

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the impact of a DSME (diabetes self-management education) web-application on self-management, quality of life and glycemic indicators in patients with type 2 diabetes

Protocol summary

Study aim

Evaluating the impact of a DSME (diabetes self-management education) web-application on self-management, quality of life and glycemic indicators in patients with type 2 diabetes

Design

Clinical trial with parallel groups, without blinding, randomized, on 60 patients, random permutation block method was used for randomization.

Settings and conduct

60 patients with diabetes referring to educational pharmacies and, if necessary, diabetes clinics affiliated to Isfahan University of Medical Sciences, who have been diagnosed with type 2 diabetes, will be included in the study (based on the inclusion and exclusion criteria of the study). After entering the study and randomly allocating patients into two intervention and control groups, the patients in the intervention group are followed up using an educational intervention program including the use of a web-based application for diabetes self-management, and no educational intervention in the control group patients. It will not be done and they use the usual care and recommendations.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes patients Willing to participate in the study and sign the informed consent form Patients who have at least high school education and have access to personal smart phones and the Internet to use the DSME web-application

Intervention groups

Intervention group: use of a DSME (diabetes self-management education) web-application Control group: No intervention

Main outcome variables

Self-efficacy score in diabetic patients quality of life score Hemoglobin A1C percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N11**

Registration date: **2024-11-02, 1403/08/12**

Registration timing: **prospective**

Last update: **2024-11-02, 1403/08/12**

Update count: **0**

Registration date

2024-11-02, 1403/08/12

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the impact of a DSME (diabetes self-management education) web-application on self-management, quality of life and glycemic indicators in patients with type 2 diabetes

Public title

Evaluating the effect of DSME (diabetes self-management education) web-application in diabetes self-management

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes Patients who have at least high school education and have access to personal smart phones and the Internet to use the DSME web-application

Exclusion criteria:

Patients not willing to participate in the study and do not sign the informed consent form

Age

From 18 years old 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 patients are selected among the patients who are eligible to enter the study and have consented to participate in the study, and then they are randomly allocated in two groups of 30 people using random permutation blocks with size 2, 4 and 6. The randomization process of assigning patients to study groups will be done using a random list created by the software with an allocation ratio of 1:1 in the block. The random order that is created in the blocks with the relevant software will be written on cards and placed inside sealed envelopes. Then envelopes are assigned to each patient in the order of entering the study and the relevant intervention is carried out.

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

Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Scien

Street address

Isfahan University of Medical Sciences, Hazar Jarib Avenue.

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Postal code

8174673461

Approval date

2024-04-16, 1403/01/28

Ethics committee reference number

IR.MUI.PHANUT.REC.1403.010

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

Self-efficacy score in diabetic patients

Timepoint

At the beginning of the study and after the end of the study

Method of measurement

The questionnaire of Fapa et al

2

Description

quality of life score

Timepoint

At the beginning of the study and after the end of the study

Method of measurement

Questionnaire of Brooks et al

3

Description

Hemoglobin A1C percentage

Timepoint

At the beginning of the study and after the end of the study

Method of measurement

Laboratory test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Training based on a web application containing principles of self-care for diabetes (weight control and associated diseases), pharmacologic and non-pharmacologic measures for diabetes control, blood sugar and other laboratory tests monitoring

Category

Behavior

2**Description**

Control group: No intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

AL Zahra hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Web page address**Person responsible for scientific inquiries****Contact**

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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

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Pharm. D., BCPS / Academic member (associate professor)

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