

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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

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

Country

Iran (Islamic Republic of)

Phone

+98 918 255 8830

Email address

fahimeh.d6850@yahoo.com

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 patients

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 Intervention

Method of measurement

Questionnaire

2

Description

Adherence To Medication

Timepoint

Before The Experiment And Three Months After The Intervention

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

7

Description

Perceived Barriers

Timepoint

Before The Experiment And Three Months After The Intervention

Method of measurement

Questionnaire

8

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

Street address

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

Arak University of Medical Sciences

Other areas of specialty/work

Street address

Department of Public Health, Golestan Alley, Mustafa
Khomeini

City

Arak

Postal code

38481-7-6941

Phone

+98 86 3368 4615

Fax

Email

fahimeh.d6850@yahoo.com

Web page address

City

Arak

Postal code

Phone

+98 86 3368 6443

Fax

Email

mohsenshamsi1360@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fahimeh Dastjani Farahani

Position

Msc

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Basij SQ,
Sardashat

City

Arak

Postal code

Phone

00

Fax

Email

fahimeh.d6850@yahoo.com

Web page address

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohsen Shamsi

Position

Assistant professor

Other areas of specialty/work

Street address

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