

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of eight weeks of Pilates training along with silymarin consumption on the levels of liver enzymes in women with non-alcoholic fatty liver disease

Protocol summary

Study aim

The effect of eight weeks of Pilates training along with silymarin consumption on the levels of liver enzymes in women with non-alcoholic fatty liver disease

Design

Clinical trial in four groups, Pilates training, silymarin, Pilates + silymarin and the control group, with parallel groups, simple randomization, Phase three on 40 patients. Balloting was used for randomization.

Settings and conduct

Sampling was done in Aria Hospital in Ahvaz. Before performing the protocol, the participants were fasting for 12 hours, and their blood samples were taken by the laboratory technician to estimate liver enzymes ALT, AST and ALP. 48 hours after the end of the protocol, another blood sampling was performed to estimate liver enzymes.

Participants/Inclusion and exclusion criteria

age range from 30 to 55 years, no cardiovascular diseases, no joint and skeletal disease

Intervention groups

The first intervention group (Pilates group) performed Pilates training for sixty minutes, three days a week for eight weeks. The second intervention group (silymarin group) consumed 140 mg silymarin capsules (Livergol Brand from GoldDaru Company, Iran) three days a week (after meals) for eight weeks. The third intervention group (Pilates + silymarin group) performed Pilates training in addition to the consumption of 140 mg silymarin capsules. The fourth intervention group (control group) did not participate in any program.

Main outcome variables

improve physical activity and immunity against disease;
to get familiar with the new practices in Pilates training;
enrich research information for the future studies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057435N1**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **retrospective**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Sedigheh Kaabomeir

Name of organization / entity

The University of Shahid Chamran of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 916 090 4022

Email address

s.kaabomeir1996@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

2022-04-20, 1401/01/31

Actual recruitment end date

2022-08-20, 1401/05/29

Trial completion date

2022-10-21, 1401/07/29

Scientific title

The effect of eight weeks of Pilates training along with silymarin consumption on the levels of liver enzymes in women with non-alcoholic fatty liver disease

Public title

The Effect of Pilates training along with Silymarin consumption on Non-Alcoholic Fatty Liver

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

women with non-alcoholic fatty liver disease age range from 30 to 55 years no cardiovascular diseases, no joint and skeletal disease no regular exercise activity in the last 6 months no use of special drugs and supplements that affect the protocol process

Exclusion criteria:

Age

From **30 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Balloting was used for randomization, so that the numbers 1 to 40 were written on cards in similar envelopes and placed in the ballot box. Each participant took a random card. The first 10 cards were assigned to group A (Pilates), the second 10 cards to group B (Pilates + silymarin), the third 10 cards to group C (silymarin) and the last 10 cards to group D (control group). According to the numbering order, the participants were placed in four groups, that is, Pilates training, silymarin, Pilates + silymarin and the control group.

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

Ethics Committee of Shahid Chamran University of Ahvaz

Street address

Floor 5, Block B3, Oil Co. 2000 Unit Houses, Resalat District

City

Ahvaz

Province

Khouzestan

Postal code

6177882869

Approval date

2022-05-13, 1401/02/23

Ethics committee reference number

EE/1401.2.24.172645/scu.ac.ir

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

levels of liver enzymes

Timepoint

24 hours before performing the protocol and 48 hours after the end of the protocol, another blood sampling was performed to estimate liver enzymes ALT, AST, ALP.

Method of measurement

Pars Azmoun kit made in Iran

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group (Pilates group) performed Pilates training in the gym for sixty minutes, three days a week for eight weeks

Category

Other

2

Description

Intervention group: The second intervention group (silymarin group) consumed 140 mg silymarin capsules (Livergol Brand from GolDaru Company, Iran) three days a week (after meals) for eight weeks.

Category

Treatment - Drugs

3

Description

Intervention group: The third intervention group (Pilates + silymarin group) performed Pilates training in addition to the consumption of 140 mg silymarin capsules

Category

Treatment - Drugs

4

Description

Control group: They did not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aria hospital

Full name of responsible person

Sedigheh Kaabomeir

Street address

Floor 5, Block B3, Oil Co. 2000 Unit Houses, Resalat District

City

Ahvaz

Province

Khouzestan

Postal code

6177882869

Phone

+98 916 090 4022

Email

s.kaabomeir1996@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Chamran University of Ahvaz

Full name of responsible person

Abdolhamid Habibi

Street address

Floor 5, Block B3, Oil Co. 2000 Unit Houses, Resalat District

City

Ahvaz

Province

Khouzestan

Postal code

6177882869

Phone

+98 916 118 4888

Email

hamidhabibi330@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Chamran University of Ahvaz

Proportion provided by this source

40

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

Shahid Chamran University of Ahvaz

Full name of responsible person

Sedigheh Kaabomeir

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Sport physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Chamran University of Ahvaz

Full name of responsible person

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Phone

+98 916 090 4022

Fax

Email

s.kaabomeir1996@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Shahid Chamran of Ahvaz

Full name of responsible person

Sedigheh Kaabomeir

Position

Masters

Latest degree

Master

Other areas of specialty/work

Physiology Sport

Street address

Floor 5, Block B3, Oil Co. 2000 Unit Houses, Resalat District

City

Ahvaz

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available