Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the effect of nutrition counseling based on carbohydrate counting, glycemic index and reducing energy consumption on glycemic, lipidemic, anthropometric control indicators, and blood pressure in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of nutritional counseling based on carbohydrate counting, glycemic profile and reducing energy consumption on glycemic, lipid, anthropometric and blood pressure control indicators of patients with T2DM referring to Urmia Imam Khomeini hospital and Tadbir clinic

Design

Randomized clinical trial before and after, with an intervention group and a control group on 94 patients

Settings and conduct

This study is a parallel randomized controlled clinical trial in the field of investigating the effect of nutritional counseling with the approach of carbohydrate counting, glycemic index and reducing energy consumption on glycemic, lipid, anthropometric and blood pressure indicators of type 2 diabetes patients referring to Imam Khomeini Hospital and Tadbir clinic in Urmia city has been designed. 94 patients will be randomly assigned to 2 intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Refer to Imam Khomeini hospital and Tadbir clinic in Urmia city; Having T2DM; No insulin injection; Exclusion criteria: pregnancy and breastfeeding; Gastroparesis; Following a special diet; Consumption of nutritional supplements in the last 3 months

Intervention groups

The control group will receive nutritional recommendations according to the nutritional training packagein the field of health by the researcher. People in the intervention group will have 3 face-to-face 20-minute counseling sessions with the researcher on a weekly basis. The sessions will include anthropometric assessment, food intake and physical activity, familiarization with the simple carbohydrate counting method, food groups and food classification in terms of glycemic index, and diet plan.

Main outcome variables

Weight; Waist circumference; fasting plasma glucose; 2 hour post prandial glucose; Lipid profile; systolic blood pressure; diastolic blood pressure

General information

Reason for update

After the implementation of this project in August and September 1402 in the registered sampling center (Dizaj Siavosh Health Center, Urmia city), due to some problems and limitations, including the insufficient number of diabetic patients to the health center and the lack of the required sample size in the estimated period of time and the lack of cooperation and follow-up of patients with the health center, the implementation of the plan was stopped and the sampling center and the method of implementation of the plan were reviewed and edited again.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170206032417N7**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **prospective**

Last update: **2025-05-16, 1404/02/26**
Update count: **2**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country
Iran (Islamic Republic of)
Phone
+98 44 3275 2375
Email address
alizadeh.m@umsu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-05, 1402/10/15
Expected recruitment end date
2024-07-05, 1403/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of nutrition counseling based on carbohydrate counting, glycemic index and reducing energy consumption on glycemic, lipidemic, anthropometric control indicators, and blood pressure in patients with type 2 diabetes

Public title
Investigating the effect of carbohydrate counting counseling in type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Refer to Imam khomeini educational-therapeutic center and Tadbir clinic in Urmia city Having T2DM based on a physician's diagnosis and FPG criteria equal to and greater than 126 mg/dL and HbA1C equal to and greater than 6.5% Age above 18 years No insulin injection
Exclusion criteria:
Pregnancy and breastfeeding Gastroparesis Following a special diet Consumption of nutritional supplements in the last 3 months
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of the samples using the Stratified Block Randomization by random allocation method based on the two variables of age and gender (use of card number 1 and also card number 2 according to the number of patients present in the study and random selection of cards) into two intervention groups and Control will be divided.
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
Research Ethics Committees of Urmia University of Medical Sciences
Street address
Resalat Blvd., emergency area, Urmia University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2023-06-24, 1402/04/03
Ethics committee reference number
IR.UMSU.REC.1402.085

Health conditions studied

1

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

Primary outcomes

1

Description
fasting blood sugar
Timepoint
Fasting blood sugar measurement at the beginning of the study (before the start of the intervention) and 16 week of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - international unit per liter

2

Description
Glycosylated hemoglobin A1c
Timepoint
Measurement of glycosylated hemoglobin A1c at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - milligrams per deciliter

3

Description
Waist circumference
Timepoint
Measurement of waist circumference at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Tape meters-centimeters

4

Description
Systolic blood pressure
Timepoint
Measurement of systolic blood pressure at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Digital sphygmomanometer - millimeters of mercury(mmHg)

5

Description
Diastolic blood pressure
Timepoint
Measurement of diastolic blood pressure at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Digital sphygmomanometer - millimeters of mercury(mmHg)

6

Description
Triglyceride
Timepoint
Measurement of triglyceride at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - milligrams per deciliter

7

Description
LDL-cholesterol
Timepoint
Measurement of LDL-cholesterol at the beginning of the study (before the start of the intervention) and week 16 of the study (12 weeks after the completion of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - milligrams per deciliter

8

Description
HDL-cholesterol
Timepoint
HDL-cholesterol measurement at the beginning of the study (before the start of the intervention) and the 16th week of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - milligrams per deciliter

9

Description
2 hour post prandial glucose
Timepoint
2 hour post prandial glucose measurement at the beginning of the study (before the start of the intervention) and the 16th week of the study (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Enzymatic method - milligrams per deciliter

