Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of self-care education on the quality of life of old women with type2 diabetes

Protocol summary

Study aim
Determining the effect of self-care training on the quality of life of elderly women with type 2 diabetes covered by health care centers of Shahid Beheshti University of Medical Sciences.

Design
Two stages before and after in two intervention and control groups, sampling by cluster method, sample size: 52 people in each group (total: 104 people), selection of 3 clusters and random selection from each center, 2 comprehensive health service centers

Settings and conduct
Explaining the objectives and duration of the study to the participants Self-care training in 7 sessions for 30 to 60 minutes for 2 months Educational materials include: general self-care, exercise and nutrition, mental health, foot care Location: comprehensive health service centers

Participants/Inclusion and exclusion criteria
Entry requirements: female gender, suffering from type 2 diabetes, having basic literacy, having a health record in the Sib system Exit conditions: immigration, death, hospitalization

Intervention groups
Providing diabetes self-care education to the intervention group Failure to provide diabetes self-care education to the control group

Main outcome variables
Quality of life of elderly women with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230305057625N1**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **retrospective**
Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date
2023-05-20, 1402/02/30

Registrant information

Name
Fatemeh sadat Nekoee Avanjee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2260 9140

Email address
nekoee1376@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-31, 1401/11/11

Expected recruitment end date
2023-05-01, 1402/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-care education on the quality of life of old women with type2 diabetes

Public title
The effect of self-care education on the quality of life of old women with type2

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The gender of the person is female. A person with type 2 diabetes. The person's age should be 60 years or older. The person has basic literacy. The person has a health record in the Sib system. A person does not suffer from severe diseases and disabilities such as blindness, amputation, heart, respiratory, brain, and kidney problems which need to be dialyzed. The person wants to participate in the study.

Exclusion criteria:

The person is blind. A person with heart disease. The person has a respiratory disease. The person has a brain disease. A person with kidney disease leading to dialysis. The person has an amputation.

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Faculty of Health and Neurosciences Shahid Beheshti University of Medical Scienc

Street address

no. 5,Zohreh Alley, Bijanpur Alley,kadoee street, Qolhak

City

Tehran

Province

Tehran

Postal code

1916767711

Approval date

2023-01-03, 1401/10/13

Ethics committee reference number

IR.SBMU.PHNS.REC.1401.111

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

Quality of Life

Timepoint

before the intervention and one month after the intervention

Method of measurement

Lipad quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1, providing self-care education in the field of diabetes in 7 sessions, each session for 30 to 45 minutes, including topics, general and special care, importance and prevalence of diabetes in the elderly, symptoms and complications of diabetes, exercise and nutrition, foot care, consumption Medicine, mental health

Category

Lifestyle

2

Description

The first control group: not providing self-care training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dokmeh chee comprehensive health service center

Full name of responsible person

Fatemeh sadat Nekoee

Street address

Kerman St

City

Tehran

Province

Tehran
Postal code
1634754691
Phone
+98 21 2252 5140
Email
nekoee1376@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Taleghani comprehensive health service center
Full name of responsible person
Fatemeh Sadat Nekoee
Street address
Dezashib St
City
Tehran
Province
Tehran
Postal code
1935617351
Phone
+98 21 2275 8689
Email
nekoee1376@sbmu.ac.ir

3

Recruitment center
Name of recruitment center
Salavati Comprehensive Health Service Center
Full name of responsible person
Fatemeh sadat Nekoee
Street address
Piroozi street
City
Tehran
Province
Tehran
Postal code
000000000
Phone
+98 21 7742 8070
Email
nekoee1376@sbmu.ac.ir

4

Recruitment center
Name of recruitment center
Chizar comprehensive health service center
Full name of responsible person
Fatemeh sadat Nekoee
Street address
Chizar
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 2221 9085
Email
nekoee1376@sbmu.ac.ir

5

Recruitment center
Name of recruitment center
Ahmadi comprehensive health service center
Full name of responsible person
Fatemeh Sadat Nekoee
Street address
Damavand St
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 7758 3367
Email
nekoee1376@sbmu.ac.ir

6

Recruitment center
Name of recruitment center
Jafari Comprehensive Health Service Center
Full name of responsible person
Fatemeh Sadat Nekoee
Street address
17 Shahrivar St
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 3313 1812
Email
nekoee1376@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Student Blvd , Shahid Beheshti University of Medical Sciences, Faculty of Health and Safety
City
Tehran
Province
Tehran
Postal code

1983535511
Phone
+98 21 2243 1993
Email
mkarami@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
This plan has no financial support
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fatemeh Sadat Nekoee
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Geriatrics
Street address
No.5,Zohreh Alley, bijanpour st, kadooee st,Qolhak
City
Tehran
Province
Tehran
Postal code
1916767711
Phone
+98 21 2260 9140
Email
nekoee1376@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Ramezankhi
Position
Professor, faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
ولنجک، بلوار دانشجو، دانشکده بهداشت و ایمنی
City
Tehran
Province
Tehran
Postal code
1985717444
Phone
+98 21 2243 2040
Email
dr.aliramezankhani@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fatemeh Sadat Nekoee
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Geriatrics
Street address
No.5,Alley Zohreh, bijjanpour St, Kadoee St, Qolhak
City
Tehran
Province
Tehran
Postal code
1916767711
Phone
+98 21 2260 9140
Email
nekoee1376@sbmu.ac.ir

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
The data that can be published from this study include the following: patient age, education, employment status, life status, level of quality of life before and after the intervention, level of anxiety and depression before

and after the intervention, level of changes in self-care scores before and after From the intervention, the amount of changes in life satisfaction scores before and after the intervention, the amount of changes in life status scores before and after the intervention

When the data will become available and for how long

The access period will start 6 months after the project results are published in the form of an article.

To whom data/document is available

The data obtained from this study will be available to researchers who intend to design a similar study.

Under which criteria data/document could be used

It is possible to use the data to evaluate the effectiveness of self-care training and conduct analyzes that compare the average of the variables.

From where data/document is obtainable

Researchers can contact the person in charge of data collection through the following email to get the data:nekoee1376@sbmu.ac.ir

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

The applicant must first submit the proposal and the code of ethics of the project that he intends to implement to the person in charge of collecting the project, and after the review by the project executive team, the information will be provided to him within a period of one month.

Comments