Embodied learning-based phonemic training to improve executive functions

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|------------------------------|---|--|--|--|
| 25/12/2024 | | ☐ Protocol | | |
| Registration date 31/12/2024 | Overall study status Completed | Statistical analysis plan | | |
| | | Results | | |
| Last Edited | Condition category Other | Individual participant data | | |
| 25/03/2025 | | [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)

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment, Efficacy

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(s)

- 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.

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

6 years

Sex

All

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 410003

Sponsor information

Organisation

Universidad Autonoma de Manizales

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

Results and Publications

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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |