

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of Educational Intervention on Self-Care Behaviors among Patients with Diabetes: an Application of PRECEDE Model

Protocol summary

Summary

Objectives: This survey was aimed to assess the effect of educational intervention on self-care behaviors among patients with diabetes: an application of PRECEDE model. **Design:** A randomized clinical trial study was conducted. **Setting and conduct:** This survey was conducted on 106 patients with type 2 diabetes who had active records in the diabetes clinics (just two clinics) in the Iranian city of Gorgan. **Participants:** Inclusion main criterion was having type 2 diabetes more than two years, and exclusion criterion was treatment with insulin. **Intervention:** Patients were randomly assigned in the control (53 patients) and intervention (53 patients) arms. **Main outcome measures:** Self-care behaviors, glycosylated hemoglobin, body mass index and constructs of PRECEDE model.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112817736N9**

Registration date: **2017-01-20, 1395/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

International Campus of Tehran University

Expected recruitment start date

2015-09-05, 1394/06/14

Expected recruitment end date

2016-04-02, 1395/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Educational Intervention on Self-Care Behaviors among Patients with Diabetes: an Application of PRECEDE Model

Public title

Self-Care Behaviors among Patients with Diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having type 2 diabetes more than two years; inclines to participate in the study; age less than 60 years; and lack of debilitating disease. Exclusion criteria: Treatment by insulin; disable to exercise (such as walking); gestational diabetes; cognitive disorders that may interfere with completing the questionnaire.

Age

To **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 106

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Sciences of International Campus

Street address

Tehran

City

Tehran

Postal code

Approval date

2015-03-21, 1394/01/01

Ethics committee reference number

9223489001

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Glycated hemoglobin (HbA1C)

Timepoint

Pre-intervention, 1, 3 and 6 month after intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Self-care behavior

Timepoint

Pre-intervention, 1, 3 and 6 month after intervention

Method of measurement

A standardized self-care behavior questionnaire

Intervention groups

1

Description

Control group: Patients in the control group were received the routine education that usually provided in the diabetes clinics. Totally, patients were received a maximum education of 7-10 (the mean time of these sessions were usually 20-30 minutes). Education in this arm was provided by a general physician.

Category

Prevention

2

Description

Intervention group: All content of intervention group were presented by the workshop. Additionally, lecture, enquiry, group discussion and snow balling techniques were also used during the workshop. Sessions were held for four weeks (two hours per week) in the diabetes clinic in Gorgan city. Approximately, 25 patients took part in the each session. In the final of sessions, patients were provided by brochures and necessary guidance. To increase the reinforcing factors and family supports, patients were asked to participate in the sessions with one of their family members. In final, a single session was held for the members of patient's family to avoid ambiguity, as well. Education in this group was delivered by two persons including a general physician and by a specialist in health education and promotion.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Street address

Floor 2, Sayyad Shirazi avenue, Sayyad Shirazi Hospital

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Health School, Tehran University of Medical Science,
International Campus

Full name of responsible person

Sepideh Zamiri

Street address

No 124, 3 Floor, International Pardis Unit, Avenue of
Shahid Baradaran of Mozafar Shomali, Dameshgh
Street, Vali Asr Street, Tehran, Iran.

City

Tehran

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

Yes

Title of funding source

Health School, Tehran University of Medical Science,
International Campus

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**

Golestan University of Medical Science

Full name of responsible person

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Position

Associated Professor

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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

