Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of acceptance and commitment therapy on diabetes management self-efficacy and psychological well-being in elderly people with diabetes:a randomized controlled clinical trial

Protocol summary

Study aim
Determining the effect of acceptance and commitment therapy on diabetes management self-efficacy and psychological well-being in elderly people with diabetes

Design
This study is a randomized clinical trial without blinding.

Settings and conduct
This study is a randomized clinical trial without blinding that will be conducted at the diabetes clinic at Vali Asr Hospital, Fasa University of Medical Sciences.

Participants/Inclusion and exclusion criteria
This study will enroll 60 elderly patients with diabetes. Inclusion criteria include willingness to participate in the study, age over 65 years, ability to attend educational sessions, literacy, and diagnosis and confirmation of diabetes by an endocrinologist. Exclusion criteria will include perceptual and cognitive impairments.

Intervention groups
The educational intervention program will be implemented in 6 sessions of 90 minutes each, two days a week for 3 weeks. The educational sessions will use lecture, group discussion, question and answer, and brainstorming methods. The educational sessions include the first session of introduction and training on acceptance and commitment therapy, the second session of creating flexible patterns of behavior through value-based exposure, the third session of moving towards a valuable life with an accepting and observant self, the fourth session of strategies for responding to intrusive and stressful thoughts, the fifth session of self-awareness and self-control behaviors, and the sixth session of setting goals based on values and taking effective actions to achieve those goals and stay on the path of values.

Main outcome variables
Diabetes management self-efficacy and Psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190917044802N13**
Registration date: **2025-09-07, 1404/06/16**
Registration timing: **prospective**

Last update: **2025-09-07, 1404/06/16**
Update count: **0**

Registration date
2025-09-07, 1404/06/16

Registrant information

Name
Mostafa Bijani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5331 5012

Email address
bizhani_mostafa@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of acceptance and commitment therapy on diabetes management self-efficacy and psychological well-being in elderly people with diabetes:a randomized controlled clinical trial

Public title
Investigating the effect of acceptance and commitment therapy on psychological well-being and management self-efficacy in elderly people with diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being over 65 years old Ability to participate in training sessions Being literate in reading and writing Diagnosing and confirming diabetes with an endocrinologist Willingness to participate in the study

Exclusion criteria:
Having perceptual and cognitive disorders

Age
To **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
60 cards are placed in a sealed envelope. 30 cards are put on stickers (A intervention group) and labels are placed on other 30 cards (B control group). Then the patients participating in the study are asked to take one of the cards. People who take card A will be in the intervention group and people who take card B will be in the control group.

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 Fasa University of Medical Sciences

Street address
Fars Province. Fasa City. Ibn Sina Square

City
Fasa

Province
Fars

Postal code
7461686688

Approval date
2025-08-04, 1404/05/13

Ethics committee reference number
IR.FUMS.REC.1404.117

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Diabetes management self-efficacy

Timepoint
Before, immediately and three months after training

Method of measurement
Diabetes Management Self-Efficacy Questionnaire by Bijl et al.

2

Description
Psychological well-being

Timepoint
Before, immediately and three months after training

Method of measurement
Psychological Well-Being Questionnaire by Riff et al.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The educational program will be implemented in the form of 6 sessions of 90 minutes each session and two days a week for 3 weeks. Lectures, group discussions, questions and answers, and brainstorming methods are used in the training sessions by a psychologist who has already completed the training course. In this research, the general treatment guide based on acceptance and commitment will be used. Acceptance and commitment therapy is a

psychotherapy technique that promotes acceptance of negative thoughts, feelings, and events. In fact, this psychotherapy technique encourages a person to consciously participate in activities. The training sessions include the first session of familiarization and training regarding treatment based on acceptance and commitment, the second session of creating flexible patterns of behavior through value-oriented encounter, the third session of moving towards a valuable life with an accepting and observant self, the fourth session of ways to respond to thoughts Disturbing and stressful, the fifth session is self-awareness and self-control behaviors, the sixth session is setting goals based on values and taking effective measures to achieve those goals and stay on the path of values.

Category

Lifestyle

2

Description

Control group: The control group will only receive the educational package and will not receive the educational intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Clinic
Full name of responsible person
Mostafa Bijani
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461686688
Phone
+98 917 330 8451
Email
bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Mojtaba Farjam
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461686688
Phone
+98 917 330 8451
Email
farjam@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Mostafa Bijani
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7461686688
Phone
+98 71 5334 2311
Email
bizhani_mostafa@yahoo.con

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Mostafa Bijani
Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ibn Sina Square

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5334 2311

Email

bizhani_mostafa@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Faculty member

Latest degree

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Email

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All the questionnaires used in this study as well as the content of the training program will be provided to the applicants.

When the data will become available and for how long

The time period for accessing the data is after the publication of the article extracted from the study and there is no time limit.

To whom data/document is available

Researchers, nursing managers, and hospital management can send their requests for using the results of this study to the corresponding author, Mostafa Bijani, in writing. Phone number 09173308451 Email bizhani_mostafa@yahoo.com

Under which criteria data/document could be used

Nursing managers can use the results of this study to develop educational programs for elderly patients with diabetes as well as their families.

From where data/document is obtainable

Researchers, nursing managers, and hospital management can send their requests for using the results of this study to the corresponding author, Mostafa Bijani, in writing. Phone number 09173308451 Email bizhani_mostafa@yahoo.com

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

Sending the request for the use of research documents and results to the responsible author and sending the results by the responsible author to the requesting person Tell: 09173308451 Email:bizhani_mostafa@yahoo.com

Comments