

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 month

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
Street address
Daraei Square., Arak City
City
Arak
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Markazi
Postal code
3818146851

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+98 86 3222 1891
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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
Street address
Basij Squar, Sardasht, Arak University of Medical Sciences, Deputy of Research and Technology
City
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Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3639
Fax
+98 86 3417 3645
Email
research@arakmu.ac.ir
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

Public Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Seyed Shahriar Hosseini

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Person responsible for updating data

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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