Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The Effect of Concurrent Aerobic-ResistanceTraining Period as Well as with Tribulus supplementation on cellular enzymes, inflammatory and metabolic markers,Brain-derived neurotrophic factor, memory and sexual function of overweight postmenopausal women

Protocol summary

Study aim

The Effect of Concurrent Aerobic-Resistance Training Period with Tribulus supplementation on cellular enzymes, inflammatory and metabolic markers, Brain-derived neurotrophic factor, memory and sexual function of overweight postmenopausal women

Design

A clinical trial with a control group, an exercise group, a supplement group, a simultaneous exercise and supplement group, not blinded and non-randomized, available based on the goal, the first phase of implementing the protocol on 60 participants for 10 weeks, the second phase of follow-up on the same 60 The participant is for 3 months.

Settings and conduct

Strength training with an elastic band was 30 minutes three times a week and its intensity increased from 40% to 70% of maximum heart rate. The exercises are 9 movements to work on large and small muscle groups. 20 minutes of aerobic training program, including 5 minutes of walking with 50% of the target heart rate and 15 minutes of treadmill running at 60% to 70% target heart rate, which increased incrementally until the end of the workout.

Participants/Inclusion and exclusion criteria

All people were overweight and menopausal and complained of menopausal complications. The exclusion conditions were smoking, chronic diseases and musculoskeletal injuries.

Intervention groups

Intervention group 1, simultaneous high-intensity combined exercise, intervention group 2, tribulus supplement consumption, intervention group 3, high-intensity simultaneous combined exercise with tribulus supplement consumption, the control group, did not have any other resistance or regular training.

Main outcome variables

Brain-derived Neurotrophic Factor; Memory; Estradiol; Follicle Stimulant; Testosterone; Plasma Inflammation Index; Cell Damage Index; Cortisol; Sexual Autonomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220821055765N1**
Registration date: **2022-09-23, 1401/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-23, 1401/07/01**
Update count: **0**

Registration date

2022-09-23, 1401/07/01

Registrant information

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Islamic Azad University Rasht Branch
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-15, 1401/06/24

Expected recruitment end date
2022-09-30, 1401/07/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Concurrent Aerobic-ResistanceTraining Period as Well as with Tribulus supplementation on cellular enzymes, inflammatory and metabolic markers,Brain-derived neurotrophic factor, memory and sexual function of overweight postmenopausal women

Public title
The Effect of Concurrent Aerobic-ResistanceTraining Period as Well as with Tribulus supplementation on cellular enzymes, inflammatory and metabolic markers, Brain-derived neurotrophic factor, memory and sexual function of overweight postmenopausal women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All participants have overweight. For all participants, one year passed from their last menstrual period (they are all menopause). Non of participants had hormone treatment. All participants reported difficulties from menopause. All participants had less than 1 hour exercise per week for the last year.
Exclusion criteria:
Participants who are smokers (they smoked for 6 months before starting the research). Participants with uncontrolled cardiovascular, renal, pulmonary, thyroid, and blood pressure diseases. Participants with limited mobility and musculoskeletal injury.
Age
From **55 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method, simple, lottery: In this method, 60 menopausal women with menopausal complications will be selected by available sampling method. through lottery (names of the participants are written on paper and will be divided into 4 groups (3 intervention groups and 1 control group) through random lottery).
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 Islamic Azad University, Rasht Branch
Street address
Lakan Blvd.
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Province
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Postal code
۴۱۴۷۶۵۴۹۱۹
Approval date
2022-08-13, 1401/05/22
Ethics committee reference number
IR.IAU.RASHT.REC.1401.009

Health conditions studied

1

Description of health condition studied
Menopause with excess weight
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
The role of brain-derived neurotrophic factor in the flexibility of the central nervous system, memory and its relationship with both strength and aerobic sports activities.
Timepoint
Neurotrophic factor was measured at the beginning of the study, 70 days after the intervention and 3 months after the end of the study.
Method of measurement
Measurement of neurotrophic factor with ELISA laboratory kit.

2

Description
Estradiol hormone changes.
Timepoint

Estradiol measurement was done at the beginning of the study, 70 days after the intervention and 3 months after the end of the study.

Method of measurement

Estradiol measurement by enzyme method with ELISA laboratory kit.

3

Description

Testosterone hormone changes in menopausal women.

Timepoint

Testosterone was measured at the beginning of the study and 70 days after the intervention.

Method of measurement

Testosterone measurement by enzyme method with ELISA laboratory kit.

Secondary outcomes

1

Description

Prospective and retrospective memory scores by Crawford et al based on a five-point Likert scale.

Timepoint

Memory measurement was done at the beginning of the study, 70 days after the intervention and 3 months after the end of the study.

Method of measurement

Measuring memory with Crawford et al.'s questionnaire based on a five-point Likert scale.

2

Description

Cortisol assessment after menopause.

Timepoint

Cortisol was measured at the beginning of the study and 70 days after the intervention (at 8 am).

Method of measurement

Cortisol measurement with ELISA laboratory kit.

3

Description

Anthropometric index in postmenopausal women.

Timepoint

Anthropometric measurement was done at the beginning of the study, 70 days after the intervention and 3 months after the end of the study.

Method of measurement

Anthropometric measurement by caliper with Jackson-Pollack three point method and using body density formula and Satiety equation.

4

Description

Changes in sexual self-efficacy in menopause.

Timepoint

Sexual self-efficacy was measured at the beginning of the study, 70 days after the intervention and 3 months after the end of the study.

Method of measurement

Measuring sexual efficiency with the Schwartz sexual questionnaire.

5

Description

Plasma inflammatory index in postmenopausal women.

Timepoint

The inflammatory index was measured at the beginning of the study and 70 days after the intervention.

Method of measurement

Measurement of plasma inflammatory index by immunoturbidometric method.

6

Description

Selected indicators of cell damage in postmenopausal women.

Timepoint

Variables were measured at the beginning of the study and 70 days after the intervention.

Method of measurement

Measurement of the selected index of cell damage with the German standardized enzymatic method and autoanalyzer.

Intervention groups

1

Description

Intervention group: First, high-intensity combined exercise for 10 weeks, 3 days a week and for 60 minutes each day, which included 5 minutes of warm-up, 20 minutes of aerobic exercise program, 30 minutes of resistance exercises with resistance bands. Bodybuilding and 5 minutes of cooling were done. During this period, all participants were urged to maintain their usual activities and refrain from other physical exercises.

Category

Lifestyle

2

Description

Intervention group: Second, consumption of Tribulus supplement: Tribulus supplement with Iranian name Kharkhasek and brand name Tribulus 500 mg, manufactured by Dayan Hat Company, made in Iran. Also, this supplement has phytopharmacology approval from India and China. Participants took 500 mg capsules twice a day (after breakfast and dinner) for 70 days.

Category

Lifestyle

3

Description

Intervention group: 3rd, simultaneous high-intensity combined exercise with Tribulus supplement:

simultaneous high-intensity combined exercise for 10 weeks, 3 days a week and for 60 minutes every day, where bodybuilding resistance band was performed and 500 capsules Tribulus supplements were taken twice a day.

Category
Lifestyle

4

Description
Control group: The inactive control group, although they were physically active, did not participate in any resistance training or other regular training for a year before the start of the study. The passive control group continued their normal life without any changes and at the end of the study, they were compared with three other experimental groups.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Banovan Park of Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Islamic Azad University Rasht Branch

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University Rasht Branch

Full name of responsible person
Roya Seighali

Position
PhD Student

Latest degree
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Other areas of specialty/work
Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
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