name of organization / entity
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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
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
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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