

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Clinical trial to assess the effectiveness of a Multi-dimensional Behavioral Intervention Program on decreasing HbA1C among patients with diabetes

Protocol summary

Study aim

Determining the effectiveness of multi-dimensional behavioral intervention program on HbA1c among patients with Type 2 diabetes

Design

This is a randomized trial with a control group, education based, parallel group, and without blinding. Randomization will be computerized with concealed randomization sequence. The patients will randomly be divided into control and intervention groups and a code will be allocated to them.

Settings and conduct

The study will be conducted in Khoy (West Azarbayjan, Iran) and diabetes care centers.

Participants/Inclusion and exclusion criteria

Patients with Type 2 diabetes/ Inclusion criteria: Having a registry profile in diabetes clinic of Khoy; Having consent to participant in the study. exclusion criteria: having cognitive disorders

Intervention groups

A multi-dimensional behavioral intervention program according to social cognitive theory for decreasing HbA1c will be conducted. The educational program will include adherence to medicine, self-regulation, and self care among the patients. The intervention group will participate in educational sessions for 16 sessions during 60 minutes per week.

Main outcome variables

HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111119008132N7**

Registration date: **2018-04-15, 1397/01/26**

Registration timing: **retrospective**

Last update: **2018-04-15, 1397/01/26**

Update count: **0**

Registration date

2018-04-15, 1397/01/26

Registrant information

Name

Leila Jahangiry

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 307 0128

Email address

jahangiry@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to assess the effectiveness of a Multi-dimensional Behavioral Intervention Program on decreasing HbA1C among patients with diabetes

Public title

The behavior intervention on control of glucose among diabetic patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a registry profile in diabetes clinic of Khoy Having consent to participant in the study.
Exclusion criteria:
 Having cognitive disorders

Age
From 30 days old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Randomized

Randomization description
 Diabetic patients referring to diabetes clinic will be recruited to the study through a simple randomization. Table of random numbers will be used to randomization. Random sequence generation and allocation concealment will be carried out independently by a researcher not connected to the study.

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

Ethic's comitte of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht street, Azadi Street, Tabriz, East Azarbayjan

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.TBZMED.REC.1396.192

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10-E14

ICD-10 code description

Endocrine, nutritional and metabolic diseases (E00-E90):
Diabetes mellitus

Primary outcomes

1

Description

HbA1C

Timepoint

before intervention and after 24 weeks

Method of measurement

HbA1c Test

Secondary outcomes

1

Description

Adherence to medical care

Timepoint

2 and 6 month after intervention

Method of measurement

The adherence questionnaire for diabetic patients

Intervention groups

1

Description

Education behavior program about diabetes self-care will be conducted in the multi dimensions based on self-efficacy, self-control and self-regulation strategies among diabetic patients to modify self-care behaviors and decrease HbA1c. The intervention group will participate in such educational sessions about 60 minutes per week during 6 months.

Category

Behavior

2

Description

Control group: without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khoy Shahid Madani clinical care center

Full name of responsible person

Habibeh Matin

Street address

Shahid Madani Hospital, Valiasr Ave., Khoy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Asghari

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Tabriz University of Medical Sciences, Golgasht street,
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Grant name

Vice Chancellor for research of Tabriz University of
Medical Sciences

Grant code / Reference number

IR.TBZMED.REC.1395.1268.

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

Habibeh Matin

Position

Student

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Health Education and Promotion departement, Public
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. AndoReza Shaghghi

Position

Assisstants Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Web page address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

participant data sets are to be shared.

**When the data will become available and for how
long**

starting 6 months after publication

To whom data/document is available

available for people working in academic institutions

Under which criteria data/document could be used

request from academic organization

From where data/document is obtainable

Health Education and Promotion department, Public
Health Faculty, Tabriz University of Medical Sciences,
Golgashst street, Azadi Street, Tabriz. Dr. Reza Shaghaghi

**What processes are involved for a request to access
data/document**

sending request-assess the request by study responsible,
and deliver the data

Comments