

# Physical education program to improve cognitive and motor performance in children with intellectual disabilities

<b>Submission date</b> 25/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/08/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

It is recognised in the literature that persons with intellectual disabilities have deficits in cognitive capacities and motor performance in comparison with typically developing populations. Studies on physical activity interventions exposed encouraging evidence that physical exercise can facilitate aspects in both domains (cognitive and motor), however, findings are mixed. The current study aimed to explore the effects of a 6-week enriched physical education program on cognitive control and motor performance in children with intellectual disabilities.

### Who can participate?

Children with mild intellectual disabilities (both genders) with non-specific aetiology (non-syndromic, without atypical neurological development), and chronological age between 10-14 years.

### What does the study involve?

30 students were randomly allocated to the intervention group or the control group. The first group participated in a 6-week enriched physical education program based on games (two sessions of 1 hour each per week), and the control group were required to continue normal school activities. Data were collected through two computer-based cognitive tests (inhibitory control and cognitive flexibility) and one practical gross motor skills test.

### What are the possible benefits and risks of participating?

There were potential benefits to the children who participated in this study, such as improved motor skills performance and cognitive control capacities. This study might also highlight the importance of quality physical activity, planned according to the features and needs of children with intellectual disabilities.

There were minimal risks to children's safety (no greater than those typically encountered in physical education), such as physical or mental fatigue. However, all pertinent measures were taken to reduce these risks, such as good communication and instructions or the possibility of stopping and resting when children considered it appropriate. The literature raises no sensitive

or controversial issues in similar programs and did not contain elements typically frightening to children.

Where is the study run from?

Angélica Flores Zambrano Specialized Educational Unit (Ecuador)

When is the study starting and how long is it expected to run for?

April 2019 to January 2020

Who is funding the study?

Eötvös Loránd University (Hungary)

Who is the main contact?

Angélica Liseth Mero Piedra

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## Contact information

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

KEB/2019/003

# Study information

## Scientific Title

Effects of an enriched physical education program on cognitive and motor performance in children with mild intellectual disabilities

## Study objectives

The purpose of this study was to understand the impact of a 6-weeks physical education program based on games on cognitive and motor outcomes in Ecuadorian children with mild intellectual disabilities.

It is hypothesised that students in the intervention group might receive various benefits (accuracy/reaction time improvements) in inhibitory control (including attention) and cognitive flexibility capacities.

It is also hypothesised improvement in gross motor skills performance results from participation in the physical education program.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 11/06/2019, Scientific and Research Ethical Regulations committee of Eötvös Loránd University Bárczi Gusztáv Faculty of Special Needs Education (Ecseri street 3, Budapest, 1097, Hungary; (+36) 358-5534; tudomany@barczi.elte.hu), ref: KEB/2019/003

## Study design

Interventional single-centre study with simple randomized assignment and parallel groups design (non-blinded)

## Primary study design

Interventional

## Secondary study design

Randomised parallel trial

## Study setting(s)

School

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet (in Spanish)

## **Health condition(s) or problem(s) studied**

Children with mild intellectual disabilities

## **Interventions**

Brief name of the intervention: Physical education program based on games

### **Randomisation process:**

Participants were randomly allocated to the Intervention Group (n=15) or the Control Group (n=15) using a randomisation table created by a web-based software by an independent person not associated with the study. The allocation sequence was concealed in sealed opaque envelopes until the allocation phase. The participants assigned to the Control Group were not involved in any intervention and were required to continue normal school activities.

### **Materials and procedures:**

The intervention group participated in a program based on games detailed in Tomporowski et al. (2015) book called "Enhancing children's cognition with physical activity games". Since participants had mild intellectual disabilities, we selected games developed for younger typically developing children (3-6 years old).

### **The sessions were organized as follows:**

- Initial activities: included a session introduction and warm-up (approx. 7 min).
- Main activities: included 2-3 games per session, with variations (approx. 45 min).
- Final activities: included cool-down, session review and game-related questions (approx. 8 min)

Precise details of the games can be found in the mentioned book (ISBN 1450441424, 9781450441421). Link: [https://books.google.hu/books/about/Enhancing\\_Children\\_s\\_Cognition\\_With\\_Phys.html?id=mGgoBgAAQBAJ&redir\\_esc=y](https://books.google.hu/books/about/Enhancing_Children_s_Cognition_With_Phys.html?id=mGgoBgAAQBAJ&redir_esc=y)

### **The following equipment was used for the intervention:**

- Safe and open space
- A flute
- Visual cues
- Cards in different colours
- Neck hanging cords
- Tape
- Red and green objects
- Music
- Climbing structure
- Safety mats
- Small obstacles

**Program deliverer:**

The program was conducted by a physical education teacher with 5 years of experience in special education and sports for persons with disabilities. Additionally, she was assisted by two senior PE bachelor students with some experience in the area. They completed face-to-face training by the primary investigator prior to the beginning of the study.

