

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Nutrition Education on Control Blood Sugar, Lipid Profile, liver Enzymes and Quality of life in Middle-aged Women with type 2 Diabetes.

Protocol summary

Study aim

Determining and comparing the effect of nutrition education on blood glucose control, lipid profiles, insulin resistance, anthropometric indices, liver enzymes and quality of life in women with type 2 diabetes

Design

A clinical trial with community-based and practice-oriented intervention and control group, with parallel groups, is one-way blind and parallel. Qualified individuals are randomly assigned to the intervention and control group. The sample size was calculated for each group of 32, which increased the sample size to a sample size of 50 to increase accuracy.

Settings and conduct

This interventional study was performed on 100 female patients aged 30-60 years old with type 2 diabetes in two groups (50 subjects) in intervention group and (50 persons) in control group in Larestan. The information and experiments were studied in the study. Then, the intervention group received nutritional education for three months. After three months, all of the questionnaires and tests were reassessed from both groups. Control group after the end of the intervention period, all the training that was given to the intervention group was done for the control group.

Participants/Inclusion and exclusion criteria

Women with type 2 diabetes aged 30- 59 years old who had diabetes for one year or more and who were taking oral medications to control diabetes were included. People who were pregnant, breast-feeding, uncontrolled diabetes, or sedative, hypnotic drugs were not included in the study.

Intervention groups

Intervention group received educational intervention within three months. Control group: There was no intervention on these subjects.

Main outcome variables

Fasting blood glucose; Glycosylated hemoglobin (A1C); Lipid profile; Weight; Cholesterol; Hypertension; Liver enzymes; Fasting insulin; Nutritional awareness; Quality of life; Physical activity; Homa index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181118041687N1**

Registration date: **2020-09-30, 1399/07/09**

Registration timing: **retrospective**

Last update: **2020-09-30, 1399/07/09**

Update count: **0**

Registration date

2020-09-30, 1399/07/09

Registrant information

Name

elham dezhlooon

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5888 8105

Email address

dezhloooneli@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-15, 1397/03/25

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Nutrition Education on Control Blood Sugar, Lipid Profile, liver Enzymes and Quality of life in Middle-aged Women with type 2 Diabetes.

Public title
The Effect of Nutrition Education in Women with type 2 Diabetes.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Middle Aged WWomen are 30 to 59 Years Old. Have a one Year or more History of type 2 Diabetes. Willing to Participate in the Study. Use Oral Medications to Control your Blood Sugar. Do not take Insulin. Pregnant and lactating. Do not have any Special illnesses. Have no Thyroid Problems. There is no Definite Diet. Do not have Uncontrolled Diabetes. Have Mental Disabilities. Sleep, Tranquilizer, Antihistamines and Immune System Inhibitors.
Exclusion criteria:
One does not want to Continue to Study. The Person will Absent more than one Meeting. The Person leaves the Pre-test or Post-test. Tests are Misleading.

Age
From **30 years** old to **59 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Qualified individuals were randomly assigned to intervention and control groups. (block balanced randomization). First, I wrote the letters A and B twice on six pieces of paper and put them in a container. Each time I referred, I took a piece of paper at random so that the fourth person could be identified in which group, then I put the paper in the container again I categorized those people into groups A (intervention) and B (control).

Blinding (investigator's opinion)
Single blinded

Blinding description
Only participants are unaware of the allocation of the study groups. The principal investigator is aware of the assignment of groups. The members of the intervention group were contacted confidentially and were invited to attend training classes. The control group received

training after completing the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz, Razi Blvd, Facing the Power Club, Faculty of Nutrition and Food Sciences
City
Shiraz
Province
Fars
Postal code
7153675541
Approval date
2018-02-05, 1396/11/16
Ethics committee reference number
IR.SUMS.REC.1396.181

Health conditions studied

1

Description of health condition studied
Diabetes type 2
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose above 126mg / dl and high blood glucose levels of 180mg / dl
Timepoint
The beginning of the study (before intervention) and three months after the intervention began
Method of measurement
blood test