Secondary outcomes

1

Description
Weight
Timepoint
Weight measurement at the beginning of the study (before the start of the intervention) and week 16 (12 weeks after the end of the counseling sessions of the intervention group)
Method of measurement
Scale-kilogram

2

Description
Total cholesterol
Timepoint
Total cholesterol measurement at the beginning of the study (before the start of the intervention) and week 16 (12 weeks after
Method of measurement
Enzymatic method - milligrams per deciliter

3

Description
Body mass index
Timepoint
Body mass index measurement at the beginning of the study (before the start of the intervention) and week 16 (12 weeks after
Method of measurement
Weight/ height squared

Intervention groups

1

Description
Intervention group: People in the intervention group will have 3 face-to-face 20-minute counseling sessions with the researcher on a weekly basis. In the first session, anthropometry, food intake and physical activity are evaluated. Also, the role and importance of blood sugar control in T2DM is explained and the goals of the simple carbohydrate counting method are explained. In the second session, the diet, whose calories are calculated based on 25-35 kcal per body weight, is presented to the people. The diet of people with a BMI lower than 25 is isocaloric, and 250 kilocalories will be deducted from the calories of the diet of people with a BMI higher than 25. For people with a BMI above 35, the adjusted ideal body weight will be used. (Adjusted ideal body weight is calculated by adding one-fourth of the excess weight to the ideal weight. Ideal weight is calculated using the Hammwi formula.) The percentage of energy from macronutrients will be 15 to 20% of total calories for protein, depending on the protein status. Carbohydrates will be 50-55% and fat 30%. The amount of carbohydrates is distributed in the form of shares of different food groups containing carbohydrates in 3 main meals and 3 snacks. The number of portions is given to the patient along with examples, and the method of implementing the diet, the size of the portions, and the amount of carbohydrates are explained. In this session, patients will get to know the 7 food groups of bread and grains, simple sugars, fruits, dairy, meat, vegetables and oils, and they will receive a list of food substitutions and an explanation of how to implement it. The third session explains about the nutritional composition table label of packaged food products and how to calculate their carbohydrate content. Also, the third session will include familiarization with the glycemic index of foods, which will be presented to people with relevant recommendations and a list of categories of foods according to their glycemic index. In each meeting, the topics of the previous meeting are fixed and problems are solved. Until the end of the intervention period, a 3-day food recall will be taken from the participants by phone every month. A total of 5 food recall for 3 days with 15 days of review will be collected from the participants. Also, in order to ensure compliance with the training and answer possible questions, people will be contacted every week, followed up and encouraged to continue working. Counseling for disabled and elderly patients or those unable to read is provided to the accompanying person.
Category
Treatment - Other

2

Description
Control group: People in the control group will receive a sheet of nutritional recommendations for diabetics according to the nutrition training package in the health transformation program in the field of health, by the researcher, which is a 15-minute counseling session. Until the end of the study period, a 3-day food recall (15 reminders in total) will be collected from the control group every month.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tadbir specialized and sub-specialized clinic
Full name of responsible person
Laya Hooshmand Garehbagh
Street address
Amar street-Alley 13
City
Urmia
Province
West Azarbaijan
Postal code
571478373
Phone
+98 44 3346 2420
Email
laya.hooshmand@gmail.com
Web page address
https://tadbir.umsu.ac.ir/

2

Recruitment center
Name of recruitment center
Imam Khomeini educational-therapeutic center
Full name of responsible person
Laya Hooshmand Garehbagh
Street address
Ershad Ave-Modarres Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3345 9538
Fax
+98 44 3346 9935
Email

laya.hooshmand@gmail.com

Web page address

https://imam.umsu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Amin Valizadeh Hasanloui

Street address

Urmia, Resalat Blvd., Emergency valley, Headquarters of Urmia University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3193 4150

Email

aminvalizade@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Km 11 Nazlu Highway, Urmia University of Medical Sciences, Faculty of Medicine, Department of Nutrition

City

Urmia

Province

West Azarbaijan

Postal code

5715799313

Phone

+98 44 3275 2375

Email

alizadeh.m@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

PhD in nutrition sciences/professor of Urmia University of Medical Sciences and faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Km 11 Nazlu Highway, Urmia University of Medical Sciences, Faculty of Medicine, Department of Nutrition

City

Urmia

Province

West Azarbaijan

Postal code

5315799313

Phone

+98 44 3275 2375

Email

alizadeh.m@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Pirmaddah saravani

Position

Master student of nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Km 11 Nazlu Highway, Urmia University of Medical Sciences, Faculty of Medicine, Department of Nutrition

City

Urmia

Province

West Azarbaijan

Postal code
5715799313
Phone
+98 44 3257 2357
Email
pirmaddah.f@umsu.ac.ir

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
Undecided - It is not yet known if there will be 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