

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2026

Examining the Effectiveness of health coaching approach in promotion of lifestyle of pre diabetic patients: A Randomized Control Trial Study

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of a health coaching approach on lifestyle enhancement and the improvement of clinical indicators in clients with prediabetes.

Design

A parallel-group randomized clinical trial with intervention and control groups (sample size of 31 per group) is being conducted using block randomization and a random number table to assign treatment codes A and B.

Settings and conduct

This randomized trial is being conducted at the specialized clinic of Imam Khomeini Hospital in Sowme'eh Sara on pre-diabetic patients who, following informed consent, are assigned to either an intervention group or a control group using block randomization; although the participants and intervention providers are not blinded, the assessor and the statistical analyst remain blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 18–65 with prediabetes (fasting blood glucose 100–125 mg/dL), literacy, a smartphone, ability to attend regular visits, and willingness to participate. Exclusion criteria: Presence of cardiovascular or musculoskeletal disorders, illiteracy, and lack of a smartphone.

Intervention groups

This study aims to evaluate the effectiveness of health coaching in improving the lifestyle of pre-diabetic patients; the intervention group receives coaching sessions—both in-person and virtually—over a 12-week period, whereas the control group receives only routine care and physician-prescribed pharmacological treatments.

Main outcome variables

Total score of the integrated health and wellness assessment tool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260825070797N2**

Registration date: **2026-09-22, 1405/06/31**

Registration timing: **prospective**

Last update: **2026-09-22, 1405/06/31**

Update count: **0**

Registration date

2026-09-22, 1405/06/31

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

Not yet recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the Effectiveness of health coaching approach in promotion of lifestyle of pre diabetic patients: A Randomized Control Trial Study	
Public title	Examining the Effectiveness of health coaching approach in promotion of lifestyle of pre diabetic patients: A Randomized Control Trial Study
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Individuals aged 18 to 65 with prediabetes who have a fasting blood sugar level between 100 and 125. Periodic visits to a specialist every three months. Reading and writing literacy Possessing a smartphone and the ability to use it. Willingness to change, improvement Participating in health coaching 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: 62
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, randomization is performed using a block design with blocks of six (three in the control group and three in the intervention group); the unit of randomization is the individual, and no stratification is specified. The allocation sequence is generated by preparing all possible sequences and randomly selecting ten of them using a random number table; to ensure allocation concealment, the codes are placed in sequentially numbered envelopes that are opened in order as each patient is enrolled.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
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.1405.242
Health conditions studied	
<u>1</u>	
Description of health condition studied	The study is educational and has no application.
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	The study's primary outcome variable is lifestyle improvement, measured by an integrated health and wellness score.
Timepoint	The primary outcome is measured at two time points: before the start of the intervention (pre-test) and at the end of week 12, immediately after the intervention concludes (post-test).
Method of measurement	Integrated Health and Wellness Questionnaire
Secondary outcomes	
<u>1</u>	
Description	Fasting blood sugar
Timepoint	Before the intervention (pre-test) and at the end of week 12, after the completion of the intervention (post-test).
Method of measurement	Patient's file
<u>2</u>	
Description	Weight
Timepoint	

Before the intervention (pre-test) and at the end of week 12, after the completion of the intervention (post-test).

Method of measurement

Patient's file

3

Description

Body Mass Index

Timepoint

Before the intervention (pre-test) and at the end of week 12, after the completion of the intervention (post-test).

Method of measurement

Patient's file

Intervention groups

1

Description

Intervention group: In addition to standard care, the intervention group receives health coaching sessions based on the GROW model over a 12-week period, delivered both in-person and virtually (via video calls or educational and motivational text messages).

Category

Behavior

2

Description

Control group: During the study, the control group receives only routine care and pharmacological treatments prescribed by the attending physician.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sowme'eh Sara

Full name of responsible person

Dr. Hossein Ronaghi

Street address

Sowme'eh Sara - Khorramshahr Boulevard - Next to Abrisham Park

City

Sowme'eh Sara

Province

Guilan

Postal code

4361996186

Phone

+98 13 4432 3041

Email

imamh@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 Shayesteh Fard

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Marzieh Shayesteh Fard

Position

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Person responsible for updating data

Contact

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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