Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education based on Leventhal Model on perception of disease , adherence to treatment and glycemic control in diabetic patients

Protocol summary

Study aim

Determining the effect of education based on the Leventhal model on understanding the disease, adherence to treatment and glycemic control in patients with diabetes

Design

This clinical trial study was designed with pretest-posttest design in two experimental and control groups

Settings and conduct

The population of this study included all diabetic patients (including type 1 and type 2 diabetes) with a medical record in the diabetes clinic of Musa bin Jaafar Hospital in Quchan, affiliated to Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Criteria for entering the study: - Age aged 18-65 years - At least one year have passed since their diagnosis of diabetes. - HbA1C≥7 - The absence of any mental illness that interferes with the intervention - Lack of participation in similar educational programs - Ability to understand conversation in Persian language - - Communication problems (such as loss of hearing and vision) - Lack of severe and severe underlying disease (such as metastatic cancer, severe heart failure, etc.) Non-inclusion criteria: - Absence in the curriculum - Unwilling to continue reading

Intervention groups

The teaching according to cognitive environment (identity, cause, time lines, outcomes, odrman) discussed in its regulatory model to better understand diabetes lontal, treatment adherence and improve indicators of گلیسمیک, by a nurse researcher in two 45-minute training session is offered to patients and using A questionnaire comply with treatment of the disease, understand and measure گلیسمیک (HbA1C) after 3 months, the impact of training investments.

Main outcome variables

Patient perception, compliance with treatment and HbA1C levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039251N1**
Registration date: **2018-04-20, 1397/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-20, 1397/01/31**
Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

Mansure Sadeh tabarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 4368

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hoseinirz9@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on Leventhal Model on perception of disease , adherence to treatment and glycemic control in diabetic patients

Public title

The effect of education based on Leventhal Model on perception of disease , adherence to treatment and glycemic control in diabetic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-65 years At least one year have passed since their diagnosis of diabetes The absence of any mental illness that interferes with the intervention Lack of participation in similar educational programs Ability to understand conversation in Persian language Communication problems (such as loss of hearing and vision) Lack of severe and severe underlying disease (such as metastatic cancer, severe heart failure, etc.) HbA1C≥7

Exclusion criteria:

Absence in the training session Unwillingness to attend meetings

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a randomized clinical trial with two groups of test and control. Eligible patients are selected as case study from among the records in the clinic, randomly selected from the sample (random number table) to the sample size calculated for the research, the patient is selected and after obtaining their consent To participate in the pre-test study, we used questionnaires and HbA1C measurements.Afterwards, the samples are divided into two groups of intervention and control. Contact groups will be contacted for training sessions, and training sessions will be held at the clinic. Therefore, the control and intervention group have the least amount of meeting and the contamination of the information does not occur.

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 the Faculty of Nursing and Midwifery, Tehran University

Street address

Nosrat st. Tohid sq. Tehran I.IRAN 141973317

City

Tehran

Province

Tehran

Postal code

141973317

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3291

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 1 and 2

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

perception of disease

Timepoint

Before the start of the intervention and 3 months after training perception of disease

Method of measurement

Understanding of disease questionnaire (IPQ-R), a questionnaire comply with treatment, laboratory measurement of glycated hemoglobin

Secondary outcomes

empty

Intervention groups

1

Description

The teaching according to cognitive environment

(identity, cause, time lines, outcomes, odrman) discussed in its regulatory model to better understand diabetes lontal, adherence to the treatment and improvement of HbA1c, by the nurse researcher in two 45-minute training session is offered to patients and A questionnaire comply with treatment of the disease, understanding and measurement of glycated hemoglobin after 3 months, the impact of training investments.

Category

Behavior

2

Description

Control group: No do not receive the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Musa bin Ja'far Hospital Quchan

Full name of responsible person

Ali Ansari

Street address

parastar st,Musa Ibn Jafar Hospital

City

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Province

Razavi Khorasan

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00985147233412

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sadeh.4005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yonesian

Street address

Keshavarz Blvd., Qods Street, Tehran, Tehran Province

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mansureh Sadeh Tabarian

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable