

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

To assess the effectiveness of the education based on the Idea application on the self-care behaviors of the elderly with type 2 diabetes

Protocol summary

Study aim

To determine the effectiveness of training based on Idea software on self-care behaviors of the elderly with type 2 diabetes

Design

A clinical trial with a control group and a parallel group will be randomized on 102 patients. A lottery method will be used for randomization.

Settings and conduct

The research community will be composed of elderly people with type 2 diabetes referred to Mustafavian Diabetes Clinic in Sari. Idea software will be installed on the mobile phones of participants in the intervention group. People in the intervention group will manually record diabetes self-care data on the software and receive and implement lifestyle recommendations for better diabetes self-care for one month through it.

Participants/Inclusion and exclusion criteria

Age 60 years and above Ability to communicate Having a normal cognitive status based on the cognitive status assessment tool (AMT) (scoring 7 and above) Informed consent of the patient to participate in the study Access to a smart mobile phone and the ability to work with it Internet access Literacy for reading and writing Not using care software before entering the study Diagnosed with diabetes by a doctor who has been diagnosed for at least 6 months

Intervention groups

Intervention group: installing Idea software, recording data related to diabetes self-care (nutritional information, blood sugar recording, insulin and medication recording, physical activity recording, emotion recording) manually on Idea software and receiving related trainings To self-care diabetes through the software for a month. Control group: They will receive all the recommendations in a printed file when they enter the study, but no interactive training such as question and answer will be given to them.

Main outcome variables

Self-care of diabetic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034454N5**

Registration date: **2023-08-15, 1402/05/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-15, 1402/05/24**

Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name

Ehteram Sadat Ilali

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.arab1388@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To assess the effectiveness of the education based on the Idia application on the self-care behaviors of the elderly with type 2 diabetes

Public title

Mobile phone-based self-care in diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 years and above Ability to communicate Having a normal cognitive status based on the cognitive status assessment tool (AMT) (scoring 7 and above) Informed consent of the patient to participate in the study Access to a smart mobile phone and the ability to work with it Internet access Literacy for reading and writing Diagnosed with diabetes by a doctor who has been diagnosed for at least 6 months

Exclusion criteria:

using care software before entering the study Unwillingness to participate in the study

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomly assigned into two intervention and control groups. Based on this, all people are numbered from 1 to 102. Then 51 cards with white color and 51 cards with red color without numbers are prepared and placed in a container. Then, one card for each person is randomly selected from the container and assigned to each number. If the color of the card is red, the person is assigned to the intervention group, and if it is white, the person is assigned to 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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences (Vice chancellor for research), Moallem Square

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.MAZUMS.REC.1402.193

Health conditions studied

1

Description of health condition studied

diabetic

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Self-care score in the Summary of Diabetes Self Care Activities questionnaire

Timepoint

Measuring the self-care score at the beginning of the study (before the start of the intervention) and 1 and 3 months after the start of the intervention

Method of measurement

Summary of Diabetes Self Care Activities questionnaire

Secondary outcomes

1

Description

HbA1c

Timepoint

At the beginning of the study (before the start of the intervention) and 1 and 3 months after the start of the intervention

Method of measurement

It will be measured by Tobi Sari laboratory kits

2

Description

fasting blood sugar

Timepoint

At the beginning of the study (before the start of the intervention) and 1 and 3 months after the start of the intervention

Method of measurement

Glucometer brand DIABAN and model SMM1000 made in Iran

Intervention groups

1

Description

Intervention group: After selecting the participants of the intervention group, they are invited to visit the Mustafavian diabetes clinic in Sari. In this meeting, the researcher will first introduce himself, explain the objectives of the study and obtain written informed consent. Then the desired questionnaires are completed with the help of the researcher. FBS and HbA1c tests will be taken from patients. At the end of the session, Idea software is installed for the participants of the intervention group and its performance is controlled on the phone, and with the cooperation of the patient, how to use and use it by an experienced expert (with education and experience in the field of planning and development) It will be given. If possible, it is suggested to the participants of the intervention group that a family member accompanies them in face-to-face and non-face-to-face training sessions to facilitate the process of working with Idea software. Also, along with the installed program, a pamphlet will be presented to the users, which is a guide for using the program, and it will be explained to the participants that whenever they encounter a problem during the intervention period, they can contact the researcher (a number that is available 24 hours a day). It is provided to the elderly to answer their questions. This software will allow patients to manually record diabetes self-care data (nutritional information, blood sugar records, insulin and medication records, physical activity records, emotion records) on the mobile phone, and trainings Receive information related to diabetes self-care through the software. Also, once a week, along with measuring blood sugar by the researcher, the weight of the patients will be measured using a scale and recorded in the program. The training of the participants in the intervention group will be in the form of two sessions in person and 8 sessions in person. It will be held twice a week (Mondays and Wednesdays) in the period of 15-18 on the chat page of the Idea program as a group. In this way, the educational content in the form of PDF, the recorded voice of the researcher and the educational video will be sent to the participants at 15:00 and they are requested to read the content. The researcher will have access to all the information recorded by the participants through the Idea software database and will be informed indirectly about the treatment plan and lifestyle of the patients. Also, the researcher will follow up the participants during their

participation in the training sessions.

Category

Lifestyle

2

Description

Control group: After selecting the participants of the control group, they are invited to visit the Mustafavian diabetes clinic in Sari. In this meeting, the researcher will first introduce himself, explain the objectives of the study and obtain written informed consent. Then the desired questionnaires are completed with the help of the researcher. FBS and HbA1c tests will be taken from patients. At the end of the session, they will receive all the recommendations related to diabetes self-care in the form of a printed file. But no interactive training such as question and answer is given to them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafavian Diabetes Center

Full name of responsible person

Akbardokht

Street address

Mostafavian Diabetes Center, Razi St., Amir Mazandarani St., Tabarsi District, Sari

City

Sari

Province

Mazandaran

Postal code

4849112348131

Phone

+98 11 3336 2011

Email

atefeesmailpour75@gmail.com

Web page address

https://balad.ir/p/%DA%A9%D9%84%DB%8C%D9%86%DB%8C%DA%A9-%D9%81%D9%88%D9%82-%D8%AA%D8%AE%D8%B5%D8%B5%DB%8C-%D9%85%D8%B5%D8%B7%D9%81%D9%88%DB%8C%D8%A7%D9%86-sari_medical-clinic-2FT8Aqu71DDhpc#15/36.56505/53.05468

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Research Vice-President of Mazandaran University of

Medical Sciences, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3448 4874

Fax

Email

jmums@mazums.ac.ir

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

Ehteram Sadat Ilali

Position

Associate Professor, Ph.D in Gerontology, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nasibe Nursing and Midwifery School, Vesal Street

City

Sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3329 4601

Email

paradis2082000@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Shahab Papi

Position

Assistant Professor, Ph.D in Gerontology, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nasibe Nursing and Midwifery School, Vesal street

City

Sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3336 7374

Email

Shahabpapi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Atefe Esmailpour

Position

Master Student, Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nasibe Nursing and Midwifery School, Vesal Street

City

Sari

Province

Mazandaran

Postal code

4814857137

Phone

+98 11 3339 0160

Email

atefeesmailpour75@gmail.com

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