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Validation of an assistive technology for learning through psychophysiological evaluations in elementary school children

Submission date 24/08/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/09/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/01/2025	**Condition category** Other	[X] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Assistive technology for learning has been developed to aid children with learning disabilities and to improve their capabilities in reading and mathematics. However, there is an excessive number of digital applications in the market and most of them lack a pedagogical basis in their design. Therefore, this research attempts to create a protocol to evaluate the psychophysiological effect caused by an online method for learning (OML). This study can lead to further validation of other assistive technology for learning.

Who can participate?
Children who are studying third, fourth and fifth grade of elementary school (aged 8 to 11 years) and manifest low performance in reading or mathematics

What does the study involve?
The study comprises three phases.
* Phase 1. Classification of study groups.
By the application of a first psychometric evaluation, the objective of phase 1 is to identify children with low proficiency in reading and mathematics. Firstly, a collective evaluation will be carried out in the classroom, in such a way that it is possible to evaluate a greater number of children in the shortest time. These assessments will show the general performance in reading and mathematics of the students. Then, those children with low performance, either in reading or mathematics will be individually evaluated by additional psychometric tests to confirm the learning deficiency. Finally, four groups will be created:

A. Children with low performance in reading who will start using the OML:
1. At the beginning of the study
2. 3 months after the study started
B. Children with low performance in mathematics who will start using the OML:
3. At the beginning of the study
4. 3 months after the study started at the beginning of the study.

* Phase 2. Application and monitoring of the online method for learning.
Every child will undergo the first session of EEG. In particular, the purpose of phase 2 is to determine how the brain works when children execute reading or mathematical activities. At the end of the EEG recording, groups 1 and 3 will be trained in how to interact with the OML in reading and mathematics, respectively. These children will use the OML 15-min daily for 3 months. On the other hand, groups 2 and 4 will continue with their traditional learning method

* Phase 3. Psychophysiological evaluation of the online method for learning.
The aim of this phase is to evaluate the psychophysiological effect on learning caused by the OML. All groups must be assessed by psychometric evaluations and EEG recordings after three months of OML usage (groups 1 and 3) or following the traditional learning method (groups 2 and 4). Significative neurophysiological activity changes are expected that can demonstrate improvements in reading and mathematical performance.

What are the possible benefits and risks of participating?
Benefits
1. All psychometric evaluations will have no cost and the results will be shared with parents or legal tutors.
2. Children will strengthen their reading and mathematical capabilities if they use the OML appropriately.
3. Parents or legal tutors will be able to monitor the children's performance within the OML during the 3-month period.
4. Even when the control group will use the OML after 3 months from the start of the study, they will also enjoy the benefits of the OML.
Risks
1. There is minimum risk in any phase of the study. However, the participant can withdraw his /her consent if he/she feels uncomfortable during the study.

Where is the study run from?
School of Medicine and Health Sciences from Tecnologico de Monterrey (Monterrey, Mexico)

When is the study starting and how long is it expected to run for?
August 2022 to January 2025

Who is funding the study?
1. National Council of Science and Technology (CONACYT-Mexico)
2. Tecnologico de Monterrey (Mexico)
3. Sistemas Virtuales de Aprendizaje S.L (a.k.a. Smartick) (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MOA_2022

Study information

Scientific Title
Changes in reading and mathematical performance due to an assistive technology. Can they be measured through psychometric and electroencephalographic evaluations?

Study objectives
An assistive technology for learning develops reading and mathematical skills which can be quantified by psychophysiological evaluations

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/04/2023, Ethics Committee from the Neuroscience Institute from the University of Guadalajara (Francisco de Quevedo 180. Arcos de Vallarta, Guadalajara, 4413, Mexico; +523337771150; araceli.sanz@academicos.udg.mx), ref: ET122022-356

Study design
Interventional stratified randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
School, University/medical school/dental school

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Low reading or mathematical performance in children in elementary school

Interventions
Intervention 1: Collective psychometric evaluation. Psychometric tests will be applied in the classroom in order to assess reading and mathematical performance, as well as attentional levels. All the evaluations are aimed at students from 3rd, 4th and 5th grade. These assessments will allow the identification of children with potential learning difficulties in reading and mathematics. Duration: 50 min.

Intervention 2: First individual psychometric evaluation. Additional psychometric evaluations will be applied to determine the presence of learning difficulty in reading or mathematics. Subsequently, the students will be grouped into one of the following categories: 1) experimental group with reading difficulties, 2) control group with reading difficulties, 3) experimental group with mathematical difficulties and 4) control group with mathematical difficulties. Each child will be randomly assigned to a study group (children with reading difficulties: groups 1 and 2; children with mathematical difficulties: groups 3 and 4). Duration: 60 min.

