

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of educational intervention on management of Blood Glucose and Confidence in Self-Care in patients with type 2 Diabetes by using face to face training and educational film: A randomised controlled clinical trial

#### Protocol summary

##### Summary

(1) Objectives: The effect of educational intervention on management of Blood Glucose and Confidence in Self-Care in patients with type 2 Diabetes by using face to face training and educational film. (2) Design: This study is a randomized clinical trial with two groups (intervention and control). 192 samples were determined according to the same studies. In this clinical trial, two groups, intervention and control groups will be randomly selected. Ones, with the film and to another one face to face training, in groups with 4-5 people, all required training will be given. The control group, will receive routinely training methods of Diabetes Center. Diary blood sugar, and Confidence in Self-Care Questionnaires, one week before and one month after intervention patients to be complete. And also, the amount of Glycated Hemoglobin in the last tests before and three months after the intervention will be recorded. (4) Participants: Patients with diabetes who inject Insulin themselves and Which have files in Diabetes Association. (5) Intervention: Interventions will be as training to patients. Interventions as training to patients, according to the educational content will take place. Before intervention and one month after the last training session, daily Blood Glucose diary and Confidence in Self-care Questionnaire will completed. For the control group, just Confidence in Self-Care Questionnaire and record sheet daily Blood Glucose, with time intervals similar to the experimental groups will be completed. (6) Main outcome measures variables: Average daily Blood Glucose, Confidence in Self-Care Questionnaire score and the amount of Glycated Hemoglobin

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016082412264N4**  
Registration date: **2016-10-20, 1395/07/29**  
Registration timing: **registered\_while\_recruiting**

Last update:  
Update count: **0**

##### Registration date

2016-10-20, 1395/07/29

##### Registrant information

###### Name

Farahnaz Abdollahzadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1477 0648

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

research deputy of Tabriz university of Medical Sciences

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of educational intervention on management of Blood Glucose and Confidence in Self-Care in patients with type 2 Diabetes by using face to face training and educational film: A randomised controlled clinical trial

## Public title

The effect of educational intervention on management of Blood Glucose and Confidence in Self-Care in patients with type 2 Diabetes by using face to face training and educational film: A randomised controlled clinical trial

## Purpose

Supportive

## Inclusion/Exclusion criteria

The inclusion criteria : The patient has primary education is minimal; The patient is a resident of Tabriz; The patient's age is between 40 and 70; Patients are under insulin treatment; The patient is not suffering from mental illness; The patient is willing to participate in the study; The patient has recently joined to Diabetes Society. Exclusion criteria: membership one of the family members in health care team; patient's absence from training sessions; infection or having surgery.

## Age

From **40 years** old to **70 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **192**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization: In this study, type of interventions order will be determined based on random numbers and the invisible envelope will be recorded. Whenever the number of new members (registered) reached twenty, a parcel (by the secretary of the center) is removed and it will be determined according to the type of intervention. Interventions presenter, will not be notified orders of packets until classes start time to assign people randomly occur. When Face-to-face group or Movie group terms arrive People will have determined with the numbers one to twenty. Then people with drawing, will dividing into four group with five members.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of medical sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

##### City

Tabriz

##### Postal code

5138947977

##### Approval date

2016-09-10, 1395/06/20

##### Ethics committee reference number

We're getting license

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E10, E11,

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Average daily blood sugar

#### Timepoint

One week before intervention and one month after intervention for a week

#### Method of measurement

By using Beurer Glucometer

### 2

#### Description

Confidence in Self-Care

#### Timepoint

One week before intervention and one month after intervention for a week

#### Method of measurement

Confidence in Self-Care Questionnaire

## Secondary outcomes

### 1

#### Description

Glycosylated hemoglobin

#### Timepoint

The last test before the intervention and after the

intervention first test

#### **Method of measurement**

By using Glycated Hemoglobin detection kit

### **Intervention groups**

#### **1**

##### **Description**

Intervention 1: Intervention in face to face training group will take place by using equipment needed by the researcher. in a 30-minute session, as a group (4-5 people) in the Diabetes Association, quiet and equipped with teaching aids, and researcher entire process with a glucometer, Flex Penn and correct principles of using and Insulin injections on models and practically will train and at the end of the session, the patients are given enough time for questions and answers and practical training.

##### **Category**

Prevention

#### **2**

##### **Description**

Intervention 2: In groups of videos, tutorials in terms of screening to patients, in groups (4-5 Members) will be provided. A film that is 22 minutes of Tutorials Video Film of Pars NovoNordisk company, Beuerr company and Aparat website. Content of this group with content of face to face training group are matches. Researcher by using film, all the content in a simple language and native participants will explain to patients. Watch Tutorials Video Film in place of quiet Diabetes Association and will be equipped with audio-visual equipment's. At the end of the session, patients are given enough time for questions and answers. Researcher will explain all the content in a simple language and native participants by using film, to patients. Play backing will be in Diabetes Association that is quiet place and equipped with audio-visual equipment's. At the end of the session the patient enough time for questions and answers will be given

##### **Category**

Lifestyle

#### **3**

##### **Description**

Intervention 3: In the control group, the patients will receive Routine training of the center that is lectures. Researcher will be presented, the previous educational content, in the form of lectures as a groups with 30 minutes' time length. Lecture will take place in a peaceful environment in the Diabetes Association and at the end of the session, patients are given enough time for questions and answers.

##### **Category**

Prevention

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Diabetes Association of East Azarbaijan

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

Doctor Majid Mobasseri

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

Fatmy 24 meters, North Gatran Avenue, Tabriz

###### **City**

Tabriz

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Vice-Chancellor for Research Deputy in Tabriz University of Medical Sciences

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

Doctor Mohammad Reza Rashidi

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

Tabriz University of Medical Sciences, Golgasht Avenue.

###### **City**

Tabriz

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Vice-Chancellor for Research Deputy in Tabriz 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**

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences.

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

Farahnaz Abdollahzadeh

###### **Position**

Masters of Sciences

###### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*