Effects of Noise Cancelling Headphones on Neurocognitive and Academic Outcomes in ADHD

This study is not yet open for participant recruitment.

Verified July 2017 by Duke University

Sponsor:
Duke University

Collaborator:
BOSE Corporation

Information provided by (Responsible Party):
Duke University

ClinicalTrials.gov Identifier:
NCT03216512

First received: July 6, 2017
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Last verified: July 2017

Purpose

The purpose of this study is to evaluate performance on the Attention Deficit Hyperactivity Disorder (ADHD) Battery of the Cambridge Automated Neuropsychological Test Battery (CANTAB), including spatial working memory, inhibitory control, and attention while using either a noise cancelling headphone or sham headphone control in the presence of standardized auditory distractors in children and adolescents with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Other: Use of Noise Cancelling Headphones</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Crossover Assignment
Intervention Model Description:
Proof-of-concept, randomized, within-subject cross-over design.
Masking: Participant
Masking Description:

The participant won't know whether they are receiving the noise cancelling headphones or the sham control.

Primary Purpose: Other

Official Title: A Randomized, Sham-Controlled, Crossover Study to Evaluate the Effects of Noise Cancelling Headphones on Neurocognitive and Academic Outcomes in Children and Adolescents Diagnosed With Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Noise

U.S. FDA Resources

Further study details as provided by Duke University:

Primary Outcome Measures:

- Change in CANTAB ADHD Battery [ Time Frame: Between experimental session 1 and experimental session 2 - Between 3 and 7 days ]
  Compare change from Baseline scores on the CANTAB ADHD battery with noise cancelling headphones and sham-controls.

Secondary Outcome Measures:

- Change in Academic Productivity Measures -Math [ Time Frame: Between experimental session 1 and experimental session 2 - Between 3 and 7 days ]
  Compare change from Baseline scores on academic productivity measures (math), comprehension) with noise cancelling headphones and sham-controls.

- Change in Subjective Reports of Experience [ Time Frame: Between experimental session 1 and experimental session 2 - Between 3 and 7 days ]
  Compare the self-reports of noise cancelling headphones versus sham controls

- Change in Academic Productivity Measures -Reading Comprehension [ Time Frame: Between experimental session 1 and experimental session 2 - Between 3 and 7 days ]
  Compare change from Baseline scores on academic productivity measures (Reading Comprehension).
Estimated Enrollment: 30

Anticipated Study Start Date: September 2017

Estimated Study Completion Date: December 2018

Estimated Primary Completion Date: December 2018 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Noise cancelling headphone first, then sham control headphone</td>
<td></td>
</tr>
<tr>
<td>This group will use the noise cancelling headphone during the first experimental session as they complete study assessments. They will then return within a week, for experimental session day 2, to complete the same assessments this time using a sham control headphone.</td>
<td>Other: Use of Noise Cancelling Headphones  During the 2 experimental sessions, participants will complete study assessments using either a noise cancelling headphone first (session 1) and then sham control second (session 2), or vice versa, in the presence of noise distractions.</td>
</tr>
<tr>
<td>Experimental: Sham control headphone first, then noise cancelling headphone</td>
<td>Other: Use of Noise Cancelling Headphones  During the 2 experimental sessions, participants will complete study assessments using either a noise cancelling headphone first (session 1) and then sham control second (session 2), or vice versa, in the presence of noise distractions.</td>
</tr>
<tr>
<td>This group will use the sham control headphone during the first experimental session as they complete study assessments. They will then return within a week for experimental session day 2, to redo the same assessments this time using a noise cancelling headphone.</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed Description:**

This will be a proof-of-concept, randomized, within-subject cross-over design with the administration of noise cancelling headphones or sham headphones on two separate study days. Following screening and a baseline assessment session with no headphones, participants will be assigned to complete each experimental session. During each session, they will undergo the CANTAB and Academic tasks. The order of sessions will be randomized and balanced across participants to be either noise-cancelling headphones first followed by sham headphones; or sham headphones first followed by noise-cancelling headphones. Eligible participants currently taking stimulant medications for ADHD will be asked to stop taking their medication on the day of the baseline visit and during the 2 experimental sessions.

**Eligibility**

- **Ages Eligible for Study:** 6 Years to 17 Years (Child)
- **Sexes Eligible for Study:** All
- **Accepts Healthy Volunteers:** Yes

**Criteria**

- **Inclusion Criteria:**
  - Age 6 to 17 at the time of parental informed consent.
• Male or female.
• Confirmed ADHD diagnosis at screening visit established via MINI-KID (version 7.0.2) administered by a trained clinician.
• Screening ADHD-RS-IV score ≥24.
• Estimated IQ (measured with the KBIT-2) ≥80.
• If currently medicated with a stimulant medication (amphetamine or methylphenidate formulation), off drug on day of Baseline and Experimental Sessions. May resume medication after all assessments are completed on these days.
• Able to follow written and verbal instructions (English) as assessed by the PI and/or study coordinator.
• Able to comply with all testing and requirements.

Exclusion Criteria:
• Current controlled (requiring a restricted medication) or uncontrolled, comorbid psychiatric diagnosis, based on MINI-KID and subsequent clinical interviewing, with significant symptoms including but not limited to post-traumatic stress disorder, psychosis, bipolar illness, pervasive developmental disorder, severe obsessive-compulsive disorder, severe depressive or anxiety disorder, conduct disorder, or other symptomatic manifestations that in the opinion of the Investigator may confound study data/assessments (Participants with clinical history of learning disorders will be allowed to participate as long as the disorder does not impact their ability to participate based on PI judgement).
• Current treatment with any non-stimulant medication for ADHD (e.g., atomoxetine, clonidine, guanfacine).
• Current treatment with other psychoactive drugs.
• Participant is currently considered at risk for attempting suicide by the Investigator, or is currently demonstrating active suicidal ideation or self-injurious behavior, as measured by MINI-KID Suicidality Module C.
• Documented hearing loss.
• Recent history or suspicion (within the past 6 months) of substance abuse or dependence.
• Any other medical condition that, in the opinion of the Investigator, may confound study data/assessments.

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: NCT03216512

Contacts

Contact: Nilda Itchon-Ramos 919-681-0032 nilda.itchonramos@dm.duke.edu
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Sponsors and Collaborators
Duke University
BOSE Corporation

More Information