

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of an educational intervention based on the determinant of effective and ineffective PRECEDE-PROCEED model on improving self-care quality, glucose control and lifestyle modification of Pre-diabetic persons

Protocol summary

Study aim

A study to develop and evaluate the effectiveness of a lifestyle modification program in pre-diabetic individuals in Hoveyzeh: a PRECED- PROCEED guided program

Design

A randomized, double-blind, controlled, Two-center trial conducted from, 2019 through 2020

Settings and conduct

Pre- and post a randomized controlled trial that is allocating groups selected from two different geographical areas to reduce the chance of sharing information. The reassessments will be conducted after 3 months of intervention. The educational content used in this study is in accordance with the International Federation of Diabetes (IDF) guidelines.

Participants/Inclusion and exclusion criteria

Pre-diabetic people - aged 30-75 years - resident in Hoveyzeh

Intervention groups

Educational intervention group: A program for lifestyle modification based on the most effective PRECEDE-PROCEDURE model constructs: Advice on diet changes, exercise to achieve and maintain ideal body weight, stress management techniques, regularly from training sessions, email and social networks and SMS will receive. Control group: A program for lifestyle modification based on the most ineffective PRECEDE-PROCEDURE model constructs: Advice on diet changes, exercise to achieve and maintain ideal body weight, stress management techniques, regularly from training sessions, email and social networks and SMS will receive.

Main outcome variables

Quality of life, HbA1c hemoglobin concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171226038083N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **retrospective**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Majed Meripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 5096

Email address

majed8112@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-18, 1397/10/28

Expected recruitment end date

2019-07-19, 1398/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effectiveness of an educational intervention based on the determinant of effective and ineffective PRECEDE-PROCEED model on improving self-care quality, glucose control and lifestyle modification of Pre-diabetic persons

Public title
lifestyle modification program in pre-diabetic individuals

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Pre-diabetic people Age of 30 to 75 years Resident of Hovizeh
Exclusion criteria:
Acute or chronic comorbidities such as mental illness, mental retardation, chronic infectious disease (tb), or motor disability

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **242**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Randomization: From 2000 patients with pre-diabetes identified in Hoveyzeh health centers, 242 individuals were selected by Winpepi software. Then, the subjects were randomly divided into intervention and control groups by simple randomization method. The number of intervention and control groups was equal to 121 persons.

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

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blv.

City

Ahvaz

Province

Khouzestan

Postal code

61537-15794

Approval date

2018-12-21, 1397/09/30

Ethics committee reference number

IR.AJUMS.REC.1397.689

Health conditions studied

1

Description of health condition studied

per-diabetic people

ICD-10 code

R73.03

ICD-10 code description

Prediabetes

Primary outcomes

1

Description

Hemoglobin A1c (HbA1c)

Timepoint

Starting the study and 3 months later

Method of measurement

we use CERA-STAT 2000 Analyzer (CERAGEM MEDISYS inc)

2

Description

Health-related quality of life (HR-Qol)

Timepoint

At the base-line and the end of study (0 and 6-month)

Method of measurement

Assessing the Quality of Life of the Diabetic patients by using the World Health Organization (WHO) Quality of Life Questionnaire:.. Effect of Intervention

Secondary outcomes

1

Description

The patient's readiness to change in each of the three areas of the diet, physical activity and stress

Timepoint

Before intervention and after intervention

Method of measurement

A researcher-made questionnaire based on the PRECEDE PROCESS model that will be standardized in the study process

Intervention groups

1

Description

Based on the needs assessment performed in the previous phase of the study, a lifestyle modification program included: counseling on diet changes, exercise to achieve and maintain ideal body weight, stress management techniques, etc. regularly from training sessions, email and Social networks and SMS will receive. To formulate the content, the World Diabetes Federation Reference Book will be used. This manual is used for distance education of the HOPE project to obtain PG Certificate in diabetes education. The intervention group received 4 sessions of 60 minutes on one month for the intervention group. The educational content of these 4 sessions consisted of topic importance and problem expression, diet, physical activity and exercise, and stress management. Three months after the end of the training sessions, the intervention group was re-evaluated.

Category

Lifestyle

2

Description

Control group: Only once at the beginning of a regular consultation will receive care according to the country's instructions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hoveyze Lab

Full name of responsible person

Rasol Khajeh

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Imam Reza Medical Center., Imam Reza Blvd., Koot District ., Hoveyze Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Social Determinants of Health Research Center, Ahvaz Jundishapur University of Medical Sciences

Grant code / Reference number

-SDH-9719

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Meripour Majed

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

No more information

When the data will become available and for how long

Does not have

To whom data/document is available

Any natural or legal person requesting access to information can be reviewed if the project researcher is identified as having used the information for research purposes.

Under which criteria data/document could be used

Analyzing and reviewing the effectiveness of the study

From where data/document is obtainable

Public health and health education and promotion Departments, Health Faculty, Ahvaz Jundishapur University of Medical Sciences, Esfand Ave, Farvardin Blvd, Golestan Hwy, Ahvaz Town Contact number: 0098 61 33738315 - 0098 61 33738282 -0098 61 33738269 Internal: 2874 Mobile: 0098 913371679 and 0098 9166555978 Mohamadian Hashem , Khafaie Morteza : Supervisors

What processes are involved for a request to access data/document

hmohamadian@razi.tums.ac.ir-Supervisors
m.khafaie@live.com-Supervisors

Comments

Does not have