

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Hoveyze 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

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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

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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

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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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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

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