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Does body-brain training improve measures of attention in children?

Submission date
18/05/2021

Recruitment status
No longer recruiting

Registration date
24/05/2021

Overall study status
Completed

Last Edited
11/09/2023

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 study aims
Cognitive control functions (e.g. attention, working memory, goal-management) dictate our ability to learn and accomplish selected behavioral goals, with deficiencies in these processes found in a range of mental illnesses including ADHD (among others). Cognitive training interventions and physical fitness training are two approaches that have been successfully used to enhance deficient cognitive control abilities across a variety of populations, including children with issues of inattention. Given that each approach has led to improvements in untrained cognitive abilities, the possibility exists that a 'synergistic' effect on these abilities may be attainable through the combination of each training approach. Developing such a training tool may realize these synergistic effects in humans while simultaneously providing mechanistic evidence regarding how the process of learning can be augmented using the same approach. For the main study, we propose to utilize a novel video game-based intervention ("Pediatric Body-Brain Trainer", or pediBBT) that incorporates i) adaptive algorithms critical for cognitive training, ii) physiological measures such as heart rate into the core game mechanics, and iii) motion capture technology to incorporate whole-body kinematics into game play to leverage principles of embodied cognition.

Who can participate?
Children between the ages of 7 and 12 years with school or community-based diagnosis of ADHD or parental concerns for inattention attending Neil Cummings Elementary School, where the intervention took place as an after-school program were eligible for participation.

What does the study involve?
All participants will play a game called 'pediBBT'. Participants are asked to participate in this study 4 days a week for 6-weeks, with each day consisting of 9, 3-minute sessions, with training occurring at Neil Cummings Elementary School as opposed to a clinic or laboratory. A research assistant will monitor participation and provide support and feedback to the parents and children during training. Prior to and after the intervention, children have their attention assessed and parents complete a questionnaire about their child's inattention. Certain measures will be repeated 1 year after the intervention as well.

What are the possible benefits and risks of participating?
There are no direct benefits or risks associated with participating in this study.

Where is the study run from?
University of California, San Francisco (USA)

When is the study starting and how long is it expected to run for?
January 2018 to December 2020

Who is funding the study?
University of California San Francisco Academic Senate Resource Allocation Program, Neuroscape (USA)

Who is the main contact?
Joaquin A. Anguera, Joaquin.anguera@ucsf.edu

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
Nil known

Study information

Scientific Title
Does synergistic body-brain training improve distinct measures of attention in children?

Acronym
pediBBT

Study objectives
Children with parent-reported attention concerns would benefit from an novel combined cognitive and physical fitness intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2018, University of California, San Francisco Human Research Protection Program Institutional Review Board (UCSF Office of the Committee on Human Research, Box 1288
490 Illinois Street, Floor 6, San Francisco, CA 94143, USA; +1 415-476-1814; irb@ucsf.edu), ref: 17-23723

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
See additional file ISRCTN59416198_PIS (added 01/06/2021)

Health condition(s) or problem(s) studied
Inattention in children

Interventions
Pediatric Body Brain Trainer (pediBBT), was developed for an adult cohort by Drs. Gazzaley and Anguera, and adapted with Dr. Marco's expertise for a pediatric cohort. pediBBT integrates full body motion capture technology with cardiovascular and cognitive adaptive algorithms into a high-level (art, music, story) 3D video game targeting cognitive and physical fitness goals. Children respond with their hands and feet to cognitive tasks engaging three physical control domains (aerobic, balance, and flexibility). Furthermore, the cognitive and physical demands are completely integrated by the pursuit of a common game reward goal. Thus, the cognitive and physical tasks do not compete for cortical capacity—they work in concert, overcoming a problem

in previous studies. pediBBT utilizes personalized and precise titrating of training: in contrast to the majority of cognitive training platforms, pediBBT uses continuous, closed-loop adaptivity to drive game mechanics. This involves rapid performance-based assessment, feedback, reward, and modulated challenges to establish the optimal dynamic interactivity between the player and the game environment. This is a design approach used extensively in our work over the past 10 years. Specifically, participants receive physiological and cognitive feedback on a continual basis by incorporating real-time heart rate data and cognitive performance metrics into the software's adaptive algorithms to instantly (on the order of milliseconds) titrate the demands and rewards of game play. This ensures that each individual is appropriately challenged and engaged during their training experience.

