Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Effect of a Digital Educational Intervention Based on Orem’s Self-Care Theory on Improving Self-Care Behaviors, Self-Efficacy, and Reducing HbA1c in Type 2 Diabetes Patients

Protocol summary

Study aim
To determine the effect of a digital educational intervention based on Orem’s self-care theory on improving self-care behaviors, self-efficacy, and HbA1c levels in patients with type 2 diabetes.

Design
A quasi-experimental, parallel-group, non-randomized, and open-label controlled trial involving 96 patients with type 2 diabetes (48 participants per group).

Settings and conduct
This study was conducted at rural health houses in Rasht County. Multi-stage cluster sampling was used. Questionnaires and blood samples for biochemical analysis were collected at baseline, immediately, and eight weeks post-intervention by the principal researcher.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type 2 diabetes for over one year; Age over 30 years; Smartphone literacy; Average or below-average self-care score. Exclusion criteria: Unwillingness to continue; Onset of physical or mental disorders; Lack of engagement with the intervention.

Intervention groups
Intervention group: Received eight digital educational sessions including podcasts, videos, and electronic booklets via social media over four weeks; Control group: Received routine healthcare services from the health center without any planned digital educational intervention.

Main outcome variables
HbA1c level; Diabetes self-care behaviors; Diabetes management self-efficacy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240529061941N2**
Registration date: **2026-04-11, 1405/01/22**
Registration timing: **retrospective**

Last update: **2026-04-11, 1405/01/22**
Update count: **0**

Registration date
2026-04-11, 1405/01/22

Registrant information
Name
Fatemeh Zarei
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
Phone
+98 21 8288 4546
Email address
f.zarei@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2024-03-29, 1403/01/10

Actual recruitment start date
2023-12-06, 1402/09/15

Actual recruitment end date
2024-04-08, 1403/01/20

Trial completion date
2024-04-08, 1403/01/20

Scientific title
Effect of a Digital Educational Intervention Based on

Orem’s Self-Care Theory on Improving Self-Care Behaviors, Self-Efficacy, and Reducing HbA1c in Type 2 Diabetes Patients

Public title
Digital Education and Self-Care in Type 2 Diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes >1 year; Resident in the study area; Literacy; Smartphone use; Medication adherence; Age >30; Absence of complications; Average or below SCB score.
Exclusion criteria:
Unwillingness to continue; Lack of engagement with the intervention; Onset of other diseases; Physical or mental disorders.
Age
From **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Actual sample size reached: **96**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Tarbiat Modares University
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Nasr street, Jalal Al Ahmad highway
City
Tehran
Province
Tehran
Postal code
111-14115
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.MODARES.REC.1401.161.

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
Glycated hemoglobin A1c level
Timepoint
Baseline (before the intervention) and eight weeks after the completion of the educational intervention
Method of measurement
Blood sampling by laboratory specialists and measuring the percentage of Glycated hemoglobin A1c

Secondary outcomes

1

Description
Total score of diabetes self-care activities
Timepoint
immediately after the intervention, and eight weeks post-intervention
Method of measurement
Summary of Diabetes Self-Care Activities questionnaire

2

Description
Total score of diabetes management self-efficacy
Timepoint
immediately after the intervention, and eight weeks post-intervention
Method of measurement
Diabetes Management Self-Efficacy Scale questionnaire

Intervention groups

1

Description
Intervention group: Received eight digital educational sessions over four weeks (two sessions per week, on Saturdays and Wednesdays). Content included audio podcasts, educational videos, and electronic booklets focusing on diet, physical activity, blood glucose monitoring, foot care, and medication adherence. The

content was developed based on Orem’s self-care theory and delivered via Eitaa and WhatsApp messengers. Weekly follow-up phone calls were also conducted to encourage participation.

Category

Behavior

2

Description

Control group: This group received routine care from the comprehensive rural health service centers. No digital educational intervention or additional planned content was provided to this group during the study period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health houses of rural health centers

Full name of responsible person

Ghorbanali Jennat-Fereidooni

Street address

Marzdasht Health House, Valiasr Street, Khomam Town, Rasht

City

Rasht

Province

Guilan

Postal code

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+98 13 3442 7099

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jennatferidooni.g@modares.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mohammad Javan

Street address

Faculty of Medical Sciences, Tarbiat Modares University, Nasr street, Jalal Al Ahmad highway

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141173116

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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

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Faculty of Medical Sciences, Tarbiat Modares University, Nasr street, Jalal Al Ahmad highway

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Fatemeh Zarei

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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
Part of the data related to the main outcomes can be shared

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data will be made available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Repeated measures analysis to investigate the effect of training persistence 6 months after the last intervention

From where data/document is obtainable
By sending an email to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir

What processes are involved for a request to access data/document
One week after sending the email from the requester to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir, a reply will be given.

Comments