

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

A comparative study of the effect of family-centered and patient-centered education on self-efficacy and self-esteem of patients with type 2 diabetes.

Protocol summary

Study aim

Determining the effect of family-centered and individual-centered education on self-efficacy of patients with type 2 diabetes Determining and comparing the mean score of self-efficacy in patients in the intervention and control groups before and after education Determining and comparing the mean score of self-esteem in patients in the intervention and control groups before and after education Determining and comparing the mean scores of FBS, 2HPP, TG, CHOL, HbA1C tests in patients in the intervention and control groups before and after education

Design

This clinical trial will be performed in parallel groups on 80 patients with type 2 diabetes.

Settings and conduct

This project is carried out in Yazd Diabetes Research Center. From the patients referred to the center, 80 patients are randomly selected and divided into two groups. One group receives training with a family member and the other group receives training alone.

Participants/Inclusion and exclusion criteria

History of diabetes for at least one year; Having a medical record at the Diabetes Center; Drug treatment with insulin; Lack of impaired hearing and vision problems and mental illness; Literacy for reading and writing; The patient's relatives are not medical or care staff;

Intervention groups

Patients in the intervention group are accompanied by a family member who has a caring role, will be participated in 7 sessions of 40 to 45 minutes and, the second group of patients will receive individual training.

Main outcome variables

Self-efficacy; self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200426047208N2**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **retrospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

Akram Mehrabbeik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3728 0226

Email address

mehrabbeyk@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of family-centered and patient-centered education on self-efficacy and self-esteem of patients with type 2 diabetes.

Public title

The effect of education on self-efficacy and self-esteem of patients with diabetes.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

History of diabetes for at least one year Having a medical record at the Diabetes Center Drug treatment with insulin Lack of impaired hearing and vision problems and mental illness Literacy for reading and writing The patient's relatives are not medical or care staff

Exclusion criteria:

History of depression and mental illness History of death of first-degree relatives during the last 6 months History of participating in training classes

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling is used. First, it is assigned to the file of each eligible patient and then using the software random allocation And specifying the sample size and number of groups by generating a random sequence, the samples of each group (family-centered and patient-centered) are determined.

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 shahid sadoughi university of medical sciences

Street address

Bahonar squire

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.SSU.RSI.REC.1398.048

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Self-efficacy score

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

Diabestes Management Self -Efficacy questionnaire

2

Description

Self esteem score

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

Coopersmith Self-Esteem Inventory

3

Description

FBS

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

blood test

4

Description

HA1c

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

blood test

5**Description**

Cholesterol

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

blood test

6**Description**

2hpp

Timepoint

Before the intervention and 3 months after the end of the intervention

Method of measurement

blood test

Secondary outcomes

empty

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

Intervention group1: patients with an active family member will be educated in In 7 sessions of 40 to 45 minutes for 7 weeks(one session per week).Training based on the family-centered empowerment model (empowering the patient and active family member to promote the patient's health) will be provided one week after the introductory session, thus the family-centered empowerment model in four steps of perceived limitation, problem solving, strengthening Self-esteem and evaluation will be done.

Category

Behavior

2**Description**

Intervention group2: patients will be educated in In 7 sessions of 40 to 45 minutes for 7 weeks(one session per week).Training based on the patient-centered empowerment model (empowering the patient to promote their health) will be provided one week after the introductory session, thus the patient-centered empowerment model in four steps of perceived limitation, problem solving, strengthening Self-esteem and evaluation will be done.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Research Center

Full name of responsible person

Bahare Fallah

Street address

No. 32. Shahid Beheshti Alley. South Salman Street.Yazd.

City

Yazd

Province

Yazd

Postal code

891574534396

Phone

+98 35 3824 1751

Email

baharefallah@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

The central building of Yazd University of Medical Sciences, Bahonar Square, Yazd.

City

Yazd

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Yazd

Postal code

8916978477

Phone

+98 35 3146 2136

Email

mmirzaei@ssu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Bahare Fallah

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Bahare fallah

Position

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All researchers

Under which criteria data/document could be used

Carrying out research activities by mentioning the source

From where data/document is obtainable

Bahare fallah baharefallah@gmail.com

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

The files will be sent to them one week after receiving the requesting email.

Comments