

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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 Faghieh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3842 9382

##### Email address

f.faghieh@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 science, 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 behavior

#### 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 Faghieh  
**Street address**  
Shariati hospital, Fayaz bakhsh Street, Fasa Town  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461686688  
**Phone**  
+98 71 5335 0116  
**Email**  
f.faghieh@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  
**Street address**  
Fasa University of Medical Science, Ebne Sina Square,  
Fasa Town  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461686688  
**Phone**  
+98 71 5331 6300  
**Email**  
farjam@fums.ac.ir  
**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  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Public Health  
**Street address**  
Fums, Ebne Sina Square, Fasa Town  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461686688  
**Phone**  
+98 987153316300  
**Email**  
khani\_1512@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Fasa University of Medical Sciences  
**Full name of responsible person**  
Dr. Ali Khani Jeihouni  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Public Health  
**Street address**  
Fums, Ebne Sina Square, Fasa Town  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461686688  
**Phone**  
+98 987153316300  
**Email**  
khani\_1512@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Fasa University of Medical Sciences

**Full name of responsible person**

Forough Faghhih

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Fums, Ebne Sina square, Fasa Town

**City**

Fasa

**Province**

Fars

**Postal code**

7461686688

**Phone**

+98 71 5331 6300

**Email**

f.faghhih@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.faghhih@yahoo.com

**What processes are involved for a request to access data/document**

Send an academic email to the project facilitator and supervisor

**Comments**