

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Evaluating the effectiveness of educational intervention on the nutritional behavior and physical activity in patients with type 2 diabetic based on KirkPatrick's model

#### Protocol summary

Registration timing: **retrospective**

#### Study aim

Evaluation of the Effectiveness of Educational Intervention on the Nutritional Behavior and Physical Activity of Diabetic Patients Referring to Health Care Centers Affiliated to Shiraz University of Medical Sciences Based on the Kirk Patrick Model

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

#### Registration date

2019-05-24, 1398/03/03

#### Design

Clinical trial with intervention and control group

#### Registrant information

##### Name

Maryam Mehranpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Settings and conduct

Organizing training sessions in diabetes clinics in comprehensive health centers affiliated to Shiraz University of Medical Sciences and completing satisfaction questionnaire related to participation in research.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Entry requirements: Diabetics over 30 years of age; Have a history of 1 year old diabetic disease with reading and writing skills. Conditions of non-entry: lack of participation in the classroom and reluctance to cooperate in research.

#### Expected recruitment start date

2019-04-20, 1398/01/31

#### Expected recruitment end date

2019-05-19, 1398/02/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

Control group: no intervention for the control group will be performed. Intervention group: for this group, training sessions on the effects of regular exercise and proper diet are conducted and after 2 months the results of the tests are compared with the control group.

#### Scientific title

Evaluating the effectiveness of educational intervention on the nutritional behavior and physical activity in patients with type 2 diabetic based on KirkPatrick's model

#### Main outcome variables

Reduce the complications of diabetes and improve the health of these patients

#### Public title

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181219042057N1**

Registration date: **2019-05-24, 1398/03/03**

The effect of education on diet and physical activity on reducing blood glucose

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

History of type 2 diabetes for at least one year Having at least 30 years of age for participants Having reading and writing skills Lack of other underlying diseases other than diabetes

##### **Exclusion criteria:**

The patient's unwillingness to continue to collaborate in the research Missing more than one session in training classes Patient admission to the hospital during the duration of the research Failure to reenter the patient to complete the questionnaire

#### **Age**

From **30 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Factorial

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

National Ethics Committee for Biomedical Research

###### **Street address**

no 11/2 , andishe ave , farhangshahr blvd

###### **City**

shiraz

###### **Province**

Fars

###### **Postal code**

7185954992

##### **Approval date**

2019-01-11, 1397/10/21

##### **Ethics committee reference number**

IR.SUMS.REC.1397.916

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Diabetes

##### **ICD-10 code**

E12

##### **ICD-10 code description**

Diabetes Mellitus

### **Primary outcomes**

#### **1**

##### **Description**

The effect of training on reducing blood glucose levels

##### **Timepoint**

Beforem, immediately and two months after the intervention

##### **Method of measurement**

Check blood glucose

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

The intervention group: The training group will be involved in the first training session on the objectives of the design and the motivation survey. During the other three sessions, the effect of the activity and observation of low-fat and low calorie diet will be explained and the motivational questionnaire will be repeated by the participants. Will be completed. The duration of each session will be up to 1.5 hours.

##### **Category**

Prevention

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Hakim Health Center

###### **Full name of responsible person**

Dr Mohammadi

###### **Street address**

Farhangshahr Blv , Hakim health center

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

7185643565

###### **Phone**

+98 71 3633 2905

**Email**

z.talebi\_arc89@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Poostforoosh

**Street address**Zand Street, Central Building of Shiraz University of  
Medical Sciences Shiraz city**City**

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**Province**

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71348-14336

**Phone**

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**Email**

vcrdep@sums.ac.ir

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shahrazad Yektatalab

**Position**

Ph.D. in Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**Namazi Square, School of Nursing and Midwifery,  
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71348-14338

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+98 71 3647 4254

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Shahrazad Yektatalab

**Position**

ph.d in nursing

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Mehranpour

**Position**

nursing expert

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Sharing plan

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

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

No more information

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to

make this available

### **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

No - There is not a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available