**Intervention delivery:**

The program took place at an Ecuadorian specialized education institution for students with special needs associated with disabilities in Manabí province. It was carried out in the sports facilities of the educational institution at dates and times stipulated by them. The program consisted of 12 group sessions (60 minutes per session) held with the 15 participants of the intervention group. It was delivered face to face twice a week for six consecutive weeks (November - December 2019). The sessions were organized with flexible structures, gradually increasing difficulty levels in rule complexity, intensity, and duration depending on the characteristics of each game.

**Intervention Type**

Behavioural

**Primary outcome measure**

1. Inhibitory control and attention were measured with "Nonverbal attention, inhibition and distractor interference tasks" from a computer-based information processing battery developed in the Cognition and Language Laboratory at the Graduate Center of the City University of New York, USA. Timepoint: Baseline and 7-9 weeks after intervention commencement
2. Cognitive flexibility was measured with a computer-based adaptation of the "Dimensional Change Card Sort task" developed in the Cognition and Language Laboratory at the Graduate Center of the City University of New York, USA. Timepoint: Baseline and 7-9 weeks after intervention commencement
3. Gross motor skills were measured using the paper-based "Test of Gross Motor Development-Second Edition" (TGMD-2) developed by Ulrich. Timepoint: Baseline and 7-9 weeks after intervention commencement

**Secondary outcome measures**

The attendance rate was measured using the paper-based attendance reports of the PE teacher leading the sessions. Timepoint: 7 weeks after intervention commencement

**Overall study start date**

03/04/2019

**Completion date**

09/01/2020

**Eligibility****Key inclusion criteria**

1. Children with mild intellectual disabilities with non-specific aetiology (non-syndromic, without atypical neurological development)
2. Chronological age between 10 - 14 years

**Participant type(s)**

Other

**Age group**

Child

**Lower age limit**

10 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

30

**Key exclusion criteria**

1. Significant physical/sensory limitations that could affect their participation (e.g. injuries, visual impairment)
2. Medical history of developmental or psychiatric comorbidities (e.g. autism)

**Date of first enrolment**

29/08/2019

**Date of final enrolment**

11/10/2019

**Locations****Countries of recruitment**

Ecuador

**Study participating centre**

**Angélica Flores Zambrano Specialized Educational Unit**

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**Sponsor information****Organisation**

Eötvös Loránd University

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**ROR**

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**Funder(s)**

**Funder type**

University/education

**Funder Name**

Eötvös Loránd Tudományegyetem

**Alternative Name(s)**

Eötvös Loránd University, Eotvos Lorand University, Eötvös Loránd Universität, ELTE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Hungary

**Funder Name**

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in an appropriate scientific peer-reviewed journal and a doctoral thesis.

The study protocol and statistical analysis plan have not been published. However, they can be shared upon reasonable request to the corresponding author (lisethmero@student.elte.hu). They have already freely and broadly been shared with the respective research and ethics committees from Bárczi Gusztáv Faculty of Special Needs Education of Eötvös Loránd University (Hungary), the corresponding Education District Directorate representatives and key stakeholder organisations involved (Ecuador).

It is anticipated that research papers generated as results of this study will be submitted for publication to appropriate scientific peer-reviewed journals and a PhD dissertation. The statistical analysis planned during the current study will be included in the subsequent publications of the results.

## Intention to publish date

31/12/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as informed parental consent from the children with intellectual disabilities was obtained in which they gave their permission for using the data collected only for this investigation. In addition, they agreed that the findings would be presented to people involved and key stakeholder organisations in appropriate scientific publications and a doctoral thesis. Therefore, the datasets used for this study cannot be made publicly available. However, datasets may be made available for reasonable future request upon approval by the ethics committee of Bárczi Gusztáv Faculty of Special Needs Education of Eötvös Loránd University (Hungary) and additional informed parental consent (Ecuador).

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Effects on attention and inhibitory control	17/07/2023	29/08/2023	Yes	No