

# 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)

##### Phone

+98 919 302 4326

##### Email address

mzbagheri681@gmail.com

##### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 919 302 4326

##### Email

mzbagheri681@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University

##### Full name of responsible person

Maryam Nourshahi

##### Street address

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

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##### Phone

+98 919 302 4326

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mzbagheri681@gmail.com

#### 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 scientific 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**

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

Shahid Beheshti University

**Full name of responsible person**

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**Position**

university student

**Latest degree**

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**Other areas of specialty/work**

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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