

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

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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

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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

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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

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

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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

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

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Full name of responsible person

Soghra Hejazi

Position

Masters of Health Education and Health Promotion

Other areas of specialty/work

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PhD in Health Education building community health

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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