Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 2026

The effect of theory-based education on eye care of type 2 diabetic patients referred to Diabetes Clinic of Arak city in 2018

Protocol summary

Study aim

The overall aim of this study is to determine the effect of the theory-based education on the predictive structures of eye care behavior in patients with type 2 diabetes.

Design

Firstly, we refer to the Debit City Clinic, and we will list all people who have been diagnosed with a disease for at least 5 years and who do not have clammy complications based on patient records. Then, from this locite, 94 people were selected by simple random sampling and assigned randomly into two groups of control and intervention.

Settings and conduct

Intervention - Arak Diabetes Clinic

Participants/Inclusion and exclusion criteria

Diabetic patients who have been diagnosed with at least 5 years of age. Patients who have not experienced eye problems at the time of the study Patients aged 40 to 60 years Individuals with a minimum education degree

Intervention groups

In this study, according to the existing studies and available studies, the most powerful predictive structures of eye care in diabetic patients were selected based on the theory of planned behavior and the health belief model (Khani et al.) And based on their respective structures Educational intervention is carried out on patients. According to available sources, the most predictive constructs are the components of consciousness (19%), perceived sensitivity (31%), perceived barriers (19%), attitude (18%), subjective norm (11%), perceived behavioral control (18%) and behavioral intention (25%) that intervention will be performed on the promotion of these structures in the case group and compared with the control group receiving routine training.

Main outcome variables

Preventing diabetic eye complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180819040834N1**
Registration date: **2019-05-08, 1398/02/18**
Registration timing: **retrospective**

Last update: **2019-05-08, 1398/02/18**
Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

Seyed Shahriar Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 8625

Email address

shahriyar.hoseni95@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date

2018-10-02, 1397/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of theory-based education on eye care of type 2 diabetic patients referred to Diabetes Clinic of Arak city in 2018

Public title

The effect of theory-based education on eye care of type 2 diabetic patients referred to Diabetes Clinic of Arak city in 2018

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients who have been diagnosed with at least 5 years of age Patients who have not experienced eye problems at the time of the study Patients aged 40-60 years with minimum education

Exclusion criteria:

exclusion criteria is patient are not willing to participate in this research. Affected by diabetes ocular complications

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

A list of case records of all diabetic patients referred to the Diabetes Clinic of Arak city, and then the number of cases related to patients with exclusion criteria (including diabetic patients who have been diagnosed with ocular complications during the diagnosis of a doctor, patients less than 5 years old with Diabetics are diagnosed, people with less education than guidance and dissatisfaction) have been excluded from participating in an identifiable study. The remaining files were entered in SPSS software. Then, 47 patients were randomly selected for the intervention group and the selected files were removed from the list. Again, with the simple random sampling method, 47 other file numbers for the group Control is selected.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The participants were randomly selected (based on the clinical records) and then randomly assigned by the relevant software (www.randomizer.com) into one of the intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak School of Public Health

City

Arak

Province

Markazi

Postal code

3814877991

Approval date

2018-05-13, 1397/02/23

Ethics committee reference number

IR.ARAKMU.REC.1397.045

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type II

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Preventing diabetic eye complications

Timepoint

Three months

Method of measurement

Health Belief Model Structures Questionnaire and Planned Behavior Theory

Secondary outcomes

1

Description

Prevention of diabetic eye disease

Timepoint

three mounth

Method of measurement

questionnaire

2

Description

Behavioral intention

Timepoint

three month

Method of measurement

questionnaire

3

Description

Perceived behavioral control

Timepoint

three month

Method of measurement

questionnaire

4

Description

knowledge

Timepoint

three month

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Educational intervention for this group takes place within one month through interactive educational, booklet, seminars and the presentation of educational pamphlets as reminders, and no drugs are prescribed

Category

Prevention

2

Description

Control group: .Control group: There are no educational or pharmaceutical interventions in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Fatemeh Karimi

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Daraei Square., Arak City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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Basij Squar, Sardasht, Arak University of Medical Sciences, Deputy of Research and Technology

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Web page address

https://arakmu.ac.ir/vcr/fa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Seyed Shahriar Hosseini

Position

Master Student in Health Education

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Maintain confidentiality of participants' information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable