# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

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+98 71 1725 1001

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**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 of30, 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

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**Position**

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## Person responsible for updating data

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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