Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Water-Based rhythmic exercise training on Leptin, Aldosterone and Cardiovascular risk factors in postmenopausal women with Metabolic Syndrome

Protocol summary

Study aim
The effect of Water-Based rhythmic exercise training on Leptin, Aldosterone and cardiovascular risk factors in Postmenopausal women with Metabolic Syndrome

Design
in the research, 40 postmenopausal women with metabolic syndrome voluntarily will be divided into two groups; 20 people in experimental and 20 people in control group.

Settings and conduct
The present study is a semi-experimental study among the postmenopausal women with metabolic syndrome of city of Rasht for 12 weeks. Blood sampling is performed after 12 hours of fasting and before and after 12 weeks ofWater-Based rhythmic exercise training.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having age ranges of 65-75 years, Postmenopausal, No regular exercise, Suffering from at least three of the five indicators of metabolic syndrome: abdominal obesity (waist circumference more than 88 cm), triglycerides greater than 150 mg/dl, blood pressure more than 130.85 ml of mercury, fasting blood glucose more than 110 ml/dl And high-density lipoprotein (HDL) less than 50 mg/dl and Lack of diabetes, liver, kidney, inflammation and respiratory diseases. Exclusion criteria: More than three session absence from the training, injury during training

Intervention groups
Intervention group: Water-Based rhythmic exercise training group: Twelve weeks, three times per week. Water-Based rhythmic exercise training were performed with an intensity of 50-75% of maximum heart rate
Control group: Without intervention

Main outcome variables
Leptin, Aldosterone, Albumin, Systolic and Diastolic blood Pressure, hs-CRP, fasting blood sugar, insulin, insulin resistance, TG, TC, LDL-C, HDL, body fat percentage, Body Mass Index and Waist Circumference

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200625047917N1**
Registration date: **2020-06-28, 1399/04/08**
Registration timing: **prospective**

Last update: **2020-06-28, 1399/04/08**
Update count: **0**
Registration date
2020-06-28, 1399/04/08

Registrant information
Name
Hanieh Berahman
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 13 3212 4813
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-30, 1399/04/10
Expected recruitment end date
2020-10-01, 1399/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Water-Based rhythmic exercise training on Leptin, Aldosterone and Cardiovascular risk factors in postmenopausal women with Metabolic Syndrome

Public title
The effect of Water-Based rhythmic exercise training in postmenopausal women with Metabolic Syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having age ranges of 65-75 years Postmenopausa No regular exercise Suffering from at least three of the five indicators of metabolic syndrome: abdominal obesity (waist circumference more than 88 cm), triglycerides greater than 150 mg / dl, blood pressure more than 130.85 ml of mercury, fasting blood glucose more than 110 ml / dl And high-density lipoprotein (HDL) less than 50 mg / dl Lack of diabetes, liver, kidney, inflammation and respiratory diseases

Exclusion criteria:
More than three session absence from the training injury during training

Age
From **65 years** old to **75 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
Subjects were divided into two groups (one control group and one experimental group) using the simple random method. This sampling will be done based on the red and blue balls inside the box that are randomly taken by the subjects (the red ball of the control group and the blue ball of the experimental group).

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
Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City
Rasht

Province
Guilan

Postal code
۴۱۴۷۶۵۴۹۱۹

Approval date
2020-06-22, 1399/04/02

Ethics committee reference number
IR.IAU.RASHT.REC.1399.022

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Aldosterone

Timepoint
Before and after the end of interventions

Method of measurement
using ELISA Kit

2

Description
Leptin

Timepoint
Before and after the end of interventions

Method of measurement
using ELISA Kit

3

Description
High-sensitivity C-reactive Protein (hs-CRP)

Timepoint
Before and after the end of interventions

Method of measurement
using ELISA Kit

4

Description

Fast blood sugar

Timepoint

Before and after the end of interventions

Method of measurement

using ELISA Kit

5

Description

Blood pressure

Timepoint

Before and after the end of interventions

Method of measurement

Using the blood pressure device

6

Description

Insulin hormone

Timepoint

Before and after the end of interventions

Method of measurement

Serum levels using Eliza method

7

Description

Albumin

Timepoint

Before and after the end of interventions

Method of measurement

Using Colorimetric

8

Description

Triglyceride

Timepoint

Before and after the end of interventions

Method of measurement

According to milligrams per deciliter and by Baseline blood

9

Description

Low-density lipoprotein

Timepoint

Before and after the end of interventions

Method of measurement

According to milligrams per deciliter and by Baseline blood

10

Description

High-density lipoprotein

Timepoint

Before and after the end of interventions

Method of measurement

According to milligrams per deciliter and by Baseline blood

11

Description

Cholstrol

Timepoint

Before and after the end of interventions

Method of measurement

According to milligrams per deciliter and by Baseline blood

12

Description

Waist circumference

Timepoint

Before and after the end of interventions

Method of measurement

According to cm and by Tape measure

13

Description

Body mass index

Timepoint

Before and after the end of interventions

Method of measurement

According to Kg/m2 and dividing body weight by the square of the height(m2)

14

Description

Fat percent

Timepoint

Before and after the end of interventions

Method of measurement

Using InBody

Secondary outcomes

1

Description

TSH

Timepoint

before and after the end of intervention

Method of measurement

using ELISA Kit

2

Description

T4

Timepoint

before and after the end of intervention

Method of measurement

using ELISA Kit

Intervention groups

1

Description

Intervention group:12 weeks of Water-Based rhythmic exercise training ,three sessions per week, 60 minutes each session. Exercise training program consists of 10 minutes warming up, 45 minutes Water-Based rhythmic exercise training and 5 minutes cooling down

Category
Lifestyle

2

Description
Control group: Without intervention

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Golsar Hospital

Full name of responsible person
Hanie Berahman

Street address
Golsar Hospital, Golsar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ali Delpasand

Street address
Rasht Branch, Islamic Azad University, Taleshan Bridge

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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

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

Full name of responsible person
Hanieh Berahman

Position
PhD student

Latest degree
Master

Other areas of specialty/work
exercise physiology

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Person responsible for scientific inquiries

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Other areas of specialty/work
Exercise physiology

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Person responsible for updating data

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Islamic Azad University

Full name of responsible person
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Latest degree
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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
No decision has been made yet.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable