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Artificial Intelligence digital treatment for pediatric ADHD based on neurophysiological measures: efficacy study of Sincrolab tool based on neurophysiological and neuropsychological measures

Submission date
22/02/2019

Recruitment status
No longer recruiting

Registration date
26/02/2019

Overall study status
Completed

Last Edited
19/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and objectives
Attention deficit hyperactivity disorder (ADHD) currently affects 6% or 7% of children in Western countries. These percentages vary depending on the different countries, but they have increased in recent years. These children require pharmacological and non-pharmacological treatments, such as therapy aimed at the rehabilitation of cognitive functions affected by the disease. However, many of these therapies are expensive and it is not feasible to go to the mental health professional on a daily basis, so the sessions are limited to once weekly. This produces a lack of continuity in the training that prolongs the rehabilitation process and on occasions, they are never completed. For all of the above Sincrolab S.L. has created a cognitive stimulation software with which very different patients can train daily and in a personalized way thanks to its artificial intelligence engine. Among these patients, children diagnosed with ADHD can benefit from the use of Sincrolab Kids. The objective of the tool is not to supplant the therapist but to be a complement to this and its sessions. However, it is not ruled out that it can be used without another type of specific work and/or combined with or without psychoactive medication, although always under the supervision of a mental health professional. The aim of this study is to find out whether training with Sincrolab produces cognitive and neurofunctional improvements in children who work with the platform for three months.

Who can participate?
Children aged 8 to 11 years old who are diagnosed with ADHD of combined presentation, and children (8-11 years old) without any diagnosis

What is the study?
The study begins with a cognitive and neuro-functional evaluation of the participants. The participants have to do training over 12 weeks, three days a week for 15 minutes. Participants are randomly allocated to one of two groups. One of the groups trains with Sincrolab and the

other trains with a tool that is not designed to stimulate cognitively. None of the participants know which group they belong to, but they will be informed of the existence of both groups. At the end of the study participants who do not receive training with Sincrolab receive the same training over a similar period of 12 weeks. The study ends with a cognitive and neurofunctional evaluation identical to the previous one in order to see if there is a difference between the participants who trained with Sincrolab and those who did not.

What are the possible benefits and risks of participating?
The study does not pose any risk, since neither the Sincrolab tool nor the alternative task have secondary effects. Nor does it initially consider rewarding children with any kind of reward for completing the stimulation sessions. The parents will receive the report of one of the evaluation tests so that they can take it to their reference professional.

Where is the study run from?
The study will be carried out at the Centre for Biomedical Technology (CTB) of the Polytechnic University of Madrid. The participating children will come from different therapists and mental health professionals. The training will be carried out at the home address of each of the participants and will be supervised by the person responsible for that function within the organization chart of the study.

When is the study starting and how long is it expected to run for?
May 2015 to December 2020

Who is funding the study?
Sincrolab has been financing this study thanks to a public loan granted from the Centre for the Development of Industrial Technology, a Public Business Entity affiliated with the Ministry of Science, Innovation and Universities

Who is the main contact?
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Contact information

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Scientific

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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
Functional reorganization of the cortical network based on neurophysiological and neuropsychological measures through an Artificial Intelligence digital treatment for pediatric ADHD versus pseudo placebo: simple blind randomized trial

Acronym
SINCROLAB-1

Study objectives
Neuropsychological rehabilitation with a digital treatment (Sincrolab tool) improves neurophysiological and neuropsychological outcomes in pediatric ADHD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Of Clinical Research Hospital Clinico San Carlos (en inglés), Dra. Mar García Arenilla. President of the Ethic Committee of the San Carlos Clinic Hospital, Hospital Clínico San Carlos Doctor Martín Lagos, s/n. Madrid 28040, Tel: +34 (0)91 330 34 13, Email: ceic.hcsc@salud.madrid.org, 08/01/2016, ref: C.P.-C.I. 15/575-E

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Two conditions: i) children (8-11 years old) with diagnosed ADHD combined type for ADHD group and ii) typically developed children (8-11 years old) for healthy group.

