

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A study on The Effect of performing self-efficacy increasing program on type 2 diabetic patients HbA1c control referred to Urmia society of diabetes, 2016

Protocol summary

Study aim

evaluate the effect of self-efficacy training program on HbA1c in patients with type 2 diabetes.

Design

Quasi-experimental intervention with control group, with parallel groups, available sampling and random allocation

Settings and conduct

Location: Urmia Society of Diabetes Background: Educational intervention based on the concept of self-efficacy of social cognitive theory After sampling the class was conducted and variables were investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People who are willing to participate in the study, have Type 2 diabetes diagnosis and have had a diagnosis of diabetes for at least one year, have literacy and writing skills, and have high school education, over the age of 30, and They do not use insulin. Exit criteria: Those who do not want to participate in the study, those with severe physical, cognitive and visual impairment that interfere with the ability to participate in the study and patients with gestational diabetes or other types of diabetes will be excluded from the study. Those who have to use insulin during the study will be excluded. If the patient has two or more absence during the sessions, will be exclude

Intervention groups

132 patients with type 2 diabetes will be selected through available sampling and randomly divided into two groups of intervention (Received self-efficacy educational program) and control (Received usual education). Participants in the self-efficacy-based intervention group and control group will receive regular training. The data collection tool will be self-efficacy questionnaire for patients with type 2 diabetes and HbA1c measurements. Data using descriptive and inferential statistics will be analyzed.

Main outcome variables

self-efficacy, HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180910040987N1**

Registration date: **2018-10-29, 1397/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-29, 1397/08/07**

Update count: **0**

Registration date

2018-10-29, 1397/08/07

Registrant information

Name

rasoul zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3383 4745

Email address

rnurse@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A study on The Effect of performing self-efficacy increasing program on type 2 diabetic patients HbA1c control referred to Urmia society of diabetes, 2016

Public title
A study on The Effect of performing self-efficacy increasing program on type 2 diabetic patients HbA1c control

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
People who are willing to participate in the study Have a diagnosis of type 2 diabetes One year has passed since their diagnosis of diabetes They have literacy and reading skills, and have high-level education They are over 30 years old Does not use insulin
Exclusion criteria:
Those with severe physical, cognitive and visual impairment that interfere with the ability to participate in the study (e.g., end-stage renal disease, hemodialysis, acute myocardial infarction, acute cerebrovascular accidents, or events that cause cognitive impairment)
People with gestational diabetes and type 1 diabetes will not be included in the study.

Age
From 30 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 132
Actual sample size reached: 132

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple Random unit: Individual
Randomization Tool: Cards How to create a random sequence: 66 cards with the letter A (for the intervention group) and 66 cards with the letter B (control group) written in such a way that the participant and researcher are not aware of their words randomly Will be selected.

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 Urmia University of Medical Sciences

Street address

Resalat Blvd. urmia town.

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2016-06-16, 1395/03/27

Ethics committee reference number

IR.UMSU.REC.1395.328

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

self-efficacy

Timepoint

Before the intervention, after the end of the meeting (one month) and three months after the end of the meeting

Method of measurement

Self-efficacy questionnaire for patients with type 2 diabetes

Secondary outcomes

1

Description

HbA1c

Timepoint

Before the intervention and four months later

Method of measurement

spectrography

Intervention groups

1

Description

Intervention group: The intervention group will receive

educational content based on self-efficacy. There will be four sessions in person (one session per week). The duration of the sessions is between 30 and 60 minutes. Patients in the intervention group will be divided into groups of 10. Before contacting patients, they will be contacted by telephone and will be encouraged to attend the meeting. After the end of the meeting, the patient has a phone call for up to 3 months

Category

Behavior

2

Description

Control group: The control group will receive the usual education

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

انجمن دیابت ارومیه

Full name of responsible person

Ahmad anari

Street address

Municipality Health Building, Mehrab, ave, Resalat Blvd, urmia

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5719957395

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+98 44 3336 6487

Email

khairieh.ir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Urmia University of medical sciences, Resalat Blvd, urmia

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Phone

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Email

mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Rasoul Zare

Position

Student of master of sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

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

Oroumia University of Medical Sciences

Full name of responsible person

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Position

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