

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of of self-management program based on 5A model on self efficacy and quality of life in the elderly patients with diabetic mellitus

Protocol summary

Study aim

The effect of self-management programs based on 5A model on self efficacy and quality of life in the elderly patients with diabetic mellitus

Design

Samples will be chosen from the patients admitted to Razi hospital affiliated with Mazandaran University of Medical Sciences. In this randomized controlled clinical trial, 90 patients will be randomly assigned to the experimental and control groups. The research is single blinded.

Settings and conduct

This study will be done in diabetic clinic of Razi hospital affiliated with Mazandaran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria included: the desire to participate in the study; age over 60 years old; history of diabetes mellitus at least one year; listening and speaking ability for the relationship; the absence of cognitive impairment; ability to perform daily activities independently; ability of reading and writing; lack of malignant diseases, kidney failure, thyroid disorders, psychiatric disorders; the absence of severe crises in the last three months. Exclusion criteria included: unwillingness to cooperate; exposure to extreme crisis situations; hospitalization during the study; absence more than two sessions.

Intervention groups

In the test group: this group will be educated based on 5A self-management model through giving lecture, question and answer and group discussion. The self-management program performs for each patient in 5 steps during 6 weeks. In the control group no intervention will be done for the patients.

Main outcome variables

In both groups, self-efficacy and quality of life are measured before, immediately after intervention and 4 weeks after intervention. It is measured

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N19**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

Registration date

2018-10-22, 1397/07/30

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of of self-management program based on 5A model on self efficacy and quality of life in the elderly patients with diabetic mellitus

Public title

The effect of of self-management program on elderly patients with diabetic mellitus

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

the desire to participate in the study; age over 60 years old; history of diabetes mellitus at least one year; listening and speaking ability for the relationship ; the absence of cognitive impairment; ability to perform daily activities independently; ability of reading and writing; lack of malignant diseases, kidney failure, thyroid disorders, psychiatric disorders; the absence of severe mental health crises in the last three months.

Exclusion criteria:

unwillingness to cooperate; exposure to extreme crisis situations; hospitalization during the study; absence more than two sessions

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned into two groups using permuted block randomization. Random allocation sequence will be determined using the numbers table. Opaque sealed sequentially numbered envelopes from number 1 to 90 will be used for allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyzer and data collector will be blind of the allocation of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Eligible patients will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 2:2. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 90

will be used for allocation concealment.

Secondary Ids

empty

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

Ethics committee of Shahed University

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.SHAHED.REC.1397.051

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

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

self-efficacy

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

self-efficacy scale

Secondary outcomes**1****Description**

quality of life

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Lipad Questionnaire

2

Description

self-efficacy

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

self-efficacy scale

3

Description

Mental status

Timepoint

Before intervention

Method of measurement

Abbreviated Mental Test Score

4

Description

Activity Daily Living

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Activity Daily Living Scale

5

Description

self-efficacy for managing chronic disease

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

self-efficacy for managing chronic disease questionnaire

6

Description

Diabetes Management Self -Efficacy

Timepoint

before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Diabetes Management Self -Efficacy Scale

Intervention groups

1

Description

Intervention group: Educational sessions will be held in elderly people with diabetes in 5 steps during 6 weeks and each session will be 45-60 minutes. Based on the training, the A-5- self-management program will be taught with the help of family members for possible and actual problems.

Category

Lifestyle

2

Description

Control group: Apart from routine interventions, no other intervention will be received. At parallel intervals, self-efficacy and quality of life will be measured with the test group. The questionnaires will be completed and recorded at three levels before and after the intervention and then 4 weeks after the intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Maedeh Sadeghigolafshanl

Street address

Razi hospital, Reza St, Ghaemshahr

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Ghaemshahr

Province

Mazandaran

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4765686743

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+98 11 4331 8018

Email

razi-ghh@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Vice chancellor for research, Shahed University, Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

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Kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
Nahid Rejeh
Position
Associate Professor
Latest degree
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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

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