Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
abdollahzadehf@tbzmed.ac.ir

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

Street address

Kosar Dormitory, Shariati Avenue.

City

Tabriz

Postal code
Phone
+98 41 3479 6707
Fax
Email
abdollahzadehf@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences.
Full name of responsible person
Farahnaz abdollahzadeh
Position
Master of Sciences
Other areas of specialty/work
Street address
Kosar Dormitory, Shariati Avenue.
City
Tabriz
Postal code
Phone
+98 41 3479 6707
Fax
Email
abdollahzadehf@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences.
Full name of responsible person
Mohammad Gholipour
Position
Bachelor Student
Other areas of specialty/work
Street address
Kosar Dormitory, Shariati Avenue.
City
Tabriz
Postal code
Phone
00
Fax
Email
m.gholipour1374@gmail.com
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
Data Dictionary
empty