Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 GolDaru 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 diseases; 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
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Chamran University of Ahvaz
Full name of responsible person
Sedigheh Kaabomeir
Position
Masters
Latest degree
Master
Other areas of specialty/work
Sport Physiology
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

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
Province
Khouzestan
Postal code
6177882869
Phone
+98 916 090 4022
Fax
Email
s.kaabomeir1996@gmail.com

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