

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of education based social cognitive theory on self-care behavior of type 2 diabetes

#### Protocol summary

2018-01-12, 1396/10/22

#### Study aim

The purpose of this study was to determine the effect of educational intervention based on sociological cognitive theory on self-care behaviors in type 2 diabetes patients in Mashhad

#### Design

60 Patients with diabetes will be selected based on inclusion and exclusion. 30 Patients will be in the intervention group and 30 Patients will be in the control group

#### Settings and conduct

An educational intervention in the intervention group will be conducted for a maximum of one month, with emphasis on the influential structures of the theory by using educational strategy

#### Participants/Inclusion and exclusion criteria

Having Type II Diabetes, Satisfaction to participate in the study

#### Intervention groups

Intervention group: educational intervention for a maximum of one month, with emphasis on the influential structures of the theory by using educational strategy  
Control group: No intervention

#### Main outcome variables

Self-care behaviors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160619028529N6**  
Registration date: **2018-01-12, 1396/10/22**  
Registration timing: **retrospective**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Hadi Tehrani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3853 8530

##### Email address

tehranilh@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad University of Medical Sciences

#### Expected recruitment start date

2016-09-16, 1395/06/26

#### Expected recruitment end date

2017-10-17, 1396/07/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of education based social cognitive theory on self-care behavior of type 2 diabetes

#### Public title

The effect of education on diabetes self care

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having Type II Diabetes

##### Exclusion criteria:

#### Age

No age limit  
**Gender**  
Both  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **60**  
**Randomization (investigator's opinion)**  
N/A  
**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 Mashhad University of Medical Sciences

**Street address**

Vice chancellor for research, Qoreishi Building, Daneshgah 18, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Approval date**

2016-08-05, 1395/05/15

**Ethics committee reference number**

IR.MUMS.REC.1395.155

## Health conditions studied

### 1

**Description of health condition studied**

Diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

**Description**

Diabetes Self Care

**Timepoint**

Before intervention.Immediately and 3 months after the intervention

**Method of measurement**

Questionnaire

## Secondary outcomes

### 1

**Description**

Construct of Social Cognitive Theory

**Timepoint**

Before intervention.Immediately and 3 months after the interventio

**Method of measurement**

Questionnaire

## Intervention groups

### 1

**Description**

The intervention group received educational content based on effective structures of social cognitive theory. Educational content based on predetermined objectives presented in 4 sessions(90 minutes)

**Category**

Behavior

### 2

**Description**

Control group: No intervention was done for control group.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Emam Hasan Mojtaba Health Center

**Full name of responsible person**

Mastoreh sadat Ghoreishi

**Street address**

Alley 73, Hijat St., Qasem Abad,Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Fax**

+98 51 3854 1514

**Email**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vice President of Research, Qoreishi Building,  
Daneshgah 18, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Phone**

+98 51 3841 3007

**Email**

tafaghodim@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Hadi Tehrani

**Position**

Assistance Professor of Health Education and Health  
Promotion

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

School of Public Health, Between 16th and 18th  
Daneshgah, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3854 4633

**Fax****Email**

Tehranih@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Hadi Tehrani

**Position**

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Promotion

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Email**  
Tehranih@muma.ac.ir  
**Web page address**

## 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**

No - There is not a plan to make this available

### **Clinical Study Report**

Not applicable

### **Analytic Code**

Not applicable

### **Data Dictionary**

Not applicable

### **Title and more details about the data/document**

Potential data is sharable after distinguishing people

### **When the data will become available and for how long**

Start the access period one month after the publication of result

### **To whom data/document is available**

Researchers working in academia

### **Under which criteria data/document could be used**

Data is sent through an official request and by email

### **From where data/document is obtainable**

Hadi Tehrani tehranih@mums.ac.ir

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

Data is sent through an official request and by email

### **Comments**