Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 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)

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+98 11 3533 9265

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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
Street address
School of Nursing and Midwifery, Tohid Square, Tehran
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1419733171
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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
City
Tehran
Province
Tehran
Postal code
141973317
Phone
+98 21 8163 3685
Email
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, Vesal St., Enghelab Square

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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Position
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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