Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of eight weeks of Pilates exercise and jujube supplementation on liver fat content, liver enzymes and platelet count in women with non-alcoholic fatty liver

Protocol summary

Study aim
Determining the effect of eight weeks of Pilates training and jujube extract supplementation on non-alcoholic fatty liver and platelet count in middle-aged women

Design
Clinical trial with randomized open label, parallel control group, on 40 people in four groups.

Settings and conduct
Ultrasound to diagnose fatty liver, liver tests including AST-ALT-ALP- and CBC test to determine platelet levels will be performed 48 hours before and after the intervention for all people. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. The first group will be given only jujube, the second group will only have Pilates exercises, the third group will have jujube and Pilates, and the fourth group will be the control group, which will not be interfered with.

Participants/Inclusion and exclusion criteria
Satisfaction with the study, middle-aged women aged Benin 31 to 49 years, no history of other diseases, no alcohol and tobacco use, no special diet / medication, no dietary supplements, no regular exercise in the past six months Lack of BMI above 30 and fatty liver level one and higher.

Intervention groups
We will have four intervention groups: the first group will only consume jujube The second group will only practice Pilates The third group is the jujube consumption group of Pilates exercises. The fourth group is the control group that will not be interfered with.

Main outcome variables
Main outcomes include liver fat analysis, liver enzymes and platelet count.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210413050954N1**
Registration date: **2021-08-31, 1400/06/09**
Registration timing: **retrospective**

Last update: **2021-08-31, 1400/06/09**
Update count: **0**

Registration date
2021-08-31, 1400/06/09

Registrant information
Name
Rasoul Raesi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5422 6054
Email address
raeesigr2@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-06, 1400/05/15
Expected recruitment end date
2021-08-21, 1400/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of eight weeks of Pilates exercise and jujube supplementation on liver fat content, liver enzymes and platelet count in women with non-alcoholic fatty liver

Public title
The effect of eight weeks of Pilates exercise and jujube supplementation on liver fat content, liver enzymes and platelet count in women with non-alcoholic fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Middle-aged women ranging in age from 31 to 49 Satisfaction to participate in the study BMI 30 or less Fatty liver grade one and above

Exclusion criteria:
History of other diseases Alcohol and tobacco consumption Special diet / medication Take dietary supplements Regular exercise in the last six months

Age
From **31 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The lottery method will be used for random allocation. This method is a large block the size of the total sample size to ensure a balance in the number of people assigned to each group. For this purpose, we put the same size of the sample (40 pieces) of the same shape card on which the numbers 1 to 40 are written in the same shape of the envelope and place it in a lottery container. Then randomly remove the cards and number the first 10 cards for group A (Pilates exercise), the next 10 cards for group B (Pilates and jujube), the third 10 cards for group C (jujube only) and the last 10 cards for group D (Control group) is written, the random chain of numbers and assigned groups are specified. Candidates are numbered in order of date and assigned to the groups based on the written sequence.

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 Mashhad University of Medical Sciences

Street address
modarres 15

City
khaf

Province
Razavi Khorasan

Postal code
9561717551

Approval date
2021-06-19, 1400/03/29

Ethics committee reference number
IR.MUMS.REC.1400.078

Health conditions studied

1

Description of health condition studied
non-alcoholic fatty liver

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
liver fat content

Timepoint
48 hours before the intervention and 48 hours after the intervention

Method of measurement
Diagnostic ultrasound of fatty liver

2

Description
Liver enzymes

Timepoint
48 hours before the intervention and 48 hours after the intervention

Method of measurement
Blood biochemistry tests

3

Description
Platelet count

Timepoint
48 hours before the intervention and 48 hours after the intervention

Method of measurement
Blood Cell Counting Test (CBC)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group, only jujube consumption: daily consumption of 0.4 grams of jujube fruit per kilogram of body weight will be consumed in the morning and the same amount in the evening.

Category

Treatment - Drugs

2

Description

The second intervention group, Pilates Exercise Only: The Pilates training protocol will include 60 minutes of activity in the form of 10 minutes of warm-up, 40 minutes of Pilates exercises, and 10 minutes of cooling in three sessions per week for eight weeks. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. It is done lying down and without the need for specialized equipment. In order to observe the principle of overload, the speed and repetition of movements in each session will increase compared to the previous session, so that it starts from 10 repetitions in the first week and will gradually reach 25-25 repetitions in the eighth week. Also, to control the intensity of the exercises, the formula of maximum heart rate (age -220 = maximum heart rate) and polar heart rate monitor will be used. Accordingly, exercise will begin in the first week with an intensity of 55-50% of maximum heart rate and in the eighth week will reach 75-80% of maximum heart rate (approximately 5% increase in intensity of exercise per week). It should be noted that the control group and the jujube extract group will not participate in any training or sports activities during these eight weeks.

Category

Treatment - Other

3

Description

Intervention group: The third intervention group, Pilates training and jujube consumption: will consume 0.4 grams of jujube fruit per kilogram of body weight daily in the morning and the same amount in the evening. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. Pilates largely avoids high impact, high power output, and heavy muscular and skeletal loading. It is done lying down and without the need for specialized equipment. In order to observe the principle of overload, the speed and repetition of movements in each session will increase compared to the previous session, so that it starts from 10 repetitions in the first week and will gradually reach 25-25 repetitions in the eighth week. Also, to control the intensity of the exercises, the formula of maximum heart rate (age -220 = maximum heart rate) and polar heart rate monitor will be used. Accordingly, exercise will begin in the first week with an intensity of 55-50% of maximum heart rate and in the eighth week will reach 75-80% of maximum heart rate (approximately 5% increase in intensity of exercise per week). It should be noted that the control group and the jujube extract group will not participate in any training or sports activities during these eight weeks.

Category

Treatment - Other

4

Description

Control group: they will not be interfered with.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
22 Bahman Khaf Hospital

Full name of responsible person
rasoul raesi

Street address
Moallem Square, Ferdowsi Blvd., 22 Bahman Khaf Hospital

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Razavi Khorasan

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raesi.br881@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud School of Physical Education

Full name of responsible person
rasoul raesi

Street address
Hafdeh Shahrivar St., Behzisti Alley, Mirabotaleb Dormitory

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
no

Proportion provided by this source
1

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
Mashhad University of Medical Sciences

Full name of responsible person
rasoul raesi

Position
nurse

Latest degree
Ph.D.

Other areas of specialty/work
Health Service Management

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Person responsible for scientific inquiries

Contact

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Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Health Service Management

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Person responsible for updating data

Contact

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Position
Consultant

Latest degree
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Other areas of specialty/work
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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 more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available