# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effects of 8 weeks of high-intensity interval cardio yoga and traditional interval hatha yoga on oxidative stress, inflammation, lipid markers, glycemic control, BDNF and cortisol in type 2 diabetic women: a controlled, randomized Clinical Trial

## Protocol summary


**Study aim**

Determining the effect of yoga practice at two different intensities on metabolic indices, anthropometry, inflammation, oxidative stress, cortisol, BDNF, mental health, and functional status in women with type 2 diabetes.

**Design**

This study will be a randomized, double-blind, controlled, three-arm trial involving 39 women with type 2 diabetes. Participants will be randomly assigned to one of three groups: HIICY (n=13), TIHY (n=13), and a control group (n=13). Simple randomization will be performed using a computer.

**Settings and conduct**

Yoga groups will participate in training sessions three days a week for 8 weeks under the supervision of a yoga instructor at the University of Tabriz. Nurses and laboratory technicians will be blinded during sample collection and laboratory analyses

**Participants/Inclusion and exclusion criteria**

Thirty-nine women with type 2 diabetes, having had diabetes for more than 6 months, with physical inactivity and a body mass index (BMI) of over 25 kg/m² in the past three months are eligible for inclusion. Those with a history of cardiovascular diseases, kidney disorders, or taking anti-inflammatory medications or laxatives are excluded.

**Intervention groups**

Intervention group one: High-Intensity Interval Cardio Yoga; Intervention group two: Traditional Hatha Yoga exercises; Control group: No exercise. Based on tempo, each movement will be 1.5 seconds for HIICY and 3 seconds for TIHY, with active recovery between sets. In addition, there will be meditation and breathing exercises for each group. The control group will not have training sessions.

**Main outcome variables**

High-sensitivity C-reactive protein (hs-CRP), tumor necrosis factor alpha (TNF-α), interleukin-6, interleukin-10, cortisol, metabolic indices, antioxidant capacity (TAC), malondialdehyde (MDA), brain-derived neurotrophic factor (BDNF), functional tests, anthropometric index and mental health


## General information

**Reason for update**

**Acronym**

BDNF, BMI FFM FM%, FM, HRR, hs-CRP, IL, IPAQ, MDA, NF-kβ, TAC, TNF-α, LDL, HDL,TG, VOMAX,HbA1c,TC, FBS, HIICH, HY, HR, QUICK, IPAQ, ROS, T2DM, ANCOVA, HFIAS, QHQ-28, LDL-c, LDL-ox, DQOL, DASS

**IRCT registration information**

IRCT registration number: **IRCT20250207064682N1**
Registration date: **2025-04-02, 1404/01/13**
Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**
Update count: **0**

**Registration date**

2025-04-02, 1404/01/13

**Registrant information**


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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-04-08, 1404/01/19

**Expected recruitment end date**
2025-04-19, 1404/01/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effects of 8 weeks of high-intensity interval cardio yoga and traditional interval hatha yoga on oxidative stress, inflammation, lipid markers, glycemic control, BDNF and cortisol in type 2 diabetic women: a controlled, randomized Clinical Trial

**Public title**
The effect of two kinds of yoga on lipid profile, inflammation, oxidative stress, cortisol and BDNF in type 2 diabetic women

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having diabetic for>6 months Having a stable diet and currently taking oral antidiabetic medication Sedentary (<30-minutes twice a week of high-intensity exercise, e.g., running, yoga- and mind-body movement therapies (MBMTs)) Having had a body mass index (BMI) of >25 kg/m2for the past 3 mo Diabetic will be defined as having a fasting glucose level of 126 mg/dL

**Exclusion criteria:**
Subjects will be excluded if they had a history of gastrointestinal, if they had renal, thyroid or liver disturbance; if they are pregnant or lactating pancreatic, or cardiovascular disease; If they are currently taking prebiotics, probiotics, antibiotics, antacids, alcohol, antidiarrheal, anti-inflammatory or laxative medicines If they will not attend training for more than three sessions; If they change their oral antidiabetic medication during the intervention

**Age**
From **35 years** old to **65 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **39**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Simple randomization will be used to assign participants to intervention and control groups. An independent statistician will generate a computer-produced sequence of random numbers, which will be provided to an external staff member who is not involved in the study's procedures. Participants will receive consecutive numbers after baseline measurements are taken. Participants will also be matched on BMI and age.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Participants and the yoga instructor will not be blinded to group assignment. However, nurses and lab technicians will be blinded during sample collection and laboratory analysis. The data analyst will be unblinded after all laboratory analyses are complete.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
We will use the International Physical Activity Questionnaire (IPAQ—Short Version) to assess physical health and physical activity levels. A 3-day food record will be explained to the subjects (two weekdays and one weekend), and after participants report their food and beverage intake, the data will be analyzed using the program "Nutritionist 4"

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of the University of Tabriz

**Street address**
Azerbaijan Province, Tabriz, 29 Bahman Boulevard

**City**
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**Province**
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**Approval date**
2025-01-12, 1403/10/23

**Ethics committee reference number**
IR.TABRIZU.REC.1403.139

## Health conditions studied

### 1

**Description of health condition studied**
Women with type 2 diabetes

**ICD-10 code**
E08

**ICD-10 code description**
Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

**Description**
Changes in high-sensitivity C-reactive protein (hs-CRP)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 mL of venous blood samples will be collected between 9:00 AM and 7:00 AM following an overnight fast. The immunoturbidimetry assay will be utilized to characterize the serum hs-CRP level (Pars Azmoon Co., Tehran, Iran).

