Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 dezhaloon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

dezhalooneli@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

monthe after the intervention began

Method of measurement

Based on fasting glucose and insulin concentrations

12

Description

Homeostasis model assessment insulin resistance

Timepoint

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

Method of measurement

Based on fasting glucose and insulin concentrations

13

Description

Quantitative insulin sensitivity check index

Timepoint

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

Method of measurement

Based on fasting glucose and insulin concentrations

14

Description

The level of awareness of people

Timepoint

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

Method of measurement

Questionnaire of Dr. Faqih et al

15

Description

Quality of life

Timepoint

The bigining of the study (befor intervention) and teree monthe 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 bigining of the study (befor intervention) and teree monthe 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
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Full name of responsible person
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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
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Email
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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 Dezhaloon
Position
Student
Latest degree
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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