Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effects of education based on health belief model on medication adherence in diabetic pationts

Protocol summary

Summary

The main purpose of the project including evaluation of the effects of education based on health belief model on medication adherence in diabetic patients. This study is a randomized controlled trial, cross training trials on 130 patients referred to the diabetic clinic Arak city. Inclusion criteria including Diabetic patients 30 to 55 years; Diabetic patients without chronic complications such as retinopathy, nephropathy, neuropathy; Use of insulin; The use of anti-diabetic pills; Use of insulin and anti-diabetic pills; Exclusion criteria including if the patient is not willing to continue to cooperate; If the patient is moved from the city; the absence of ongoing diabetes education sessions; the unavailability of patients during the post-test questionnaire. The present study is done through the following steps: samples selection, pre-test using the questionnaire and determine the distribution of knowledge, severity, perceived benefits, perceived barriers, manuals, self-efficacy and performance of Compliance medication regimen before the intervention, intervention for a month, post - test through redistribution of questionnaires and interviews to determine the level of knowledge, severity, perceived benefits, perceived barriers, manuals, self-efficacy and performance in patients diabetes is 3 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082018522N2**
Registration date: **2015-01-02, 1393/10/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-02, 1393/10/12

Registrant information

Name
Fahimeh Dastjani Farahani

Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research Arak University of Medical Sciences

Expected recruitment start date
2014-05-05, 1393/02/15

Expected recruitment end date
2014-08-27, 1393/06/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of education based on health belief model on medication adherence in diabetic pationts

Public title
The effect of education on adherence to drug regimen

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Diabetic patients 30 to 55 years;

Diabetic patients without chronic complications such as retinopathy, nephropathy, neuropathy and ...; Use of insulin; The use of anti-diabetic pills; Use of insulin and anti-diabetic pills; Exclusion criteria: if the patient is not willing to continue to cooperate; If the patient is moved from the city; the absence of ongoing diabetes education sessions; the unavailability of patients during the post-test questionnaire.

Age
From **30 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Arak University of Medical Sciences

Street address
Vice Chancellor for Education and Research, Pardis Educational Complex, Basij Sq, Sardashat, Arak

City
Arak

Postal code
38481-7-6941

Approval date
2014-02-24, 1392/12/05

Ethics committee reference number
92-159-9

Health conditions studied

1

Description of health condition studied
Diabete

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

2

Description of health condition studied
Diabete

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

3

Description of health condition studied
Diabete

ICD-10 code
E13

ICD-10 code description
Other specified diabetes mellitus

4

Description of health condition studied
Diabete

ICD-10 code
E14

ICD-10 code description
Unspecified diabetes mellitus

Primary outcomes

1

Description
Self Efficacy

Timepoint
Before The Experiment And Three Months After The Intervention

Method of measurement
Questionnaire

2

Description
External Practice Guide

Timepoint
Before The Experiment And Three Months After The Intervention

Method of measurement
Questionnaire

3

Description
Perceived Barriers

Timepoint
Before The Experiment And Three Months After The Intervention

Method of measurement
Questionnaire

4

Description
Perceived Benefits
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

5

Description
Internal Practice Guide
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

6

Description
Perceived Susceptibility
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

7

Description
Perceived Severity
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

8

Description
Adherence To Medication
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

9

Description
Glycosylated Hemoglobin
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Blood Biochemical Tests

10

Description
Fasting Blood Sugar
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Blood Biochemical Tests

11

Description
Awareness
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Awareness
Timepoint
Before The Experiment And Three Months After The Itervention
Method of measurement
Questionnaire

2

Description
Adherence To Medication
Timepoint
Before The Experiment And Three Months After The Itervention
Method of measurement
Questionnaire

3

Description
Glycosylated Hmoglobin
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Blood Biochemical Tests

4

Description
Fasting Blood Sugar
Timepoint
Before The Experiment And Three Months After The Intervention
Method of measurement
Blood Biochemical Tests

5

Description
Perceived Susceptibility
Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

6

Description

Perceived Severity

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

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Method of measurement

Questionnaire

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Description

Perceived Benefits

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

9

Description

Internal Practice Guide

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

10

Description

External Practice Guide

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

11

Description

Self Efficacy

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Education based on health belief model in case group consist of four sessions through lecture, and group discussion and dialog (question and answer). Data collection through self-reported questionnaires distributed at the pre-intervention and three months after intervention.

Category

Prevention

2

Description

Nonintervention in the control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Dr Mohsen Shamsi

Street address

Department of Public Health, Golestan Alley, Mustafa Khomeini Settlements, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

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Department of Public Health, Golestan Alley, Mustafa Khomeini Settlements, Arak

City

Arak

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Msc

Full name of responsible person

Fahimeh Dastjani Farahani

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty