Sleep Dysfunction and Neurocognitive Outcomes in Adolescent ADHD

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2016 by Duke University

Sponsor:
Duke University

Collaborator:
National Institute of Mental Health (NIMH)

Information provided by (Responsible Party):
Duke University

ClinicalTrials.gov Identifier:
NCT02897362

First received: September 2, 2016
Last updated: September 7, 2016
Last verified: August 2016

Purpose
This study seeks to characterize sleep physiology in adolescents with and without Attention deficit hyperactivity disorder (ADHD) and its relationship to differential neurocognitive and clinical outcomes within these groups.

<table>
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<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
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</table>

Study Type: Observational

Study Design: Observational Model: Case Control
Time Perspective: Prospective

Official Title: Sleep Dysfunction and Neurocognitive Outcomes in Adolescent ADHD

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources
Further study details as provided by Duke University:

Primary Outcome Measures:
- Objective sleep assessment [ Time Frame: 3 consecutive nights ] [ Designated as safety issue: No ]
  Ambulatory polysomnographic measures of total sleep time, sleep onset latency, wake after sleep onset, and EEG spectral dynamics.

Secondary Outcome Measures:
- Neurocognitive assessment [ Time Frame: 1 day ] [ Designated as safety issue: No ]
  Computerized measure of neurocognition.
- Executive functioning as measured by neurocognitive assessment [ Time Frame: 1 day ]
  [ Designated as safety issue: No ]

Estimated Enrollment: 60
Study Start Date: August 2016
Estimated Study Completion Date: July 2021
Estimated Primary Completion Date: July 2021 (Final data collection date for primary outcome measure)

### Groups/Cohorts

<table>
<thead>
<tr>
<th>Adolescents with ADHD</th>
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<tbody>
<tr>
<td>Adolescents, male or female, ages 13-17, confirmed diagnosis of Attention Deficit Hyperactivity Disorder (inattentive, hyperactive/impulsive, or combined presentations), medically healthy, no comorbid psychiatric diagnosis other than ODD, intelligence within normal limits. Participants will complete 3 nights of ambulatory polysomnography at home and a neuropsychological assessment in the lab.</td>
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<tr>
<th>Healthy Control Adolescents</th>
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<tbody>
<tr>
<td>Adolescents, male or female, ages 13-17, medically healthy, no psychiatric diagnoses, intelligence within normal limits. Participants will complete 3 nights of ambulatory polysomnography at home and a neuropsychological assessment in the lab.</td>
</tr>
</tbody>
</table>

**Detailed Description:**

This project will involve recruitment of 30 adolescents with ADHD and a control group of 30 healthy adolescents without psychiatric diagnoses. Participants will participate in 3 phases: Screening visit, Washout/In-Home Sleep Study, and Neurocognitive Assessment visit. To ensure consistency in sleep schedules, the three nights of the sleep study will occur on weeknights during the school year. The neurocognitive assessment will occur during the afternoon following the final night of sleep assessment.
The 2-hour screening visit will be conducted at the Duke ADHD Clinic at 2608 Erwin Road, Pavilion East, Suite 300, Durham, NC 27705. During the screening visit, participants will undergo screening to evaluate eligibility for the study.

Eligible participants will enter the 48-hour Washout (if applicable) and 3-night Sleep Study Phase (At Home). Subjects not taking stimulant medication will initiate 3 consecutive nights of ambulatory (in-home) PSG recording, beginning on the next Monday evening following the screening visit. Subjects will be instructed to maintain usual sleep routines/behaviors for all study nights. In addition, subjects will be asked to complete a "sleep diary" each morning.

If subject is currently taking stimulant medication, they will be instructed to initiate a 48-hour washout period. Subjects will be instructed to discuss this option with their prescribing physician prior to initiating the study.

Subjects will be asked to return for a three-hour neurocognitive assessment on the afternoon directly following the final night of the sleep study. In order to reduce interference with school attendance, this visit will be scheduled in the afternoon. Subjects will be able to take breaks throughout the assessment as requested.

Subjects will restart their ADHD medications on the morning following the neurocognitive assessment (if applicable).

**Eligibility**

**Ages Eligible for Study:** 13 Years to 17 Years (Child)

**Genders Eligible for Study:** Both

**Accepts Healthy Volunteers:** Yes

**Sampling Method:** Non-Probability Sample

**Study Population**

Adolescents with ADHD and healthy control adolescents

**Criteria**

**Inclusion Criteria:**

- Male or Female
- Between the ages of 13-17 years, inclusive;
- Free from significant medical/psychiatric conditions
- Cognitive functioning > 80 as assessed by the KBIT-II
- Willingness to comply with all study requirements; and
- Ability of child and parent/guardian to communicate verbally and in written form in English.

**Inclusion for the ADHD group only:**

- Confirmed diagnosis of ADHD, any subtype as determined by the MINI-KID
- Willingness to delay/suspend medication use for the 4-day duration of the study and 2 days prior to the sleep study phase.

**Exclusion Criteria:**

- History of chronic/significant medical condition
- Use of prescription medications for ADHD during the 2-day washout and/or 4-day study
- Current prescribed use of any other psychotropics, including non-stimulant medications for ADHD
- Current substance abuse or dependence or history within the last 6 months
- Estimated IQ < 80 as assessed by the KBIT-II
• First degree relative with psychosis or bipolar disorder;
• Parent/Guardian or child unable to communicate verbally and in written form in English; and
• Unable to comply with study requirements or otherwise unsuitable for participation in the opinion of the principal investigator

Exclusion for the ADHD group only:
• Meets criteria for any other Axis I Disorder (determined by the MINI-KID) besides ADHD or Oppositional Defiant Disorder (ODD)

Exclusion for the HEALTHY CONTROL group only:
• Meets criteria for any Axis I Disorder

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: NCT02897362

Contacts
Contact: Leah Akins, MSc  919-681-0013  leah.lakins@duke.edu

Locations

United States, North Carolina

Duke Child and Family Study Center
Durham, North Carolina, United States, 27705
Contact: Jessica R Lunsford-Avery, PhD  919-681-0035  jessica.r.avery@duke.edu

Sponsors and Collaborators
Duke University
National Institute of Mental Health (NIMH)

Investigators
Principal Investigator: Jessica R Lunsford-Avery, PhD  Duke University

More Information

Responsible Party: Duke University
ClinicalTrials.gov Identifier: NCT02897362  History of Changes
Other Study ID Numbers: Pro00072033  1K23MH108704-01A1
Study First Received: September 2, 2016
Last Updated: September 7, 2016
Health Authority: United States: Institutional Review Board

Individual Participant Data
Plan to Share IPD: No