Brain-Computer Interface-based Programme for the Treatment of ASD/ADHD (ASDBCI)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified November 2015 by Duke-NUS Graduate Medical School

Sponsor:
Duke-NUS Graduate Medical School

Collaborators:
Institute of Mental Health, Singapore
Agency for Science, Technology and Research

Information provided by (Responsible Party):
Lee Tih Shih, Duke-NUS Graduate Medical School

ClinicalTrials.gov Identifier:
NCT02618135

First received: November 23, 2015
Last updated: November 27, 2015
Last verified: November 2015

Purpose

This project involves creating a novel and personalised BCI training system that targets social and communication difficulties, and inattentive symptoms problems often found in ASD/ADHD children. 20 participants between the age of 8 and 12 will be recruited and they will undergo 24 training sessions over an 8-week period. During these sessions, the children will play a computer game interface specifically designed to train attention and facial and emotional recognition, while using our BCI device. To further reinforce the treatment, the training system has been enhanced with the inclusion of an eye-tracker to target the lack of preferential eye contact that children with ASD exhibit. The investigators hypothesize that participants will show improvements in social skills and attention post treatment.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td></td>
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<tr>
<td>Autism Spectrum Disorders</td>
<td>Other: Intervention Group</td>
</tr>
<tr>
<td></td>
<td>Other: Control Group</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Effectiveness of a Brain-Computer Interface-based Programme for the Treatment of Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder in Children: A Pilot Study

Resource links provided by NLM:
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Genetic and Rare Diseases Information Center resources: Children's Interstitial Lung Disease
U.S. FDA Resources

Further study details as provided by Duke-NUS Graduate Medical School:

Primary Outcome Measures:
- ADHD Rating Scale (clinicians) [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The primary outcome of this study will be the change in the inattentive score on the ADHD Rating Scale as rated by the clinicians from week 1 to week 8.

Secondary Outcome Measures:
- ADHD Rating Scale (parent) [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in the inattentive score of the ADHD RS rated by parent from week 1 to week 8.
- ADHD Rating Scale (clinician and parent) [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in the inattentive score of the ADHD RS rated by clinician and parent from week 1 to week 8.
- ADHD Rating Scale [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in parent rated ADHD-RS from week 1 to week 8.
- Social Responsiveness Scale [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in parent rated SRS from week 1 to week 8.
- Clinical Global Assessment Scale (C-GAS) [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in clinician rated CGAS and CGI scores from week 1 to week 8.
- Clinical Global Impression Severity Scale (CGI-S) [ Time Frame: Week 1 to Week 8 ] [ Designated as safety issue: No ]
The change in clinician rated CGAS and CGI scores from week 1 to week 8.
Clinical Global Impression Improvement Scale (CGI-I) [ Time Frame: Week 1 to Week 8 ]
[ Designated as safety issue: No ]
The change in clinician rated CGAS and CGI scores from week 1 to week 8.

Estimated Enrollment: 20

Study Start Date: December 2015

Estimated Study Completion Date: July 2018

Estimated Primary Completion Date: August 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Intervention Group</td>
<td>10 child participants in the intervention group will take part in a total of 24 sessions spread over an 8-week period, and a final follow-up review 1 month after the completion of the training session. If sessions are missed during the 8-weeks period due to unforeseen circumstances (e.g. sickness, travel plans), arrangements will be made for participants to attend up to 5 BCI-based therapy sessions per week. All participants will have to complete a minimum of 20 sessions within the 8-weeks period for treatment efficacy. Other: Intervention Group Each participant will first need to master a simple concentration task before moving on to play a series of training tasks. An eye gaze tracker connected to the computer will detect the location of eye gaze on the computer screen. The game progresses according to how well the participant can focus their eye gaze on correct objects and sustain their attention. Each task employs the BCI system, and is controlled by the child's concentration. As the child attends to activities on a computer screen, their EEG waves will be recorded simultaneously via the EEG sensors through Bluetooth technology. Other Name: BCI Training</td>
</tr>
<tr>
<td>Control Group</td>
<td>10 child participants in the control group will not receive BCI training during the first 8 weeks of their study participation; they will act as controls. At week 9, subjects in this group will go through the BCI training similar to the intervention group. If sessions are missed during the 8-weeks period due to unforeseen circumstances (e.g. sickness, travel plans), arrangements will be made for participants to attend up to 5 BCI-based therapy sessions per week. All participants will have to complete a minimum of 20 sessions within the 8-weeks period for treatment efficacy. They will take part in a total of 24 sessions spread over an 8-week period, followed by a final follow-up review 1 month. Other: Control Group Participants will wait for 8 weeks before training intervention begins. Each participant will first need to master a simple concentration task before moving on to play a series of training tasks. An eye gaze tracker connected to the computer will detect the location of eye gaze on the computer screen. The game progresses according to how well the participant can focus their eye gaze on correct objects and sustain their attention. Each task employs the BCI system, and is controlled by the child's concentration. As the child attends to activities on a computer screen, their EEG waves will be recorded simultaneously via the EEG sensors through Bluetooth technology.</td>
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</tbody>
</table>
after the completion of the training sessions.

Technology.

Other Name: Waitlist BCI Training

Show Detailed Description

Eligibility

Ages Eligible for Study: 8 Years to 12 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Meets diagnostic criteria for ASD, based on Autism Diagnostic Observation Scale (ADOS) and Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5);
- Meets diagnostic criteria for ADHD inattentive or combined subtype, based on the Computerised Diagnostic Interview for Children (C-DISC);
- Score 12 and above on the ADHD Rating Scale (ADHD-RS);
- IQ above 70;
- If on medication, dose has been stable or unchanged for at least preceding 3 months
- Parents and teachers are English-speaking

Exclusion Criteria:

1. Co-morbid severe psychiatric condition or known sensory-neural deficit e.g. complete blindness or deafness.
2. Color blindness
3. History of epileptic seizures.
4. Known to have developmental delay (i.e. IQ 70 and below).
5. Predominantly hyperactive/impulsive subtype of ADHD.
6. Change in dosage of medication (if on medication)

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02618135

Contacts

Contact: Tih-Shih Lee 65167461 tihshih.lee@duke-nus.edu.sg

Locations

Singapore
Sponsors and Collaborators
Duke-NUS Graduate Medical School
Institute of Mental Health, Singapore
Agency for Science, Technology and Research

Investigators
Principal Investigator: Choon Guan Lim Institute of Mental Health

Publications:


Responsible Party: Lee Tih Shih, Associate Professor, Duke-NUS Graduate Medical School

ClinicalTrials.gov Identifier: NCT02618135 History of Changes

Other Study ID Numbers: 2015/00841

Study First Received: November 23, 2015

Last Updated: November 27, 2015
<table>
<thead>
<tr>
<th>Additional relevant MeSH terms</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Attention Deficit Disorder with Hyperactivity</td>
<td>Mental Disorders</td>
</tr>
<tr>
<td>Child Development Disorders, Pervasive</td>
<td>Mental Disorders Diagnosed in Childhood</td>
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<tr>
<td>Disease</td>
<td>Nervous System Diseases</td>
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<tr>
<td>Hyperkinesis</td>
<td>Neurologic Manifestations</td>
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<tr>
<td>Attention Deficit and Disruptive Behavior Disorders</td>
<td>Pathologic Processes</td>
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<tr>
<td>Dyskinesias</td>
<td>Signs and Symptoms</td>
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ClinicalTrials.gov processed this record on December 01, 2015