

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of The Effect of Self-Care Program Training in Two Ways Face-to-Face and Smartphone Application On Adherence to Treatment Regimen and Glycosylated Hemoglobin of Patients with Type 2 Diabetes

Protocol summary

Adherence to treatment, Glycosylated hemoglobin

Study aim

Comparison of the effect of self-care program training in two ways, face-to-face and smartphone application, on adherence to treatment regimen and glycosylated hemoglobin of type 2 diabetes patients.

Design

Clinical trial with two intervention groups for comparison, with parallel groups, unblinded and randomized, on 60 patients. For randomization, the random select option of spss software is used.

Settings and conduct

Patients with type 2 diabetes who were referred to Shahid Qudsi and Parsian clinics in Mashhad during the study, If they are eligible, will enter the study and will be assigned to two groups 1 (face-to-face) and 2 (smartphone application) by a simple random method.

Participants/Inclusion and exclusion criteria

The research population is all patients with type 2 diabetes referring to the mentioned clinics. Inclusion criteria: over 18 years of age, having consent to study, having at least reading and writing literacy to complete the questionnaire, patients diagnosed with type 2 diabetes for at least 6 months, diagnosed by a specialist, having a smart phone and being able to use it; Exclusion criteria: suffering from mental illness and other chronic diseases diagnosed by a doctor, suffering from complications caused by diabetes such as diabetic neuropathy

Intervention groups

Group 1: this group is trained in a face to face self-care program in 3 one-hour sessions within 3 weeks. Group 2: this group has also been trained in a self-care program using smartphones for a month, and the designed app, which has content related to type 2 diabetes patients, will be installed for patients in a 15-30 minute session and the essential instructions will be given as well.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221028056323N1**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

Mahsa GharehGoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

gharehgm981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effect of Self-Care Program Training in Two Ways Face-to-Face and Smartphone Application On Adherence to Treatment Regimen and Glycosylated Hemoglobin of Patients with Type 2 Diabetes

Public title

The Effect of Teaching Self-Care Program in Patients with Type 2

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age above 18 years Having consent to study Having minimum reading and writing literacy to complete the questionnaire Patients diagnosed with type 2 diabetes for at least 6 months Diagnosis of the disease by a specialist Having a smartphone and being able to use it

Exclusion criteria:

Having another chronic disease as diagnosed by a doctor Mental illness diagnosed by a doctor Having a complication caused by diabetes such as diabetic neuropathy

Age

From **18 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

The randomization unit is individual and the tool being used is SPSS. In this way, all eligible patients will be randomly selected and will be divided into two groups; A and B, using SPSS 26 software. To perform randomization by SPSS, the "Data" option is selected from the toolbar. Next, in the new window, the "select cases" is selected. Then, in the "Select" box, first a click on "Random sample of cases" and then on "select" option will be done. After the "Exactly" option has been selected in the new window, the number of patients in each group and the total number of samples are respectively entered in the empty boxes (in this study, 30 and 60 respectively). After that, a click on the "Continue" and "OK" options will be done and finally, the generated random variables are randomly divided into two equal groups with codes 1 and 0 on the "Data view" page which conventionally, code 1 is assigned to the intervention group and code 0 to the control group. Patients will be randomly placed in either the intervention or control groups by someone other than the main researcher and statistical analyst.

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 Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Qurashi Building, Near Hovaze Cinema, Daneshgah St, Mashhad, Khorasan Razavi, Iran

City

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Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-08-02, 1401/05/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.071

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Adherence to the treatment regimen

Timepoint

Before and 3 months after the intervention

Method of measurement

Questionnaire of adherence to the treatment of chronic diseases

2**Description**

Glycosylated hemoglobin

Timepoint

Before and 3 months after the intervention

Method of measurement

Glycosylated hemoglobin test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, self-care training is done face-to-face during three one-hour sessions at intervals of one week. The patients are placed in groups of 6 to 8 people and the researcher will provide necessary information related to self-care training (nutrition management, drug management, activity management, and blood sugar check).

Category

Behavior

2

Description

Intervention group 2: In this group, self-care training conducted for three months through a smartphone application. This application includes specific training in the field of self-care for type 2 diabetes patients (nutrition and activity management, medication management, and blood sugar check). This app is a type of educational app that has self-care educational facilities (text, audio, and video) and important titles are presented in a highlighted form. It is also possible to communicate with the researcher in the form of text, and the patient will receive his answer after sending the question, and if he goes online, he will be able to learn new materials. After designing and building the above application, in a 15-20 minute session, the application will be installed on the phone and necessary explanations will be given to the patients regarding how to use it. Two weeks after the application is installed, the patients will be contacted and the ability and efficiency of the application will be evaluated.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Parsiyan Diabetes Clinic of Mashhad

Full name of responsible person

Aliakbar Raoofsaeb

Street address

Parsiyan building, between chamran 8 and Golestan, Chamran street, Mashhad, Iran

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2

Recruitment center

Name of recruitment center

Shahid Ghodsi

Full name of responsible person

Susan Daulatabadi

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Web page address

<http://behdasht3.mums.ac.ir/index.php/43-persian-category/229-ghodsi>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

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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

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahsa Garehgholi
Position
Nursing Graduate Student
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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