

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of BEHZEE diabetic mobile application on medical adherence and self-care in patients with diabetes mellitus type 2

Protocol summary

Study aim

The effect of Behzi mobile application on drug adherence and self-care in patients with type 2 diabetes

Design

Samples are selected by Convenience method from patients referred to Tehran University hospitals. Then, the subjects will be randomly assigned to the control and intervention groups (65 people each).

Settings and conduct

Behzi application will be installed on the phones of people in both groups and its application will be explained by an expert person. Then demographic, self-care questionnaires for diabetics, Moriski drug compliance, informed consent form will be completed by samples in both groups and HbA1C will be checked. The intervention group will receive lifestyle recommendations within 3 months. But the control group does not have any interactive training such as questions and answers and enters the application only to answer the questions of the questionnaires. At the end of 3 months, both groups will be complete the above-mentioned questionnaires as well as the amount of HbA1C will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age>18 years, literacy, HgA1C level higher or equal to 8%, ability to use cell phones, Internet access and diagnosis of the disease up to one year.

Exclusion criteria: Unwillingness to continue participation, not received more than two sessions of training, and hospitalization.

Intervention groups

The intervention group will receive and implement the ADEA's lifestyle recommendations in seven main areas.

Main outcome variables

This study intends to implement a care program for people with type 2 diabetes using this application and evaluate its effectiveness on drug adherence, improving self-care, physical activity and improving the status of diabetes indicators as a secondary outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210416050992N1**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Mohammad Salehpoor Emran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3533 9265

Email address

ms_82820@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of BEHZEE diabetic mobile application on medical adherence and self-care in patients with diabetes mellitus type 2

Public title

Effect of BEHZEE APP on medical adherence and self-care

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

HgA1C level higher or equal to 8% Be literate Ability to use cell phone Diagnosed type 2 diabetes at least one year ago

Exclusion criteria:

Not intention to continue participation Absence in more than two educational sessions hospitalization due to new complication during the intervention

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected by available method from diabetic patients referred to the hospitals of Tehran University of Medical Sciences. Selected samples with random allocation will be divided into two intervention and control groups . This method is used to prevent significant imbalances in the number of participants assigned to each group. Block randomization ensures that no significant imbalance is established between groups at any time during randomization, and at certain points the number of participants in each group is equal. Blocks of 4 will be considered to complete the sample size. Then the list of blocks will be written and the numbers will be assigned to them: AABB (1) - ABAB (2) - ABBA (3) - BBAA (4) - BABA (5) - BAAB (6). For this purpose, all possible modes for quadruple blocks will be determined as 2 items in the test group and 2 items in the control group (6 modes in total). Then the numbers will be selected from a table of random numbers and the allocation of individuals in the test and control groups will be done as follows. Dark envelopes will be used to conceal the allocation.

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**

Joint Organizational Ethics Committee of the School of Nursing, Midwifery and Rehabilitation, Tehran

Street address

School of Nursing and Midwifery, Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.TUMS.FNM.REC.1399.139

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

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

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

Self-care of diabetic patients

Timepoint

Before the intervention and 3 months after it

Method of measurement

Diabetes self-care questionnaire

2**Description**

Drug adherence

Timepoint

Before the intervention and 3 months after it

Method of measurement

Morisky Drug Adherence Questionnaire

Secondary outcomes**1****Description**

Fasting blood sugar

Timepoint

Before the intervention and three months after

Method of measurement

Mg / dl

2**Description**

HbA1C

Timepoint

Before and 3 months after intervention

Method of measurement

Blood Sample

Intervention groups**1****Description**

Intervention group: Within 3 months, the intervention team will receive and implement lifestyle recommendations in 7 key areas recommended for better diabetes self-care recommended by the American Diabetes Educators Association: 1. Recommendations for type 2 diabetes management training, 2. Adequate mobility and use of all muscles in the body 3. Proper nutrition in this disease 4. Proper and continuous use of drugs prescribed by a doctor and adaptation to them 5. Sleep and rest in type 2 diabetes 6. Management of interaction with the environment and reduction of high-risk behaviors, appropriate to the disease 7. How to manage and promote mental health in this disease.

Category

Lifestyle

2**Description**

Control group: The control group receives all the recommendations as a printed file when they go to the hospital and enter the study, but no interactive training such as questions and answers is done with them and only to answer questions Logs in to complete the questionnaires through the application.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology and Rheumatology Department of Imam Khomeini Hospital, Tehran

Full name of responsible person

Sarieh Poortaghi

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School of Nursing and Midwifery, Tohid Square, Tehran

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s-poortaghi@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dean of Research deputy, TUMS

Street address

Research Deputy, 6th Floor, Main house, Keshavarz Blvd, Tehran, Iran

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vcr@tums.ac.ir

Web page address

<https://vcr.tums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad salehpoor emran

Position

Postgraduate student of nursing

Latest degree

Bachelor
Other areas of specialty/work
Nursery
Street address
No. 52, Vesal Shirazi Dormitory, Italy Intersection,
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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main data of the study can be shared after being unidentifiable through contacting with correspond conductor of this study

When the data will become available and for how long

Starting after publication

To whom data/document is available

Data is only available for people working in academic institutions

Under which criteria data/document could be used

It is essential to agree on the type of use and purpose of the data access request when submitting the request.

From where data/document is obtainable

Through the following email address: s-poortaghi@sina.tums.ac.ir

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

Mention the purpose of the request Mention the type of data usage Access to data at least one month after receiving the request

Comments