Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of six weeks of Pilates training and dill supplementation on serum levels of Nesfatin-1, insulin resistance with an overweight and obese woman

Protocol summary

Study aim

Comparison of the effects of Pilates exercises and dill supplementation on serum levels of Nesfatin-1 and insulin resistance and in overweight and obese women

Design

A randomized controlled clinical trial with factorial groups, triple blinded

Settings and conduct

Blood sampling of subjects in the luteal phase of menstruation after 12 hours of night fasting, 48 hours before the start of exercise program and 48 hours after the last exercise session (to prevent acute inflammation caused by exercise on biochemical variables) between 8 and 10 am Antibody in the amount of 10 ml was performed in Imam Reza Hospital (Birjand) by laboratory scientists and was stored in special tubes containing anticoagulant sodium citrate and the tube caps were closed with para-film. Blood samples for plasma separation were centrifuged and stored at minus 80 ° C for 5 minutes at 3000 rpm. Blood samples were collected for serum levels of Nesfatin-1, insulin and glucose in the pre- and post-test stages. Anthropometric characteristics were measured by the researcher at the beginning of the design and at the end of the 6 week

Participants/Inclusion and exclusion criteria

Inclusion criteria: having general physical and mental health, not participating in sports during the last 6 months, as well as diet and the use of certain herbal and chemical drugs. Exclusion criteria were cardiovascular disease, diabetes, hormonal disorders, kidney disease, liver and surgery, smoking, and any therapeutic intervention affecting the laboratory results.

Intervention groups

Pilates + dill supplement Pilates + placebo They performed Pilates exercises for 45 minutes for 6 weeks and three sessions a week. People in the dill supplement group were asked to take one dill tablet (1.1 g) after each meal (breakfast, lunch, dinner) The placebo group received similar amounts of starch

Main outcome variables

Serum levels of Nesfatin-1 glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220107053655N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Fatemeh Sabzevari

Name of organization / entity

The University of Birjand

Country

Iran (Islamic Republic of)

Phone

+98 56 3241 0949

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-07, 1397/04/16

Expected recruitment end date

2018-09-07, 1397/06/16

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of six weeks of Pilates training and dill supplementation on serum levels of Nesfatin-1, insulin resistance with an overweight and obese woman

Public title
Effect of Pilates with dill supplement on obesity
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Overweight and obese women (BMI more than 25 kg per square meter) with an age range of 25 to 45 years
Exclusion criteria:
Overweight and obese women (BMI more than 25 kg per square meter) with an age range of 25 to 45 years
Age
From **25 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in this study were Simple Random Sampling by throwing the dice
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants, data collectors, outcome assessors are blinded in this study, after informing all participants about their grouping and study objectives and they will give informed consent, they will be randomly categorized into each group. For placebo groups, capsules of the same size and the same weight as the dill capsules will be prepared. The data collectors included a laboratory expert, a blood sampler who did not know the procedure of grouping. And all participants will be treated equally on the sampling day. The statistical expert will be unaware of the participant's identities and the file containing the data and groups will be given to him/her
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University
Street address
Sajjad street
City
Birjand
Province
South Khorasan
Postal code
9718993444
Approval date
2018-05-08, 1397/02/18
Ethics committee reference number
IR.BUMS.REC.1397.180

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nesfatin-1
Timepoint
12 hours before the start of the intervention and 12 hours after the end of the intervention. Duration of intervention 6 weeks
Method of measurement
Blood test

Secondary outcomes

1

Description
Insulin resistance
Timepoint
12 hours before the start of the intervention and 12 hours after the end of the intervention. Duration of intervention 6 weeks
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Pilates+Dill supplement. Do Pilates 3 times a week. 45 minutes per session. Take one dill (1.1g) tablet daily after each meal (breakfast, lunch, dinner)
Category
Lifestyle

2

Description
Intervention group: : Pilates+placebo. Do Pilates 3 times a week. 45 minutes per session. Take one placebo tablet daily after each meal (breakfast, lunch, dinner)
Category
Lifestyle

3

Description
Control group: : dill supplement. Take one tablet (1.1 g) daily after each meal (breakfast, lunch, dinner)
Category
Lifestyle

4

Description
Control group:placebo.Take one placebo tablet daily after each meal (breakfast, lunch, dinner)
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
The University of Birjand
Full name of responsible person
Fateme Sabzevari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Birjand
Full name of responsible person
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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
The University of Birjand
Proportion provided by this source
50
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
The University of Birjand
Full name of responsible person
Fateme Sabzevari
Position
Master graduate
Latest degree
Master
Other areas of specialty/work
Exercise Physiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data such as information about the primary outcome

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
All researchers working in in academic and scientific institutions

From where data/document is obtainable
fatima.sabzevari@gmail.com

What processes are involved for a request to access data/document
After reading their request as soon as possible if the researcher find out the request valid

Comments