Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education based on health belief model on behavior related to carbohydrate consumption in type 2 diabetic patients referred to comprehensive health service centers in Arak in 2019

Protocol summary

Study aim

Determining the effect of theory-based training on the related behavior of carbohydrate consumption in type 2 diabetic patients in Arak

Design

Controlled educational trial on about 80 patients with type 2 diabetes referred to the comprehensive health service centers of Arak (40 people in the two experimental and control groups) randomized using rand excel function software

Settings and conduct

Comprehensive health centers of Arak, a total of 4 centers will be assigned to the experimental group and 4 centers to the control group, and the samples from each center will be selected at random. There are 10 people in each group from each center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients aged 60-30 years; at least 5 literacy classes; not having chronic complications of diabetes such as retinopathy; resident of Arak city; taking oral medications; diagnosed as diabetes for at least a year; not using a special diet. Exclusion criteria: unwillingness to continue cooperation; if the patient migrates from Arak; lack of continuous attendance at training sessions.

Intervention groups

The intervention is based on theory-based training in the intervention group. Before the start of training classes, both FBS and HbAc BMI test were measured and for the experimental group, the number of training sessions was 60. Up to 90 minutes (3 sessions) were adjusted according to the learning and demographic . The methods used for training according to the needs assessment in the cross-sectional study included lectures, questions and answers and group discussions that used the powerpoint program, posters, ...

Main outcome variables

Knowledge; constructs of health belief theory; self-efficacy; performance; fasting blood sugar and blood sugar of the last 3 months (HbA1c) and BMI (body mass index)

General information

Reason for update

Acronym

CIBDM

IRCT registration information

IRCT registration number: **IRCT20190303042901N1**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Fatemeh Mohebian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date
2019-09-23, 1398/07/01
Actual recruitment end date
2019-12-22, 1398/10/01
Trial completion date
2020-06-21, 1399/04/01

Scientific title
The effect of education based on health belief model on behavior related to carbohydrate consumption in type 2 diabetic patients referred to comprehensive health service centers in Arak in 2019

Public title
The Effect of Theory-Based Education on Carbohydrate Consumption Behavior in Type 2 Diabetic Patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetic patients aged 60 to 30 years old Type 2 diabetic patients with at least 5 reading and writing classes Patients with type 2 diabetes who have chronic diabetes complications, such as retinopathy, nephropathy, neuropathy, etc., will be identified by examining patients' medical records Type 2 diabetic patients who live in Arak are included in the study Type 2 diabetic patients taking oral medications Type 2 diabetic patients who have been diagnosed with diabetes for at least one year Type 2 diabetic patients who do not use a specific diet
Exclusion criteria:
If the patient is reluctant to continue to cooperate If the patient migrates from Arak Continuous absence of diabetic patients at training sessions (overtime absences (half sessions) in educational intervention sessions) Unavailability of patients when completing a post-test questionnaire If patients have any of the complications of diabetes Change the drug program (from the oral to the injectable form) and the use of diet during the program that leads to changes in the patient's diet plan
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study is a control educational trial on about 80 patients with type 2 diabetes referred to the comprehensive health service centers in Arak (40 people in the two experimental and control groups). The method of selecting individuals was performed using the multi-stage method. In the first stage, the residents of Arak city are divided into four categories according to the opinion of the health deputy staff based on the socio-economic status. These four classes include centers with covered populations with relatively good, average, low-average, and poor economic status. Then, two health centers from each category were selected at random, so that the first selected center belongs to the experimental group and the second selected center belongs to the control group, so a total of 4 centers were assigned to the experimental group and 4 centers to the control group. In the second step, samples are randomly selected from each center. In order to perform a simple random method, a list of type 2 diabetic patients who are registered in the Apple system and are covered by that health center to receive care, is prepared in each center and then randomly we selected people from the list of type 2 diabetic patients registered in that health center. The number of samples selected from each center is 10 people in each group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Payambar Azam University Complex, Basij Square, Sardasht
City
arak
Province
Markazi
Postal code
38481-76941
Approval date
2019-05-31, 1398/03/10
Ethics committee reference number
IR.ARAKMU.REC.1398.079

