Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Assessing the Effect of Educational Intervention Based on Health Belief Model in improving metabolic indices of type2 diabetic patients

Protocol summary

Study aim

Determining the Effect of Educational Intervention Based on Health Belief Model in improving metabolic indices of type2 diabetic patients

Design

In this study, patients Will be selected randomly from one or two villages (as needed) and the patients of the one or two other villages as a control group are selected. then, 50 patients with type 2 diabetes are included in the study.

Settings and conduct

the programmed educational intervention will be conducted a session in a week, during 6 sessions (60 minutes), the program is according to the Health Belief Model. this study will be done at Shamshir Comprehensive Rural Health Service Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: at least one year have passed from a definitive diagnosis of type 2 diabetes, being in the age group of 30 to 65 years old, the HbA1c test is equal or higher than 7% and no perceptual problem. exclusion criteria include: patients who do not attend more than one session in the educational intervention, patients who do not perform the required tests completely and Patients who are not willing to cooperate in the study anyway.

Intervention groups

Intervention group: educational intervention will be conducted a session weekly, during 6 sessions (60 minutes) with a designed program according to the Health Belief Model. this intervention will be implemented in three stages. the first stage consists of one session, the goal of this stage is to increase the susceptibility to diabetes complications. topics to be considered at this meeting including the acquaintance of patients with the nature of diabetes and its complications, the definition of diabetes control and the importance of monitoring blood glucose. the second stage consists of three sessions, the goal of this stage is to increase perceptions to pros and cons of the adhering to diet, drug orders and physical activity. the third stage consists of two sessions with the goal of facilitating and encouraging patients to perform their intended behavioral goals and enhancing their self-efficacy by inviting a successful diabetic patient and an active family member. control group: The control group receives only routine training during this time.

Main outcome variables

1. Age 2. Sex 3. Education level 4. Employment status 5. marital status 6. A history of diabetes 7. Number of family members 8. Educational intervention 9. Perceived Susceptibility 10. Perceived Severity 11. Perceived Benefits 12. Perceived Barriers 13. Cues to action 14. Self-efficacy 15. body mass index (BMI) 16. Fasting blood sugar (FBS) 17. glycated haemoglobin (HbA1c) 18. Cholesterol 19. Triglyceride (TG) 20. High-density lipoprotein (HDL) 21. Low-density lipoprotein (LDL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170619034641N2**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

Alireza Abdi

Name of organization / entity

nursing and midwifery school, Kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3725 0111

Email address

arabdi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the Effect of Educational Intervention Based on Health Belief Model in improving metabolic indices of type2 diabetic patients

Public title

Assessing the Effect of Educational Intervention in metabolic indices of diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria include: at least one year have passed from a definitive diagnosis of type 2 diabetes, being in the age group of 30 to 65 years old, their HbA1c test is equal or higher than 7% and no perceptual problem.

Exclusion criteria:

Exclusion criteria include: patients who do not attend more than one session in the educational intervention, patients who do not perform the required tests completely and Patients who are not willing to cooperate in the study anyway.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients Will be selected randomly from one or two villages (as needed) and the patients of the one or two other villages are considered as the control group randomly.

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 Kermanshah University of Medical Sciences

Street address

Shahid Beheshty BLV., Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714634698

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.KUMS.RES.1396.387

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Glycated haemoglobin (HbA1c)

Timepoint

Before the intervention and three months after the intervention

Method of measurement

A1C care device

2

Description

Fasting blood sugar (FBS)

Timepoint

Before the intervention and three months after the

intervention

Method of measurement

AutoAnalyzer

3

Description

Triglyceride (TG)

Timepoint

AutoAnalyzer

Method of measurement

AutoAnalyzer

4

Description

Cholesterol

Timepoint

Before the intervention and three months after the intervention

Method of measurement

AutoAnalyzer

5

Description

High-density lipoprotein (HDL)

Timepoint

Before the intervention and three months after the intervention

Method of measurement

AutoAnalyzer

6

Description

Low-density lipoprotein (LDL)

Timepoint

Before the intervention and three months after the intervention

Method of measurement

AutoAnalyzer

7

Description

Perceived Susceptibility

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

8

Description

Perceived Severity

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

9

Description

Perceived Barriers

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

10

Description

Perceived Benefits

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

11

Description

Cues to action

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

12

Description

Self-efficacy

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Health belief model researcher-made questionnaire

13

Description

body mass index (BMI)

Timepoint

Before the intervention and three months after the intervention

Method of measurement

DETECTO-MEDIC Height and Weight Measurement Device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: educational intervention will be conducted weekly during 6 sessions (60 minutes) with a designed program according to the Health Belief Model.

this intervention will be implemented in three stages. the first stage consists of one session, the goal of this stage is to increase the susceptibility to diabetes complications. topics to be considered at this meeting including the acquaintance of patients with the nature of diabetes and its complications, the definition of diabetes control and the importance of monitoring blood glucose. the second stage consists of three sessions, the goal of this stage is to increase perceptions of the benefits and obstacles, adhering to diet, drug orders and physical activity. the third stage consists of two sessions with the goal of facilitating and encouraging patients to perform their intended behavioral goals and enhancing their self-efficacy by inviting a successful diabetic patient and an active family member.

Category

Lifestyle

2

Description

Control group: The control group receives only routine training during this time.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shamshir Comprehensive Rural Health Service Center

Full name of responsible person

alireza abdi

Street address

Paveh Shamshir Rural

City

Paveh

Province

Kermanshah

Postal code

00988338279394

Phone

+98 83 3835 8258

Email

arabdi@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

معاونت تحقیقات و فناوری دانشگاه علوم پزشکی کرمانشاه

Full name of responsible person

Behrooz Hamzeh

Street address

Vice Chancellor for Research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

00988338279394

Phone

+98 83 3835 8258

Email

arabdi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

معاونت تحقیقات و فناوری دانشگاه علوم پزشکی کرمانشاه

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

Kermanshah School of Nursing and Midwifery

Full name of responsible person

alireza abdi

Position

PhD in Nursing Education-Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv. Kermanshah

City

kermanshah

Province

Kermanshah

Postal code

00988338279394

Phone

+98 83 3835 8258

Email

arabdi@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah School of Nursing and Midwifery

Full name of responsible person

alireza abdi

Position
PhD in Nursing Education

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv. Kermanshah

City
kermanshah

Province
Kermanshah

Postal code
00988338279394

Phone
+98 83 3835 8258

Email
arabdi@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah School of Nursing and Midwifery

Full name of responsible person
Alireza Abdi

Position
PhD in Nursing Education, Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv. Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
00988338279394

Phone
+98 83 3835 8258

Email
arabdi@kums.ac.ir

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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
if the desired journal or research deputy will request the data, the file will be in their disposal.

When the data will become available and for how long
after two years from data collection

To whom data/document is available
research deputy of KUMS, and editor in chief of the raised journal

Under which criteria data/document could be used
to publish the paper and offering the final report of the project

From where data/document is obtainable
contact to corresponding author

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

Comments