Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of family-centered empowerment model on the life style, self-efficacy and HbA1C of diabetic patients in Lavasan center

Protocol summary

Summary

In this clinical trial, purposive sampling method will be used. After ethical consideration and inclusion criteria, the samples will be divided into two groups and HbA1C testing is done in patients in the intervention group and the control. Then questionnaires of demographic and lifestyle information and self-efficacy for data collection (patients) will be completed in two groups and then will be collected. After that, family-centered empowerment model for the intervention group (patients and family members) within 5 to 7 meeting (almost six weeks) will be implemented. In the control group, education without the involvement of family will be provided for patients. Gathered data by using SPSS 20 software, descriptive and inferential statistics will be analyzed. Upon completion of the study and report the results, in order moral considerations, empowerment model will be implemented in the control group, too.

General information

Acronym

Ḍiabetic Patient

IRCT registration information

IRCT registration number: **IRCT2017022832817N1**
Registration date: **2017-03-18, 1395/12/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-18, 1395/12/28

Registrant information

Name

Homeira Atashzadeh Shoorideh

Name of organization / entity

School of Medicine, SBMU

Country

Iran (Islamic Republic of)

Phone

+98 21 2226 6171

Email address

h_atashzadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered empowerment model on the life style, self-efficacy and HbA1C of diabetic patients in Lavasan center

Public title

Effect of family-centered empowerment model on the life style, self-efficacy and HbA1C of diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. Have at least 6 months history of diabetes 2. Have HbA1C>7% 3. Ability to speech and have not any hearing or speech problem 4. Have at least literacy 5. Age 40-65 6. Have not any Psychological disease, dementia, mental or psychological problems, end stage of liver or kidney disease, cancer and CVA 7. No nurse or physician 8. Ability to participate in study and completion the questionnaire 9. Have a tendency to

participate in study 10. Have medical record in Lavasan Center Exclusion criteria: 1. No participation/involvement of patient or her/his active member of family in research 2. No tendency to complete of questionnaire 3. Participation of patient or her/his active member of family in other study during this research 4. Establish any disorder or disease which can be effect on this intervention

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Training process in intervention group consists of four stages: perceived threat (assess of knowledge, awareness, and ambiguities), troubleshooting / problem solving (defining problems and solutions, and problem solving), participation in training (training to the patient's family member provided by patient) and evaluation. In control group all of stages (without stage three [participation in training]) will be done. These sessions will be conducted in six weeks and the follow-up period will be done (in six weeks). The total of these steps is three months.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee in school of Medicine, Shahid Beheshti University of Medical Sciences

Street address
Iran, Tehran Velenjak St. , Shahid Chamran Highway Tel : +98 21 23871

City
Tehran

Postal code

Approval date
2016-07-19, 1395/04/29

Ethics committee reference number
IR.SBMU.MSP.REC.1395.150

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E12

ICD-10 code description
Malnutrition-related diabetes mellitus

Primary outcomes

1

Description
life style,

Timepoint
Pre intervention, immediately after intervention, 3 months after intervention

Method of measurement
questionnaire, Blood Test

2

Description
self-efficacy

Timepoint
Pre intervention, immediately after intervention, 3 months after intervention

Method of measurement
questionnaire

3

Description
HbA1C

Timepoint
Pre intervention, 3 months after intervention

Method of measurement
Blood Test

Secondary outcomes

empty

Intervention groups

1

Description
Training process in intervention group consists of four stages: perceived threat (assess of knowledge, awareness, and ambiguities), troubleshooting / problem solving (defining problems and solutions, and problem solving), participation in training (training to the patient's family member provided by patient) and evaluation.

Category
Lifestyle

2

Description
Training process in control group consists of three stages: perceived threat (assess of knowledge, awareness, and ambiguities), troubleshooting / problem solving (defining problems and solutions, and problem solving), and evaluation. In control group all of stages (without stage three [participation in training]) will be done.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Lavasan Center

Full name of responsible person
Dr. Homeira Atashzadeh-Shoorideh

Street address

City
tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vice-Chancellor in Research Affairs

Street address
Dr. Afshin Zarghi

City
Tehran

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
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
School of Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Shahnam Arshi

Position
PhD

Other areas of specialty/work

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Shahid Beheshti University of Medical Sciences, Velenjak St., Chamran Highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity
School of Medicine, SBMU

Full name of responsible person
Homeira Atashzadeh-Shoorideh

Position

Other areas of specialty/work

Street address

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00

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h_atashzadeh@sbmu.ac.ir

Web page address

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