Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of comprehensive empowerment program on age-related outcomes in older patients with diabetes

Protocol summary

Study aim
Determining the effect of comprehensive empowerment program on age-related outcomes in older patients with diabetes.

Design
A clinical trial, single-blinded, with a control group, of 40 participants in each group, blocking will be implemented for randomization.

Settings and conduct
The research environment consists of medical and endocrinology wards and endocrinology and metabolic clinics in educational and medical centers affiliated with Shahid Beheshti University of Medical Sciences and other centers and forums out of the mentioned settings. After introducing the researcher, and the aim of the study to the eligible participants and taking informed consent from them in the research environment, available sampling will be implemented. After selection, they will be randomly divided into intervention and control groups. The Analyser will be blinded to the control and intervention group by giving unidentified codes to each control and intervention group.

Participants/Inclusion and exclusion criteria
Being diagnosed of diabetes for at least one year. Being able to speak Farsi. Being 65 years old and more Mark 5 or more on the constipation assessment scale The older adult or his/her crucial caregiver can access and use electronic devices to connect to the web, watch videos and read text.

Intervention groups
The intervention group will receive the empowerment program which consists of the physical aspect (knowing about the disease, monitoring signs and symptoms, constipation management, and the importance of compliance to the therapy), psycho-social aspect (stress management and relaxation methods), and spiritual aspect.

Main outcome variables
Constipation; blood pressure; glycosylated hemoglobin; active aging; poly-pharmacy; health costs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220314054282N1**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**
Update count: **0**

Registration date
2022-12-19, 1401/09/28

Registrant information

Name
Amin Mohammadi Nochaman

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3264 0707

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aminmohammadi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of comprehensive empowerment program on age-related outcomes in older patients with diabetes

Public title
comprehensive empowerment program in older patients with diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being diagnosed of diabetes for at least one year. Being able to speak Farsi. Being 65 years old and more Mark 5 or more in constipation assessment scale The older adult or his/her key caregiver has access and ability to use electronic devices for connecting to the web, watching video and reading text.

Exclusion criteria:
Affliction of covid-19 during the in-person sessions, mental health or cognitive disorders Participation in similar empowerment programs Being in the acute and emergency conditions like keto-acidosis, and life-threatening hyperglycemic attacks Not being able to continue the participation (death, intensive care needs, immigrations) Not participating in all sessions or even alternative/compensatory sessions

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be randomly assigned to the intervention and control groups by blocking; selecting subjects will be from person to person. For allocation concealment, each control and intervention group will be given a letter (A and B), and blocks will be put into the non-transparent envelopes after production; then, the first subject will be asked to pick an envelope; the first letter will demonstrate the group of the mentioned subject and the other letters in this block will show the order of following subjects. After finishing this block, the next subject will be asked to pick an envelope, and the assignment will be implemented in this manner till the sampling is completed.

Blinding (investigator's opinion)
Single blinded

Blinding description
the information given to the analyser will be in codes which compliment the classification to the intervention and control groups and the subjects themselves.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

Street address
Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-10-25, 1401/08/03

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.162

Health conditions studied

1

Description of health condition studied
Being diagnosed of diabetes type 2 for at least one year.

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

2

Description of health condition studied
Being 65 years old and more

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Mark 5 or more in constipation assessment scale

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Glycemic control
Timepoint
At first and then 3 months later
Method of measurement
Will be determined by draining 2-3 cc blood and measuring glycosylated hemoglobin at first and then 3 months later.

2

Description
Constipation
Timepoint
Measuring at the beginning, one month after starting the study and 3 months after starting the study
Method of measurement
Utilizing constipation assessment scale

3

Description
Polypharmacy
Timepoint
Measuring at the beginning, one month after starting the study and 3 months after starting the study
Method of measurement
Utilizing Screening Tool of Older persons' potentially inappropriate prescriptions (STOPP) Version 2

4

Description
Active aging
Timepoint
Measuring at the beginning, one month after starting the study and 3 months after starting the study
Method of measurement
Active Aging Measurement Instrument

5

Description
Health costs
Timepoint
Measuring at the beginning, one month after starting the study and 3 months after starting the study
Method of measurement
Researcher-made questionnaire

6

Description
Blood pressure
Timepoint
Measuring at the beginning, one month after starting the study and 3 months after starting the study
Method of measurement
Using manual blood pressure measurement instrument under TRUE consortium standards

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will comprehensive empowerment program besides routine care. The comprehensive empowerment program will be implemented in the physical aspect (introduction to the disease, monitoring the signs and symptoms, constipation management, and the importance of therapeutic adherence), psycho-social aspect (stress management and relaxation methods), and spiritual aspect (promotion of hope and focusing on the strengths and recommendation of coping strategies and personal meaning of the subject in life). The empowerment sessions will be in-person, 30 to 60 minutes (as needed), in groups of a few. They will be held in an environment with suitable ventilation and considering health protocols. The number of sessions and the context will be determined, edited, and validated under the suggestion of consultants who are specialists in the mentioned aspects and empowerment. Participants will be followed up by means of a phone call between sessions to be answered if there is any question or ambiguity. The presence of a key family caregiver will be necessary for some sessions so the family caregiver will be asked if there is any question or ambiguity.
Category
Other

2

Description
Control group: will receive routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Mohammad Reza Haji Esmaeili
Street address
Southern Kargar Ave., Lashgar inter-section, Makhsoos St. Tehran.
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Postal code
13333635445
Phone
+98 21 5102 5000
Email

loghman.hospital@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
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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19839-63113
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+98 21 2243 9770
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info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Marzieh Pazokian
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is 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

Title and more details about the data/document

Not decided yet.

When the data will become available and for how long

Not decided yet.

To whom data/document is available

Not decided yet.

Under which criteria data/document could be used

Not decided yet.

From where data/document is obtainable

Not decided yet.

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

Not decided yet.

Comments