

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational intervention based on behavioral reasoning theory on self-management behaviors in patients with type 2 diabetes

Protocol summary

Study aim

The effect of teaching self-management behaviors in patients with type 2 diabetes, using BRT theory, will be for the first time in Bushehr

Design

A simple non- randomized clinical trial on 120 patients with type 2 diabetes in the control and intervention groups

Settings and conduct

120 patients with type 2 diabetes will be randomly selected from 4 health centers and bases in Bushehr, if they meet the inclusion criteria, and after obtaining informed consent in writing, randomly, patients will be divided into two groups. Control and intervention will be divided. The educational content will be provided to the intervention group in person and virtually, and at the end of the work, the educational content will be available to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study are: Type 2 diabetes based on a definite diagnosis by a doctor • At least one year has passed since the definitive diagnosis of the disease • Ability to read, write and speak Persian • Having a smartphone and the ability to use WhatsApp • Age between 30 and 60 years • No severe complications from diabetes, including eye disease, kidney disease and foot / skin ulcers • Willingness to participate in the study
Exclusion criteria are: • Severe complications of diabetes during the study period • Withdrawal from continuing to participate in the study • Death .Migration

Intervention groups

The intervention group consists of 2 patients with type 2 diabetes (the target group first selected from four comprehensive health centers in Bushehr, then divided into two groups of control and intervention, followed by fasting blood sugar, HBA1C and height and size of patients size. It will be obtained and will be completed by the target group at a group meeting of demographic questionnaires and questionnaires based

Main outcome variables

Improving the quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131014015015N21**

Registration date: **2022-08-14, 1401/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-14, 1401/05/23**

Update count: **0**

Registration date

2022-08-14, 1401/05/23

Registrant information

Name

Leila Ghahremani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

ghahramanl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-22, 1401/02/02

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of educational intervention based on behavioral reasoning theory on self-management behaviors in patients with type 2 diabetes

Public title
The effect of teaching self-management behaviors in patients with type 2 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
At least one year has passed since the definitive diagnosis of the disease Ability to use WhatsApp No severe complications from diabetes, including eye disease, kidney disease and foot / skin ulcers Willingness to participate in the study
Exclusion criteria:
• Severe complications of diabetes Lack of interest in training and attending meetings History of mental illness Death

Age
From **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Schools of Health, Nutrition and Food Sciences - Shiraz University of Medical Sc

Street address

No. 6, Mehr Alley 18, Sabzabad Street, Bushehr City, Bushehr Province, Iran

City
Bushehr

Province
Boushehr

Postal code
7516979833

Approval date
2022-02-26, 1400/12/07

Ethics committee reference number
IR.SUMSSCHEANUT.REC.1400.101

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Educating and promoting self-management behaviors in patients with type 2 diabetes by the educator

Timepoint

Three and six months after the educational intervention

Method of measurement

Questionnaire and behavior assessment checklist

Secondary outcomes

empty

Intervention groups

1

Description

"The intervention group" will include 60 patients with type 2 diabetes over 30 years old, residing in Bushehr, which will be offered in a combination of eight in-person and virtual training sessions for two months. Virtual training content contains short videos, text and audio messages and photos, including fasting blood glucose checks, HBA1C and patients' height and weight, and a notebook will be given to people daily.

Category

Behavior

2

Description

"The control group "will include 60 patients with type 2 diabetes over the age of 30, residing in Bushehr, which will receive only regular education and care in the health system during this period. Three and six months after the end of the educational interventions, questionnaires

based on the structures of behavioral reasoning model will be completed by the two groups

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr health centers and health centers

Full name of responsible person

Fatemeh Ranjbar

Street address

No. 2 Mehr Alley, Sabzabad Street, Bushehr, Bushehr Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

30

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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Ranjbar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Leila Ghahramani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable