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

Submission date
25/11/2021

Recruitment status
No longer recruiting

Registration date
29/11/2021

Overall study status
Completed

Last Edited
29/08/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Public

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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

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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Organisation

Eötvös Loránd University

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Sponsor type
University/education

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ROR
https://ror.org/01jsq2704

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?
Results article	Effects on attention and inhibitory control	17/07/2023	29/08/2023	Yes	No