

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 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

**Postal code**

۴۳۴۱۱۵۱۸۸۸

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

141173116

**Phone**

+98 21 8288 4546

**Email**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

14115111

**Phone**

+98 21 8288 4546

**Email**

f.zarei@modares.ac.ir

**Person responsible for scientific 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

**City**

Tehran

**Province**

Tehran

**Postal code**

14115111

**Phone**

+98 21 8288 4546

**Email**

f.zarei@modares.ac.ir

**Person responsible for updating data**

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

14115111

**Phone**

+98 21 8288 4546

**Email**

f.zarei@modares.ac.ir

**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**