

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of web-based education on self-management and HbA1C in type 2 diabetic patients, discharged from Alzahra hospital in Isfahan in 2020

Protocol summary

Study aim

The effect of web-based education on self-management and HbA1C in type 2 diabetic patients, discharged from Alzahra hospital in Isfahan in 2020

Design

Clinical trial with test and control group, Random allocation

Settings and conduct

The study is being conducted at Alzahra Hospital, Isfahan, for all patients with type 2 diabetes discharged in 2019 who meet the inclusion criteria. First of all, we list people who meet the inclusion criteria. We will then ask for their consent to participate in the program by telephone and will list those who have consented. The samples will be randomly assigned. The test group is introduced to the training website and observed throughout the course. At the end of the training period and three months later, both groups will be re-examined with self-management questionnaire and HbA1C test.

Participants/Inclusion and exclusion criteria

Diagnosed with type 2 diabetes; Having a smartphone and a caregiver at home; Exclusion criteria: Lack of chronic and advanced diabetes complications; Lack of mental retardation or psychological disorders.

Intervention groups

Intervention group: In the intervention group, at first, a how to use website guidance pamphlet and a card containing username and password to login the website will be given. In the next step, patients could watch the Health Promotion Model constructs-based training course on the website in a two week period. In addition, at the end of the training program up to 3 months after, will receive reminder messages to encourage to view the educational content uploaded on the website once a week via SMS. Evaluating will be done through questionnaire before the intervention, two weeks and 3 months after intervention

Main outcome variables

Web-based educational intervention is an independent variable and self-management and HbA1C are dependent variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044449N1**
Registration date: **2021-01-19, 1399/10/30**
Registration timing: **retrospective**

Last update: **2021-01-19, 1399/10/30**

Update count: **0**

Registration date

2021-01-19, 1399/10/30

Registrant information

Name

Maryamsadat Shahshahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7585

Email address

shahshahani@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of web-based education on self-management and HbA1C in type 2 diabetic patients, discharged from Alzahra hospital in Isfahan in 2020

Public title
The effect of web-based educational intervention on self-management in type diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Patients should be type 2 diabetics diagnosed at least one year before the research according to a physician. They should be Persian. The patient and his/her primary caregiver should be able to use the smart phone and have the application installed. They should have attended at least one session in the patient education program at Al-Zahra Hospital. Have an interest and informed consent to participate in the program. Having a glucometer at home.
Exclusion criteria:
Diagnosed with type 1 diabetes Experiencing chronic and advanced diabetes complications such as: nephropathy, proliferative retinopathy, amputation Mental retardation, or diagnosis of psychological disorders before diabetes diagnosis or having a severe psychological disorder after diabetes diagnosis Patients with long-term diabetes and no caregivers.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects who were registered in the statistics office of Al-Zahra Health Education Office in 1398-99 will be selected in the initial list, then we will telephone call and explain the objectives of the study units with the main caregiver (support person). after that, The units will invitations and informed consent form and pre-test questionnaire and completed then they will be divided into two groups of test and control using randomization software (Random Allocation Software Version 1.0, May 2004).

Blinding (investigator's opinion)
Single blinded

Blinding description

The consent form is obtained from all selected individuals and then randomly divided into two groups of control and test. The control group will receive the usual training and the test group will receive the training based on the web-based teaching method. Therefore, all participants in this study are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Ave., Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673465

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.493

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Self management of diabetes

Timepoint

Completion of the questionnaire at baseline (before intervention), 21 days later and three months later

Method of measurement

Schmidt et al. Diabetes self-management questionnaire

2

Description

HbA1C changes

Timepoint

HbA1C measurement

Method of measurement

HPLC method and Siba electro-foresight device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, at first, a how-to-use website guidance pamphlet and a card containing username and password to login the website will be given. in the next step, patients could watch the Health Promotion Model constructs-based training course on the website in a two week period. In addition, at the end of the training program up to 3 months after, will receive reminder messages to encourage us to view the educational content uploaded on the website once a week via SMS Evaluating will be done through the questionnaire before the intervention, two weeks and 3 months after the intervention. Control group: the control group patients receive routine training in the ward. Evaluating will be done through questionnaires before the intervention, two weeks, and 3 months after the end of the intervention. After doing the final measurement, participants in the control group will receive a Website`s pamphlet guidance and a card containing username and password to view educational content

Category

Rehabilitation

2

Description

Control group: 'In this group, after the initial assessment of blood sugar and evaluation through a questionnaire (routine hospital training will be done), they are asked to return again in the next three weeks. A telephone call will be made to call the participating units for the second test and three months later for the final test and HbA1C test. After the last measurement, the participants of the control group will receive a training guide for using the website and a card containing the password and username to receive the training content.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Center

Full name of responsible person

Majid Rezvani

Street address

Alzahra Medical Center., Safeh Boulevard., Isfahan

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Isfahan

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Isfahan

Postal code

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Phone

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Email

alzahra@mui.ac.ir

Web page address

<http://alzahra.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Tahereh Changiz

Street address

Hezar Jerib street, Isfahan

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Postal code

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Email

changiz@med.mui.ac.ir

Web page address

<http://mui.ac.ir/>

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

Maryam Eghtedari

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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eghtedari.dl@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryamsadat Shahshahani

Position

Faculty Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

Faculty Instructor

Latest degree

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Other areas of specialty/work

Nursery

Street address

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Fax**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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Results from demographic data, questionnaires and blood tests can be shared anonymously. The study protocol will be announced.

When the data will become available and for how long

Start access period after printing results

To whom data/document is available

According to the research title, all interested people will have access to the results.

Under which criteria data/document could be used

The results will be published in scientific journals and in addition ; the researchers' emails will be available

From where data/document is obtainable

The way to communicate is emails.
shahshahani@nm.mui.ac.ir eghtedari.dl@gmail.com

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

It will be answered at least 1 week after request.

Comments

Only the results and study protocol will be presented.