

# 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)

##### Phone

+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

**Street address**

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

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**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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Sari St.

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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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

Assiatant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**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**

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**Street address**

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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**