Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 spoke 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

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Iran (Islamic Republic of)

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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 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