

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 8 weeks of high-intensity functional training and gamification on inhibitory control and brain activity in overweight and obese women

Protocol summary

Study aim

Determining the effect of 8 weeks of high-intensity and cognitive functional training on inhibitory control and brain activity in overweight and obese women

Design

Clinical trial with control groups, with parallel groups, unblinded, non-randomized on 40 people

Settings and conduct

The levels of this research will be carried out in the Faculty of Sports and Health Sciences of Shahid Beheshti University and the National Brain Mapping Laboratory of Tehran University. After grouping, in pre-test body composition, a go/no-go task will be conducted to evaluate inhibitory control and record brain activity using the fNIRS method. After two months of high-intensity functional training (a combination of aerobic and strength training that will be 3 sessions of 1 hour per week) and a game (a mobile game designed to strengthen inhibitory control, 20 minutes daily) in the post-test, the cases Measured in the pre-test will be checked again.

Participants/Inclusion and exclusion criteria

Inclusion criteria BMI greater than 25, right-handedness No history of using mobile and computer games and high intensity functional training. Exclusion criteria: Not using weight loss programs (exercise, diet, medicine, etc.). No history of chronic disease, neurological disorders and special medical or orthopedic conditions Not during pregnancy and breastfeeding.

Intervention groups

Intervention groups: Control group: will not receive any intervention during the research period. High-intensity functional training group: will receive the exercise training intervention. Game group: will receive the game intervention. Combined group: will receive the intervention of exercise training and games during the research period.

Main outcome variables

Inhibitory control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056301N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

Marzieh Bagheri

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of high-intensity functional training and gamification on inhibitory control and brain activity in overweight and obese women

Public title

The effect of exercise training and gamification on inhibitory control and brain activity in overweight and obese women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index greater than 25 Being right-handed No history of using mobile and computer games for more than 2 hours per week in the past 12 months No experience of high-intensity functional training Not participating in a regular exercise program for more than 2 hours per week in the past 12 months

Exclusion criteria:

Overweight and obesity are not due to the use of medicine. Not using weight loss programs (exercise, diet, medicine, etc.) during the last 12 months No history of chronic disease (diabetes, blood pressure, cardiovascular diseases, etc.) No history of neurological and psychiatric disorders (eating disorder, depression, etc.) Absence of medical or orthopedic conditions that prohibits doing exercises. Not during pregnancy and breastfeeding.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Shahid Beheshti University

Street address

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-10-07, 1401/07/15

Ethics committee reference number

IR.SBU.REC.1401.109

Health conditions studied**1****Description of health condition studied**

Obesity due to excess calories

ICD-10 code

E66.0

ICD-10 code description

چاقی به دلیل کالری اضافی

Primary outcomes**1****Description**

Inhibitory control

Timepoint

At the beginning of the study and after 2 months of exercise training and cognitive training.

Method of measurement

In the study "Effect of exercise and cognitive training on inhibitory control and brain activity", the method of measuring inhibitory control can be the Go/No-go task. Also, the method of measuring brain activities can be the Functional near-infrared spectroscopy method.

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: In this study, the control group will not receive any intervention. Also, at the beginning of the study and after 2 months, measurements of body composition, inhibitory control and brain activity will be done.

Category

N/A

2

Description

The first intervention group: the group of high-intensity functional training, which in this study will perform high-intensity functional exercises training for 2 months, 3 sessions a week for 1 hour under the supervision of the researcher. Each session, participants will first warm up for 10 to 15 minutes using aerobic activities such as running and stretching, then for the main part of the training, a combination of aerobic activities (such as jumping rope), strength activities for the upper body (such as power swimming), the lower body (such as squats) and the central part of the body (such as sit-ups) will be used for 40-45 minutes. At the end of the session, stretching movements will be used to cool down for 10 to 15 minutes to return to the initial state.

Category

N/A

3

Description

The second intervention group: The game group in this study will play a mobile game designed to strengthen inhibitory control daily for 20 minutes for 2 months. This game is a serious game and is designed to target inhibitory control behavior related to eating. Also, the stages of the game are varied from easy to difficult.

Category

N/A

4

Description

The fourth intervention group: The combined group in this study will perform high-intensity functional exercises for 2 months at the same time, 3 sessions of 1 hour per week (the details of the intervention are described in the second intervention group). Also, they will play a mobile game designed to strengthen inhibitory control for 20 minutes daily (the details of the intervention are described in the third intervention group).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

National Brain Mapping Lab

Full name of responsible person

Marzieh Bagheri

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Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Maryam Nourshahi

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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

Shahid Beheshti 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

Shahid Beheshti University

Full name of responsible person

Marzieh Bagheri

Position

University student

Latest degree

Master

Other areas of specialty/work

Sport physiology

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

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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

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