Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Street address
Shiraz, Zand Street, Shiraz University of Medical Sciences Central Building, 7th Floor, Research and Technology Deputy
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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
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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Person responsible for updating data

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Full name of responsible person
Azadeh Salemi
Position
Employee
Latest degree
Bachelor
Other areas of specialty/work
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azadehsalemi87@gmail.com

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