

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Assessment of the effect of theory-based health literacy educational program on lifestyle of diabetics

Protocol summary

Summary

This interventional study was conducted on 170 patients with type II diabetes divided into control and intervention groups via block randomization. The educational intervention was performed for the intervention group through four 55-60-minute educational sessions. The intervention in this study was carried out through an educational program focusing on health literacy. The data were collected using health literacy level assessment questionnaire, health-improving lifestyle questionnaire, and self-efficacy assessment questionnaire. Inclusion criteria of the study were confirmation of type II diabetes by a specialist (two instances of fasting blood sugar scoring above 126 mg/deciliter), having the ability to read and write, aging between 25-55 years, signing a written informed consent for participating in the study, and absence of advanced diabetes symptoms, such as diabetic foot and joint disease. On the other hand, the exclusion criteria were lack of proper physical conditions to respond to the questions, catching chronic diseases (other than diabetes) including cancer and asthma, absence from training for more than one session, and not taking the tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507226261N12**

Registration date: **2015-10-13, 1394/07/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-13, 1394/07/21

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-01-15, 1392/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of theory-based health literacy educational program on lifestyle of diabetics

Public title

of the effect of theory-based health literacy educational program on lifestyle of diabetics

Purpose

Health service research

Inclusion/Exclusion criteria

inclusion criteria of the study were confirmation of type II diabetes by a specialist (two instances of fasting blood sugar scoring above 126 mg/deciliter); having the ability to read and write; aging between 25-55 years; signing a written informed consent for participating in the study;

and absence of advanced diabetes symptoms such as diabetic foot and joint disease. On the other hand; the exclusion criteria were lack of proper physical conditions to respond to the questions; catching chronic diseases (other than diabetes) including cancer and asthma; absence from training for more than one session; and not taking the tests.

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **170**

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**

Ethical committee of Shiraz University of Medical Sciences

Street address

Zand street, Central building of Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2013-12-22, 1392/10/01

Ethics committee reference number

92-6852

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11.8

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes**1****Description**

Health literacy

Timepoint

Before intervention, one week and two months after the intervention

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Lifestyle

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

2**Description**

Self-efficacy

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

3**Description**

nutrition

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

4**Description**

exercise

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

5**Description**

stress management

Timepoint

Before intervention, one week and two months after the

intervention.

Method of measurement

Questionnaire

6

Description

interpersonal relations

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

7

Description

health responsibility

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

8

Description

self-actualisation

Timepoint

Before intervention, one week and two months after the intervention.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 1. direct education on the basis of the provided educational content, using active teaching-learning methods including lectures, question and answer, small group discussions, and exchange of ideas, and 2. indirect education via manuals, pamphlets, and CDs. The intervention was carried out through educational aids, such PowerPoint, video projection, and video clips.

Category

Other

2

Description

control group: In control group was not intervention performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nader Kazemi Medical Clinic

Full name of responsible person

Hoseini

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR Syed Basir Hashemi

Street address

Zand ave, Central Building Shiraz University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hosein Kaveh

Position

Phd in Health Education , administrator of Health Education

Other areas of specialty/work

Street address

Ruzi bul, School of Health

City

Shiraz

Postal code

Phone

+98 717251002

Fax
Email
kaveh@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohamad hosein kaveh
Position
Phd in Health Education
Other areas of specialty/work
Street address
School of Health, Ruzi bul
City
Shiraz
Postal code
Phone
+98 717251002
Fax
Email
kaveh@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences
Full name of responsible person
Khadije sadat Hoseini moghadam
Position
Graduate student Health Education
Other areas of specialty/work
Street address
City
Yasuj
Postal code
Phone
00
Fax
Email
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