

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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)

##### Phone

+98 58 3272 4459

##### Email address

garshad@Nkums.ac.ir

##### 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

##### Street address

Ansar 8, Payambar Azam Highway, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

36200329

##### Phone

+98 915 120 5545

##### Email

seyedimr3@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bojnourd University of Medical Sciences

##### Full name of responsible person

Amir Ali Ghahremani

##### Street address

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

##### City

bojnurd

##### Province

North Khorasan

##### Postal code

9418636595

##### Phone

+98 58 3151 1420

##### Email

modiriat.pajoheshi@gmail.com

#### 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

**Street address**

Faculty of Nursing, Shahriar Street

**City**

Bojnourd

**Province**

North Khorasan

**Postal code**

9418636595

**Phone**

+98 58 3272 4459

**Email**

Garshsad@NKUMS.ac.ir

## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

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Bojnourd University of Medical Sciences

**Full name of responsible person**

Afsaneh Garshad

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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