Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of consuming a diet based on high adherence to the Global Diet Quality Score (GDQS) with a standard diet on the control of sugar factors, mental health and anthropometric indicators in patients with type 2 diabetes: a randomized clinical trial

Protocol summary

Study aim

Comparing the effect of GDQS diet with standard diet on blood sugar control, mental health and anthropometric indicators in people with type 2 diabetes

Design

A randomized, parallel, controlled clinical trial. The number of 134 participants qualified to participate in the study will be divided into one of 2 intervention and control groups (n=67) using a simple randomization method

Settings and conduct

This study will be done in Yazd Diabetes Clinic Center. A total of 134 eligible people will be randomly assigned to 2 groups for 12 weeks to receive GDQS or standard dietary recommendations. At the beginning of the study and after 12 weeks from the start of the study, HBA1C, fasting glucose, weight, height, body mass index, waist circumference, depression, anxiety, quality of life, quality of sleep and people's adherence to diets will be evaluated

Participants/Inclusion and exclusion criteria

People with type 2 diabetes with age ≥ 18 years and body mass index ≤ 40 kg / m2 who complete the consent form to enter the study. Conditions of non-entry: including uncontrolled diabetes (HbA1C more than 9 mg / dL). , pregnancy, breastfeeding, acute mental disorders, consumption of alcohol, drug abuse, use of thiazide diuretics

Intervention groups

Intervention group: Subjects will receive the GDQS diet. Participants will learn the GDQS diet in 3 face-to-face sessions. They will also receive GDQS dietary advice during the course. Control group: subjects will receive standard diet. Participants will learn the standard diet in 3 face-to-face sessions. They will also receive standard dietary advice throughout the course. The duration of the intervention and study will be 12 weeks.

Main outcome variables

HBA1C, fasting glucose, weight, height, body mass index, waist circumference, depression, anxiety, quality of life, quality of sleep and people's adherence to diets

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N4**
Registration date: **2023-12-01, 1402/09/10**
Registration timing: **prospective**

Last update: **2023-12-01, 1402/09/10**
Update count: **0**

Registration date

2023-12-01, 1402/09/10

Registrant information

Name

Sayyed Saeid Khayyatzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

khayyatzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date
2024-09-22, 1403/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of consuming a diet based on high adherence to the Global Diet Quality Score (GDQS) with a standard diet on the control of sugar factors, mental health and anthropometric indicators in patients with type 2 diabetes: a randomized clinical trial

Public title
Investigating the effect of diet consumption based on high adherence to the global diet quality score on the control of sugar factors, mental health and anthropometric indicators in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants with type 2 diabetes Fasting blood glucose level ≥ 126 mg/dL The two-hour plasma glucose level ≥200 mg/dL Consumption of oral hypoglycemic medications Body mass index (BMI) ≤ 40 kg/m2 Completion of informed consent
Exclusion criteria:
Uncontrolled diabetes (HbA1C more than 9 mg/dl) Suffering from diabetic nephropathy History of ischemic heart disease pregnancy Lactation History of hospitalization for the treatment of heart disease during the last 6 months History of cancer treatment in the last 5 years Suffering from proteinuria History of steroid treatment during the last 3 months Suffering from thyroid disease History of lung disease and compliance with special diet Suffering from hepatitis Suffering from gastrointestinal disease Suffering from pancreatitis Suffering from inflammatory bowel disease Bowel resection Infected with AIDS Suffering from acute mental disorders Suffering from Cushing's syndrome Alcohol consumption Drug abuse Taking thiazide diuretics Taking antidepressants
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization based on gender (male and female) and BMI (above and below 25) as randomization stratified randomization with a block size equal to 8 and 2 times will be repeated. The group assigned to the people will be placed in sealed envelopes in advance and then when the participant visits and after the approval of the eligible The condition of entering the study is that the envelope will be opened and will be placed in the designated group.
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
Ethics Committee of Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences and Health Services Campus- Shohadaye Gomnam Blvd- Alem Square- Yazd
City
Yazd
Province
Yazd
Postal code
8915173160
Approval date
2023-11-25, 1402/09/04
Ethics committee reference number
IR.SSU.SPH.REC.1402.104

Health conditions studied

1

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

Primary outcomes

1

Description
HBA1C
Timepoint
Before the intervention, 12 weeks after the intervention

Method of measurement
Blood test

2

Description
Fasting Plasma Glucose (FPG)
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

3

Description
Insulin
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

4

Description
Insulin resistance index
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Formula

5

Description
Triacyl glyceride (TG)
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

6

Description
Total cholesterol
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

7

Description
High Density Lipoprotein (HDL)
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

8

Description
Low Density Lipoprotein (LDL)
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Blood sample

9

Description
Anxiety
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Beck validated questionnaire

10

Description
Depression
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Beck validated questionnaire

11

Description
Sleep quality
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Pittsburgh validated questionnaire

12

Description
Quality of Life
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
SF-36 validated questionnaire

