

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

2022-10-25, 1401/08/03

Ethics committee reference number
IR.MODARES.REC.1401.161.

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

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

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Phone

+98 13 3442 7099

Email

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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Tehran

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141173116

Phone

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mjavan@modares.ac.ir

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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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