Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 fot 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

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Shadi Farsaei

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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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
Shadi Farsaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Esfahan University of Medical Sciences
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associate professor
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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