

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of empowerment program implementation with and Without telenursing on Self-efficacy and Quality of life of and Glycosylated hemoglobin index in Type II Diabetic patients : A double-blind randomized clinical trial

Protocol summary

Summary

This study aims to determine the effects of implementing empowerment program and empowerment with telenursing on self-efficacy, quality of life and Glycosylated hemoglobin of type 2 diabetes . The most important inclusion criteria are the presence of type 2 diabetes (at least one year), the age range of 30-70 years, and residence in Tabriz city. The most important exclusion criteria are hospitalization during the study period, disconnection for 2 weeks In the first month of intervention and 3 weeks in the second and third months of the study. The sample size in this study is based on the level of observed effect size through empowerment intervention on the self-efficacy score of the diabetic patients in the previous similar studies, which with the power of 90%, was calculated 43 for each group, and considering 20% loss, it will increase to 52 people. Using the sites related to stratified random sampling, the qualified individuals will be classified in three groups 1 (empowerment), the intervention group 2 (empowerment program with telenursing) and the control group. For groups 1 and 2, the empowerment program will be held for 2 weeks following the application of pretest. For the intervention group 2, telenursing program will be held for 12 weeks. Post-test for the three groups will be held after 14 weeks. In other words, three variables of self-efficacy, quality of life and glycosylated hemoglobin are measured in weeks 0 and 14.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608276918N25**

Registration date: **2017-08-22, 1396/05/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-22, 1396/05/31

Registrant information

Name

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Name of organization / entity

Faculty of Nursing & Midwifery

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz Medical University of Sincece

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of empowerment program implementation with and Without telenursing on Self-efficacy and Quality of life of and Glycosylated hemoglobin index in Type II Diabetic patients : A double-blind randomized clinical trial

Public title

Implementation of empowerment program along with telenursing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with type II diabetes aged 30 to 70 years; having diabetes for at least one year; conscious patients able to communicate; lack of speech and hearing problems, lack of participation in educational programs of other diabetes educational centers; residing in Tabriz; having access to regular phone or mobile phones. Exclusion criteria: being hospitalized during the study period; disconnecting the phone for 2 weeks during the first month of intervention and 3 weeks during the second and third months of the study; people suffering from mental or psychological problems according to the patient; taking psychotropic drugs according to the patient; and in cases where the individuals have some reason not to attend the sessions

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Tabriz University of Medical Science

Street address

Tabriz, Daneshgah St.

City

Tabriz

Postal code**Approval date**

2017-03-04, 1395/12/14

Ethics committee reference number

IR.TBZMED.REC.1396.436

Health conditions studied**1****Description of health condition studied**

Diabet

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Self-efficacy

Timepoint

Before intervention and 14 Week After Intervention

Method of measurement

Diabetes Self-efficacy Scale

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before intervention and 14 week after intervention

Method of measurement

Diabetis spesific QOL Questionnaire

2**Description**

Glycosylated hemoglobin

Timepoint

Before intervention and 14 week after intervention

Method of measurement

Bionik kits, unit: percent

Intervention groups**1****Description**

Educating of empowerment program without telenursing

Category

Behavior

2**Description**

Educating of empowerment program with telenursing

Category

Behavior

3

Description

Without intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Tabriz

Full name of responsible person

Hadi Azhdari

Street address

Shariety South St. Tabriz Faculty of Nursing and Midwifery Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Tabriz, Azadi Street, Golgasht Street , headquarters of Tabriz University of Medical Sciences

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Tabriz

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 Tabriz 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

Tabriz Faculty of Nursing and Midwifery

Full name of responsible person

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Position

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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