

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

Submission date 18/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 24/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/09/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Contact name
Prof Joaquin Anguera

ORCID ID
<https://orcid.org/0000-0002-7216-0674>

Contact details
675 Nelson Rising Lane
San Francisco
United States of America
94158
+1 4155027322
joaquin.anguera@ucsf.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 a 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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

12 years

Sex

All

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
San Rafael
United States of America
94903

Sponsor information

Organisation
University of California, San Francisco

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

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?
Results article		12/04/2023	11/09/2023	Yes	No
Participant information sheet			01/06/2021	No	Yes
Protocol file			16/08/2022	No	No