

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The effect of educational intervention based on diet-related beliefs on fasting blood glucose, HbA1c and type 2 diabetes patient's adherence to healthy diet

Protocol summary

Study aim

The present study is a clinical trial aiming to determine the effect of educational intervention on type 2 diabetes patient's adherence to healthy diet and glycemic control in Isfahan, Iran.

Design

A concealed, randomized, controlled clinical trial with a parallel group design of 145 patients (73 in the intervention group; 72 in the control group), enrolling between December 2017 and January 2018, and following for 3 months after the end of the intervention.

Settings and conduct

Educational intervention was conducted through group education and individual counseling on type 2 diabetes in Isfahan.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: having a history of high or uncontrolled blood sugar; a disease history of three months or longer; lack of other chronic diseases (except diseases associated with complications of diabetes); not having previous experience of participating in training sessions similar to this study; and willingness to take part in the study. Exclusion criteria: not having active records in diabetes clinics or healthcare centers; and having physical disease limiting patients to participate in training sessions.

Intervention groups

Intervention group: educational interventions related to diabetic diet in 8 sessions. Control group: no educational intervention.

Main outcome variables

Mean score of fasting blood glucose. Mean score of glycated hemoglobin in patients (HbA1c). Nutritional behavior of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180308039008N1**

Registration date: **2018-04-15, 1397/01/26**

Registration timing: **retrospective**

Last update: **2018-04-15, 1397/01/26**

Update count: **0**

Registration date

2018-04-15, 1397/01/26

Registrant information

Name

Arash Salahshouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3244

Email address

aidin_salahshoori@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

2017-12-01, 1396/09/10

Actual recruitment end date

2017-12-31, 1396/10/10

Trial completion date

empty

Scientific title

The effect of educational intervention based on diet-related beliefs on fasting blood glucose, HbA1c and type 2 diabetes patient's adherence to healthy diet

Public title

The effect of educational intervention on type 2 diabetes patient's adherence to healthy diet

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a history of high or uncontrolled blood sugar; A disease history of three months or longer; Lack of other chronic diseases (except diseases associated with complications of diabetes); Not having previous experience of participating in training sessions similar to this study; Willingness to take part in the study.

Exclusion criteria:

Not having active records in diabetes clinics or healthcare centers; Having physical disease limiting patients to participate in training sessions.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Actual sample size reached: **145**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done systematically from the registers of diabetic patients and then, they were divided into two intervention and control groups using the random numbers table.

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 Isfahan University of Medical Sciences

Street address

Department of Health education and promotion, school of Health, Isfahan University of Medical Sciences, Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.MUI.REC.1396.3.522

Health conditions studied

1

Description of health condition studied

Care and examination of type 2 diabetes patient's adherence to healthy diet

ICD-10 code

E12

ICD-10 code description

Care and examination of type 2 diabetes patient's adherence to healthy diet

Primary outcomes

1

Description

Beliefs related to diabetic diet

Timepoint

Before the intervention and 3 months after educational intervention

Method of measurement

Researcher-made Questionnaire

Secondary outcomes

1

Description

Mean score of fasting blood glucose

Timepoint

Before the intervention and 3 months after the end of the educational intervention

Method of measurement

Laboratory tests

2

Description

Mean score of glycated hemoglobin in patients (HbA1c)

Timepoint

Before the intervention and 3 months after the end of the educational intervention

Method of measurement

Laboratory tests

3

Description

Nutritional behavior of patients

Timepoint

Before the intervention and 3 months after the end of the educational intervention

Method of measurement

Perceived Dietary Adherence Questionnaire

Intervention groups

1

Description

Intervention group: educational interventions related to diabetic diet in 8 sessions.

Category

Behavior

2

Description

Control group: no educational intervention

Category

Behavior

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Arash Salahshouri

Street address

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2

Recruitment center**Name of recruitment center**

Healthcare Center No.2, Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

Street address

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Arash Salahshouri

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Firoozeh Mostafavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

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Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on primary and secondary outcome will be shared
in the form of a spss file

When the data will become available and for how long

The access period will be from December 2018

To whom data/document is available

Researchers of academic institutions

Under which criteria data/document could be used

The researcher will give the data to other researchers for
scientific use only.

From where data/document is obtainable

Send an e-mail to aidin_salahshoori@yahoo.com

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

People who want the data, send your request by e-mail
to the above address. The researcher, after consulting
the research team, sends the data to them, if they agree.

Comments