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus
ICD-10 code
E08
ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Performance
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

2

Description
Knowledge
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

3

Description
Perceived sensitivity
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

4

Description
Perceived severity
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

5

Description
Perceived benefits
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

6

Description
Perceived barriers
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

7

Description
Internal action guide
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

8

Description
External action guide
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

9

Description
Efficacy
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Determining the behavior carbohydrate consumption
Timepoint
At the beginning of the study and 3 months after
Method of measurement
questionnaire

2

Description
Check the level of FBS blood index
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Blood test is determined in the laboratory and with a device

3

Description
Check the level of HbA1c blood index
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Blood sampling using CERA-STAT 2000 Analyzer manufactured by Korean company CERAGEM MEDISYS

4

Description
Measuring BMI
Timepoint
At the beginning of the study and 3 months after
Method of measurement
Meters and scales

Intervention groups

1

Description

Intervention group: Pre-test by distributing a standard questionnaire and determining the level of knowledge, sensitivity, severity, perceived benefits and barriers, internal and external practice guides, self-efficacy and performance on carbohydrate consumption behavior before the intervention for case and control groups, then Evaluation of blood levels of HbA1c, FBS and BMI before interventionIn the next stage, conducting an educational intervention based on cross-sectional study and finally post-test by redistributing the questionnaire and determining the level of knowledge, sensitivity, severity, benefits and perceived barriers and action guides on carbohydrate consumption behavior for case and control groups. In 3 months after the educational intervention and examination of HbA1c, FBS and BMI levels after the interventionTo compare the mean score of knowledge, sensitivity, severity, perceived benefits and barriers and self-efficacy and practice guidelines on carbohydrate consumption behavior in the case and control groups, parametric tests such as independent t-test and paired t-test are used. Tests and include non-parametric tests such as Kruskal-Wallis, Wilcoxon, Mann-Whitney, and Spearman correlation tests.

Category

Behavior

2

Description

Control group: 1- Sample selection 2- Pre-test by distributing a standard questionnaire and determining the level of knowledge, sensitivity, severity, perceived benefits and barriers, internal and external practice guides, self-efficacy and performance regarding behavior related to carbohydrate consumption in Control group.3- Assessment of HbA1c, FBS and BMI levels - Post-test by redistributing the questionnaire and determining the level of knowledge, sensitivity, severity, perceived benefits and barriers and action guides on carbohydrate consumption behavior for the control group in 3 months Examination of HbA1c, FBS and BMI levels and retesting 3 months later to compare means in individuals who have not undergone educational intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers of Arak city

Full name of responsible person

Dr. Mahboubeh Khorsandi

Street address

Building No. 2, Arak University of Medical Sciences, Golestan Alley, Mostafa Khomeini Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Payambar Azam University Complex-Deputy of Research and Technology

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Email

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Web page address

http://research.arakmu.ac.ir/fa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, 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
Mahboubeh Khorsandi

Position
Associate

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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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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Department of Health Education, Faculty of Health, Arak University ofMedical Sciences, Arak

Latest degree
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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Fatemeh Mohebian

Position
Graduate student

Latest degree
Bachelor

Other areas of specialty/work
Public Health

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Some of the data such as information about the main outcome and model structures can be shared.

When the data will become available and for how long
Start of access period from 1400 and 6 months after printing the results

To whom data/document is available
For all academics and diabetics

Under which criteria data/document could be used
If the source is mentioned, its use is unrestricted

From where data/document is obtainable
Website and postal address and e-mail of the responsible

author Ms. Mahboubeh Khorsandi

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

By requesting the e-mail, the responsible author can access the requested items after a complete review.

Comments