

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the impact of empowerment program on the quality of life of elderly people with Diabetes type 2

Protocol summary

Study aim

Determining the impact of empowerment training on the quality of life of the elderly with type 2 diabetes

Design

It is a randomized clinical trial with a control group on 90 elderly patients with type 2 diabetes. Blocking of four is used for randomization.

Settings and conduct

The research population includes elderly people with type 2 diabetes who referred to the endocrinology clinic of ValiAsr Hospital in Qaem Shahr city and their disease was confirmed by a specialist doctor, and they have a medical record. Sampling is done in a convenience way. Blinding was done in such a way that the person who gives the questionnaires to the participants and the statistician during the data analysis do not know which is the intervention group and which is the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 60 years Willingness to participate in the study Ability to speak and communicate Obtaining a score of 7-10 according to the short mental test questionnaire (AMT) Obtaining a score of 11-14 according to the Instrumental Activities of Daily Living (IADL) questionnaire Obtaining a score of 15-45 according to the quality of life questionnaire of diabetes patients (DQoL) Exclusion criteria: Having mental illness Participating in courses and educational classes about diabetes in the last 6 months

Intervention groups

Before the intervention, they will complete the diabetic quality of life questionnaire. In addition to the previous treatments, the patients in the intervention group will participate in empowerment sessions. The sessions will last for one month and two sessions per week (8 sessions in total) and each session will last for 45. The method of implementing the empowerment program in this research is based on Anderson's empowerment program, which is implemented through speaking and giving pamphlets.

Main outcome variables

Quality of life of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180609040020N2**

Registration date: **2023-09-12, 1402/06/21**

Registration timing: **retrospective**

Last update: **2023-09-12, 1402/06/21**

Update count: **0**

Registration date

2023-09-12, 1402/06/21

Registrant information

Name

Ali Hesamzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3336 7342

Email address

a.hesamzadeh@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-11, 1399/10/22

Expected recruitment end date

2021-06-12, 1400/03/22

Actual recruitment start date

2022-03-21, 1401/01/01

Actual recruitment end date

2023-02-20, 1401/12/01

Trial completion date

2023-03-11, 1401/12/20

Scientific title

Investigating the impact of empowerment program on the quality of life of elderly people with Diabetes type 2

Public title

Investigating the impact of empowerment program on the quality of life of elderly people with Diabetes type 2

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years Willingness to participate in the study Ability to speak and communicate Being under the care and treatment of a doctor or a medical group Obtaining a score of 7-10 according to the short mental test questionnaire (AMT) Obtaining a score of 11-14 according to the Instrumental Activities of Daily Living (IADL) questionnaire Obtaining a score of 15-45 according to the quality of life questionnaire of diabetes patients (DQoL)

Exclusion criteria:

Having mental illness Participating in courses and educational classes about diabetes in the last 6 months

Age

From **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the samples will be placed randomly in blocks (of 4) in two control and test groups (45 people in each group). For random assignment, it will be done in such a way that each group is considered to be 4 states and therefore 6 different states can be occur: AABB-ABAB-ABBA-BAAB-BABA-BBAA. The number of people in each group is equal and this work is repeated for 90 patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

The intervention group and the control group are marked with the letters A and B, and the person who gives the questionnaires to the participants and the statistician during the data analysis do not know which is the test group and which is the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee of Mazandaran University of Medical Sciences

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Deputy of Research and Technology Building, Moalem Sq., Moalem Blvd.

City

Sari

Province

Mazandaran

Postal code

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Approval date

2020-08-26, 1399/06/05

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.057

Health conditions studied**1****Description of health condition studied**

Low quality of life of the elderly with diabetes

ICD-10 code

Z72

ICD-10 code description

Problems related to lifestyle

Primary outcomes**1****Description**

Quality of life score of patients with diabetes

Timepoint

Measuring the quality of life of patients with diabetes at the beginning of the study and 60 days after the intervention

Method of measurement

Quality of life questionnaire for patients with diabetes

Secondary outcomes

empty

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

Intervention group: Before the intervention, they will complete the diabetic quality of life questionnaire. In addition to the previous treatments, the patients in the

intervention group will participate in empowerment sessions. The sessions will last for one month and two sessions per week (8 sessions in total) and each session will last for 45. The method of implementing the empowerment program in this research is based on Anderson's empowerment program, which is implemented through speaking and giving pamphlets.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital of Qaemshahr

Full name of responsible person

Ali Hesamzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of
Mazandaran University of Medical Sciences

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Hesamzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To conduct meta-analysis research

From where data/document is obtainable

Correspondence with email address:

a.hesamzadeh@mazums.ac.ir

What processes are involved for a request to access data/document

Investigating the possibility of implementing the request by the responsible researcher and sending the document within less than a month

Comments