

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of digital games on self-management of type 2 diabetic patients

#### Protocol summary

##### Study aim

The effect of digital games on self-management of type 2 diabetic patients

##### Design

Clinical trial with control group, with parallel groups, not blinded, randomized, phase 2 on 104 patients. The RANDBETWEEN function of Excel software was used for randomization.

##### Settings and conduct

Background: Patients with type 2 diabetes Location: Diabetes Clinic and Endocrinologist's Office in Mashhad  
How to do it: After providing explanations to patients who have been diagnosed with type 2 diabetes, and considering the inclusion criteria, they are randomly assigned to the intervention or control group. Methods: In the intervention group, a self-management game application will be installed on their phone and the necessary explanations will be provided to them. In the control group, according to the usual procedure and without any intervention, examination, training and treatment will be performed by the treating physician. There is no possibility of blindness in this research.

##### Participants/Inclusion and exclusion criteria

inclusion criteria informed consent, diagnosis of type 2 diabetes, having a smartphone, does not have eye complications, 25 to 65 years old exclusion criteria Cancellation of continuing cooperation, the occurrence of eye complications of diabetes

##### Intervention groups

Intervention group: The group receiving digital game training for self-care patients with type 2 diabetes  
Control group: group receiving routine care

##### Main outcome variables

HBA1C

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210524051382N1**

Registration date: **2021-08-07, 1400/05/16**

Registration timing: **prospective**

Last update: **2021-08-07, 1400/05/16**

Update count: **0**

##### Registration date

2021-08-07, 1400/05/16

#### Registrant information

##### Name

Sara Ghodousi moghadam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2429

##### Email address

ghodousims971@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The effect of digital games on self-management of type 2 diabetic patients

#### Public title

The effect of digital games on self-management of type 2 diabetic patients

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

informed satisfaction and willingness to participate in the study  
Diagnosis of type 2 diabetes  
Having a smartphone with Android operating system  
The patient has no ocular complications (due to limited mobile work)  
Patients range in age from 25 to 65 years

#### Exclusion criteria:

Withdrawal from continuing cooperation at any point in time  
Incidence of ocular complications of diabetes

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: **104**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization method: Block randomization with size 4  
Randomization tool: Excel software  
Hiding method: using matte envelopes  
Method: After generating a random chain in Excel software, the generated codes are written on the Opaque envelopes and then the patients receive their envelopes in order to enter the study.

### 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 Mashhad University of Medical Sciences

##### Street address

Deputy of Research and Technology, Ghorashi Building, next to Hoveyeh Cinema, University Street

##### City

مشهد

##### Province

Razavi Khorasan

##### Postal code

9138813944

### Approval date

2021-07-17, 1400/04/26

### Ethics committee reference number

IR.MUMS.REC.1400.105

## 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

Average blood sugar of patients (HBA1C)

#### Timepoint

Start of study - about 3 months after the start of the study - about 6 months after the start of the study

#### Method of measurement

glucometer and clinical laboratory

## Secondary outcomes

### 1

#### Description

knowledge

#### Timepoint

Start of study - about 3 months after the start of the study - about 6 months after the start of the study

#### Method of measurement

KAP (Knowledge, Attitude and Practice) Questionnaire

### 2

#### Description

Diabetes comorbidity

#### Timepoint

end of study

#### Method of measurement

medical records

### 3

#### Description

Quality of life

#### Timepoint

Beginning and end of the study

#### Method of measurement

Quality Of Life questionnaire

## Intervention groups

## 1

### Description

Control group: Receiving routine care in the diabetes clinic, including examination, education and treatment of patients with type 2 diabetes by the treating physician without any changes or interventions

### Category

Lifestyle

## 2

### Description

Intervention group: Digital game of self-management training for type 2 diabetic patients, which is installed on patients' mobile phones and uses game techniques, necessary training on proper diabetic nutrition, proper drug use and the importance of physical activity, depending on Each patient's condition is given in the form of educational and motivational messages during the game.

### Category

Lifestyle

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Office of Dr. Zahra Mazlum Khorasani

#### Full name of responsible person

Dr. Zahra Mazlum Khorasani

#### Street address

Unit 705, Waterfall Building, between Moallem 8 and 10, Moallem Boulevard

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9188879287

#### Phone

+98 51 3601 7449

#### Email

MazlounZ@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi Piadeh Gheibi

#### Street address

Department of Medical Informatics, School of Medicine, University of Medical Sciences, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177948564

#### Phone

+98 51 3800 2000

#### Email

MDS.Dean@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

Zahra Mazloun Khorasani

#### Position

Associate Professor of Internal Medicine

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Department of Internal Medicine, School of Medicine, Metabolic Syndrome Research Center, Ghaem Hospital, Mashhad University of Medical Sciences

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#### Province

Razavi Khorasan

#### Postal code

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#### Phone

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#### Email

MazlounZ@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Hamed Tabesh

**Position**

Assistant Professor of Biostatistics

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biostatistics

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**Email**

ghodousims971@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

After the publication of the article

**When the data will become available and for how long**

After the publication of the article

**To whom data/document is available**

After the publication of the article

**Under which criteria data/document could be used**

After the publication of the article

**From where data/document is obtainable**

After the publication of the article

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

After the publication of the article

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

sara ghoddousi moghaddam

**Position**

student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Informatics

**Street address**

Department of Medical Informatics, School of  
Medicine, Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan