# 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

**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.1405.242

## 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 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

**1**

**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

**2**

**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**
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 updating data

**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

## 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