Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

To evaluate the efficacy of a psychological intervention mobile application in improving treatment adherence in individuals with type 2 diabetes.

Protocol summary

Study aim

To evaluate the efficacy of the application in improving treatment adherence and glycemic control in individuals with type 2 diabetes.

Design

A randomized controlled trial with two parallel groups and 120 participants, allocated using block randomization to the application plus usual care or usual care alone, with 60 participants per group. Trial phase: not applicable.

Settings and conduct

Eligible participants will be recruited from the Gabric Diabetes Education Association. Following informed consent and baseline assessment, they will be randomized. The intervention will be delivered through the application over four months. Treatment adherence and glycemic outcomes will be assessed at baseline and at months two and four.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Diagnosis of type 2 diabetes:Type 2 diabetes diagnosed by an endocrinologist. 2. Insufficient current treatment adherence 3. Age: Between 20 and 55 years. 4. Access to a smartphone 5. No participation in other ongoing studies or use of similar applications. 6. Ability to use the application:** Basic digital literacy sufficient to use mobile applications. Exclusion Criteria 1. Physical or psychological limitations affecting application use 2. Other severe chronic 3. Pregnant or breastfeeding women

Intervention groups

Intervention group: Use of a psychological intervention mobile application alongside usual care for four months, including education, motivational support, reminders, and monitoring of diabetes-related treatment behaviors. Control group: Usual diabetes care without using the application for four months.

Main outcome variables

Treatment adherence; glycated hemoglobin (HbA1c) level; number of blood glucose readings outside the target range.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261012071406N1**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date

2026-10-14, 1405/07/22

Registrant information

Name

Somayeh Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4469 8591

Email address

som.azizi@uswr.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-07-23, 1406/05/01

Expected recruitment end date

2027-11-22, 1406/09/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To evaluate the efficacy of a psychological intervention mobile application in improving treatment adherence in individuals with type 2 diabetes.

Public title
Effect of a Psychological Intervention Mobile Application on Treatment Adherence in Individuals with Type 2 Diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of type 2 diabetes: Type 2 diabetes diagnosed by an endocrinologist. Insufficient treatment adherence: A score below 45 on the Summary of Diabetes Self-Care Activities (SDSCA) measure and below 6 on the eight-item Morisky Medication Adherence Scale (MMAS-8). Age: Between 20 and 55 years. Ability to use the application: Basic digital literacy and the ability to install, use, and update the application. Access to a smartphone: Access to a stable internet connection (Wi-Fi or mobile data) and enabled GPS for location-based features. No participation in other ongoing studies or use of similar applications.
Exclusion criteria:
Physical or psychological limitations affecting the ability to use the application: Individuals who lack sufficient physical or psychological capacity to use the application, including those with neurological conditions, cognitive impairments, psychiatric disorders requiring medication, or severe visual impairments, are not eligible to participate. Pregnancy or breastfeeding: Pregnant or breastfeeding women are not eligible due to the metabolic changes that may occur during pregnancy or breastfeeding. Other severe chronic diseases: Individuals with other severe chronic diseases, such as cancer, heart disease, or kidney failure, are not eligible, as these conditions may confound the effects related to diabetes or lead to deterioration in health during the study.
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
All participants will first undergo a baseline assessment. They will then be randomly assigned to either the intervention or the control group using block randomization. The allocation sequence will be generated in Microsoft Excel using block randomization with a 1:1 allocation ratio. Possible sequences containing equal numbers of assignments to the intervention and control groups within each block will be selected using a random number generation function. The final sequence will be saved before participants are allocated.
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
Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences
Street address
University of Social Welfare and Rehabilitation Sciences, Koodakyar Alley, Daneshjoo Ave.
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2025-04-30, 1404/02/10
Ethics committee reference number
IR.USWR.REC.1404.009

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
Medication adherence
Timepoint
In both groups, at baseline (before the intervention begins), and at two and four months after the start of the intervention.

Method of measurement
Eight-item Morisky Medication Adherence Scale

2

Description
Diabetes self-care behaviors
Timepoint
In both groups, at baseline (before the intervention begins), and at two and four months after the start of the intervention.
Method of measurement
Summary of Diabetes Self-Care Activities measure

Secondary outcomes

1

Description
Glycated hemoglobin level
Timepoint
In both groups, at baseline (before the intervention begins), and at two and four months after the start of the intervention.
Method of measurement
Blood testing to measure glycated hemoglobin levels, based on participants' laboratory results

2

Description
Number of blood glucose readings outside the target range
Timepoint
In both groups, at baseline (before the intervention begins), and at two and four months after the start of the intervention.
Method of measurement
Counting blood glucose readings outside the target range in the recorded data

Intervention groups

1

Description
Intervention group: Participants in the intervention group will use a psychological intervention mobile application for four months alongside usual diabetes care. The application provides education, personalized motivational and psychological interventions, reminders, and recording and monitoring of medication use, blood glucose, diet, and physical activity. Training on application use and technical support will also be provided.
Category
Behavior

2

Description
Control group: Participants in the control group will receive usual diabetes care under the supervision of their treating physician for four months, without using the psychological intervention mobile application being evaluated
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gabric Diabetes Education Association
Full name of responsible person
Somayeh Azizi
Street address
No. 4, 16th Street, Seyed Hassan Nasrallah (Vozara) Street
City
Tehran
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Postal code
1511767111
Phone
+98 21 5827 1000
Email
info@gabric.ir
Web page address
https://gabric.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mohammad Saeed Khanjani
Street address
Koodakyar Alley, Daneshjoo Ave.
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1985713871
Phone
+98 21 2218 0061
Email
sa.khanjani@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Somayeh Azizi
Position
Student
Latest degree
Master
Other areas of specialty/work
Psychology
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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
To protect participants' confidentiality and privacy, there is no plan to share individual participant data, even in de-identified form.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available