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Embodied learning-based phonemic training to improve executive functions

Submission date	Recruitment status	[_] Prospectively registered
25/12/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/12/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/03/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study explores how combining body movements with learning sounds of words (called FONEMACOR) can improve thinking skills in preschool children. The goal is to see if this method helps with skills like self-control and flexible thinking in children aged 5 to 6 years.

Who can participate?
Children aged 5 to 6 years can participate in this study.

What does the study involve?
Participants will be divided into three groups:
The first group will learn to recognize and manipulate sounds in words while doing physical activities like running, jumping, and throwing.
The second group will learn the same sound tasks but with minimal movement, mostly sitting and using printed materials.
The third group will continue with their usual classroom activities, which involve minimal movement.
The study will last for 8 weeks, with measurements taken before and after to see the effects.

What are the possible benefits and risks of participating?
Benefits may include improved thinking skills, self-control, and flexible thinking. There are no significant risks expected from participating in this study.

Where is the study run from?
Universidad Autónoma de Manizales (Colombia)

When is the study starting and how long is it expected to run for?
March 2023 to March 2025

Who is funding the study?
Ministerio de Ciencia y Tecnología - Minciencias (Colombia)

Who is the main contact?
Piedad Rocío Lerma Castaño, piedad.lermac@autonoma.edu.co

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of phonemic awareness training based on embodied learning (FONEMACOR) on inhibitory control and cognitive flexibility in children 5 to 6 years old

Acronym
FONEMACOR

Study objectives

There are significant differences in inhibitory control and cognitive flexibility in the groups of children aged 5 to 6 years who receive a phonemic awareness training program based on embodied learning (FONEMACOR) and those of the same age who receive training without embodied learning.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2024, Research Ethics, Bioethics and Scientific Integrity Committee Scientific CEIBIC-UAM (Antigua Estación del Ferrocarril, Manizales, 170001, Colombia; +57 (0)(6)8727272 ext 105; comitedebioeticauam@autonoma.edu.co), ref: Acta No. 172 de 2024 - 225-172

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Childcare/pre-school

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Executive functions in typically developing children 5 to 6 years of age

Interventions
Experimental Group 1:
Children will receive embodied learning-based training consisting of teaching phonemic awareness tasks (identify phonemes, skip phonemes, segment words into phonemes, synthesize phonemes and substitute phonemes) based on the CONCRES training designed and validated by Bertel and Suarez, 2023 that will include the combination of movements of fundamental motor skills such as throwing, catching, kicking, dribbling, hitting, walking, running, jumping, hopping called FONEMACOR. The training consists of 24 sessions of 60 minutes during 8 weeks.

Experimental Group 2:
CONCRES training with an emphasis on Phonological Awareness designed and validated by (Bertel and Suarez, 2023) consists of teaching phonemic awareness tasks (identify phonemes, omit phonemes, segment words into phonemes, synthesize phonemes and substitute phonemes) teaching that involves minimal movements, i.e., sitting in a chair with print letters, sheets, etc.

Control Group:
Classroom project applied in the institution (teaching involving minimal motor movements (i.e., sitting in a chair with paper and pencil).

Randomization method: Simple randomization, groups will be matched for sex, age and IQ.

Intervention Type
Behavioural

Primary outcome measure
1. Inhibitory Control is measured using the Flanker Inhibitory Control and Attention task from the NIH Toolbox at baseline and at the end of the intervention at 9 weeks.
2. Cognitive Flexibility is measured with Dimensional Change Card Sorting from the NIH ToolBox at baseline and at baseline and at the end of the intervention at 9 weeks.

Secondary outcome measures
1. Variable Phonemic awareness measured with the test for the evaluation of phonological knowledge of syllabic and phonemic type (PECO) Ramos and Cuadrado (2019) at baseline and at the end of the intervention at 9 weeks.
2. Variable Visuospatial working memory measured with Corsi Cubes from the WMIII battery at baseline and at the end of the intervention at 9 weeks.
3. Sociodemographic variables will be measured with a sociodemographic questionnaire designed by the researcher at baseline.

Overall study start date
06/03/2023

Completion date
21/03/2025

Eligibility

Key inclusion criteria
1. Children with typical development
2. Be in good health conditions to participate in physical activities that will be performed during the study
3. Children between 5 and 6 years of age who are enrolled in preschool
4. Children with normal hearing screening

Participant type(s)
Learner/student

Age group
Child

Lower age limit
5 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Children diagnosed with neurological disorders and neuromotor disorders
2. Children with psychiatric disorders
3. Children with speech sound or language development disorders
4. Children with phonological language problems

Date of first enrolment
30/06/2024

Date of final enrolment
30/07/2024

Locations

Countries of recruitment
Colombia

Study participating centre
Educational Institution María Cristina Arango de Pastrana Sede Mi pequeño Mundo
Calle 36 # 8-10 Barrio las granjas
Neiva Huila
Colombia
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Sponsor information

Organisation
Universidad Autonoma de Manizales

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Sponsor type
University/education

Website
https://www.autonoma.edu.co/

ROR
https://ror.org/00jfare13

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia, Tecnología e Innovación

Alternative Name(s)
Minister of Science, Technology and Innovation, Ministre des Sciences, de la Technologie et de l'Innovation, Ministra da Ciência, Tecnologia e Inovação, Minciencias

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Colombia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Piedad Rocío Lerma Castaño (piedadlermac@autonoma.edu.co)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Spanish version 1	04/06/2015	31/12/2024	No	Yes