

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Comparison of the Effects of Two Educational Programs on Dietary Regimen Compliance in Patients with Type 2 Diabetes Mellitus

Protocol summary

Study aim

The Comparison of the Effects of Two Educational Programs on Dietary Regimen Compliance in Patients with Type 2 Diabetes Mellitus

Design

Three parallel group randomized trial which 378 patients participated.

Settings and conduct

This study was performed in the diabetic clinic affiliated to Ahvaz University of Medical Sciences. Participants were allocated to oral education group, video education group and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria to the study: Eighteen years or older; being able to speak in Farsi or Arabic. Exclusion criteria to the study: Having other chronic diseases; having visual, hearing, and speech impairments; being pregnant.

Intervention groups

Participants were allocated to verbal education, video education, and control groups. The participants in the oral education group received four educational sessions during a two-week interval. The participants in the video education group received educational movie. Also, an abstract of the educational content was provided to the participants of oral education group in writing for home use. The educational movie was provided to the participants of video education group in the form of DVDs for home use.

Main outcome variables

Patients' weight and Biochemical parameters (such as Fasting Blood Sugar (FBS), Glycated hemoglobin (HbA1c), Total Cholesterol (TC), Triglyceride Levels (TG), low-Density Lipoprotein (LDL), and High Density Lipoprotein (HDL))

General information

Reason for update

Added more details.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150302021307N4**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **retrospective**

Last update: **2021-03-24, 1400/01/04**

Update count: **2**

Registration date

2020-03-24, 1399/01/05

Registrant information

Name

Mojtaba Miladinia

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 613333333

Email address

miladinia.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-17, 1398/11/28

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

2020-02-17, 1398/11/28

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-10, 1398/12/20

Scientific title

The Comparison of the Effects of Two Educational

Programs on Dietary Regimen Compliance in Patients with Type 2 Diabetes Mellitus

Public title

The Comparison of Two Educational Programs on Dietary Regimen Compliance in Patients with Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Eighteen years or older Being able to spoke in Farsi or Arabic

Exclusion criteria:

Having other chronic diseases Having visual, hearing, and speech impairments Being pregnant

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **378**

Actual sample size reached: **364**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized in a 1:1:1 ratio using a permuted block method with varying block sizes to video education, oral education, or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer and those assessing the outcomes were blinded. we gave a code to the each study group and they did not know each patient was in which groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Science

Street address

Research center, Golestan Blv

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.AJUMS.REC.1398.901

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E 11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar (FBS)

Timepoint

2 days before the intervention was measured. The laboratory index was measured again 90 days later.

Method of measurement

After fasting for 12 hours using laboratory Kit was measured.

2

Description

Lipid profile (TG, Cholesterol, LDL, and HDL)

Timepoint

2 days before the intervention were measured. The laboratory indices were measured again 90 days later.

Method of measurement

After fasting for 12 hours using laboratory Kit were measured.

3

Description

Glycated hemoglobin (HbA1c)

Timepoint

2 days before the intervention was measured. The laboratory index was measured again 90 days later.

Method of measurement

After fasting for 12 hours using laboratory Kit was measured.

4

Description

Patients' weight

Timepoint

2 days before the intervention was measured. The patients' weight was measured again 90 days later.

Method of measurement

The patients' weight was measured using a digital scale.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The participants in the oral education group received 4 educational sessions during a two-week interval. The educational program was implemented in a quiet conference room. Each session was 45-minute.

Category

Lifestyle

2

Description

Second intervention group: The participants in the video education group received educational movie. The educational movie was displayed in two sessions during a two-week interval. The total movie length was two hours.

Category

Lifestyle

3

Description

Control group: The participants in the control group received routine care and a educational pamphlet by clinical nurses.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetic clinic affiliated to Ahvaz University of Medical Sciences

Full name of responsible person

Shahram Molavynejad

Street address

Ahvaz University of Medical Sciences., Esfand Ave., Golestan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mr Mohammad Badavi

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Research center, University of Medical Science, Golestan Blv, Ahvaz, Iran

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Miladinia

Position

Instructor of faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data file will be subscribed to by the SPSS software format. Only the original outcome can be shared.

When the data will become available and for how long

The start of the access period is 12 months after the publication of the results and for 3 months.

To whom data/document is available

Data will only be available to researchers working in academia.

Under which criteria data/document could be used

Data will only be available for use in review and meta-analyzes studies.

From where data/document is obtainable

Mojtaba Miladinia Academic email:
miladinia.m@ajums.ac.ir

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

First, send an e-mail to the author and mention the purpose of obtaining the information. In the absence of a problem, you will receive information one to three weeks later.

Comments