Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effect of educational intervention based on Pender's health promotion model on the level of treatment compliance in elderly people with type 2 diabetes referring to health care centers.

Protocol summary

Study aim
Determining the effect of educational intervention based on Pender's health promotion model on the level of treatment compliance in the elderly with type 2 diabetes.

Design
Clinical trial with control group, with parallel groups, without blinding, randomized, on 80 patients, Excel software is used for randomization.

Settings and conduct
First, the samples will be selected from the elderly diabetics of Bojnord with the help of a statistical consultant. If you have consent to participate in the study and meet the entry criteria, you will be registered as part of the study units. Then, the elderly selected by a person outside the study are randomly assigned to two groups using assigned codes. Randomization and random sequence will be determined by a statistician as a block randomization of 4 or 6 using Excel software in the form of A, B. A written informed consent will be obtained from them to participate in the study.

Participants/Inclusion and exclusion criteria
1- Obtain written informed consent 2- Age 60 and above 3- Diagnosing type 2 diabetes by a specialist doctor based on the patient's file and under medical treatment (pills or insulin). 4- At least 6 months have passed since the diagnosis of diabetes 5- The elderly should be able to physically attend classes. 6- The elderly should be aware of the person, time and place. 7- Persistence of diabetes 8- HbA1c level between 6.5 and 8.5

Intervention groups
Ten groups of four people, eight training sessions, each session is 45 minutes, are trained by lectures, film screenings, group discussions, questions and answers, and role playing. The program will be adjusted and implemented based on the variables of Pender's health promotion model and the Iran-American Diabetes Association. 40 people in the control group do not receive the training.

Main outcome variables
Improving the health of Pender Medication compliance Hemoglobin A1c level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221013056162N1**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date
2022-11-02, 1401/08/11

Registrant information

Name
Zahra Salehee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 935 547 1634

Email address
z.salehee@nkums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-01, 1401/08/10

Expected recruitment end date
2022-12-01, 1401/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of educational intervention based on Pender's health promotion model on the level of treatment compliance in elderly people with type 2 diabetes referring to health care centers.

Public title

Investigation of educational intervention on adherence to treatment of diabetic patients.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Obtain written informed consent Age 60 and above Diagnosing type 2 diabetes by a specialist doctor based on the patient's file and under medical treatment (pills or insulin). At least 6 months have passed since the diagnosis of diabetes The elderly should be able to physically attend classes. The elderly should be aware of the person, time and place. Persistence of diabetes HbA1c level between 6.5 and 8.5

Exclusion criteria:

Withdrawal from the study Death of the participant Having another underlying disease mental disorder Patients who, for any reason, cannot attend more than 4 alternating sessions or two consecutive sessions. Having type 1 diabetes Not doing homework Participation in other educational programs

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and random sequence will be determined by a statistician in the form of block randomization of 4 or 6 using Excel software in the form of A, B.

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

Vice President of Research and Information Technology University of Medical Sciences, next to Imam Ali Hospital, Shahryar St., Bojnord

City

BOJNORD

Province

North Khorasan

Postal code

9417694780

Approval date

2022-09-28, 1401/07/06

Ethics committee reference number

4000278

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E10-E14

ICD-10 code description

With other specified complicationsDiabetic arthropathy (M14.2*)Neuropathic diabetic arthropathy (M14.6*).7 With multiple complications.8 With unspecified complications.9 Without complications

Primary outcomes

1

Description

Medication adherence score based on Moriski questionnaire

Timepoint

Measurement of medication adherence before the start of the intervention, immediately after the last training session and three months after the last training session.

Method of measurement

Questionnaire

2

Description

Health promotion score based on Pender health promotion model questionnaire.

Timepoint

The health improvement score is checked at the beginning of the study (before the start of the intervention), after the end of the last training session and three months after the end of the last training session.

Method of measurement
Pender Health Promotion Questionnaire

3

Description
Age according to birth certificate
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

4

Description
gender
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

5

Description
marital status
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

6

Description
Level of education
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

7

Description
Average body mass
Timepoint
The average body mass is checked at the beginning of the study (before the intervention), after the end of the last training session and three months after the end of the last training session.
Method of measurement
Digital meters and scales

8

Description
The amount of monthly income
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

9

Description
place of income
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

10

Description
Employment status
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

11

Description
Living condition
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

12

Description
Drug treatments prescribed by the attending physician
Timepoint
The beginning of the study
Method of measurement
Demographic questionnaire

13

Description
blood pressure
Timepoint
Blood pressure measurement is checked at the beginning of the study (before the intervention), after the end of the last training session and three months after the end of the last training session.
Method of measurement
Mercury sphygmomanometer

Secondary outcomes

1

Description
Glycosylated blood sugar
Timepoint
At the beginning and three months after the study
Method of measurement
blood sample

Intervention groups

1

Description
Intervention group: The first intervention group
Category

Lifestyle

2

Description
Control group: The first control group
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Mrs. Dr. Shakri's diabetes clinic
Full name of responsible person
Dr. Habiba Shakri
Street address
Dr. Hekmati Doctors Building, South Shariati St., Bojnord
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2

Recruitment center
Name of recruitment center
Bojnoord Health Center
Full name of responsible person
Dr. Ibrahim Bazkhane
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Bojnoord Health Center, 19 Chamran St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Vice Chancellor of Research and Information Technology of the University
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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
Zahra salehee
Position
University student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
It is possible to share the entire data.
When the data will become available and for how long
one year later.
To whom data/document is available
All people and especially researchers.
Under which criteria data/document could be used
There are no special conditions.
From where data/document is obtainable
Websites and my phone number. 05832248001
What processes are involved for a request to access data/document
During a written request or visiting the site.
Comments