Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Cognitive–Motor Training Intervention and Active Video Games on Motor Skills, Executive Function, and Selective Attention in Obese Children with Learning Disabilities

Protocol summary

Study aim
Determining the Effect of a Cognitive-Motor Exercise Intervention and Active Video Games on Motor Skills, Executive Function, and Selective Attention in Obese Children with Learning Disabilities

Design
A randomized controlled clinical trial with a parallel-group design involving three study groups was conducted among 45 eligible children aged 8–12 years. Participants were randomly allocated using Microsoft Excel to three equal groups: a cognitive-motor training group, an active video game group, and a control group, with 15 participants in each group. The rand function in Microsoft Excel was used to perform the randomization. Blinding of participants and intervention providers was not feasible due to the nature of the interventions. The clinical trial phase was not applicable to this study.

Settings and conduct
This randomized controlled trial used a parallel-group design involving 45 children aged 8–12 years with obesity and learning disorders, randomly allocated to cognitive-motor training, exergaming, or control groups (15 per group). The interventions were conducted at the children's schools, three times weekly for eight weeks, with each session lasting 45 minutes. Blinding of participants and intervention providers was not feasible due to the nature of the interventions.

Participants/Inclusion and exclusion criteria
Being between 8 and 12 years of age. Having a body mass index (BMI) greater than 30 kg/m². Having a learning disorder diagnosed by a qualified specialist. Having no physical limitations that would prevent participation in physical activity. Providing written informed consent from a parent or legal guardian.

Intervention groups
Cognitive-Motor Educational Interventions and Exergames

Main outcome variables
Gross and fine motor skills; response inhibition; working memory; cognitive flexibility; selective attention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260519069455N3**
Registration date: **2026-10-29, 1405/08/07**
Registration timing: **prospective**

Last update: **2026-10-29, 1405/08/07**
Update count: **0**

Registration date
2026-10-29, 1405/08/07

Registrant information
Name
Maryam Khalaji
Name of organization / entity
University of Tehran
Country
Iran (Islamic Republic of)
Phone
+98 21 6111 8865
Email address
maryam.khalaji@ut.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-06, 1405/08/15

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive–Motor Training Intervention and Active Video Games on Motor Skills, Executive Function, and Selective Attention in Obese Children with Learning Disabilities

Public title

The Effect of Different Exercise Interventions on Motor and Cognitive Skills in Obese Children with Learning Disabilities

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being between 8 and 12 years of age Having a Body Mass Index (BMI) greater than 30 Diagnosis of a learning disorder by a qualified specialist Absence of physical limitations for participating in physical activity Written parental consent

Exclusion criteria:

Absence from more than two consecutive sessions Sustaining an injury during the execution of exercises Presence of any serious medical or psychiatric condition that could affect participation or study outcomes Use of medications that may impact cognitive or physical performance (e.g., ADHD stimulants) Participation in other interventional studies within the past six months that could influence the results Unwillingness to continue participation throughout the course of the research

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting 45 eligible children, the participants were allocated to three equal groups using a block randomization method: a cognitive-motor training group, an active video game group, and a control group. Microsoft Excel and the rand function were used to perform the randomization. Ultimately, 15 participants were assigned to each group. Unit of randomization: The unit of randomization was the individual; that is, each child was treated as an independent unit and assigned to one of the three study groups. Randomization strata: Stratified randomization was not used, and participants were allocated without stratification based on variables such as age, sex, or body mass index. Randomization tool: Microsoft Excel and the rand function were used to perform the random allocation process. Method of generating the randomization sequence: The allocation sequence was generated using Microsoft Excel, and participants were assigned to the three study groups according to the resulting sequence. The allocation process aimed to establish three equal groups, with 15 participants in each group. Allocation concealment: Allocation concealment as a separate procedure was not specified in the available information regarding the study implementation.

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

Research Ethics Committee of the Faculty of Sport Sciences and Health, University of Tehran

Street address

Faculty of Sport Sciences and Health, University of Tehran, North Kargar Street, Between 15th and 16th Streets, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

8835173037

Approval date

2025-09-14, 1404/06/23

Ethics committee reference number

ETHIC-202504-1426

Health conditions studied

1

Description of health condition studied

Overweight with a learning disability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1. Gross Motor Skills: Gross motor skills score based on the relevant subtests of the Bruininks–Oseretsky Test of

Motor Proficiency, compared across the three groups at pre-test and post-test following the eight-week intervention.2. Fine Motor Skills: Fine motor skills score based on the relevant subtests of the Bruininks–Oseretsky Test of Motor Proficiency, compared across the three groups at pre-test and post-test following the eight-week intervention.3. Response Inhibition: Performance score on the response inhibition assessment, based on the scoring indicator specified in the study protocol, compared across the three groups at pre-test and post-test.4. Working Memory: Performance score on the working memory assessment, based on the scoring indicator specified in the study protocol, compared across the three groups at pre-test and post-test.5. Cognitive Flexibility: Performance score on the cognitive flexibility assessment, based on the scoring indicator specified in the study protocol, compared across the three groups at pre-test and post-test.6. Selective Attention: Performance score on the Stroop Color–Word Test, based on the scoring indicator specified in the study protocol, compared across the three groups at pre-test and post-test.

