Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Self-management Education in Teach Back Method on Medication and Nutritional Adherence of Elderly Patients with Type 2 Diabetes

Protocol summary

Study aim

Determining the impact of self-management training in a retrospective manner on the level of medication and dietary compliance of the elderly referring to selected comprehensive health service centers in Mashhad in 2022

Design

From among 93 comprehensive health service centers in Mashhad, with the help of random number software, one center was selected, then from the entire list of diabetic patients in Sina system, 104 members of the sample were divided into two groups using random sampling method

Settings and conduct

En After randomly selecting people and obtaining written consent, demographic information questionnaires, medication compliance questionnaires and dietary compliance questionnaires will be completed for both groups of the elderly and training will be conducted during six sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older thanr 60 years old; having type 2 diabetes for at least one year since diagnosis; obtaining written consent; being literate and not suffering from debilitating complications caused by diabetes; able to speak and communicate; absence of cognitive problems. Exclusion criteria: unwillingness to continue cooperation in the study; failure to participate even in a training session; participation in similar training sessions; having education in the field of medical sciences.

Intervention groups

In the feedback training intervention group, the trainer uses simple and understandable language; He teaches the client individually and after the end of teaching each topic, he asks the client to repeat the content in his own language as he understood it. If the client does not repeat the contents well, the trainer repeats the contents for the client until he fully understands

Main outcome variables

Medication compliance; food compliance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221011056146N2**
Registration date: **2023-01-03, 1401/10/13**
Registration timing: **prospective**

Last update: **2023-01-03, 1401/10/13**
Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Afsaneh Garshad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3272 4459

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-22, 1401/12/03

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Self-management Education in Teach Back Method on Medication and Nutritional Adherence of Elderly Patients with Type 2 Diabetes

Public title

Evaluation of the Effect of Self-management Education in Teach Back Method on Medication and Nutritional Adherence of Elderly Patients with Type 2 Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Having type 2 diabetes, at least one year has passed since the definitive diagnosis of the disease by a doctor No visual problems The ability to read the line of a magazine or newspaper from a distance of 30 cm No movement problems Having at least reading and writing literacy Not suffering from severe and debilitating complications caused by diabetes, such as kidney failure, etc. Able to speak and communicate Absence of cognitive problems

Exclusion criteria:

Reluctance to continue cooperation in the study - - Participation in similar training sessions - Failure to participate in even one training session Having an education in the field of medical sciences

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

From among 93 comprehensive health service centers of Mashhad with the help of random number software, one center was selected, then from the entire list of diabetic patients in the Sina system using random sampling method with Using the software, a number of 104 diabetic patients will be selected. These people will enter the study randomly and will be placed in one of the training or control groups as an uninformed strain. After checking that these people meet the conditions for entering the study. In order for the studied subjects to be homogeneous in terms of gender and education in two groups, stratified randomization method was used and the studied subjects were stratified according to these variables, then the required sample in each group (52 people) was An equal form of classification is done by simple random allocation method (randomization will be done using a computer) or according to the conditions after classifying the samples using block random allocation with two groups A (training group) and B (control group) samples will be allocated in two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Each selected diabetic patient was contacted and the work steps were explained to all patients and the patient will be informed that there is a possibility of being placed in any training or control group for the patient and that the patient will be placed in which group. is unaware

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Sciences

Street address

Shahyar St

City

Boujnurd

Province

North Khorasan

Postal code

9418636595

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.NKUMS.REC.1398.122

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Medication compliance

Timepoint

Before training and six sessions after training

Method of measurement

En Questionnaires for demographic information, Moriski medication adherence questionnaire for the elderly in both groups of return education and education in the usual way

2

Description

Food compliance

Timepoint

Before training and six sessions after training

Method of measurement

En Questionnaire of demographic information, dietary compliance questionnaire (Mediterranean diet adherence tool) for the elderly in both groups of return education and education in the usual way.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the contents (diabetes disease, drug therapy in diabetes, diet in diabetes, exercise activity in diabetes, blood sugar measurement methods, effect of stress on diabetes disease) are presented in the form of feedback training, which is taught by the teacher who is a researcher. is responsible for education; content in simple and understandable language; without using specific medical terms, he teaches the client individually and after the end of the training, he asks the client to understand the content; to tell in his own language; If the client has not understood and narrated the content well; person teaching until full understanding; He will repeat the content for the client. The number of sessions is 6, twice a week, each session is 20 minutes, which will be completed within 3 weeks.

Category

Lifestyle

2

Description

Control group: Teaching subjects: diabetes disease, drug therapy in diabetes, diet in diabetes. Exercise activity in diabetes. Blood sugar measurement methods. The effect of stress on diabetes. The number of sessions is 6 sessions, twice a week, each session is 20 minutes, which will be completed within 3 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Health Service Center

Full name of responsible person

Marzie Seyedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Amir Ali Ghahremani

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Vice President of Research and Technology, North Khorasan University of Medical Sciences, Shahriar St.

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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

Bojnourd 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
Bojnourd University of Medical Sciences

Full name of responsible person
Afsaneh Garshad

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

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