

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effectiveness of Two Months of Cyclic Yoga Exercise on Glycemic Indices, Liver Enzymes and Anthropometric Indices in Type 2 Diabetes Patients with Non-alcoholic fatty liver disease

Protocol summary

Study aim

Investigating the Effect of 2 Months of Cyclic Yoga Exercise on Glycemic Indices, Liver Enzymes and Anthropometric Indices in Type 2 Diabetes with Non-Alcoholic Fatty Liver Disease

Design

In this clinical trial with a control group, 40 patients who had research entry criteria, non-randomly divided into two groups based on fatty liver grade.

Settings and conduct

The research method will be quasi-experimental with two yoga exercise group and control groups with pretest and post test. Subjects are 40 type 2 diabetic women with fatty liver. After reviewing the patients' files, about 60 eligible subjects will be invited to start the study. Yoga exercises will be done in Rize Vandy gym for two months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic women with non-alcoholic fatty liver disease- Type 2 diabetic women aged 45 to 55 years with overweight Exclusion criteria: No treatment with insulin - no complications of diabetes (neuropathy, nephropathy, retinopathy) - no use of drugs and alcohol - no participation in regular sports activities - no history of heart, respiratory or mental diseases - no history of fracture, surgery or joint diseases - lack of hormone therapy and three or more absences in training sessions

Intervention groups

Yoga exercise group: Cyclic yoga exercise for 8 weeks, three days a week Control group: Without regular exercise for 8 weeks

Main outcome variables

Alanine amino transferase, aspartate amino transferase, alkaline phosphatase, glycosylated hemoglobin, fasting blood glucose, cholesterol, LDL cholesterol, HDL cholesterol, triglyceride, waist circumference, blood pressure, IGF-1 hormone, insulin hormone, body fat

percentage, body mass index, hip circumference, fatty liver grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110527006611N4**

Registration date: **2023-05-17, 1402/02/27**

Registration timing: **retrospective**

Last update: **2023-05-17, 1402/02/27**

Update count: **0**

Registration date

2023-05-17, 1402/02/27

Registrant information

Name

Zahra Bayat

Name of organization / entity

The University of Tehran

Country

Iran (Islamic Republic of)

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+98 83 3822 9422

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

2022-06-10, 1401/03/20

Actual recruitment end date

2022-06-10, 1401/03/20

Trial completion date

2022-09-21, 1401/06/30

Scientific title

The Effectiveness of Two Months of Cyclic Yoga Exercise on Glycemic Indices, Liver Enzymes and Anthropometric Indices in Type 2 Diabetes Patients with Non-alcoholic fatty liver disease

Public title

The Effectiveness of Two Months of Cyclic Yoga Exercise on Type 2 Diabetes Patients with Non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetic women with Non-alcoholic fatty liver disease Type 2 diabetic women 45 to 55 years old with overweight

Exclusion criteria:

No insulin treatment No complications of diabetes (neuropathy, nephropathy, retinopathy) No use of drugs and alcoholic drinks, Not participating in regular exercise activities No history of cardiovascular and mental illness No history of fractures, surgery or joint diseases, Three times or more Absence in training sessions Lack of hormone therapy

AgeFrom **45 years** old to **55 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **37****Randomization (investigator's opinion)**

Not randomized

Randomization description**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**

Research Ethics Committees of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti blvd- in front of Imam Ali Hospital Building No. 2

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kermanshah

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Kermanshah

Postal code

6714673159

Approval date

2021-11-07, 1400/08/16

Ethics committee reference number

IR.KUMS.REC.1400.070

Health conditions studied**1****Description of health condition studied**

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2**Description of health condition studied**

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Glycosylated Hemoglobin

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with Pishtaz Teb kit

2**Description**

Fasting blood glucose

Timepoint

At the beginning of the study (before the intervention) and two months after the intervention

Method of measurement

Blood test with BioSystems kit

3**Description**

fatty liver grade

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Alanine Aminotransferase enzyme

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

2

Description

Aspartate Aminotransferase enzyme

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

3

Description

Alkaline phosphatase enzyme

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

4

Description

LDL Cholesterol

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

5

Description

Triglyceride

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

6

Description

HDL Cholesterol

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

7

Description

Cholesterol

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with BioSystems kit

8

Description

Insulin Hormone

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test Siemens kit made in America

9

Description

Waist Circumference

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Standard tape meter

10

Description

Blood Pressure

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

brachial digital blood pressure monitor

11

Description

IGF-1 Hormone

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Blood test with DiaSorin kit

12

Description

Hip Circumference

Timepoint

At the beginning of the study (before the intervention)
and two months after the intervention

Method of measurement

Standard tape meter

Intervention groups**1****Description**

Intervention group: Yoga exercise group: This group performed cyclic yoga exercise for two months, three days a week. Cyclic Yoga is the art of sequencing yoga asana, pranayama and mudra techniques to maximize their benefits and energize the mind and body. The program of selected cyclic yoga exercises includes stretching exercises for large and small pectoral muscles, internal rotators of the arm, glutes, hamstrings, and strengthening the trapezius and rhomboid muscles and the external rotators of the arm and the central muscles of the body were performed in the style of cyclic yoga.

Category

Lifestyle

2**Description**

Control group: The control group does not participate in any regular exercise activities during the intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Fatemeh Rezvan Madani office

Full name of responsible person

Fatemeh Rezvan Madani

Street address

The office of Dr. Rezvan Madani, Ground Floor, Negin Golestan Apartment, Chahardah Metri-ye-Shariat Street, Emami Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

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No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah city

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

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 Tehran

Full name of responsible person

Zahra Bayat

Position

PhD from University of Tehran

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Biochemistry and Metabolism

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Mersad Gym, Sangar Crossroad, 22 Bahman, Kermanshah

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor, Fertility and Infertility Research Center, Health Technology Institute, Kermans

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Person responsible for updating data

Contact

Name of organization / entity

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study will start after obtaining the informed consent form of the patients and obtaining the code of ethics and permission of the University of Medical Sciences. After the completion of the study, the data will be collected and analyzed, and the final results will be made available to the researchers and relevant authorities based on the approval of the ethics committee and in accordance with the ethical standards based on the format of the university research department without mentioning the names of the participants. The final result will be presented to the university in the form of a final project report.

When the data will become available and for how long

Start of the 8 month period after the research

To whom data/document is available

For university students and students in research related fields

Under which criteria data/document could be used

There are no specific conditions to provide such information

From where data/document is obtainable

Zahra Bayat Email: z.bayat@ut.ac.ir

What processes are involved for a request to access data/document

Send message to the person responsible for providing the data Email: z.bayat@ut.ac.ir

Comments