

# 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

+98 51 3859 1511

##### 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**

Mashhad

**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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944-91388

##### Phone

+98 51 3858 4040

##### Email

info@parsiantiabetes.com

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Ghodsi

##### Full name of responsible person

Susan Daulatabadi

##### Street address

Shahid Ghodsi Center , Sanabad Street , Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944-91388

##### Phone

+98 51 3844 0077

##### Email

dolatabadis1@mums.ac.ir

##### 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

##### Street address

University of Medical Sciences, university street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

GhayourM@mums.ac.ir

##### 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**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ibn Sina Street, Doctora Crossroads, University Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
+98 51 3859 1511  
**Email**  
Gharehgm981@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Reza Mazloun  
**Position**  
science Committee  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ibn Sina Street, Doctora Crossroads, University Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan

**Postal code**  
9137913199  
**Phone**  
05138598019-207  
**Email**  
mazlomr@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Mahsa Gharehgholi  
**Position**  
Nursing Graduate Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ibn Sina Street, Doctora Crossroads, University Street  
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**Email**  
Gharehgm981@mums.ac.ir

## 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