

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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		Ethics committees	
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
		<u>1</u> 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. City Isfahan Province Isfahan Postal code 8174673461 Approval date 2024-04-16, 1403/01/28 Ethics committee reference number IR.MUI.PHANUT.REC.1403.010	
		Health conditions studied <u>1</u> Description of health condition studied type 2 diabetes mellitus ICD-10 code E11 ICD-10 code description Type 2 diabetes mellitus	
		Primary outcomes <u>1</u> 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	
		<u>2</u> 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	
		<u>3</u> 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

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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

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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**

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Full name of responsible person

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Position

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