### 2

**Description**
Tumor necrosis factor-alpha (TNF-α)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 mL of venous blood samples will be collected between 9:00 AM and 7:00 AM following an overnight fast. Based on the biotin double antibody sandwich technique, commercial enzyme-linked immunosorbent assay (ELISA) kits (Diaclone, Besancon, France) will be used to analyze the levels of TNF-α.

### 3

**Description**
Changes in Interleukin 6 (IL-6)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 milliliters of venous blood samples will be collected between 7 AM and 9 AM after an overnight fast. Based on a double biotin sandwich antibody method, commercial ELISA kits (Diaclone, Besançon, France) will be used to analyze IL-6 levels.

### 4

**Description**
Changes in Interleukin 10 (IL-10)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 milliliters of venous blood samples will be collected between 7 AM and 9 AM after an overnight fast. Based on a double biotin sandwich antibody method, commercial ELISA kits (Diaclone, Besançon, France) will be used to analyze IL-10 levels.

### 5

**Description**
Changes in Low-Density Lipoprotein (LDL)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 ml of venous blood samples will be collected between 9 am and 7 am after an overnight fast. LDL concentration will be determined by enzymatic colorimetric methods (Cholesterol CHOD-PAP and Trig lycerides GPO-PAP, Pars-Azmone, IRI) on an automated analyzer (Abbott, model Alcyon300, USA), serum LDL-c will be determined based on the Friedewald equation. TC/HDL-c and LDL-c/HDL-c ratios will determine the relative risk of coronary artery disease, they will also be calculated.

### 6

**Description**
Changes in glycosylated hemoglobin (HbA1c)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Initially and at the end of the trial, 10 mL of venous blood sample will be collected between 7 and 9 AM after an overnight fast. The level of Hemoglobin A1c (HbA1c) will be measured using the HPLC D-10 chromatography system (Bio-Rad Laboratories, Hercules, California, USA).

### 7

**Description**
Changes in insulin concentration
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and at the end of the trial, 10 mL of venous blood will be collected between 7:00 and 9:00 AM after an overnight fast. Serum insulin will be measured using the chemiluminescent immunoassay method (LIAISON analyzer 310360; Diasorin S.P.A, Vercelli, Italy).

### 8

**Description**
Changes in insulin resistance (HOMA-IR)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
The evaluation of the insulin resistance homeostasis model (HOMA-IR) was calculated using the following formula: [Fasting insulin (μU/mL) × FPG (mg/dL)]/405.

### 9

**Description**
Changes in Antioxidant Capacity (TAC)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 milliliters of venous blood will be collected between 9 AM and 7 AM after an overnight fast. TAC levels will be assessed using spectrofluorimetric and colorimetric methods ( Randox kits, Randox Laboratory, UK).

## 10

**Description**
Changes in Malondialdehyde (MDA)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 milliliters of venous blood will be collected between 7 and 9 AM after an overnight fast. The levels of malondialdehyde (MDA) will be assessed using spectrophotometric and colorimetric methods ( Kontron, model SFM 25A, Italy).

## 11

**Description**
Sleep quality
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using the Pittsburgh Sleep Quality Index (PSQI).

## 12

**Description**
General health
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using the General Health Questionnaire (GHQ-28).

## 13

**Description**
Guality of life
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using the Diabetes Quality of Life Questionnaire developed by Thomas et al. (DQOL).

## 14

**Description**
Food insecurity,
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using the General Health Questionnaire (GHQ-28).

## 15

**Description**
Depression, anxiety, stress
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using the Depression, Anxiety, and Stress Scale (DASS-21).

## 16

**Description**
Blood pressure
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
It will be measured using a mercury sphygmomanometer.

## 17

**Description**
Changes in cortisol concentration
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 milliliters of venous blood samples will be collected between 7 and 9 AM after an overnight fast. Serum cortisol will be measured using ELISA kits (eBioscience, San Diego, California) according to the manufacturer’s instructions.

## 18

**Description**
Insulin Sensitivity (QUICKI)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Insulin sensitivity will be assessed using the QUICKI index, calculated with the following formula: QUICKI = [log fasting glucose (mg/dL) + log fasting insulin (μU/mL)] - 1.

## 19

**Description**
brain-derived neurotrophic factor (BDNF)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 ml of venous blood samples will be collected between 9 am and 7 am after an overnight fast. Serum BDNF concentrations will be measured using ELISA kits (Human BDNF ELISA Kit, Boston, USA;) according to the manufacturer's instructions.

## 20

**Description**
fasting blood glucose (FBS)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
At the beginning and end of the trial, 10 ml of venous blood samples will be collected between 9 am and 7 am after an overnight fast. Fasting plasma glucose (FPG) concentration will be measured enzymatically using an Abbot ModelAclyon 300 autoanalyzer (USA) with a Pars Azmoun kit (Tehran, Iran).