Secondary outcomes

1

Description
Height
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Tape measure

2

Description
Weight
Timepoint
Before the intervention, 12 weeks after the intervention
Method of measurement
Weighting scale

3

Description
Body Mass Index (BMI)
Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

4

Description

Waist circumference

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Tape measure

5

Description

Hips circumference

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Tape measure

6

Description

Fat mass

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

7

Description

Fat free mass

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Body composition analyzer

8

Description

Blood pressure

Timepoint

Before the intervention, 12 weeks after the intervention

Method of measurement

Measurement of systolic and diastolic blood pressure (mmHg)

Intervention groups

1

Description

Intervention group:In the diet group based on the GDQS index, people with type 2 diabetes were given GDQS diet training for 3 sessions (the first week before the start of the intervention, the fourth week, and the eighth week of the intervention) and each session lasted 30 minutes. they take. People with type 2 diabetes will be randomly selected and placed in the standard or GDQS group. If there were two participants from the same family with type 2 diabetes, both would be randomly assigned to the standard or GDQS group. The amount of prescribed energy intake for people is calculated according to the Harris-Benedict equation. If the body mass index of people is less than 25, the current weight of people is used to calculate energy; But if the body mass index is more than 25, the adjusted weight of people according to the body mass index of 25 is used to calculate energy. The weight loss phase for overweight and obese people ends immediately after reaching a body mass index of less than 25. People will be taught how to cook different foods according to dietary recommendations. Diet recommendations based on GDQS will be adjusted according to the amount of energy needed by the person, which for a diet containing 1600 calories, 6-8 servings of fruits and vegetables per day, 7-8 servings of nuts and seeds per week, at least 6.5 servings of grains (half 2-3 daily servings of non-fat and low-fat dairy products, maximum 150 grams of meat (with an emphasis on fish and chicken), will be recommended. In training sessions, dietary recommendations based on GDQS will be fully explained to people. These recommendations will be based on the economic status of people's access to food and the status of some other diseases such as digestive diseases. Also, people will be taught how to cook different foods according to dietary recommendations. People's adherence to the diet will be checked once a week through a phone call. People are taught to consume a piece of fruit, a glass of drink with barley bread or crispy bread when mild hypoglycemic symptoms occur (hunger, sweating, increased heart rate, and confusion)

Category

N/A

2

Description

Control group:Prescribing diet in the standard group: the amount of prescribed energy intake for people is calculated according to the Harris-Benedict equation. If the body mass index of people is less than 25, the current weight of people is used to calculate energy; But if the body mass index is more than 25, the adjusted weight of people according to the body mass index of 25 is used to calculate energy. The weight loss phase for overweight and obese people ends immediately after reaching a body mass index of less than 25. People will be taught how to cook different foods according to dietary recommendations. The recommendations of the control diet will be adjusted according to the amount of energy needed by the individual and will contain 55% carbohydrates, 15% protein, 30% fat, and less than 5% energy from simple sugars. These recommendations will be based on the economic status of people's access to food and the status of some other diseases such as digestive diseases. Also, people will be taught how to cook different foods according to dietary recommendations. People's adherence to the diet will be checked once a week through a phone call. The number of training sessions in the standard diet group will be 3 sessions (the first week before the intervention, the fourth week, and the eighth week of the intervention)

and healthy food recommendations will be taught to people. People are taught to consume a piece of fruit, a glass of drink with barley bread, or crispy bread when mild hypoglycemic symptoms occur (hunger, sweating, increased heart rate, and confusion). People with type 2 diabetes are randomly placed in this group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center and Clinics

Full name of responsible person

Sayyed Saeid Khayyatzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Vice President of Research and Technology of Shahid Sadoughi University of Medical Sciences, Imam Reza Research Educational Complex, Student Blvd, Imam Hossein Square, Yazd City

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dvc.research@ssu.ac.ir

Grant name

Dr. Amin Salehi Abargouei/ Vice Chancellor of Research and Technology, Shahid Sadoughi University of Medical Sciences, Yazd

Grant code / Reference number

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

No

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Sara Bagherpour

Position

Master student in nutrition science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Full name of responsible person
Sara Bagherpour
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Master Student in nutrition science
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Not applicable
Title and more details about the data/document
primary outcome will be available at the end of study
When the data will become available and for how long
From January 2024
To whom data/document is available
Academic institutions
Under which criteria data/document could be used
Academic institutes can send their official request to the email of the scientific director of the project. the data will be sent after confirmation of ethics committee of shahid sadoughi university of medical sciences. It is not possible to perform statistical analysis on the data.
From where data/document is obtainable
Sayyed Saeid Khayyatzadeh Assistant professor of nutrition in Shahid Sadoughi university of medical sciences Khayyatzadeh@yahoo.com 00983538209100
What processes are involved for a request to access data/document
Academic institutes can send their official request to the email of the scientific director of the project. The data will be sent after confirmation of ethics committee of Shahid Sadoughi university of medical sciences
Comments