

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of education based on self-management empowerment model on empowerment level of elderly patients with type 2 diabetes

Protocol summary

Study aim

The purpose of this study was to determine the effect of education based on self-management empowerment model on the ability of elderly people with type 2 diabetes.

Design

Clinical trial with intervention and control group, with parallel groups, random sampling in intervention and control group, sample size 60.

Settings and conduct

The study is an educational / counseling intervention in Mashhad health centers. In the intervention group, the educational package is based on the concepts of self-management empowerment model and in the routine care and routine control group. One blind blind with a lack of expert knowledge of statistics.

Participants/Inclusion and exclusion criteria

Having a 60 year old age, having diabetes for at least 6 months

Intervention groups

The intervention group receive a 12-week Intervention in 5 stages based on self-management empowerment model. The control group receives routine care/

Main outcome variables

The ability of elderly people with type II diabetes

General information

Reason for update

Acronym

EED

IRCT registration information

IRCT registration number: **IRCT20110728007143N5**

Registration date: **2018-05-22, 1397/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-22, 1397/03/01**

Update count: **0**

Registration date

2018-05-22, 1397/03/01

Registrant information

Name

Hamid Chamanzari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1605 8548

Email address

chamanzarih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on self-management empowerment model on empowerment level of elderly patients with type 2 diabetes

Public title

The effect of education based on self-management empowerment model on empowerment level of elderly patients with type 2 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Up 60 age Not having cognitive impairment based on Abbreviated Mental Test The history of type 2 diabetes for at least six months Use of diabetes medications Non-acute complications of diabetes (dialysis and diabetic foot ulcers) Ability to speak Persian Not having severe visual impairment Not having severe hearing impairment

Exclusion criteria:

Acute illness Unwilling to participate in the study

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the research units, randomized assignment was done in two groups by lottery method. In this way, on the same two tabs, the word "intervention and control" is written and the research unit is asked to select one of these two leaves. According to the selection, the research unit is assigned to the intervention and control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data was provided to the statistician without any knowledge of the research units.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

University Street, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

ir.mums.rec.1396.226

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**

The empowerment of diabetes

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Short form diabetes empowerment scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: The intervention group intervenes in self-management empowerment in 5 stages (self-awareness of the level of performance and expectations by the client-the desired goal-setting by the client-planning-intervention-evaluation) based on the model of self-management empowerment. Strategies are provided within one or two full-time 45-minute empowerment sessions. Elders use one-month approaches and the researcher will follow through on the phone. Meanwhile, solutions are provided to the elderly in the form of a booklet in the second session of empowerment for use in a one-month period.

Category

Lifestyle

2**Description**

Control group: During the research, control group will not receive any educational intervention and will receive the usual care and education at the health center. However, after the end of the study (after the end of stage 3), the training booklet is provided to the elderly of the control group Will be placed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Danesh Amooz Center

Full name of responsible person

Shahin Marhamati

Street address

Farhang Square.,Danesh Amooz Blvd.,Vakil Abad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188994864

Phone

+98 51 3893 2322

Email

marhamatish1@mums.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Hashemi Nejad Center

Full name of responsible person

Hashem Hosseini

Street address

Gas crossroads,Tabarsi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

917752365

Phone

+98 51 3273 5905

Email

hoseinih3@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

Street address

University Street,21/5000 Deputy of Research and Technology,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

917751365

Phone

+98 51 3841 1538

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Atiyeh Haddad Alizadeh

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

University Street, Faculty Nursing, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Haddadaa931@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Chamanzari

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery
Street address
University Street, Faculty Nursing, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
ChamanzariH@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Atiyeh Haddad Alizadeh
Position
Graduate Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
University Street, Faculty Nursing, Mashhad, Iran
City
Mashhad

Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
Haddadaa931@mums.ac.ir

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