PediBBT uses off-the-shelf Microsoft Xbox Kinect 2™ kinematics and a Garmin™ heart rate monitor to capture heart rate data in real time during game play. These devices are advanced yet affordable consumer-level sensors, facilitating community application quickly and feasibly, yet preserving laboratory-quality registration and metrics.

pediBBT modules: There are three pediBBT modules, with each targeting a different aspect of cognitive control: a visual search task for attention (with increasing distraction), a spatial span task for working memory, and a task-switching paradigm targeting goal management abilities.

All participants will play pediBBT. Participants are asked to participate in this study 4 days a week for 6-weeks, with each day consisting of 9, 3-minute sessions, with training occurring at Neil Cummings Elementary School as opposed to a clinic or laboratory. A research assistant will monitor participation and provide support and feedback to the parents and children during training. Prior to and after the intervention, children have their attention assessed and parents complete a questionnaire about their child's inattention. Certain measures will be repeated 1 year after the intervention as well.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
pediBBT

Primary outcome measure
1. Parent report of inattention using the Vanderbilt at baseline and post-intervention (6 weeks later)
2. Objective measure of attention using the Continuous Performance Task (CPT) at baseline and post-intervention (6 weeks later)
3. Objective measure of attention using EEG during the Continuous Performance Task (CPT) at baseline and post-intervention (6 weeks later)

Secondary outcome measures
1. Objective measure of Multitasking using the NeuroRacer Multitasking Assessment at baseline and post-intervention (6 weeks later)
2. Objective measure of Working Memory using the delayed recognition working memory task (AID) at baseline and post-intervention (6 weeks later)
3. Objective measure of Basic Response Time (BRT) using the BRT task at baseline and post-

intervention (6 weeks later)
4. Surveys of physical fitness at baseline and post-intervention (6 weeks later)
5. Surveys of general health at baseline and post-intervention (6 weeks later)

Overall study start date
02/01/2018

Completion date
02/12/2020

Eligibility

Key inclusion criteria
1. Children between the ages of 7 and 12 years
2. School or community-based diagnosis of ADHD or parental concerns for inattention

Added 16/11/2021:
3. Had no concerns of ADHD or inattention but were simply interested in participating

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
30

Total final enrolment
27

Key exclusion criteria
1. Concern for Autism Spectrum Disorder (Social Communication Questionnaire score <15)
2. Prematurity (gestational age <32 weeks)
3. Seizures requiring current medication management, psychosis or mood disorder (as assessed by Behavior Assessment System for Children, Second Edition)

Date of first enrolment
20/01/2018

Date of final enrolment

20/02/2020

Locations

Countries of recruitment
United States of America

Study participating centre
University of California, San Francisco
675 Nelson Rising Lane
San Francisco
United States of America
94080

Study participating centre
Neil Cumming Elementary School
58 Mohawk Ave
Corte Madera
United States of America
94925

Study participating centre
Cortica Marin
4000 Civic Center Drive, STE 100
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Sponsor type
University/education

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ROR
https://ror.org/043mz5j54

Funder(s)

Funder type
University/education

Funder Name
UC San Francisco Academic Senate Resource Allocation Program

Funder Name
Neuroscape Network

Funder Name
University of California, San Francisco

Alternative Name(s)
UC San Francisco, University of California San Francisco, Toland Medical College, The Medical Department of the University of California, UCSF

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

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

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Joaquin.Anguera@ucsf.edu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/06/2021	No	Yes
Protocol file			16/08/2022	No	No
Results article		12/04/2023	11/09/2023	Yes	No