2

Description
Hemogolobin A1C above 6.5%
Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement
Koromatografi

3

Description

fasting Ansulin

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Fasting serum insulin concentration using a commercial kit

Secondary outcomes

1

Description

Weight

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Weight using seca scales with an accuracy of one hundred grams

2

Description

Waist

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Scales

3

Description

Body mass index

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Ratio of weight(in terms of kilogram) to the power of height(in terms of meters)

4

Description

Blood pressure

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Using a standard mercury barometer

5

Description

High density of lipoprotein cholestrol

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

6

Description

Low density of lipoprotein cholestrol

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

7

Description

Triglyceride

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

8

Description

Cholesterol

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

9

Description

Alanine trans aminase

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

10

Description

Aspartate transaminase

Timepoint

The bigining of the study (befor intervention) and teree monthe after the intervention began

Method of measurement

Blood test

11

Description

Homeostasis model assessment beta cell

Timepoint

The bigining of the study (befor intervention) and teree

month after the intervention began

Method of measurement
Based on fasting glucose and insulin concentrations

12

Description
Homeostasis model assessment insulin resistance

Timepoint
The beginning of the study (before intervention) and three months after the intervention began

Method of measurement
Based on fasting glucose and insulin concentrations

13

Description
Quantitative insulin sensitivity check index

Timepoint
The beginning of the study (before intervention) and three months after the intervention began

Method of measurement
Based on fasting glucose and insulin concentrations

14

Description
The level of awareness of people

Timepoint
The beginning of the study (before intervention) and three months after the intervention began

Method of measurement
Questionnaire of Dr. Faqih et al

15

Description
Quality of life

Timepoint
The beginning of the study (before intervention) and three months after the intervention began

Method of measurement
Twelve quality of life questionnaire

16

Description
Get food

Timepoint
Three reminders at the beginning of the intervention and three reminders after the end of the educational intervention (Three months after the start of the training intervention)

Method of measurement
Using a 24-hour recall form

17

Description
Physical activity

Timepoint
The beginning of the study (before intervention) and three months after the intervention began

Method of measurement
Physical activity questionnaire metabolic equivalent Of task (MET)

Intervention groups

1

Description
Intervention group: Educational intervention with 4 sessions of nutrition training class in groups of 5-10 people with educational content of sessions including: stages of diabetes progression, symptoms of each stage and its side effects, providing nutritional recommendations to control diabetes and the importance of diet. Food groups and emphasis on increasing the number of meals, reducing the consumption of fats and simple carbohydrates, consuming whole grains and increasing the consumption of fruits and vegetables were held for the intervention group during three months. The average time per session was 70 minutes. The first session at the beginning of the study and in the form of an interactive lecture; The second session was held two weeks after the start of the study by small group techniques, the third session was held four weeks after the start of the study as an interactive lecture and the fourth session was held six weeks after the start of the study by lecture method. It was done by phone and all the recommendations were briefly reminded to the patient again.

Category
Lifestyle

2

Description
Control group: Educational intervention with 4 sessions of nutrition training class in groups of 5-10 people with educational content of sessions including: stages of diabetes progression, symptoms of each stage and its complications, providing nutritional recommendations to control diabetes and the importance of diet. They did not receive any intervention during these three months and were asked not to change their physical activity and diet during this period. But after the intervention, they received all the training provided to the intervention group.

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahib Alzaman Clinic of Larestan
Full name of responsible person
Dr. Abbas Nasri
Street address
Old Town, North Modarres St., Coastal Street, Sahib Al-Zaman Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Larestan University of Medical Sciences
Full name of responsible person
Dr. Abbas Nasri
Street address
New Town - Azadi Blvd. Larestan Healthcare Network
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Email
dezhalooneli@yahoo.com

Grant name

Shiraz University of Medical Sciences

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

2

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
دکتر سیاوش باباجعفری
Street address

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Elham Dezhatoon
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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