

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of the family-centered empowerment model on adherence to the diet regimen of elderly patients with type II diabetes mellitus

Protocol summary

Study aim

Determine the review effect of the family-centered empowerment model on adherence to the diet regimen of elderly patients with type II diabetes mellitus

Design

A clinical trial with an intervention / control / randomized group on 148 patients who were studied for three months.

Settings and conduct

In this study, 148 type 2 diabetic patients were admitted to the experimental and control groups after performing a pretest by random allocation in parallel. A researcher-made questionnaire is used to assess diet awareness and adherence and HbA1C index is used as a metabolic control. Then, the intervention will be performed based on the family-centered empowerment model for the experimental group and after three months, the level of knowledge and the degree of diet adherence will be re-evaluated using a questionnaire and HbA1C values will be measured.

Participants/Inclusion and exclusion criteria

Society: Elderly patients of type 2 and one active family member, inclusion criteria: informed consent, an active member of the patient family and access to the Internet and smartphones, more than three months history of the disease, age 50 years and older, departure: Failure to complete the questionnaire of mental disorders, hospitalization due to other health problems

Intervention groups

Samples are collected from patients referred to clinics in Shushtar city, then the groups are matched and placed in two groups of control and intervention. Proper diet will be taught. A researcher-made questionnaire will be used to assess diet awareness and adherence and the HbA1C index will be measured. Intervention will be performed. The process evaluation will be done one week after the intervention and the final evaluation will be done three months after the intervention through a questionnaire.

Main outcome variables

Adherence to diet; HBA1C index; Level of knowledge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211018052796N1**

Registration date: **2022-04-09, 1401/01/20**

Registration timing: **retrospective**

Last update: **2022-04-09, 1401/01/20**

Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Elham Abdolahi shahvali

Name of organization / entity

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

2021-10-26, 1400/08/04

Expected recruitment end date

2022-02-23, 1400/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of the family-centered empowerment model on adherence to the diet regimen of elderly patients with type II diabetes mellitus

Public title
The effect of family-centered empowerment model on adherence to the diet regimen of elderly patients with type II diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent, an active member of the patient's family and access to the Internet and mobile phone, more than three months of the disease, age 50
Exclusion criteria:
Failure to complete a questionnaire for mental disorders, hospitalization due to other health problems

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **148**

Randomization (investigator's opinion)
Randomized

Randomization description
Elderly people with type 2 diabetes who were eligible for the study are collected from patients referred to clinics in Shoushtar city in such a way that based on the duration of the disease, age, and sex, the groups are matched and randomly divided into two groups: control and Interventions are placed. Randomization will be carried out using a random number table generated by Excel software and participants will be randomly allocated to one of the two groups. The control group will receive face-to-face education and the intervention groups will receive a 12-week nutrition education intervention in addition to face-to-face education.

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

Shoushtar Faculty of Medical Sciences

Street address

Khozestan, Shoushtar, Shahid Rajaei Crossroads, in front of Hosseinih Azam, Alhadi Hospital, Vice Chancellor for Research and Student Culture.

City

shoushtar

Province

Khouzestan

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Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.SHOUSHTAR.REC.1399.042

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

HBA1C index

Timepoint

Before the start of the training and three months after the training

Method of measurement

Check the percentage of HBA1C

Secondary outcomes

1

Description

Diet adherence

Timepoint

Before the start of training and three months after

Method of measurement

Completion of the questionnaire

Intervention groups

1

Description

Intervention group: Appropriate diet will be taught by a nutritionist and during nutrition counseling sessions according to the disease status and other underlying diseases of the participants. In these sessions, patients will be taught the glycemic index and glycemic load of

carbohydrate foods. You will also be taught how to choose, cook, and process carbohydrate-rich foods to help control your blood sugar levels. It consists of 20 points and is divided into good, medium and poor levels. Will be used and the HbA1C index will be used as a follow-up to the diet, which will be recorded for all samples. For the intervention group, the family-centered empowerment model in four steps; Perceived threat, self-efficacy, self-esteem and evaluation, through group training, group problem solving and training participation, will take place during 3-5 sessions of 30 minutes per week in one of the faculty classes and training cards and training booklets are available. Research and will be an active member of their family. The control group will receive routine care. Patients' competency indicators (perceived threat, self-efficacy and self-esteem) are assessed before the intervention and after the intervention and three months later, but no intervention will be performed in the control group. Leha will act face to face with the patient; and in the same session, the empowerment questionnaire of the active family member will be completed by themselves in the presence of the researcher and if the researcher has a question, after analyzing the data related to the pre-test, intervention in Three steps will be performed for the experimental group in groups of 3-5 people. In the first step, "perceived threat" sessions aimed at increasing the perceived threat by increasing their level of knowledge and awareness about the problems that threaten the patient and the problems and In the first and second sessions, the researcher will explain the nature and process of the disease and its prognosis, the symptoms and the possibility of complications and its consequences, and prevention and treatment strategies, medication regimen, and follow-up treatment plan. The participants themselves continue the discussion and discuss in order to continue learning Training cards will also be used outside of these sessions. Patients will be given educational cards with explanations in simple language and illustrative images in each session related to the topic of discussion. In the second step (self-efficacy through problem-solving), the patient actively participates in the care program while being aware of and deeply aware of the disease process and its complications with confidence and feeling that I can play a role in improving my condition. Problem-solving sessions will be held and problems and problems related to the disease will be discussed through group discussions, such as the correct use of the glucometer. In the third step (self-esteem), the patient was asked to participate in the training of an active family member by conveying the material discussed in each session to the active family member on behalf of the family, and in addition For each session, educational cards will be sent by the researcher to the active member of the family, which contains content and illustrations in plain language and two related questions on the back of the cards. Intervention and final evaluation three months after the intervention through The questionnaire will be implemented. At the end of the work, ie about three months, the awareness questionnaire will be completed again by both groups. The HbA1C of both groups will be

measured. They will be analyzed after data collection.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک دیابت بیمارستان خاتم النبیا شهرستان شوشتر

Full name of responsible person

Elham Abdolahi Shahvali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shooshtar University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shooshtar 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

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Shooshtar University of Medical Sciences

Full name of responsible person

Elham Abdolahi Shahvali

Position

MSc of nursing, Department of nursing, Shoushtar
Faculty of Medical Sciences, Shoushtar, Iran

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Nursery

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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City

Shoushtar

Province**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

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