Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of 12 weeks of pilates training and turmeric supplementation on SIRT1, Klotho gene and Quality of life in middle-aged Overweight females

Protocol summary

Study aim

Effect of Pilates training and turmeric supplementation on serum sirtuin1, Klotho and quality of life in overweight middle-aged women.

Design

A randomized, double-blinded, sham controlled clinical trial with a parallel group design of 48 participants (12 person in every group)

Settings and conduct

Synchronization sessions, initial measurements, counseling and distribution of capsules and Pilates exercises will be held at the Vira Club located at Shariati Street. Blood sampling will be carried out at Iran Medical Laboratory of Tabriz. Blinding participants and researcher will be used to administer turmeric and placebo capsules by distributing capsules by third person.

Participants/Inclusion and exclusion criteria

Entry requirements include age range of 35-55 years, overweight, lack of regular exercise, no use of medication and supplements, having a regular menstrual cycle, Withdrawal conditions including the incidence of any illness and the presence of allergies to spices and the unwillingness of the subject to cooperate with the researcher

Intervention groups

1) Pilates Exercise Group: participate in Pilates practice program (3 sessions per week) for 12 weeks and receive 3 placebo tablets per day. 2) Turmeric Group: receive three tablets of 700 milligrams of turmeric receive daily for 12 weeks 20 min after eating. 3) Practice group and turmeric: The group will also conduct Pilates training sessions (three sessions per week) for 12 weeks and will consume daily three tablets of 700 mg of turmeric immediately after eating for 12 weeks Will 4) Control group: They will receive three placebo tablets a day, 20 min after eating for 12 weeks, but will not participate in the training program.

Main outcome variables

Serum sirtuin1; klotho gene and Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038785N1**
Registration date: **2018-03-15, 1396/12/24**
Registration timing: **prospective**

Last update: **2018-03-15, 1396/12/24**
Update count: **0**

Registration date

2018-03-15, 1396/12/24

Registrant information

Name
Rahele Dolgari
Name of organization / entity
The university of Tabriz
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Iran (Islamic Republic of)
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+98 41 3551 7007
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-02, 1397/01/13

Expected recruitment end date

2018-05-03, 1397/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of 12 weeks of pilates training and turmeric supplementation on SIRT1, Klotho gene and Quality of life in middle-aged Overweight females

Public title
Effects of pilates training and turmeric supplementation on SIRT1, Klotho gene and Quality of life

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age range of 35 to 55 years Being Overweight(BMI: 25-30 kg/m²) Without regular physical activity No drug and supplementation Having menstrual period

Exclusion criteria:
illness allergy to spices Unwillingness or person's cooperation

Age
From **35 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random numbers table, individuals were grouped into four groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is carried out in the distribution of turmeric and placebo capsules so that the third person (researcher assistant) will distribute the capsules and and the participants and researchers do not know if they are receiving capsules of turmeric or placebo.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
No 2 building, Tabriz University of Medical Sciences,Golgasht St,

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2017-11-05, 1396/08/14

Ethics committee reference number
IR.TBZMED.REC.1396.699

Health conditions studied

1

Description of health condition studied
Aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sirtuin1

Timepoint
Before and after the intervention (3 month later)

Method of measurement
Sirtuin 1 content will be measured by using Human Sirtuin1 ELISA kit, made by Shanghay Crystal D company.

2

Description
Serum Klotho gene

Timepoint
Before and after the intervention (3 month later)

Method of measurement
Human Klotho ELISA kit, made by Shanghay Crystal D company

3

Description
Quality of life

Timepoint
Before and after the intervention (3 month later)

Method of measurement
Quality of life questionare

Secondary outcomes

1

Description
Weight
Timepoint
Before and after intervention (3 month later)
Method of measurement
With Omron Digital Scale

2

Description
Body fat percent
Timepoint
Before and after intervention (3 month later)
Method of measurement
Using body composition analyzer

3

Description
Fat-free mass
Timepoint
Before and after intervention (3 month later)
Method of measurement
Using body composition analyzer

Intervention groups

1

Description
Intervention group (training) : Participate in 12 weeks of Pilates training (3 sessions per week with intensity of 40 -70 % maximum heart rate)
Category
Lifestyle

2

Description
Intervention group (supplement): Daily consumption of three tablets of 700 mg turmeric, 20 min after meal.
Category
Prevention

3

Description
Intervention group (training-supplement): Participate in 12 weeks of Pilates training (3 sessions per week with intensity of 40 -70 % maximum heart rate) and daily consumption of three tablets of 700 mg turmeric, 20 min after meal.
Category
Prevention

4

Description
Control group: daily consumption of three placebo tablets of 700 mg starch, 20 min after meal.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz city health center
Full name of responsible person
Parastoo Ahmadi
Street address
Qods St
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5166616471
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology Development of Tabriz University
Full name of responsible person
Abolgasem Jooyban
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Emam Khomeini St
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ajouyban@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology Development of Tabriz University
Proportion provided by this source
100
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 Tabriz
Full name of responsible person
Rahele Dolgari
Position
instructor
Latest degree
Master
Other areas of specialty/work
exercise matabolism
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Abuse is possible
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data file will be provided after encoding
When the data will become available and for how long
6 months after printing results
To whom data/document is available
all persons
Under which criteria data/document could be used
Use is not allowed
From where data/document is obtainable
Rahele Dolgari
What processes are involved for a request to access data/document
Send request via email and receive
Comments