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Remediating attention deficits in children with sensory processing dysfunction

Submission date
09/09/2016

Recruitment status
No longer recruiting

Registration date
13/09/2016

Overall study status
Completed

Last Edited
15/09/2016

Condition category
Mental and Behavioural Disorders

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sensory Processing Dysfunction (SPD) is a condition in which the brain is unable to receive and respond to information that comes in through the senses (sight, hearing, touch, taste, and smell) properly. A person with SPD finds it difficult to process information received through the senses, which can make performing everyday tasks very difficult and lead to withdrawal (avoidance) or seeking of sensory inputs (sights, sounds, etc.). Studies have shown that children with SPD also show signs of attention problems. The aim of this study is to understand if children with SPD would show benefit from an attention training iPad app.

Who can participate?
Children aged between 9-12 who have SPD and healthy children of the same age.

What does the study involve?
All participants are given access to the iPad app called 'EVO'. Participants are asked to use the app 5 days a week for 4-weeks, with each day consisting of 7, 3-4 minute EVO sessions, with training occurring in the comfort of their own homes as opposed to a clinic or laboratory. Research assistants remotely monitor EVO play and provide support and feedback to the parents and children during training. If a research assistant notices a participant had more than two incomplete days of training, a reminder phone call would be made to the parents. Before using the app and then after 20 days of EVO training, children have their attention assessed and parents complete a questionnaire about their child's inattention. The parent questionnaire is repeated again at nine months.

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?
The study is run from University of California, San Francisco and takes place in participant homes (USA)

When is the study starting and how long is it expected to run for?
January 2014 to February 2015

Who is funding the study?
1. Mickelson-Brody Family Foundation (USA)
2. Wallace Research Foundation (USA)
3. James Gates Family Foundation (USA)
4. Kawaja-Holcombe Family Foundation (USA)

Who is the main contact?
1. Dr Joaquin Anguera (scientific)
2. Dr Elysa Marco (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Differentially remediating attention deficits in children with Sensory Processing Dysfunction

Study objectives
Children with comorbid sensory processing dysfunction and parent-reported attention concerns would show greater benefit from an iPad-based attention intervention than those without attention concerns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of California, San Francisco Human Research Protection Program Institutional Review Board (IRB), 01/02/2014, ref: 10-01940

Study design
Non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Not Specified

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Sensory processing dysfunction

Interventions
The intervention used in this trial is a cognitive training iPad application called ‘EVO’. EVO is an iPad-based program developed by Akili Interactive Labs, specifically designed as a medical device to assess and adaptively target improvements in cognitive control for populations with cognitive disorders and executive function deficits.The EVO intervention is a self-guided treatment designed for at-home use that involves a combination of visuomotor and perceptual discrimination tasks. Each training run consists entirely of the multitasking condition, and lasts approximately 4 minutes, with 7 training runs comprising one day of training. As the participants improve their performance throughout this intervention, they are transported to different visual “worlds” in the EVO universe, meant to immerse the player and enhance the depth of

engagement and compliance. In addition, frequent EVO assessments are given to the player to obtain information as to how the player is improving throughout training, and adaptively set a personalized therapeutic regimen based specifically on the user's own performance levels. Adaptive mechanics are employed in the training sessions. Since the adaptive mechanics strive to keep the player at ~80% accuracy, the player is challenged to constantly improve upon their own cognitive control performance in order to reach the next level. Treatment involved participant engagement with EVO 5 days a week for 1 month, with each day consisting of 7, 3-4 minute EVO sessions. After a participant completed 20 days of EVO training (~4 weeks), a follow-up research appointment was scheduled with the parents. In this trial our outcome measures were focused on attention as measured by direct assessment (computerized attention assessments), neural measurements (midline frontal theta), and parent reports of attention deficits (Vanderbilt Parent report). These assessments were collected before the intervention and immediately after. The parent questionnaire is also repeated 9 months after the intervention was completed.

Intervention Type
Device

Primary outcome measure
1. Cognitive control is measured from computerized assessments at baseline and 4 weeks
2. Midline frontal theta is measured using EEG at baseline and 4 weeks

Secondary outcome measures
Parent reports of inattention is measured via online questionnaires (Vanderbilt ADHD Parent Rating Scale) at baseline, 4 weeks and 9 months.

Overall study start date
03/01/2014

Completion date
21/02/2015

Eligibility

Key inclusion criteria
Sensory processing dysfunction (SPD) group:
1. A community diagnosis of SPD
2. A score on the Sensory Profile in the "Definite Difference" range (<2% probability) in one or more of the sensory domains (auditory, visual, oral/olfactory, tactile, vestibular, or multisensory processing)
3. Between the ages of 9-12

Typically developing controls (TDC):
Between the ages of 9-12

Participant type(s)
Mixed

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
65

Key exclusion criteria
1. Brain malformation or injury
2. Movement disorder
3. Bipolar disorder
4. Psychotic disorder
5. Hearing impairment
6. Perceptual Reasoning Index (PRI) score <70 on the Weschler Intelligence Scale for Children Fourth Edition (Wechsler, 2003)

Date of first enrolment
20/02/2014

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
United States of America

Study participating centre
University of California, San Francisco
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Sponsor information

Organisation
University of California, San Francisco

Sponsor details

675 Nelson Rising Lane
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Sponsor type
University/education

ROR
https://ror.org/043mz5j54

Funder(s)

Funder type
Charity

Funder Name
Mickelson-Brody Family Foundation

Funder Name
Wallace Research Foundation

Funder Name
James Gates Family Foundation

Funder Name
Kawaja-Holcombe Family Foundation

Results and Publications

Publication and dissemination plan
Planned publication will discuss the outcomes from the trial, specifically that the SPD group with comorbid inattention symptoms show the greatest improvement from the intervention

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date