

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Investigating the effect of team-oriented educational intervention on promoting self-care in women with type 2 diabetes; A cluster randomized controlled trial using social-cognitive theory

#### Protocol summary

##### Study aim

Determining the effect of team-oriented educational intervention on promoting self-care in women with type 2 diabetes; A cluster randomized controlled trial using cognitive-social theory in Boushehr city, south of Iran.

##### Design

The study has two intervention and control groups, which were selected by regular random method, the target sample size is 110 people, and there is no blinding

##### Settings and conduct

This research was conducted among women aged 30 to 59 years old with diabetes, whose disease was registered in the integrated health system of selected comprehensive health service centers, by conducting a team-oriented educational intervention and by forming a team including a health care provider, doctor, patient, peers and the patient's family. Blood tests and questionnaires will be completed before and after the training

##### Participants/Inclusion and exclusion criteria

Entry requirements: Type 2 diabetes based on the definitive diagnosis entered in the file At least one year has passed since the definitive diagnosis of the disease Ability to read, write and speak Farsi Age between 30 and 59 years Not having severe complications caused by diabetes, including eye disease, kidney disease, and leg/skin ulcers Willingness to participate in the study Exit conditions: The occurrence of a severe health condition that prevents the person from continuing to attend and participate in the course Leaving the research environment for any reason (withdrawal, death and migration) Absence of more than 2 sessions of the training program Failure to participate in the pre-test and post-test• Participation in the ongoing program similar to the present study

##### Intervention groups

Team-oriented educational intervention using social

cognitive model in women with type 2 diabetes

##### Main outcome variables

Knowledge;behavioral intention;outcome expectation; perceived social support;self-efficacy;HbA1c; FBS;self-care

#### General information

##### Reason for update

##### Acronym

SCT

##### IRCT registration information

IRCT registration number: **IRCT20230521058243N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

##### Registration date

2023-05-31, 1402/03/10

##### Registrant information

##### Name

Azadeh Salemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3333 0741

##### Email address

azadehsalemi87@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-23, 1402/03/02

##### Expected recruitment end date

2023-07-22, 1402/04/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of team-oriented educational intervention on promoting self-care in women with type 2 diabetes; A cluster randomized controlled trial using social-cognitive theory

**Public title**

Investigating the effect of education on self-care in women with type 2 diabetes

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Type 2 diabetes based on the definitive diagnosis entered in the file At least one year has passed since the definitive diagnosis of the disease Ability to read, write and speak Farsi Age between 30 and 59 years Not having severe complications caused by diabetes, including eye disease, kidney disease, and leg/skin ulcers Willingness to participate in the study

**Exclusion criteria:**

The occurrence of a severe health condition that prevents the person from continuing to attend and participate in the course Leaving the research environment for any reason (withdrawal, death and migration) Absence of more than 2 sessions of the training program Failure to participate in the pre-test and post-test • Participation in the ongoing program similar to the present study

**Age**

From **30 years** old to **59 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To select the samples using a multi-stage cluster method, first, among the 12 comprehensive health service centers in Boushehr, all of which provide services in the diabetes prevention and control program to people with diabetes, 4 comprehensive health service centers were selected. A simple random method will be selected, then in this step, in order to prevent information leakage of these 4 centers, 2 centers were selected by a simple random method (lottery method) and assigned to the intervention groups and 2 centers to the control groups. They will be .In the next step, a list of people with diabetes who meet the criteria for entering the study will

be prepared by using the information registered in the Integrated Health System (SIB). Then, with regular random method, the desired sample size will be selected from among them. After obtaining informed consent from the people, and having the entry criteria, then they complete the prepared questionnaires.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

**Street address**

Shiraz, Zand Street, Shiraz University of Medical Sciences Central Building, 7th Floor, Research and Technology Deputy

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2023-05-20, 1402/02/30

**Ethics committee reference number**

IR.SUMS.SCHEANUT.REC.1402.024

**Health conditions studied**

**1**

**Description of health condition studied**

Diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

**Primary outcomes**

**1**

**Description**

Changes in the mean scores of knowledge related to diabetes

**Timepoint**

before the intervention and 3 months after the

intervention

**Method of measurement**

Questionnaire

**2**

**Description**

Changes in the mean scores of diabetes self-care behavior intention

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

Questionnaire

**3**

**Description**

Changes in the mean scores of participants' outcome expectations

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

Questionnaire

**4**

**Description**

Changes in the mean scores of participants' perceived social support

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

Questionnaire

**5**

**Description**

Changes in the mean scores of participants' perceived self-efficacy

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

Questionnaire

**6**

**Description**

Changes in the average amount of glycosylated hemoglobin

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

blood test

**7**

**Description**

Changes in the average amount of fasting blood sugar

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

blood test

**8**

**Description**

Changes in the mean scores of participants' self-care behavior

**Timepoint**

before the intervention and 3 months after the intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Education about diabetes and the importance of self-care and its elements, familiarity with controlling and monitoring blood sugar and blood pressure, prevention of diabetes complications, healthy eating and physical activity, correct use of medicine, foot care and interaction with peer group, family, health care provider and doctor , in person to the intervention group, in 6 sessions of 60 to 80 minutes with the method of interactive lectures, group discussions and also using media such as: slide show in PowerPoint format, clip show, practical show and booklet in line with knowledge structures. Behavioral intention, outcome expectancy, perceived self-efficacy and perceived social support will be conducted

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Comprehensive urban health service centers of Bushehr province

**Full name of responsible person**

Mohammad Hosein Kaveh

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Shiraz, Razi Blvd

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Hashem Hshempour

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Shiraz, Zand Street, Shiraz University of Medical Sciences Central Building, 7th Floor, Research and Technology Deputy

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vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Azadeh Salemi

**Position**

Employee

**Latest degree**

Bachelor

**Other areas of specialty/work**

Public Health

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Bushehr, Moalem St., in front of Friday prayer, Bushehr University of Medical Sciences and Health

Services

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Hosein Kaveh

**Position**

Professor

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Ph.D.

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Health Promotion

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## Person responsible for updating data

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Public Health

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to confidentiality of information

**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**

No - There is not 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**

Not applicable