

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

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 than 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: **IRCT20221011056146N1**

Registration date: **2022-12-18, 1401/09/27**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **0**

Registration date

2022-12-18, 1401/09/27

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

2023-03-05, 1401/12/14

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

2023-03-05, 1401/12/14
Actual recruitment end date
 2023-07-22, 1402/04/31
Trial completion date
 2023-10-23, 1402/08/01

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 Not having visual problems (able to read the line of a magazine or newspaper from a distance of 30 cm) Not having movement problems and having minimal reading and writing literacy and not suffering from severe and debilitating complications Caused by diabetes such as kidney failure and... able to speak and communicate; Absence of cognitive problems Random allocation: At first, the patients who met the criteria for entering the study were divided into two intervention and control groups according to the table of random numbers (even odd) Exclusion: variables that could not be controlled and could have a strong effect on the research results were included in the entry and exit criteria. Consideration and homogenization: variables that cannot be eliminated, with the help of statistical tests Chi-square, Fisher, independent t, will be analyzed and homogenized. These variables They include: level of education, income, marital status, insurance status and use of other drugs. Community Verified icon No cognitive problems
Exclusion criteria:
 Reluctance to continue cooperation in the study Failure to participate in even one training session Participation in similar training sessions Having education in the field of medical sciences

Age
 From **60 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **104**
 Actual sample size reached: **104**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The patients who met the conditions for entering the study were divided into two intervention and control

groups according to the random number table. We will try to select patients as much as possible, until two groups are homogeneous in terms of age, sex, education and other variables. to be selected and also to check the homogeneity of the demographic variables in the two training and control groups, from the detailed test

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 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

E16.4

ICD-10 code description

Type 2 diabetes

Primary outcomes

1

Description

Return training

Timepoint

Food compliance

Method of measurement

Medication compliance

Secondary outcomes

1

Description

Medication compliance

Timepoint

Before training and six sessions after training

Method of measurement

Questionnaires for demographic information, Morisky 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

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.

Intervention groups

1

Description

Intervention group In this group, the content is presented in the form of feedback training, where the trainer, who is a researcher himself, is responsible for the training; 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 contents for the client. Number of sessions: 6 sessions, twice a week, each session is 20 minutes, which will be completed within 3 weeks. Session topics: diabetes, drug therapy in diabetes, diet in diabetes. Exercise activity in diabetes. Blood sugar measurement methods. The effect of stress on diabetes

Category

Lifestyle

2

Description

Control group: Control group: teacher, subjects: diabetes, 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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Ansar 8, Payambar Azam Highway, Mashhad

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available