

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A comparison of the effectiveness of empowerment program of nurses and health services providers in self-care of middle-aged people with diabetes of selected comprehensive health centers of Isfahan in 2018.

Protocol summary

Study aim

The effectiveness of empowerment program of nurses and health services providers in self-care of middle-aged people with diabetes of selected comprehensive health centers

Design

This study is a non-blinded clinical trial. The study population will be included nurses and health care providers at Isfahan Health Center No. 1. A total of 480 eligible people will be selected conveniently and randomly will be assigned to four groups (two intervention groups and two control groups)

Settings and conduct

This study which will be conducted in Isfahan Health Center No. 1, is non-blinded one. At the beginning of the study and the end of the study, self-care questionnaire will be provided for middle-aged people

Participants/Inclusion and exclusion criteria

Inclusion criteria: Service providers (nurses and health care providers) working in comprehensive health centers; Middle-aged people aged between 30- 59 years old
Exclusion criteria: Not having a bachelor's degree in nursing and carers be the bachelor of disease control, public health or family health; Illiterate

Intervention groups

In the first intervention group, nurses will be trained self-care in empowerment program of nurses and health services providers of Comprehensive Health Services Centers for seven sessions. In the second intervention group, health care providers will be involved in self-care education of Comprehensive Health Services Centers for seven sessions. In the first control group, nurses will not receive any training. In the second intervention group, health care providers will not receive any training

Main outcome variables

Self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181225042121N1**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

masoume karimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3500 2118

Email address

masoume.karimian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness of empowerment program of nurses and health services providers in self-care of middle-aged people with diabetes of selected comprehensive health centers of Isfahan in 2018.

Public title

A comparison of the effectiveness of empowerment program of nurses and health services providers in self-care of middle-aged people with diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Receive notification from the health department of Isfahan province. Service providers (nurses and health care providers) working in comprehensive health centers. Diagnosis of type 2 diabetes by the doctor (FBS $\geq$ 126 or taking diabetes medication. Middle aged people aged between 30- 59 years old

Exclusion criteria:

Not having a bachelor's degree in nursing and carers be the bachelor of disease control, public health or family health. Illiterate

Age

From **30 years** old to **59 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **480**

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**

Committee Ethics, Islamic Azad University Esfahan Branch

Street address

University Blvd. Arghavaniyeh, East G Street,

City

Esfahan

Province

Isfahan

Postal code

3999811001

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.157

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

Type II diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

self-care

Timepoint

The beginning and end of the study

Method of measurement

Based on the self-care questionnaire of Tubert

Secondary outcomes

empty

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

In the first intervention group, nurses will be trained self-care in empowerment program of nurses and health services providers of Comprehensive Health Services Centers for seven sessions

Category

Lifestyle

2**Description**

In the second intervention group, health care providers will be involved in self-care education of Comprehensive Health Services Centers for seven sessions

Category

Lifestyle

3**Description**

In the first control group, nurses will not receive any

training.
Category
Other

4

Description

In the second intervention group, health care providers will not receive any training

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Center No. 1 in Isfahan
Full name of responsible person
Masomeh Karimian
Street address
Roknulmolk crossroad, Feyz Street,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Majid Toghyani
Street address
University Blvd, Arghavaniyeh, East G Street
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Research@khuisf.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Islamic Azad University
Full name of responsible person
Masomeh Karimian
Position
MSc student of Nursing and Midwifery
Latest degree
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Person responsible for updating data

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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

5 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