Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of blended learning based on the Theory of Planned Behavior on adopting health-promoting lifestyle and self-efficacy in patients with type 2 diabetes

Protocol summary

Study aim
Determining the effect of blended learning on a health-promoting lifestyle and self-efficacy in patients with type 2 diabetes

Design
Clinical trial with control group on 80 patients

Settings and conduct
Patients with type 2 diabetes who are referred to the diabetes clinic in Hamadan will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using a randomized block design. The study is unblinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of type 2 diabetes by an internal medicine specialist, at least 6 months since the onset of the disease, age between 18 and 70 years, access to a smartphone by the patient or their caregiver, literacy. Exclusion criteria: Presence of a specific underlying disease that makes participation in the study impossible.

Intervention groups
Intervention group: In the intervention group, in addition to receiving routine services, a three-component educational intervention (face-to-face, virtual, and reminder) is also provided. Face-to-face education is provided for four weeks (one 45-60 minute session each week) using lectures. Face-to-face education includes familiarization with diabetes, complications, the importance of self-care, physical activity, and adherence to health guidelines. Virtual education is provided using the "Diabetes Assistant" application, which has sections for individual profiles, educational content, reminders for medication use, and complications of the disease, and is available to patients for 6 weeks. Reminders are also provided by sending health messages via daily text messages. Control group: The control group uses routine education.

Main outcome variables
health-promoting lifestyle؛ self efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180421039371N1**
Registration date: **2025-04-28, 1404/02/08**
Registration timing: **prospective**

Last update: **2025-04-28, 1404/02/08**
Update count: **0**

Registration date
2025-04-28, 1404/02/08

Registrant information

Name
Sahar khoshravesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0360

Email address
s.khoshravesh@edu.umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-10, 1404/02/20

Expected recruitment end date
2025-10-12, 1404/07/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of blended learning based on the Theory of Planned Behavior on adopting health-promoting lifestyle and self-efficacy in patients with type 2 diabetes

Public title

Investigating the effect of blended learning on adopting health-promoting lifestyle and self-efficacy in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of type 2 diabetes by an internal medicine specialist At least 6 months have passed since the onset of the disease Absence of specific complications of diabetes Age between 18 and 70 years Absence of pregnancy and acute heart disease Access to a smartphone by the patient or their caregiver Being literate

Exclusion criteria:

The presence of a specific underlying condition that makes participation in the study impossible.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

First, convenience sampling will be performed among patients with type 2 diabetes who meet the study inclusion criteria. Then, participants will be randomly assigned to blocks of four using the random block method. For this purpose, 20 blocks of four will be prepared. Each block will be placed in an envelope and the envelopes will be opened randomly by an independent person from the research team.

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 Hamadan University of Medical Scieneces

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamedan

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2025-04-13, 1404/01/24

Ethics committee reference number

IR.UMSHA.REC.1404.029

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11.00

ICD-10 code description

Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)

Primary outcomes

1

Description

Adopting health-promoting lifestyle

Timepoint

Before and three months after the intervention

Method of measurement

Walker Health Promoting Lifestyle Questionnaire: This questionnaire was psychometrically validated in Iran by Zaidi et al. The questionnaire consists of 49 questions that measure 6 dimensions of self-actualization, responsibility, interpersonal relationships, stress management, physical activity, and nutritional behaviors using a four-point Likert scale (never, sometimes, often, and usually).

2

Description

Self-efficacy

Timepoint

Before and three months after the intervention

Method of measurement

Diabetic Self-Efficacy Questionnaire (DSES): This questionnaire was designed by the Stanford University Research Center in the United States to measure the

self-efficacy of people with diabetes. It has 8 questions with a score range from 1 to 10 on a Likert scale, and the answers are categorized as 1 (not at all sure) to 10 (completely sure). The questionnaire was psychometrically validated by Bastani et al. in Iran.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to receiving routine services, an educational intervention with three components (face-to-face, virtual, and reminder) is also provided. Face-to-face training is provided for four weeks (one 45-60 minute session each week) using lectures and showing educational clips. During these four sessions, educational content is presented as follows: Session 1: Introduction to the goals and framework of the training course, definition of diabetes, Session 2: Importance of self-care behaviors in improving lifestyle, Session 3: Recommendations for physical activity, Session 4: Emphasis on adhering to health guidelines. Virtual training is provided using the "Diabetes Assistant" application. This application is designed by an experienced team and has sections for individual profiles, educational content, reminders for medication use, complications of the disease, conversation, and support, which are available to patients for 6 weeks. Reminders are also provided by sending health messages via SMS daily for one month simultaneously with face-to-face training.

Category

Lifestyle

2

Description

Control group:The control group will receive routine education. This means that they will visit the clinic if needed and receive routine health and medical services for type 2 diabetes patients. In order to comply with ethical principles, all educational content will be made available to the control group at the end of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Research Center in Hamedan city

Full name of responsible person
Leila Jamali Fashi

Street address
Mahdieh No. 4, Khedrian Ave., Hamedan

City
Hamedan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3264 6702

Email
leilajamali6464@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Alireza Soltanian

Street address
Fourth floor, Headquarters, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamedan

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۴۸۷۳۶

Phone
+98 81 3131 4042

Email
Fanavari@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Leila Jamali Fashi

Position
Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Community Health Nursing Department, Faculty of Nursing and Midwifery, Shahid Fahmideh Blvd., Hamedan

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

38380150 081 0098

Email

leilajamali6464@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sahar Khoshravesh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Community Health Nursing Department, Faculty of Nursing and Midwifery, Shahid Fahmideh Blvd., Hamedan

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

38380150 081 0098

Email

khoshraveshsahar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Leila Jamali Fashi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Community Health Nursing Department, Faculty of Nursing and Midwifery, Shahid Fahmideh Blvd., Hamedan

City

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۶۵۱۷۸۳۸۷۳۶

Phone

38380150 081 0098

Email

leilajamali6464@gmail.com

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

Requires approval from the research team.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available