

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of concurrent training combine with Chamomile consumption on glucose homeostasis, anxiety, depression, general health, body composition and physical fitness in overweight and obese women

Protocol summary

Study aim

Assessing the effects of eight weeks concurrent training combine with Chamomile consumption on the level of glucose homeostasis, anxiety, depression, general health, body composition and physical activity in overweight and obese women

Design

Randomized clinical trial, with parallel groups

Settings and conduct

Among the women's of Khomam city, 30 overweight and obese women will be select and randomly divide in to three equal groups including concurrent training group, concurrent training combine with Chamomile consumption and control groups. concurrent aerobic-resistance training will be conducting three time per week and Chamomile will be consuming on a daily basis. The study duration will be eight weeks. The level of glucose homeostasis, anxiety, depression, general health, body composition and physical activity will be measuring before and after the end of interventions period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: be woman; age ranges of 20-45 years old; have overweight or obese; be active; not have metabolic or orthopedic disorders Exclusion criteria: have allergy to chamomile; not regular consumption of chamomile; more than three session absence from the training

Intervention groups

Concurrent training group: eight weeks, three times per week, each session 60-90 min (including warm up, aerobic interval training, resistance training and cool down) Concurrent training combine with Chamomile consumption group: eight weeks, three time concurrent training per week (similar to concurrent training group) combine with daily consumption of 1.5 g Chamomile (before three main meal) Control group: no intervention

Main outcome variables

Glucose homeostasis; Anxiety, Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022498N11**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 13 3375 2715

Email address

shabani@iaurasht.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-22, 1396/06/31

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2017-10-06, 1396/07/14

Actual recruitment end date

2017-10-22, 1396/07/30

Trial completion date

empty

Scientific title

Effects of concurrent training combine with Chamomile consumption on glucose homeostasis, anxiety, depression, general health, body composition and physical fitness in overweight and obese women

Public title

Effects of concurrent training combine with Chamomile consumption in overweight and obese women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

be woman age ranges of 20-45 years old have overweight or obese be active not have metabolic or orthopedic disorders

Exclusion criteria:

have allergy to chamomile not regular consumption of chamomile more than three session absence from the training

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

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

-

Approval date

2017-09-18, 1396/06/27

Ethics committee reference number

IR.IAU.RASHT.REC.1396.103

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**

Glucose homeostasis

Timepoint

Before and 24 hour after the interventions period

Method of measurement

Measuring fasting blood glucose, insulin and HOMA

2**Description**

Anxiety

Timepoint

Before and after the end of interventions

Method of measurement

Using beck questionnaire

3**Description**

Depression

Timepoint

Before and after the end of interventions

Method of measurement

Using beck questionnaire

Secondary outcomes**1****Description**

General health

Timepoint

Before and after the end of interventions

Method of measurement

Using questionnaire

2

Description

Body composition

Timepoint

Before and after the end of interventions

Method of measurement

Using body mass index, waist to hip ratio, fat percent and fat free mass

3

Description

Physical fitness

Timepoint

Before and after the end of interventions

Method of measurement

Measuring muscle endurance and maximum oxygen consumption

Intervention groups

1

Description

Concurrent training group: eight weeks, three times per week, each session consist of 60-90 min (including warm up, aerobic interval training, resistance training and cool down)

Category

Prevention

2

Description

Concurrent training combine with Chamomile consumption: eight weeks, three time concurrent training per week (Similar to concurrent training group) combine with daily consumption of 1.5 g Chamomile (before three main meal)

Category

Prevention

3

Description

Control group: no intervention will be conducting.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomam city

Full name of responsible person

Hadis Heidary

Street address

Khomam, Guilan, Iran

City

Khomam

Province

Guilan

Postal code

-

Phone

+98 13 3385 6174

Email

fa.izaddoust@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Delpasand

Street address

Islamic Azad University Rasht Branch, Taleshan Bredge

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3385 6174

Email

fa.izaddoust@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

personality, Researcher

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hadis Heidary

Position

MA student

Latest degree

Master

Other areas of specialty/work

Others

Street address

Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3385 6174

Email

fa.izaddoust@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Ramin Shabani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3375 2715

Email

dr.ramin.shabani@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Fatemeh Izaddoust

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Others

Street address

Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

4186886987

Phone

+98 13 3385 6174

Email

fa.izaddoust@gmail.com

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