

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2026

Examining the Effectiveness of the Teach-Back approach on activating self-management behaviors among prediabetic patients: A Randomized Control Trial Study

Protocol summary

Study aim

The aim is to determine the effectiveness of the educational feedback approach on activating self-management behavior and improving health-related indicators in clients with prediabetes and helping prevent its progression to type 2 diabetes.

Design

A randomized, controlled clinical trial with a parallel design and two intervention and control groups, pre-test-post-test, was conducted on 60 clients with prediabetes; randomization was performed using a block method with blocks of 6 (3 people in each group) and using a random number table, and sealed and numbered envelopes were used to conceal allocation.

Settings and conduct

This study is conducted in the field of prevention and self-management of prediabetes at Razi Subspecialty Clinic. As a randomized, controlled clinical trial, eligible individuals are randomly assigned to two intervention and control groups, and the effectiveness of the educational feedback approach on activating their self-management behavior is evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 18–65 with prediabetes (fasting blood sugar 100–125), literate, with a smartphone, regular visits, and willingness to participate. Exclusion criteria: Diabetes, lack of cooperation or responsiveness, absence from two consecutive sessions, failure to respond to two consecutive text messages, withdrawal, and incomplete completion of the questionnaire.

Intervention groups

In the intervention group, the educational feedback approach is presented in the form of short, interactive sessions to teach and reinforce self-management and lifestyle modification, while the control group receives usual care.

Main outcome variables

Self-management score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260825070797N1**

Registration date: **2026-09-11, 1405/06/20**

Registration timing: **prospective**

Last update: **2026-09-11, 1405/06/20**

Update count: **0**

Registration date

2026-09-11, 1405/06/20

Registrant information

Name

Marzieh Shayestehfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3255 5056

Email address

m.shayestefard@gums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Examining the Effectiveness of the Teach-Back approach on activating self-management behaviors among prediabetic patients: A Randomized Control Trial Study

Public title
Examining the Effectiveness of the Teach-Back approach on activating self-management behaviors among prediabetic patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 People between the ages of 18 and 65 with prediabetes whose fasting blood sugar level is between 100 and 125. Periodic visits to a specialist every 3 months Literacy Possession of a smartphone and the ability to use it Desire to change and improve Participate in teach-back sessions
Exclusion criteria:
 Presence of unstable cardiovascular disorders Presence of musculoskeletal disorders Lack of literacy Not having a smartphone

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is a block randomization with blocks of 6; in each block, 3 people are assigned to the control group (A) and 3 people to the intervention group (B), then all possible sequences A and B are prepared and the required number (10 blocks) is selected using a random number table and combined sequentially to create a final sequence of 60 people. The randomization unit is a client with prediabetes. The randomization tool is a random number table and the allocation sequence is prepared by the executive researcher before the patients start arriving. Allocation concealment is done using sealed and numbered envelopes 1 to 60 and each envelope is opened for each person in their presence after meeting the conditions and obtaining informed consent, respectively, to determine the group code; the purpose of this is to prevent bias in allocation.

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 if Guilan university of medical sciences
Street address
 Shahid Beheshti Highway, Daneshjoo Street, Shahid Beheshti School of Nursing and Midwifery, Rasht
City
 Rasht
Province
 Guilan
Postal code
 41469-39814
Approval date
 2026-08-19, 1405/05/28
Ethics committee reference number
 IR.GUMS.REC.1405.237

Health conditions studied

1

Description of health condition studied
The study is educational and has no application.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome variable is the level of self-management behavior activation in clients with prediabetes, which is assessed using the Patient Activation Questionnaire (PAM) before and three months after the intervention.

Timepoint
Measurement of research variables is carried out at two points: at the beginning of the study (before the intervention) and three months after the start of the intervention.

Method of measurement
Patient Activation Measure-13.

Secondary outcomes

1

Description

Changes in fasting blood sugar

Timepoint

At the beginning of the study (before the intervention) and at the end of the twelfth week (after the intervention).

Method of measurement

Based on laboratory results and information in the patient's file

2

Description

Weight changes

Timepoint

At the beginning of the study (before the intervention) and at the end of the twelfth week (after the intervention).

Method of measurement

Based on case information and direct weight measurement

3

Description

Body mass index changes

Timepoint

At the beginning of the study (before the intervention) and at the end of the twelfth week (after the intervention).

Method of measurement

Based on file information and direct measurement of the patient's weight and height

Intervention groups

1

Description

Intervention group: Intervention group: The intervention group included four 20-minute in-person sessions (weeks 1, 4, 8, and 12) of lifestyle modification education with Teach-Back approach, along with sending 24 educational-motivational SMS messages and 8 short animations between sessions, for patients with prediabetes.

Category

Lifestyle

2

Description

Control group: Control group: The control group consists of clients with prediabetes who receive routine medical care (including periodic visits every three months by the treating physician and receiving standard treatment and care recommendations) and will not receive any educational intervention with Teach-Back approach, text messages, or animations.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Rasht Specialized and Subspecialized Polyclinic

Full name of responsible person

Kamran Pouryousef

Street address

Shahid Beheshti Boulevard - Bilalzadeh Street

City

Rasht

Province

Guilan

Postal code

41469-39814

Phone

+98 13 3354 1001

Email

m.shayestefard@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Alavi

Street address

Nurse Street - Head Office Building of Guilan University of Medical Sciences

City

Rasht

Province

Guilan

Postal code

41937-13111

Phone

+98 13 3332 6061

Email

riasat@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Marzieh Shayestefard

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Highway, Daneshjoo Street, Shahid Beheshti School of Nursing and Midwifery, Rasht

City

Rasht

Province

Guilan

Postal code

41469-39814

Phone

+98 13 3255 3202

Email

m.shayestefard@gums.ac.ir

Email

m.shayestefard@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

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Dr. Marzieh Shayestefard

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41469-39814

Phone

+98 13 3255 3202

Email

m.shayestefard@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Marzieh Shayestefard

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Province

Guilan

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41469-39814

Phone

+98 13 3255 3202

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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