

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 ($\text{age} - 220 = \text{maximum heart rate}$) 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. 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 ($\text{age} - 220 = \text{maximum heart rate}$) 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrour School of Physical Education

Full name of responsible person

rasoul raesi

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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
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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