Effect of aerobic exercise and green tea supplementation on body composition, and cardio metabolic risk factors of overweight and obese women.

Protocol summary

Study aim
Assessing the effect of aerobic exercise and green tea supplementation on body composition, and cardio metabolic risk factors of overweight and obese women

Design
In this research, 39 overweight and obese women will be select and randomly divide in to three equal groups including aerobic- group, aerobic combine with green tea consumption and control groups.

Settings and conduct
The present study is a semi-experimental study on the women of city of Lasht-e Neshan. Aerobic training will be conducting three time per week and green tea will be consuming on a daily basis. The study duration will be eight weeks. The level of fasting blood sugar, blood lipid, Rest heart rate, blood pressure and body composition will be measuring before and after the end of interventions period

Participants/Inclusion and exclusion criteria
The woman age ranges of 22-34 years old have overweight or obese not have cardiovascular or orthopedic disorders No regular exercise

Intervention groups
Aerobic training group: eight weeks, three times per week, each session consist of 80-90 min , with intensity 40- 80% target heart rate Aerobic training combine with green tea consumption: Aerobic training combine with green tea consumption: eight weeks, three time training (Similar to aerobic training group) combine with daily consumption of 33 mg green tea (After three main meal) Control group: no intervention will be conducting.

Main outcome variables
fasting blood sugar, blood lipid, Rest heart rate, blood pressure and body composition

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20150531022498N17
Registration date: 2018-02-07, 1396/11/18
Registration timing: retrospective

Last update: 2018-02-07, 1396/11/18
Update count: 0

Registration date
2018-02-07, 1396/11/18

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-05-21, 1395/03/01
Expected recruitment end date
2016-08-21, 1395/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
Scientific title
Effect of aerobic exercise and green tea supplementation on body composition, and cardio metabolic risk factors of overweight and obese women.

Public title
Effect of aerobic exercise and green tea supplementation in overweight and obese women.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
The woman age ranges of 22-34 years old have overweight or obese not have cardiovascular or orthopedic disorders No regular exercise
Exclusion criteria:
More than three session absence from the training

Age
From 20 years old to 40 years old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 39

Randomization (investigator's opinion)
Randomized

Randomization description
En Assigning samples using Simple random-lottery method

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
۹۱۹۴۵۶۷۴۱۴

Approval date
2016-09-18, 1395/06/28

Ethics committee reference number
IR.IAU. RASHT.REC.1395.25

Health conditions studied

1
Description of health condition studied
Overweight and obese women

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1
Description
Fasting Blood Glucose

Timepoint
Before and after the end of interventions

Method of measurement
Serum levels using Glucose oxidase / per oxidase method (mg/dl)

2
Description
Total cholesterol

Timepoint
Before and after the end of interventions

Method of measurement
Serum levels using photo metric method (mg/dl)

3
Description
Low density cholesterol

Timepoint
Before and after the end of interventions

Method of measurement
Serum levels using photo metric method (mg/dl)

4
Description
High density cholesterol

Timepoint
Before and after the end of interventions

Method of measurement
Serum levels using photo metric method (mg/dl)

5
Description
Triglyceride

Timepoint
Before and after the end of interventions

**Method of measurement**
Serum levels using photo metric method (mg/dl)

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**Description**
Rest heart rate

**Timepoint**
Before and after the end of interventions

**Method of measurement**
By measuring the pulse

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**Description**
Blood pressure

**Timepoint**
Before and after the end of interventions

**Method of measurement**
Pressure device

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**Secondary outcomes**

1. **Description**
Body composition

**Timepoint**
Before and after the end of interventions

**Method of measurement**
Using weight, body mass index, waist to hip ratio and fat percent

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**Intervention groups**

1. **Description**
Aerobic training group: eight weeks, three times per week, each session consist of 80-90 min, with intensity 40-80% target heart rate

**Category**
Prevention

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2. **Description**
Aerobic training combine with green tea consumption:Aerobic training combine with green tea consumption: eight weeks, three time training (Similar to aerobic training group) combine with daily consumption of 33 mg green tea (After three main meal)

**Category**
Prevention

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3. **Description**
Control group: no intervention will be conducting.

**Category**
Other

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**Recruitment centers**

1. **Recruitment center**
   - **Name of recruitment center**
   Lasht-Nesha city
   - **Full name of responsible person**
   Hajar Amozadeh
   - **Street address**
   Lasht-Nesha, Guilan, Iran
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**Sponsors / Funding sources**

1. **Sponsor**
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   - **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**
Islamic Azad 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**
Persons
Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
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Hajar Amozadeh
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Master
Latest degree
Master
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Person responsible for updating data

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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