Timepoint

Pre-test and after 8 weeks of intervention, a post-test was taken

Method of measurement

All primary outcomes, including gross motor skills, fine motor skills, response inhibition, working memory, cognitive flexibility, and selective attention, were measured at two time points: at baseline before the intervention (pre-test) and immediately after completion of the eight-week intervention (post-test).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention Group 1: Participants in the cognitive–motor training program attended three sessions per week for eight weeks, with each session lasting 45 minutes. The training sessions were conducted in the school setting under the researcher's supervision and involved combined cognitive–motor activities designed to simultaneously engage executive functions, including attention, working memory, and response inhibition, as well as gross and fine motor skills, balance, hand–eye coordination, and reaction speed. Outcome measures were assessed before the intervention began and after completion of the eight-week program.

Category

Rehabilitation

2

Description

Intervention Group 2: Participants in the active video game program attended three sessions per week for eight weeks, with each session lasting 45 minutes. The sessions were conducted in the school setting using an Xbox One Kinect console under the researcher's supervision. The selected games were designed to engage gross and fine motor skills, hand–eye coordination, reaction speed, and decision-making. Outcome measures were assessed before the intervention began and after completion of the eight-week program.

Category

Rehabilitation

3

Description

Control group: Participants in this group did not receive cognitive–motor training or active video game interventions during the eight-week study period. Outcome measures were assessed at baseline and again after eight weeks, following the same assessment procedures used for the two intervention groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra School

Full name of responsible person

Mrs. Khastehvaneh

Street address

Fatemeh Zahra School, Sharbaty Street, Sari, Mazandaran Province, Iran.

City

Sari

Province

Mazandaran

Postal code

4745175894

Phone

+98 11 3323 8422

Email

h_masoudi13@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Sport Sciences and Health, University of Tehran

Full name of responsible person

Seyyed Hamed Mousavi

Street address

Faculty of Sport Sciences and Health, North Kargar Street, Tehran, Iran.

City

Tehran

Province

Tehran
Postal code
8835173037
Phone
+98 21 6111 8812
Email
musavihamed@ut.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Sport Sciences and Health, University of Tehran
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Sport Sciences and Health, University of Tehran
Full name of responsible person
Maryam Khalaji
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Sciences and Health
Street address
Faculty of Sport Sciences and Health, University of Tehran, North Kargar Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
8835173037
Phone
+98 21 6111 8865
Email
maryam.khalaji@ut.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of sport sciences and health, university of Tehran
Full name of responsible person
Daryoush Khajavi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport sciences and health
Street address
Faculty of Sport Sciences and Health, University of Tehran, North Kargar Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
8835173037
Phone
+98 21 6611 8963
Email
d-khajavi@araku.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Sport Sciences and Health
Full name of responsible person
Maryam Khalaji
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
sport sciences and health
Street address
Faculty of Sport Sciences and Health, University of Tehran, North Kargar Street, Tehran, Iran.
City
tehran
Province
Tehran
Postal code
8835173037
Phone
+98 21 6611 8865
Email
maryam.khalaji@ut.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from this study will be available for sharing in anonymized form after removing participants' identifying and confidential information, in accordance with research ethics principles. Data from pre- and post-intervention assessments, including gross and fine motor skills, response inhibition, working memory, cognitive flexibility, and selective attention, along with the data dictionary and descriptions of the variables, will be made available upon request to qualified researchers, subject to approval by the principal investigator. Requests will be submitted and reviewed through correspondence with the principal investigator. Identifiable information about the children and other confidential information will not be shared with third parties. The data will be used solely for scientific and research purposes, in compliance with ethical principles and confidentiality requirements.

When the data will become available and for how long

Six months after publishing the paper

To whom data/document is available

Researchers

Under which criteria data/document could be used

Requests for access to the data must be submitted by qualified researchers through correspondence with the principal investigator. 2. Each request must specify the scientific and research purpose, the research questions to be addressed, and the intended statistical analyses. 3. Access to the data is subject to review and approval by the principal investigator. 4. The data may be used solely for approved scientific and research purposes. Secondary statistical analyses, including descriptive and inferential analyses relevant to the research objectives, are permitted, provided that they comply with research ethics principles and confidentiality requirements. 5. Re-identification of participants, attempts to determine their identities, or linkage of the data to identifiable information are strictly prohibited. 6. Transferring or sharing the data with third parties without the authorization of the principal investigator is not permitted. 7. Any publication of findings derived from the data must comply with research ethics principles and appropriately cite the original study. 8. No identifiable or confidential information relating to participants will be provided to requesters.

From where data/document is obtainable

Maryam khalaji

What processes are involved for a request to access data/document

Researchers wishing to access the anonymized study data must submit a request to the principal investigator by email. The request should include the applicant's name and institutional affiliation, the purpose of the request, the research questions, and the planned analyses. The principal investigator will review the request to ensure that the proposed use is consistent with the study objectives, research ethics principles, and confidentiality requirements. Applicants may be contacted if additional information or clarification is required. Following approval, the anonymized data and relevant documentation, including the data dictionary and variable descriptions, will be provided electronically via email or another mutually agreed secure method. The process is expected to take approximately 2–4 weeks from receipt of a complete request, depending on the complexity of the request and the time required for review. No personally identifiable or confidential participant information will be shared.

Comments