

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 >45 and <27 Exclusion criteria: Use of insulin, GLP-1 agonists, and SGLT-2 inhibitors, anti-obesity drugs, Recent routine HbA1c $\geq 10\%$, 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

Name

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Name of organization / entity

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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 $\geq 10\%$ 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

AgeFrom **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

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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.

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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

Parvin mirmiran

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