

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of short term health literacy promotion program on self-care behaviors and quality of life among patients with type 2 diabetes: a Randomized Controlled Trial

Protocol summary

Study aim

The purpose of this study is The effect of educational intervention on increasing health literacy, self-care behaviors and quality of life in patients with type 2 diabetes in Chaldoran.

Design

The groups are extracted randomly from the list of patients in the Chaldoran Health Network and they are categorized into groups. The sample size was 40.

Settings and conduct

After selecting the intervention and control groups, the data will be collected using a questionnaire before intervention and 3 and 6 months after the intervention. In the pre-intervention phase, a pre-test is performed in a test group and a control. And then by analyzing the data of this stage, resources, limitations, needs and strengths and weaknesses are identified in different fields. And then the educational intervention is designed.

Participants/Inclusion and exclusion criteria

The main inclusion criteria: patients with diabetes, Iranian nationality, absence of formal education about nutrition; exercise and self-care over the past 6 months and consent to participate in the study. Exclusion criteria: having mental disorders such as dementia, Alzheimer's disease and mental retardation; having severe motor constraints such as limb disability; having illnesses such as cardiovascular diseases.

Intervention groups

Intervention group: includes 80 people that the training program will be implemented for them. The number of sessions is 5 and the duration of the training will be one month. Control group: includes 80 people in whom an educational program will not be running.

Main outcome variables

Awareness; health literacy; self-care behaviors; hemoglobin A1c; quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131116015422N7**

Registration date: **2019-02-25, 1397/12/06**

Registration timing: **retrospective**

Last update: **2019-02-25, 1397/12/06**

Update count: **0**

Registration date

2019-02-25, 1397/12/06

Registrant information

Name

Towhid Babazadeh

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-12, 1397/06/21

Expected recruitment end date

2018-12-17, 1397/09/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of short term health literacy promotion program on self-care behaviors and quality of life among patients with type 2 diabetes: a Randomized Controlled Trial

Public title
The Effect of Health Literacy Improvement on Self-care Behaviors and Quality of Life in Diabetic Patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diabetes Iranian nationality Absence of formal education about nutrition, exercise and self-care over the past 6 months Consent to participate in the study
Exclusion criteria:
Mental disorders such as dementia, Alzheimer's disease, mental retardation Having severe motor constraints such as limb disability Having diseases such as cardiovascular disorder

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**
Actual sample size reached: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
For this purpose, a simple random allocation method will be used and patients will be divided into intervention and control groups by lottery. In this way, patients will be numbered without observing the particular order then the patients with odd numbers will be assigned to the intervention group and the patients with even numbers will be assigned in the control group.

Blinding (investigator's opinion)
Not 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 Tabriz University of Medical Sciences
Street address
Ethics Committee, Third Floor, Central Building No. 2, Tabriz University of Medical Science, Golgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-08-27, 1397/06/05
Ethics committee reference number
IR.TBZMED.REC.1397.459

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Health literacy
Timepoint
Before the intervention, 3 and 6 months after the intervention
Method of measurement
Questionnaire

2

Description
Awareness
Timepoint
Before the intervention, 3 and 6 months after the intervention
Method of measurement
Questionnaire

3

Description
Behavior
Timepoint
Before the intervention, 3 and 6 months after the intervention
Method of measurement
Questionnaire

4

Description

Quality of Life

Timepoint

Before the intervention, 3 and 6 months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

HbA1c

Timepoint

Before the intervention, 3 and 6 months after the intervention

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group: In this group pre-test will be performed and in this study the intervention will be performed through training sessions. The intervention would be based on information obtained from the questionnaire. 5 sessions in a one-month period will be held as follows: Session 1: Understanding the goals of the training program and raising the awareness of patients (40 minutes) Session 2: Increasing patient awareness (45 minutes), Session 3: Promoting Health Literacy (Reading and Understanding Skills, 40 Minutes), Session 4: Improving Health Literacy (Decisions, 30 minutes), Session 5: Improving self-care behaviors (40 minutes).

Category

Behavior

2

Description

Control group: In this group pre-test will be performed but the training is not done and after the end of data collection in the end of study, educational pamphlets will be given to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Chaldoran Health Network

Full name of responsible person

Hakim Ahmadzadeh Heidaranloo

Street address

Chaldoran Health Network, County Chaldoran, West Azerbaijan province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolqasem Jouyban

Street address

Deputy for Research and Technology, Third Floor, Central Building 2, Tabriz University of Medical Sciences, Golgasht, Tabriz

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ajouyban@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hakim Ahmadzadeh Heidaranloo

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Department of Health Promotion and Education,
Faculty of Health and Nutrition, Golgashte Street,
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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

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

Analytic Code

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

Data Dictionary

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