Intervention 3: First session of EEG recording. Children will undergo a first EEG session, where groups 1 and 2 will be performing reading activities while neural activity is being recorded. Similarly, math activities will be displayed for groups 3 and 4 during EEG acquisition. Afterwards, an online method for learning will be given to experimental groups for 3 months, who will start using the app after their first EEG session. For control groups, they will continue with their traditional method of learning, and they will use the online method for learning three months after their first EEG session. Duration: 26 min.

Intervention 4: Psychophysiological evaluation of the online method for learning. All participants must return for a second psychometric and EEG session. These results will determine the psychophysiological effect on learning due to the technology, as well as the identification of neuromarkers related to reading and mathematical abilities in children. Duration: 71 min.

The randomization process will be carried out by creating a binary random vector in MATLAB, where 1 refers to experimental group and 0 to control group. This process will be simultaneously applied for the reading and mathematical difficulties groups.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Measured at the beginning of the study and 3 months after:
1. READING PROFICIENCY.
1.1. Psychometric tests results.
Test 1. Word dictation: evaluates orthographic knowledge
Test 2. Manual of procedures for the promotion and assessment of reading competence in the classroom: evaluates reading speed, errors in reading and reading comprehension
Test 3. PROLEER-R: evaluates spelling, pseudowords matching, antonyms, synonyms, non-words, and stressed syllable identification
Test 4. D2 for attention: evaluates concentration
1.2. Psychophysiological marker - EEG pattern

2. MATH PROFICIENCY.
2.1. Psychometric tests results.
Test 1. PREDISCAL: reading, calculation and mathematical logic
Test 2. WRAT-4: counting, arithmetical operations and algebra
Test 3. D2 for attention: evaluates concentration
2.2. Psychophysiological marker - EEG pattern

Secondary outcome measures
Measured at the beginning of the study and 3 months after:
1. READING PROFICIENCY
in-app performance:
1.1 Daily score from the activities within the app (scores from 1) each topic and 2) global general performance)
1.2 Daily interaction time with the app measured using the OML internal database
1.3 Overall interaction days with the app measured using the OML internal database
2. MATH PROFICIENCY
in-app performance:
2.1 Daily score from the activities within the app (scores from 1) each topic and 2) global general performance)
2.2 Daily interaction time with the app measured using the OML internal database
2.3 Overall interaction days with the app measured using the OML internal database

Overall study start date
24/08/2022

Completion date
31/01/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/04/2024:
1. Students from second, third, fourth, fifth, and sixth grade of elementary school (7 to 12 years).

2. Low performance in reading or mathematics
3. Indistinct socioeconomic status
4. To reside in Monterrey Metropolitan Area

Previous inclusion criteria as of 27/04/2023:
1. Students from third, fourth, fifth, and sixth grade of elementary school (8 to 12 years).
2. Low performance in reading or mathematics
3. Indistinct socioeconomic status
4. To reside in Monterrey Metropolitan Area

Previous inclusion criteria:
1. Students from third, fourth or fifth grade of elementary school.
2. Low performance in reading or mathematics
3. Indistinct socioeconomic status
4. To reside in Monterrey Metropolitan Area

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
112

Total final enrolment
76

Key exclusion criteria
1. Suffering from intelectual disabilities or autism spectrum disorder
2. Having failed one or more school years
3. Denied authorization of parents/carers or child in participating in the study

Date of first enrolment
01/09/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
Mexico

Study participating centre
Tecnologico de Monterrey, Escuela de Ingeniería y Ciencias
Av. Eugenio Garza Sada 2501 Sur, Tecnológico
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Sponsor information

Organisation
Instituto Tecnológico y de Estudios Superiores de Monterrey

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Sponsor type
University/education

Website
https://maestriasydiplomados.tec.mx/programas/posgrados?locale=en

Funder(s)

Funder type
Industry

Funder Name
Sistemas Virtuales de Aprendizaje S.L (in English: Virtual Learning Systems) (a.k.a. Smartick)

Funder Name
Instituto Tecnológico y de Estudios Superiores de Monterrey

Alternative Name(s)
Tecnológico de Monterrey, Tec de Monterrey, Monterrey Institute of Technology, Monterrey Institute of Technology and Higher Education, ITESM, Tec

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Mexico

Funder Name
National Council of Science and Technology (CONACYT-Mexico)

Results and Publications

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

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/04/2024	15/04/2024	Yes	No
Dataset	psychophysiological data gathered according to Inverventions 1 to 3	28/05/2024	30/08/2024	No	No
Dataset	psychophysiological data gathered according to Inverventions 1 to 3	28/05/2024	30/08/2024	No	No