Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

Name

Mostafa khani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 926 3371

Email address

khani_ms@yahoo.com

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
Tabriz

Province
East Azarbaijan

Postal code
5164736931

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
Mostafa Khani

Street address
pastor

City
Tabriz

Province
East Azarbaijan

Postal code
5138883716

Phone
+98 905 799 0847

Email
khani_ms@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Tabriz

Full name of responsible person
Jalal Shiri

Street address
Tabriz, Abersan 29 Bahman Blvd.

City
Tabriz

Province
East Azarbaijan

Postal code
5164736931

Phone
+98 905 799 0847

Email
khani_ms@yahoo.com

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
University of Tabriz

Full name of responsible person
Mostafa Khani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
exercise physiology

Street address
Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5164736931

Phone
09067990847

Email
khani_ms@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Tabriz

Full name of responsible person
Sanaz Salahpour

Position
Master's student in exercise physiology

Latest degree
Master

Other areas of specialty/work
Exercise physiology

Street address
Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138883716

Phone
09067990847

Email
salapoursanaz@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
University of Tabriz

Full name of responsible person
Sanaz Salahpour

Position
Master's student in exercise physiology

Latest degree
Master

Other areas of specialty/work
Exercise physiology

Street address
Pastor

City
Tabriz

Province
East Azarbaijan

Postal code
5138883716

Phone
+98 905 799 0847

Email
salapoursanaz@gmail.com

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