Interventions
Children of each condition (ADHD and healthy subjects) will be randomly assigned to the experimental or control group. There will be two experimental groups (one for ADHD and another for healthy subjects) and two control groups (one for ADHD and another for healthy subjects); four arms in total. Baseline assessment for each child (magnetoencephalography and neuropsychological measures) will be performed at the Centre for Biomedical Technology (CTB) before the training phase. Both pairs of arms will participate in a 3-month training phase. Experimental groups will train with the Sincrolab tool and controls will do the same but with a placebo (ludic videogames). The training phase consists of 15-minute sessions, 3 times per week for 12 weeks. Identical assessments (magnetoencephalography and neuropsychological measures) will be performed at CTB once the training phase is over.

Intervention Type
Behavioural

Primary outcome measure
Cognitive performance, measured through the Nepsy II neuropsychological battery, the WAIS IV battery digit test, the Corsi cube test of the WWM IV battery and the CPT III test of conners. After an initial training phase in each of the subtests, the subjects will execute each of the subtests following the same order. The evaluations will be carried out under the guidance and supervision of the assigned research staff, always being a qualified professional for such purposes.
The execution of the tests will be carried out at an initial moment, after randomization and prior to the training phase and after the training phase.

Secondary outcome measures
Measured at an initial moment, after randomization and prior to the training phase and after the training phase:
1. Executive function measured using the BRIEF questionnaire: Behavior Rating Inventory of Execution Function
2. Symptoms of ADHD measured using the EDAH questionnaire: Attention Deficit and Hyperactivity Disorder Scale
3. Brain connectivity measured by magnetoencephalography

Overall study start date
01/05/2015

Completion date
31/12/2020

Eligibility

Key inclusion criteria
ADHD Group:
1. Diagnosis of ADHD of combined presentation, issued by collegiate health professional and under compliance with criteria of the Diagnostic and Statistical Manual of Mental Disorders DSM-IV-TR
2. Age between 8 and 11 years under the consent of a legal guardian
3. Withdrawal of psychoactive drug 3 days prior to the assessment phases prior and after the intervention. Psychoactive drugs include: ADDERALL XR®, VYVANSE®, CONCERTA®, FOCALIN XR®, RITALIN LA®, METADATE CD, Strattera®, or other generic-type analogues approved by the Spanish or European agency of the drug
4. Do not present additional psychoactive medication
5. Do not present psychiatric comorbidities
6. Preserved reading-writing
7. Provision for compliance with all phases of the study

Healthy Volunteer Group:
1. Age between 8 and 11 years under the consent of legal guardian
2. Typical development
3. Absence of mental or neurological diagnosis
4. Absence of perceptual or motor difficulties
5. No use of psychoactive or depression drugs that in the opinion of the researcher could be a confounding factor
6. Ability to follow verbal or written instructions

Participant type(s)
Mixed

Age group
Child

Lower age limit
8 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
80

Total final enrolment
29

Key exclusion criteria
ADHD group:
1. Begin or abandon behavioural therapies or psychoactive drugs during the three-month period comprising the training phase. Changes in the pharmacological dose should be reported to the researchers
2. Motor difficulties that make the use of the tool impossible
3. Use of psychoactive drug that in the opinion of the researcher could be a confounding factor
4. Presence or suspicion of substance abuse in the last 6 months
5. Presence of blindness or uncorrected visual acuity difficulties
6. Medication and/or concomitant therapy
7. The use of psychotropic medications is not allowed
8. The use of other drugs is not allowed except those commonly used (for example: ibuprofen, paracetamol) and medical prescription (antibiotics)
9. Do not initiate, abandon or change types of therapy or medication

Healthy volunteers:
Positive screening on EDAH's scales

Date of first enrolment
01/03/2016

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Spain

Study participating centre
Centre for Biomedical Technology - Polytechnic University of Madrid
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Sponsor information

Organisation
Sincrolab Ltd

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Sincrolab Ltd

Results and Publications

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

Intention to publish date
30/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2021	30/11/2021	Yes	No
Protocol file	version 1.2		30/08/2022	No	No
Results article		17/02/2022	06/03/2024	Yes	No