# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 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)
**Phone**
+98 83 3822 9422
**Email address**
zahra_bayat2008@yahoo.com

**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
**Age**
From **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
**City**
kermanshah
**Province**
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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Rezvanimadani@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Cyrus Jalili
**Street address**
No. 2 Central Building, Kermanshah University of Medical Sciences, Shahid Beheshti Street, Kermanshah city
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**Province**
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**Fax**
+98 83 3838 4185
**Email**
cjalili@kums.ac.ir
**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
**Street address**
Mersad Gym, Sangar Crossroad, 22 Bahman, Kermanshah
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**Web page address**

## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**
Houshang Nemati

**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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Beheshti Blvd, Kermanshah University of Medical Sciences, Kermanshah City

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
The University of Tehran

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**Position**
PhD from University of Tehran

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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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**Province**
Kermanshah

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6714649939

**Phone**
+98 83 3838 3184

**Email**
z.bayat@ut.ac.ir

## 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**