Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of HBM education to diabetic patients on their self-care and biochemical indexes

Protocol summary

Study aim

The Effectiveness of Health Belief Model Education on Self-Care and Biochemical Parameters in Patients with Diabetes

Design

With control group, with parallel, randomized groups

Settings and conduct

80 patients were selected at the center of Imam Ali Hospital, Isfahan. They were randomly assigned to control and intervention groups and completed before and four months after the intervention based on Health Belief Model, fasting blood glucose and health beliefs and self-care questionnaires by the patients. They will be.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A person with type 2 diabetes is covered by the Khorasgan Health Services Center. The disease has been diagnosed or approved by the Ministry of Health and Medical Education in accordance with the directions of the Ministry of Health and Medical Education. The patient is between the ages of 30 and 65. Have the least reading and writing skills. Satisfaction to participate in the study. Non- Inclusion criteria: Having severe psychological and physical disorders (preventing attendance in the classroom).

Intervention groups

The control group is trained by the researcher in the manner commonly used by the health care provider and the HBM intervention group. Group training and workshops with 4 sessions per week and 1.5 hours for each intervention group at Imam Ali Center in Isfahan. Before and 4 months after completing the training program, patients will be evaluated for fasting blood glucose tests and completing the health belief and self-care questionnaire. The control group will receive no special training.

Main outcome variables

A Study on the Modification of Life Pattern for self-care in diabetic patients based on Health Belief Model

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N5**
Registration date: **2019-02-03, 1397/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-03, 1397/11/14**
Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

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tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of HBM education to diabetic patients on their self-care and biochemical indexes

Public title
The effect of education on health beliefs in patients with diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
A person with type 2 diabetes will be covered by the comprehensive health services center in Khorasgan, Isfahan. The disease has been diagnosed or approved by the Ministry of Health and Medical Education in accordance with the instructions of the Ministry of Health and Medical Education. Patients are between the ages of 30 and 65 years. Have the least reading and writing skills. Satisfaction to participate in the study.
Exclusion criteria:
Having severe psychological and physical disorders (preventing attendance in the classroom)
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
80 patients were randomly selected. This means that all patients with the conditions of entry to study were included in the study to complete the sample size and then, using computer coding, were randomly divided into two groups of 40 controls and intervention.
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
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-11-13, 1397/08/22
Ethics committee reference number
IR.MUI.MED.REC.1397.125

Health conditions studied

1

Description of health condition studied
Self-care education in health beliefs in diabetic patients
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
The effect of health education on self-care of patients with diabetes
Timepoint
Before and 4 months after the end of the intervention
Method of measurement
51 health belief questionnaires and 29 self-care self-care questionnaires with 5 Likert option spectra will be considered. The score range for the Health Beliefs 51 to 255 is for the areas of awareness, sport activities, perceived severity of the disease and its side effects, perceived sensitivity, perceived benefits, perceived barriers, patient self-efficacy, and guidance for action. The self-care questionnaire with a score of 29-145 is about diet, physical activity and exercise, early-onset complications, late-onset complications, and foot care.

2

Description
The Effect of Health Belief Training on the Biochemical Parameters of Patients with Diabetes
Timepoint
Before and 4 months after the end of the intervention
Method of measurement
Fasting Blood Glucose Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, group training and a workshop of 4 sessions per week and 1.5 hours each session will be conducted to train the health belief model to improve self-care quality and biochemical parameters in diabetic patients. Before and 4 months after the intervention, the health beliefs and self-confidence questionnaires will be completed and a fasting blood glucose test will be performed.

Category

Lifestyle

2

Description

Control group: There will be no training in this group. At the same time as the intervention group, the health beliefs and self-care questionnaires will be completed before and 4 months after the intervention, and the fasting blood glucose test will be performed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital Khorasgan

Full name of responsible person

Ahmad Mahmoudian

Street address

Alley of Social Security, Jay Street, Khorasgan.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Deputy of Research of Isfahan University of Medical Sciences, Hezar Jerib Ave.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Mahmoudian

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Public Health/Community Medicine

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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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Position

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Latest degree

Medical doctor

Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Ahmad Mahmoudian
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information can be published after being unidentifiable and with the opinion of the vice chancellor of research of Isfahan University of Medical Sciences.
When the data will become available and for how long
Two years after the publication of the results and in coordination with the vice chancellery of the Isfahan University of Medical Sciences, the information is available.
To whom data/document is available
Physicians, specialists and assistants from the Department of Social Medicine and the Department of Psychology and Psychology as well as professors and students and assistants of the Department of Endocrinology and Metabolism.
Under which criteria data/document could be used
If a method is used other than health belief and in order to compare the effectiveness of the other method with the present method
From where data/document is obtainable
Send the request clearly by e-mail a_mahmoudian@med.mui.ac.ir and with the permission of the vice chancellor of research of Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
After registering the application, e-mail a_mahmoudian@med.mui.ac.ir and with the permission of the vice chancellor of the Isfahan University of Medical Sciences, information will be provided to the applicants.
Comments