

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The design and effectiveness of self-care training package based on cultural educational needs of patients with type II diabetes on some health indicators

Protocol summary

Study aim

- The design and effectiveness of self-care educational package based on the educational-cultural needs of patients with type 2 diabetes and its effect on health indicators such as HA1C and quality of life, health literacy and self-care behaviors

Design

In this study, 70 patients with type 2 diabetes were selected randomly from the diabetic patient referred to Valiasr clinic in the city of Darreh. Four groups were randomly divided into two groups of 35 experimental and control groups

Settings and conduct

Clinical trial - Clinic of Vali Asr Hospita

Participants/Inclusion and exclusion criteria

Entry requirements: 40 years of age and over-six months longer than their diabetes - no mental, mental or hearing impairment

Intervention groups

In this study, the intervention would be face-to-face group training and lecture using a booklet, a pamphlet, a poster. The content of the patient's package of education based on assessing the needs of patients and the problems of diabetic patients, as well as the content of the self-care program of the patient in diabetic patients (Correct and timely delivery of insulin, dietary observation, regular exercise activities, identification of signs of hyperglycemia, Regular use of medications, foot care, communication skills, problem solving, emotional management and excitement) In Six sessions for 45 minutes. the intervention group will be provided. For the control group during the intervention will not be any training. After finishing the third stage and collecting final data, the control group will be awarded a booklet

Main outcome variables

Diabetic Patients' Health Literacy, Diabetic Patients' Quality, Diabetic Patients' Awareness, Self-Efficacy of

Patients with Diabetes, Self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170819035769N3**

Registration date: **2018-07-14, 1397/04/23**

Registration timing: **retrospective**

Last update: **2018-07-14, 1397/04/23**

Update count: **0**

Registration date

2018-07-14, 1397/04/23

Registrant information

Name

Behnaz Amozadeh

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 3522 9119

Email address

behnaz1079@yahoo.com

Recruitment status

Recruitment complete

Funding source

Supply by student

Expected recruitment start date

2017-12-04, 1396/09/13

Expected recruitment end date

2018-02-02, 1396/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The design and effectiveness of self-care training package based on cultural educational needs of patients with type II diabetes on some health indicators

Public title

Self-care education for diabetics

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Six months after the diagnosis of diabetes The age group is 40 years and older

Exclusion criteria:

There are sensory and perceptual problems, and visual, hearing and communication disorders

AgeFrom **40 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

A randomized block design with four blocks has been used to randomly assign to the control and experimental groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

Interviews with diabetic patients to meet the educational needs of the region's culture

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of the Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Tehran,

Vanak, Vanak Square, Mollasadra Street

City

Tehran

Province

Tehran

Postal code

Iran

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.BMSU.REC.1395.342

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

Diabet

ICD-10 code

E10

ICD-10 code description

E10-E14

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

Diabetic Patients' Awareness,

Timepoint

Before the intervention, immediately after the intervention, three months after the intervention

Method of measurement

knowledge questionnaire of diabetes

2**Description**

Efficacy

Timepoint

Before the intervention - one month later and three months later

Method of measurement

Self-efficacy questionnaire

3**Description**

Self-care behaviors

Timepoint

Before the intervention - one month later and three months later

Method of measurement

Self-care behaviors questionnaire

4**Description**

Quality of Life

Timepoint

Before the intervention - one month later and three months later

Method of measurement
Quality of Life Questionnaire

5

Description

Health literacy

Timepoint

Before the intervention - one month later and three months later

Method of measurement

Health literacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Initially, training packages and educational pamphlets based on educational needs were provided for the intervention group. Then, they will be taught in questions and answers and face-to-face in groups of 5 or 6 in six 45-minute sessions. Immediately after training, and three months later, the questionnaires will be completed and analyzed again.

Category

Lifestyle

2

Description

The control group did not receive any intervention and will receive only the final instruction booklet.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Behnaz amozadeh

Street address

Ilam - Darreshahr - Health Center Darreshahr

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2

Recruitment center

Name of recruitment center

Taleghani kuye Center - Shaheed Mo'airi Center

Full name of responsible person

Behnaz amozadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Vice chancellor for research, baqiyatallah University of Medical Sciences. Dr. Mohammad Alishiri

Street address

baqiyatallah (AJ) University, Nosrati Alley, Sheikh Bahai South Avenue, Mollasadra St, Vanak, Tehran

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behnaz1079@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Darreshahr Health Center

Full name of responsible person

behnaz amozadeh

Position

Graduate

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Darrehshahr- shahid jafari street- dareeshahr health center

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Web page address<http://dareshahr.medilam.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Akram parandeh

Position

doctorial

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Vank Square, Mulla Sadra Ave., Sheikh Bahaee Avenue, next to Baqiyatallah (AS) Mosque - Shahid Nasrati Alley - Baqiyatallah University of Medical Sciences (AJ) - Faculty Building - Faculty of Nursing - Sixth Class.

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Web page address<http://www.bmsu.ac.ir/Services/Departments/?ObjId=193&PageId=785>**Person responsible for updating data****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

behnaz amozadeh

Position

nurs

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Web page address<http://dareshahr.medilam.ac.ir>**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

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available