

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The interactive effect of Pilates training and nano-curcumin supplementation on body composition and selected indices of non-alcoholic fatty liver disease in obese and overweight females

Protocol summary

Study aim

The interactive effect of 8 weeks of Pilates training and nanocurcumin supplementation on body composition and selected indicators of non-alcoholic fatty liver in obese and overweight women

Design

Two arm parallel group trial with a blind, Pre-test and post-test, not randomized

Settings and conduct

The current single blind study (blind subject) with a pre-test and post-test design with the presence of a placebo is performed in NAFLD patients referred to the specialized gastro-hepatology clinic in Rasht. The 8-week research protocol includes daily consumption of 80 mg nano-curcumin supplement or placebo and 3 days per week selected aerobic pilates exercises for 1 hour per day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with confirmed non-alcoholic fatty liver and BMI>25, WHR>0.85
Exclusion criteria: suffering from other liver diseases, diabetes, cancer, cardiovascular diseases, thyroid disorders, taking drugs affecting on research variables

Intervention groups

The control group includes exercise-placebo and the intervention group includes exercise-supplement.

Main outcome variables

Body composition, liver enzymes and other selected liver indicators, severity of fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220518054903N1**
Registration date: **2023-03-05, 1401/12/14**

Registration timing: **retrospective**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

leila rezaei

Name of organization / entity

Faculty of Physical Education and Sports Sciences of Guilan

Country

Iran (Islamic Republic of)

Phone

+98 13 3342 2616

Email address

star_6439@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-21, 1401/05/30

Expected recruitment end date

2022-09-01, 1401/06/10

Actual recruitment start date

2022-08-21, 1401/05/30

Actual recruitment end date

2022-09-01, 1401/06/10

Trial completion date

2022-11-03, 1401/08/12

Scientific title

The interactive effect of Pilates training and nano-curcumin supplementation on body composition and selected indices of non-alcoholic fatty liver disease in

obese and overweight females	
Public title	Interactive effect of Pilates training and nano-curcumin on fatty liver disease
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Non-alcoholic fatty liver disease patients being Overweight or obese (WHR>0.85, BMI>25) Exclusion criteria: participating in a regular exercise program for the past 6 months Presence of musculoskeletal injury sensitivity to turmeric and curcumin Consumption of dietary supplements in the last 3 months smoking and alcohol Taking drugs that lower blood glucose, blood lipids and anti-inflammatory drugs and any drugs that affect liver function Other liver diseases and diabetes, cancer, cardiovascular disease and thyroid disorders pregnancy or breastfeeding
Age	From 25 years old to 60 years old
Gender	Female
Phase	3
Groups that have been masked	Participant
Sample size	Target sample size: 30 Actual sample size reached: 12
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Single blinded
Blinding description	The participants are divided into two groups, supplement and placebo, and they do not know which one will receive the supplement and which one will receive the placebo. Nanocurcumin supplement is available in the form of orange jelly capsules. The placebo capsules will be prepared in the same colour. The capsules will be removed from the strips of the manufacturing company and will be given to the participants in the same package as the placebo capsules. In addition, the subjects take the supplements at home and do not see how other people use them.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Persian Gulf Highway, km 5 Qazvin Road, Guilan University Complex

City

Rasht

Province

Guilan

Postal code

۴۱۹۹۶۱۳۷۷۶

Approval date

2022-07-13, 1401/04/22

Ethics committee reference number

IR.GUILAN.REC.1401.025

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty Liver

ICD-10 code

K76.0

ICD-10 code description

کبد چرب غیر الکلی

Primary outcomes

1

Description

The degree of hepatic steatosis

Timepoint

48 hours before and after the intervention

Method of measurement

Fibroscan machine made in Germany using abdominal elastography method

Secondary outcomes

1

Description

Body fat percentage

Timepoint

48 hours before and after the intervention

Method of measurement

Lafayette caliper made in America with Jackson and Pollock three-point method

2

Description

BODY MASS INDEX

Timepoint

48 hours before and after the intervention

Method of measurement

Height and weight measurement from Seca model 220 scale made in Germany and put in BMI formula

3

Description

visceral fat

Timepoint

48 hours before and after the intervention

Method of measurement

meter reading

4

Description

serum concentration of liver enzymes

Timepoint

48 hours before and after the intervention

Method of measurement

using the Biorex Fars kit, made in Iran and with an auto-analyzer device

5

Description

lipid profile

Timepoint

48 hours before and after the intervention

Method of measurement

using the Biorex Fars kit, made in Iran and with an auto-analyzer device

Intervention groups

1

Description

Intervention group: Pilates-curcumin group for 8 weeks and 3 days a week for 1 hour participating in a selected activity from Pilates exercises and daily consumption of two 40 mg nanocurcumin capsules produced by Exsir-Nano Sina company.

Category

Treatment - Drugs

2

Description

Control group: Pilates-placebo group for 8 weeks and 3 days a week for 1 hour participating in a selected activity from Pilates exercises and daily consumption of two 40 mg capsules of corn starch (placebo)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Gastroenterology and Liver Clinic

Full name of responsible person

Dr. Shafaqi Afshin

Street address

2nd floor, next to Mellat Laboratory, Shahid Ahmadzadeh Ave, Shahid Ansari Blv

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Drafshinshafaghi@gmail.com

2

Recruitment center

Name of recruitment center

Baasat super specialty clinic

Full name of responsible person

Dr. Seyyedeh Amineh Hojjati

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Enghelab Ave (Haji Abad)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gilan Faculty of Physical Education and Sports Sciences

Full name of responsible person

Research assistant

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Persian Gulf Highway (km 5 of the Rasht-Qazvin road), Gilan University Complex

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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

Gilan Faculty of Physical Education and Sports Sciences

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

Gilan Faculty of Physical Education and Sports Sciences

Full name of responsible person

Ebrahimi Maryam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Full name of responsible person

Ebrahimi Maryam

Position

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Latest degree

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Person responsible for updating data

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Ebrahimi Maryam

Position

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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