Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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 Hoveyzeh 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Mohsen Tafaghodi Piadeh Gheibi

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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
Zahra Mazloum Khorasani

Position
Associate Professor of Internal Medicine

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

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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