

# 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

Seyed Kamaladdin Mirkarimi

###### Name of organization / entity

Golestan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 1553 2872

###### Email address

k.mirkarimi@goums.ac.ir

###### 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**

Seyyed Kamal Mirkarimi

**Position**

Associated Professor

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Sari Road

**City**

Gorgan

**Postal code****Phone**

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**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*