### 21

**Description**
Balance test
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Functional tests: Rhomborig (eyes closed), Rhomborig (eyes open),

### 22

**Description**
Flexibility test
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
sit-and-reach test (trunk flexibility), shoulder flexibility,

### 23

**Description**
Muscular endurance test
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
30-second hand raising test, 30-second chair standing and sitting test

### 24

**Description**
High-density lipoprotein (HDL)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Initially and at the end of the trial, 10 mL of venous blood sample will be collected between 7 and 9 AM after an overnight fast. The level of HDL will be measured using an automatic analyzer (Abbot Aclyon 300, USA).

### 25

**Description**
Triglycerides
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Initially and at the end of the trial, 10 mL of venous blood sample will be collected between 7 and 9 AM after an overnight fast. The level of Triglycerides will be measured using an automatic analyzer (Abbot Aclyon 300, USA).

## Secondary outcomes

### 1

**Description**
Body weight changes
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
The patients' weight before and after the intervention will be measured using a Seca dial scale made in Germany with an accuracy of 100 grams with minimal clothing and no shoes. The patients' height will also be measured using a tape measure mounted on the wall with an accuracy of 0.1 cm.

### 2

**Description**
Waist circumference
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Waist circumference was measured using a non-elastic tape measure in the standing position at the midpoint of the lower edge of the lowest rib and the superior border of the iliac crest after normal breathing (without clothing). Waist circumference was measured according to standard methods described elsewhere.

### 3

**Description**
Hip circumference
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
The circumference of the hips will also be measured at the area of the greatest curvature of the buttocks without pressing the skin.

### 4

**Description**
Body composition (FFM, FM, and FM%)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
A body composition analyzer (Tanita BC-418, Tanita Corp., Tokyo, Japan) will be used to measure the participants' body composition.

### 5

**Description**
Maximum oxygen consumption (VO2 max)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**
Aerobic fitness will also be assessed with a standardized submaximal treadmill walking protocol, which will be modified from the Balke 27 maximal protocol, to be appropriate for participants with various chronic conditions.

### 6

**Description**
Body Mass Index (BMI)
**Timepoint**
First intervention and 2 months after intervention.
**Method of measurement**

BMI will also be calculated using the relevant formula by dividing weight (kg) by height squared (m2).

## Intervention groups

### 1

**Description**

This study will be a three-arm randomized controlled trial. Participants will be randomly assigned to one of three groups. The first intervention group: High-Intensity Interval Cardio Yoga (HIICY; n=13). HIICY group participants will train three days a week for 8 weeks. All training sessions will be conducted under the supervision of a qualified yoga instructor at the Faculty of Physical Education and Sports Sciences, University of Tabriz. For both training sessions and the HIICY sequence, the Surya Namaskar B sequence, which includes 19 physical exercises (asanas), will be used. Based on tempo, each movement will last 1.5 seconds for HIICY, using a metronome. The total duration for both styles will be 60 minutes, including 2 sets of 10 minutes of HIICY and a 10-minute active recovery between sets. Active recovery will be performed by walking at 40-45% of estimated HRmax, as suggested in a previous study, followed by 7-10 minutes of breathing and 5-10 minutes of guided relaxation. Participants will record the start and end of their yoga sessions on a Fitbit Sense FB512GLWT device and will fill out a one-minute post-session report, recording their heart rate, effort, and impact.

**Category**

Lifestyle

### 2

**Description**

The second intervention group: Traditional Hatha Yoga (TIHY; n=13), TIHY group participants will train three days a week for 8 weeks. All training sessions will be conducted under the supervision of a qualified yoga instructor at the Faculty of Physical Education and Sports Sciences, University of Tabriz. For both training sessions and the TIHY sequence, the Surya Namaskar B sequence, which includes 19 physical exercises (asanas), will be used. Based on tempo, each movement will last 3 seconds for TIHY, using a metronome. The total duration for both styles will be 60 minutes, including 2 sets of 10 minutes of TIHY and a 10-minute active recovery between sets. Active recovery will be performed by walking at 40-45% of estimated HRmax, as suggested in a previous study, followed by 7-10 minutes of breathing and 5-10 minutes of guided relaxation. Participants will record the start and end of their yoga sessions on a Fitbit Sense FB512GLWT device and will fill out a one-minute post-session report, recording their heart rate, effort, and impact.

**Category**

Lifestyle

### 3

**Description**

Control group: Participants assigned to the control group did not have structured training sessions, but for ethical reasons, they were invited to attend an introductory session where standard advice on general physical activity guidelines was provided. In addition, every 2 weeks, both the training and control groups would meet for thematic sessions on topics such as nutrition or physical activity to improve trial adherence.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Diabetes Association of Iran

**Full name of responsible person**
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## Sponsors / Funding sources

### 1

**Sponsor**

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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**
University of Tabriz

**Proportion provided by this source**

10

**Public or private sector**
Private

**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**
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## Person responsible for updating data

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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**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available