

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of peer support on adherence to treatment, quality of life and health literacy in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of peer support on treatment adherence, quality of life and health literacy of type 2 diabetic patients

Design

This clinical trial has a control group. It has been randomized and will be performed on 80 patients without blinding. Randomization is done using cards A and B.

Settings and conduct

The research community includes type 2 diabetic patients who refer to diabetes clinic on September 8 in Aligudarz city. After 3 days of diabetes training for patients, 80 people will be selected by convenience sampling and the samples will be randomly divided into two groups of intervention and control. Patients in the intervention group will again be randomly assigned to 4 groups under the same training for 3 months

Participants/Inclusion and exclusion criteria

eligible criteria: At least 6 months have passed since the doctor diagnosed them with type 2 diabetes, Be over 18 years old, Do not have a history of participating in educational programs in the field of diabetes during the past year, Have a desire to participate in the present study, Do not have cognitive problems, Do not have a physical disability, Do not need diabetic foot surgery, Do not have medical or related education Not eligible criteria: The patient has physical problems that she is not able to take care of herself, Patients who do not wish to participate in the study.

Intervention groups

The intervention program will receive a diabetes training program from its counterparts. In addition to the usual care, the Regular care Control group participates in their 3-day care program.

Main outcome variables

HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150525022406N2**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **retrospective**

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

arezoo shahsavari

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-01, 1398/12/11

Expected recruitment end date

2020-04-07, 1399/01/19

Actual recruitment start date

2020-03-04, 1398/12/14

Actual recruitment end date

2020-05-08, 1399/02/19

Trial completion date

2020-08-25, 1399/06/04

Scientific title

The effect of peer support on adherence to treatment, quality of life and health literacy in patients with type 2 diabetes

Public title

The effect of peer support on adherence to treatment in patients with diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 6 months have passed since the doctor diagnosed them with type 2 diabetes Be over 18 years old Do not have a history of participating in educational programs in the field of diabetes during the past year Have a desire to participate in the present study Do not have cognitive problems Do not have a physical disability Do not need diabetic foot surgery -Do not have medical or related education It is possible to make a direct phone call with the patient

Exclusion criteria:

Do not want to participate in the study The patient has physical problems that they are not able to take care of themselves

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly divided into intervention and control groups. In order to randomly assign participants in two groups, first 35 cards A (intervention group) and 35 cards B (control group) will be prepared. After shuffling the cards, participants are asked to take a card in order, then the samples will be placed in one of the intervention or control groups based on the removed card. In this way, all participants will have an equal chance to be in two groups.

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

School of pharmacy and Nursing & Midwifery-shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2020-03-01, 1398/12/11

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.348

Health conditions studied

1

Description of health condition studied

Diabetes type II

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

HbA1C

Timepoint

Before intervention , 3 months after the intervention

Method of measurement

Patient blood sample in the laboratory

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention , Immediately after the intervention, 3 months after the intervention

Method of measurement

Quality of life questionnaire

2

Description

Health literacy

Timepoint

Before intervention , 3 months after the intervention

Method of measurement

Questionnaire Health literacy (TOFHLA)

3

Description

Diabetes self care dimension

Timepoint

Before intervention , Immediately after the intervention, 3 months after the intervention

Method of measurement

Diabetes Self-Care Questionnaire

4

Description

Percieved Social Support(PRQ-85)

Timepoint

Before intervention , 3 months after the intervention

Method of measurement

Percieved Social Support Questionnair

5

Description

Body Mass Index

Timepoint

Before intervention , 3 months after the intervention

Method of measurement

Weight and height measurement

Intervention groups

1

Description

In this study, after identifying eligible individuals and obtaining informed consent for the first time, questionnaires of quality of life, adherence to treatment, health literacy, perceived social support were completed during the face-to-face interview and blood samples for HbA1c, height and Weight measurement will be done for each participant. Then, group training will be prepared for 3 days in order to match the basic information of the participants according to the latest current instructions of the Ministry of Health and after simplifying the concepts, it will be implemented. Questionnaires will be completed immediately after the end of the 3-day course and for the second time. Patients will then be randomly divided into intervention and control groups. The selection of peers will be done with the participation of health care providers present in the center, a checklist for assessing the ability of peers and face-to-face interviews with qualified individuals. The selected peers will then be trained. In addition to diabetes care knowledge, this training will include training specific skills needed by peers such as communication and problem solving skills. In the next stage, the participants of the intervention group will be randomly trained in one of the 4 groups. In order to randomize the cards A, B, C, D (10 cards each) will be prepared and the members of the intervention group will be asked to choose one after

shuffling the cards. In this way, people will be randomly placed in one of the four peer training groups. By introducing peers to patients in each group, the peer support intervention program will begin for 3 months. In addition to the usual care program, this program will include a monthly group training session with a discussion approach and participation of all members (3 sessions in total), a monthly group exercise program session (3 sessions in total). In addition, according to the schedule, peers can call their patients during the agreed hours and talk to them about each patient's specific care issues. 3 months after the start of the intervention for the third time, the questionnaires will be completed for both intervention and control groups. Also, HbA1c and patients' BMI will be measured and recorded again.

Category

Lifestyle

2

Description

Control group: usually diabetes clinic care includes weekly visit of a nutritionist and general practitioner and training using pamphlets in the diabetes center. Individuals in this group will also receive 3 days of diabetes care training, similar to the intervention group

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Aligudarz city specialized clinic on 17 September

Full name of responsible person

Sarlak Masomeh/Diabetes Nurse

Street address

Nourth Vali-Asr st

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6861716118

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zarghi, Afshin. Vice- Chancellor in Research Affairs

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t 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo

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Intl_office@sbmu.ac.ir

Web page address

http://retech.sbmu.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahsavari, Arezoo

Position

Phd student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Publication of the article The effect of peer support on the dependent variables of quality of life, adherence to treatment, perceived social support, glycosylated hemoglobin and body mass index
When the data will become available and for how long

Up to five years after sampling
To whom data/document is available
Supervisor and Research Consultants
Under which criteria data/document could be used
Only for the publication of scientific articles
From where data/document is obtainable
Deputy of Research, Shahid Beheshti School of Nursing and Midwifery, Tehran
What processes are involved for a request to access data/document
Written request to the research deputy of Shahid Beheshti School of Nursing and Midwifery, sent to the research deputy of the university and accept or reject the request
Comments