Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The Effect of Educational Program on Self-care Behaviors Based on Theory Reasoned Action in Women Patients Type II Diabetes

Protocol summary

Study aim

Determine and compare the attitudes of type 2 diabetic women about self-care behaviors before and 3 months after intervention in the control and experimental group

Design

The study was a controlled clinical trial, semi experimental, and prospective interventional, with parallel groups, one blind, randomized

Settings and conduct

Before the educational intervention, the questionnaire was completed by both the control and experimental groups and Both patients were referred to the Fatemiyeh Clinic Lab with introduction letter for checking HbA1c test. Educational intervention was conducted for the experimental group in the form of 10 training sessions.Three months after the intervention, the questionnaire was completed by both the experimental and control groups. The patients were referred for checking HbA1c test and the results were recorded.

Participants/Inclusion and exclusion criteria

Patients who have at least one year of diabetes history; Have literacy to read and write; age over 30 years old will be included in the study. Exit criteria are: patients with hypertension and history of mental disorders

Intervention groups

10 sessions, including 60 minutes of lectures, group discussion, question and answer, use of educational videos were created for the intervention group. At the end of the sessions, an educational book was given to them.The WhatsApp Group was formed for the exchange of information. A monthly follow-up meeting was held to conduct their care and exchange of views. Control group members were deprived of training sessions.

Main outcome variables

Self-care behaviors in diabetic patients participating in the study; Measure the constructs of the theory of reasoned action; Attitude of women with type 2 diabetes about self-care behaviors; Behavioral intention of women with type 2 diabetes about self-care behaviors; HbA1c levels in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040372N1**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **retrospective**

Last update: **2018-09-29, 1397/07/07**
Update count: **0**

Registration date

2018-09-29, 1397/07/07

Registrant information

Name

Forough Faghih

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3842 9382

Email address

f.faghih@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-22, 1396/11/02

Expected recruitment end date

2018-02-05, 1396/11/16

Actual recruitment start date

2018-02-12, 1396/11/23

Actual recruitment end date

2018-02-21, 1396/12/02

Trial completion date

2018-06-10, 1397/03/20

Scientific title
The Effect of Educational Program on Self-care Behaviors Based on Theory Reasoned Action in Women Patients Type II Diabetes

Public title
The Effect of Educational Program on Self-care Behaviors in Women Patients Type II Diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic women who have diabetes for at least 1 year
Have literacy to read and write Diabetic women aged over 30
Exclusion criteria:

Age
From **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly & alternately divided into two groups of control and test according to case number.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding will be done on participants in the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Fasa University of Medical Sciences
Street address
Fasa university of medical sience, Ebne sina square
City
Fasa
Province
Fars
Postal code
7461686688

Approval date
2018-06-19, 1397/03/29

Ethics committee reference number
IR.FUMS.REC.1397.25

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Self-care behaivior

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
Questionnaire Measuring self-care behaviors

Secondary outcomes

1

Description
Attitude and belief of participants in the study toward self-care behaviors

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
A questionnaire that measures the constructs of the theory of reasoned action

Intervention groups

1

Description
Intervention group: Ten training sessions featuring educational videos, PowerPoint for 55 to 60 minutes in three weeks

Category
Behavior

2

Description
Control group:do not do extra work

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Forough Faghih
Street address
Shariati hospital, Fayaz bakhsh Street, Fasa Town
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7461686688
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f.faghih@fums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr.Mojtaba Farjam
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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
Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Dr. Ali Khani Jeihouni
Position
Assistant professor
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Person responsible for updating data

Contact
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Full name of responsible person
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Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Fasa
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Fars
Postal code
7461686688
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+98 71 5331 6300
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f.faghih@fums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is shared
When the data will become available and for how long
6 months after printing results
To whom data/document is available
Researchers working in academia
Under which criteria data/document could be used
Any kind of analysis on the data is allowed
From where data/document is obtainable
executor of Plan. Email adress: forough.faghih@yahoo.com
What processes are involved for a request to access data/document
Send an academic email to the project facilitator and supervisor
Comments