

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigation the Effect of the Educational intervention based on self-efficacy theory on health literacy, self-efficacy and self-care behaviors in patients with type 2 diabetes

#### Protocol summary

##### Summary

Aim: The aim of this study is to evaluate the effect of educational intervention based on self-efficacy theory on health literacy, self-efficacy and self-care behaviors in patients with type 2 diabetes. Materials and Methods: The study is a quasi-experimental study carried out on 70 patients with type 2 diabetes who are randomly divided into experimental and control groups of 35 people. The data collection instruments are Test Of Functional Health Literacy In Adults (sTOHFLA), Summary of Diabetes Self-Care Activities Measure (SDSCA) Healthy and Confidence in Diabetes Self-Care Scale (CIDS). Inclusion criteria: Willingness to participate in the study; The definitive diagnosis of Type II Diabetes; a case in diabetes unit; Medication (tablets - insulin); Good physical and mental condition. exclusion criteria: Patients with severe complications; Adverse physical and psychological conditions; unwillingness to continue to participate in the study; The absence of one or more of the class sessions. intervention: The educational intervention was designed based on the self-efficacy theory and was performed in four educational sessions lasting 60 minutes by group discussion, brainstorming, questions and answers. Immediately and three months after the intervention, post tests were done. main outcome measures: Change in self-efficacy, health literacy and self-care behaviors.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017010328863N8**  
Registration date: **2017-09-15, 1396/06/24**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-15, 1396/06/24

##### Registrant information

###### Name

Nooshin Peyman

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 502 6195

###### Email address

peymann@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Chancellor for research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-12-13, 1395/09/23

##### Expected recruitment end date

2017-01-19, 1395/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation the Effect of the Educational intervention based on self-efficacy theory on health literacy, self-efficacy and self-care behaviors in patients with type 2 diabetes

**Public title**

Education based on the theory of self efficacy theory on health literacy, self efficacy and self-care in Diabetics patients.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria:Willingness to participate in the study;The definitive diagnosis of Type II Diabetes; a case in diabetes unit; Medication (tablets , insulin); Good physical and mental condition . exclusion criteria: Patients with severe complications; Adverse physical and psychological conditions; unwillingness to continue to participate in the study ;The absence of one or more of the class sessions.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**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**

School of Health, Daneshgah18 Street, Danshgah Avenue, Mashhad

**City**

Mashhad

**Postal code**

9138813944

**Approval date**

2017-03-11, 1395/12/21

**Ethics committee reference number**

IR.MUMS.REC.1395.603

**Health conditions studied****1****Description of health condition studied**

diabetes

**ICD-10 code**

(E10-E14)

**ICD-10 code description**

Diabetes mellitus

**Primary outcomes****1****Description**

Health Literacy

**Timepoint**

Before - immediately and 3 months later

**Method of measurement**

Test of Functional Health Literacy in Adults questionnaire

**2****Description**

Self- efficacy

**Timepoint**

Before - immediately and 3 months later

**Method of measurement**

Healthy and Confidence in Diabetes Self-Care Scale

**3****Description**

Self-care

**Timepoint**

Before - immediately and 3 months later

**Method of measurement**

Summary of Diabetes Self-Care Activities Measure

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The educational intervention was designed based on the self-efficacy theory and was performed in four educational sessions lasting 60 minutes by group discussion,brainstorming, questions and answers.

**Category**

Lifestyle

**2****Description**

Control group:35 Diabetic patients who is not receive any special training by researchers.

**Category**  
Lifestyle

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Ghodsi

**Full name of responsible person**

Mehri Bolandashyain

**Street address**

Shahid Ghodsi Center , Sanabad Street , Mashhad

**City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Chancellor for research of Mashhad University of Medical Sciences

**Full name of responsible person**

Nooshin Peyman

**Street address**

School of Health, Daneshgah 18 Street, Danshgah Avenue, Mashhad

**City**

Mashhad

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Chancellor for research of Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Soghra Hejazi

**Position**

Masters of Health Education and Health Promotion

**Other areas of specialty/work**

**Street address**

School of Health, Daneshgah 18 Street, Danshgah Avenue, Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 513854443

**Fax**

**Email**

hejazis1@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**

Nooshin Peyman

**Position**

دکترای تخصصی آموزش بهداشت و ارتقای سلامت

**Other areas of specialty/work**

**Street address**

School of Health, Daneshgah 18 Street, Danshgah Avenue, Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3854 4643

**Fax**

+98 38522755

**Email**

peymann@mums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Nooshin Peyman

**Position**

PhD in Health Education building community health

**Other areas of specialty/work**

**Street address**

School of Health, Daneshgah 18 Street, Danshgah Avenue, Mashhad

**City**

Mashhad

**Postal code**

9138813944

**Phone**

+98 51 3854 4633

**Fax**

+98 38522755

**Email**

peymann@mums.ac.ir

**Web page address**

## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*