Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of intensive lifestyle intervention including two diets, calorie-carbohydrate restricted diet and the time restricted feeding on glycemic biomarkers, eating disorders, and appetite, in overweight and obese type 2 diabetic patients: a randomized controlled trial study

Protocol summary

Study aim

Investigating the effect of intensive lifestyle intervention including two diets, calorie-carbohydrate restricted diet and the time restricted feeding on glycemic biomarkers, eating disorders, and appetite, in overweight and obese type 2 diabetic patients

Design

The clinical trial has 2 intervention groups and a control group, without blinding, with 30 patients in each group. Randomized with 2 phases, each phase 3 months. Randomization will be done in the form of (1:1:1) through the method of randomized blocks.

Settings and conduct

Patients from the endocrinology clinic in Tehran. They enter the first phase. Then they enter the maintenance and monitoring phase. Measurements will be done at the beginning, 3 months, and 6 months after the start of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women 18-65 years old Less than 5 years duration of type 2 diabetes Use of at least one blood glucose-lowering medication HbA1c more than 10 percent Body mass index>45and<27 Exclusion criteria: Use of insulin, GLP-1 agonists, and SGLT-2 inhibitors, anti-obesity drugs, Recent routine HbA1c ≥10%, Weight loss of more than 5 kg in the last 6 months, kinds of diseases, Pregnancy or breastfeeding, or planning to become pregnant in the next 12 months, Drug abuse, Inability to perform physical activities

Intervention groups

phase1: Group1: Intermittent fasting group+calorie restriction and carbohydrate restriction+physical activity+ Behavior modification Group2:The calorie and carbohydrate restriction+physical activity+Behavior modification Control group: Standard care Phase2: Group1 and2: Weight maintenance diet Group3: Control group and standard care

Main outcome variables

Glycemic biomarkers (glycosylated hemoglobin, fasting blood sugar, fasting insulin, insulin resistance index) and appetite self-report score using a visual analog scale and eating disorder score

General information

Reason for update

Because this project is a thesis, professors' opinions, and needs assessment in diabetic patients during the implementation of the project, changes were made, including the addition of behavioral intervention and examination of the eating disorder factor in these patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230917059447N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-13, 1405/02/23**
Update count: **2**

Registration date

2023-09-24, 1402/07/02

Registrant information

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Saba Mohammadpour
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-23, 1402/07/01
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
Comparison of the effect of intensive lifestyle intervention including two diets, calorie-carbohydrate restricted diet and the time restricted feeding on glycemic biomarkers, eating disorders, and appetite, in overweight and obese type 2 diabetic patients: a randomized controlled trial study

Public title
Comparison of the effect of intensive lifestyle intervention including two diets, calorie-carbohydrate restricted diet and the time restricted feeding on glycemic biomarkers, eating disorders, and appetite in type 2 diabetes patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 18-65 years old Less than 5 years duration of type 2 diabetes (diagnosis based on 2 tests recorded at the diagnostic level, HbA1c and/or blood glucose) Use of at least one blood glucose-lowering medication HbA1c more than 43 mmol/mol (6.1%) with hypoglycemic drugs Body mass index (BMI) >45 and <27
Exclusion criteria:
Use of insulin Use of diabetes drugs from the category of GLP-1 agonists and SGLT-2 inhibitors Recent routine HbA1c ≥ 10% Weight loss of more than 5 kg in the last 6 months Impaired kidney function (eGFR < 60 ml per minute) Uncontrolled blood pressure (more than 160 mm Hg systolic or more than 100 mm Hg diastolic) Diseases including cancer - heart disease - gout - diagnosed eating disorders - patients with confirmed mental disorders Current treatment with Anti-obesity medications History of bariatric surgery Currently pregnant or lactating, or planning to become pregnant in the next 12 months Drug abuse Night shift workers Inability to perform physical activities
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The purpose of randomization is to control the effect of all the influencing variables on the results of the study and prevent interference between treatment groups. Randomization will be done in the form of (1:1:1) through the randomized block method, and the sealed envelope method will be used to randomize, so that people will be randomly assigned to one of the three study groups. including providing a carbohydrate-restricted intermittent fasting diet, a continuous calorie-restricted diet with carbohydrate restriction, or receiving care based on guidelines (control). Due to the nature of the intervention under study, participants, intervention providers will be aware of the group allocation.
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 beheshti University of Medical Sciences
Street address
6th Floor, Building No. 2, Central Headquarters of Shahid Beheshti University of Medical Sciences and Health Services, Arabi St., Yaman St., Shahid Chamran Highway, Tehran, Iran.
City
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Province
Tehran
Postal code
1983969411
Approval date
2023-07-24, 1402/05/02
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1402.038

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Appetite self-report score
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Visual Analogue Scale

2

Description
Eating Disorder Examination Score
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Eating Disorder Examination Questionnaire (EDEQ)

Secondary outcomes

1

Description
Height
Timepoint
Baseline
Method of measurement
Tape

2

Description
Weight
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Scale

3

Description
Body mass index
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Body composition analyzer

4

Description
Waist circumference
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Tape

5

Description
Hip circumference
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Tape

6

Description
Fat mass
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Body composition analyzer

7

Description
Fat free mass
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Body composition analyzer

8

Description
Diabetes remission
Timepoint
3 months and 6 months after the start of the study
Method of measurement
Glycosylated hemoglobin

9

Description
Total cholesterol
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

10

Description
Low-density lipoprotein
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

11

Description
High-density lipoprotein
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

12

Description
Triglyceride
Timepoint
First, 3 months and 6 months after the start of the study

Method of measurement
Blood test

13

Description
Emotional distress
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Problem Areas in Diabetes(PAID) Questionnaire

14

Description
Quality of life
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
The quality-adjusted life year (QALY) Questionnaire

15

Description
Glycosylated hemoglobin
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

16

Description
Fasting blood sugar
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

17

Description
Insulin
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Blood test

18

Description
Insulin resistance index
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Formula

19

Description
Binge eating score
Timepoint
First, 3 months and 6 months after the start of the study
Method of measurement
Gormally Binge eating questionnaire

Intervention groups

1

Description
Intervention group: Intermittent fasting group plus calorie restriction and carbohydrate restriction+ Physical activity + Behavior modification
Category
N/A

2

Description
Intervention group: Calorie and carbohydrate restriction group+ Physical activity+ Behavior modification
Category
N/A

3

Description
Control group: Control group and standard care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Hadaeq's Endocrine Clinic
Full name of responsible person
Farzad hadaegh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Research project of Shahid Beheshti University of Medical Sciences - Institute of Nutritional Research and Food Industries of the country

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Professor

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

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