

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of multimedia educational intervention based on the Health Belief Model on Adherence to Preventive Behaviors of Type 2 Diabetes (Nutrition and Physical Activity) pre-diabetic patients

Protocol summary

Study aim

Determining the effect of multimedia educational program based on health belief model on adherence to preventive behaviors of type 2 diabetes (diet and physical activity) in patients with prediabetes covered by comprehensive health service centers in Bushehr in 1399.

Design

A clinical trial with a control group, with parallel, randomized groups, on 78 patients. R software will be used.

Settings and conduct

The study will be performed on pre-diabetic patients in Bushehr Comprehensive Health Service Centers

Participants/Inclusion and exclusion criteria

- People with pre-diabetes (FBS =100-125) registered in the apple system whose test time is during recent one month.
- Age 30 to 60 years
- No pregnancy
- Willingness to participate in the study
- Be literate
- Having a computer or tablet or smart phone and be familiar with working with it
- Internet access
- Do not have a chronic illness recorded in the person's electronic file or barrier for physical activity based on it.
- The participant does not read the educational content at the specified time.

Intervention groups

Intervention groups receive educational content (based on the Health Belief Model) uploaded to the website by entering their username and password. The control group will be given a card containing a username and password to view the educational content along with a guide for using the website, after performing the final assessment in order to observe the ethics in the research.

Main outcome variables

FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200901048585N1**

Registration date: **2020-09-25, 1399/07/04**

Registration timing: **prospective**

Last update: **2020-09-25, 1399/07/04**

Update count: **0**

Registration date

2020-09-25, 1399/07/04

Registrant information

Name

sedh skenh basri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3354 8037

Email address

sh.basri63@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of multimedia educational intervention based on the Health Belief Model on Adherence to Preventive Behaviors of Type 2 Diabetes (Nutrition and Physical Activity) pre-diabetic patients

Public title

Effect of multimedia educational intervention based on the Health Belief Model on Adherence to Preventive Behaviors of Type 2 Diabetes (Nutrition and Physical Activity) pre-diabetic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

- People with pre-diabetes (FBS =100-125) registered in the apple system whose test time belongs to recent 1 month.
- Age 30 to 60 years
- No pregnancy
- Willingness to participate in the study
- literacy for reading and writing
- Having a computer or tablet or smart phone and be familiar with working with it
- Internet access
- Do not have a chronic illness recorded in the person's electronic file or barrier on physical activity based on it.

Exclusion criteria:

- The participant does not view the educational content at the specified time.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Bushehr city has 10 comprehensive health service centers. In this study, initially, out of 10 comprehensive health service centers in Bushehr, 5 centers are selected as intervention groups and 5 centers as control groups. Blocking to balance the number of units allocated to study groups. In this study, the blocks are considered as dual blocks AB and BA (A: intervention group and B: treatment group). For example, if the block sequence obtained randomly by lot is ABABBAABBA, after the list of centers, the first center to the intervention group (A), the second center to the control group (B) and .. and the last center Assigned to intervention group (A). Then, pre-diabetic eligible individuals from each center (28 in the control group and 28 in the intervention group) are included in the study. In each group, the number of samples selected from each center will be proportional to the number of people eligible to enter the center. At each center, a list of pre-diabetic names with initial entry criteria is extracted through the Apple system. Necessary samples are selected randomly and by simple method and lottery. By contacting these other people, the inclusion criteria (having a computer and smartphone, internet access) and the willingness to participate in the

study are checked. In the absence of inclusion criteria, it was randomly replaced from the rest of the list.

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**

Ethics Committee of Bushehr University of Medical Sciences

Street address

Salman Farsi St. Bushehr University of Medical Sciences

City

Busher

Province

Boushehr

Postal code

7514633341

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.BPUMS.REC.1399.064

Health conditions studied**1****Description of health condition studied**

Pre-diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

FBS

Timepoint

Before training and three months after training

Method of measurement

View FBS test results

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The educational content in this study, based on the constructs of the health belief model, is uploaded on the website after developing and people are asked to read the trainings for a maximum of 2 weeks.

Category

Behavior

2

Description

Control group: Routine training of health centers and after the final assessment to comply with research ethics, participants in the control group will be given a card containing a username and password to view the educational content along with a guide to using the website.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr Comprehensive Health Service Centers

Full name of responsible person

Engineer Hassan Fakhraei

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Salman Farsi St. Bushehr University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Mahnoosh Raisi

Position

Assistant Professor

Latest degree

Ph.D.

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

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