Sleep Extension and Behavior of Young Children

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03446716

Recruitment Status : Completed
First Posted : February 27, 2018
Last Update Posted : February 27, 2018

Sponsor:
University of Massachusetts, Amherst

Collaborators:
National Institutes of Health (NIH)
National Heart, Lung, and Blood Institute (NHLBI)

Information provided by (Responsible Party):
Rebecca Spencer, University of Massachusetts, Amherst

Study Description

Go to Brief Summary:
This pseudo-randomized intervention study examined change in inhibitory control following a sleep manipulation in which children with and without ADHD were instructed to advance their bedtime by 90 minutes for five days.

Condition or disease

Attention Deficit Hyperactivity Disorder

Detailed Description:

Objective: To evaluate the efficacy of a sleep extension intervention in young children with ADHD and determine whether sleep extension improves inhibitory control, a primary deficit in ADHD.

Design: Children with and without ADHD completed two 5-day assessments: a baseline condition in which children followed their normal bedtime routine and a sleep extension condition in which children were instructed to go to bed 90 minutes earlier than their habitual bedtime. Sleep was assessed with actigraphy and, on the final night, polysomnography. A Go/No-Go task was used to assess inhibitory control.

Setting: Participants slept in their home on nights 1-4 and in the sleep laboratory on night 5 of each condition.

Main Outcomes and Measures: Of interest is actigraph measurement of total sleep time for the baseline compared to the sleep extension condition. Polysomnography will be used to compared changes in sleep physiology. The primary behavioral outcome is inhibitory control, indexed by accuracy on No-Go trials in the Go/No-Go task.

Study Design

Go to Study Type : Interventional (Clinical Trial)
Actual Enrollment: 27 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Intervention Model Description: Participants are assigned to the ADHD or Typically Developing group based on diagnosis history. Each then completes the intervention (EXTENSION) either preceded or followed by a week of baseline sleep (CONTROL). The order is pseudo-randomized.

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: Effects of Sleep Extension on Sleep Physiology and Behavior of Young Children

Actual Study Start Date: December 1, 2015

Primary Completion Date: August 1, 2017

Study Completion Date: August 1, 2017

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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</thead>
<tbody>
<tr>
<td>Experimental: EXTENSION</td>
<td>Behavioral: Sleep Extension Child attempted to go to bed 90 mins in advance of their normal bedtime.</td>
</tr>
<tr>
<td>During the extension condition, caregivers were instructed to put their child to bed 90 minutes earlier than their habitual bedtime for five consecutive nights. Caregivers were provided a list of tips to aid in implementing the earlier bedtime.</td>
<td></td>
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<tr>
<td>No Intervention: CONTROL</td>
<td>Children followed their normal bedtime routine for five consecutive nights.</td>
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Outcome Measures

Primary Outcome Measures:
1. total sleep time [Time Frame: 5 days (actigraph watch is worn for 5 days in each condition and overnight sleep time is identified and averaged across these 5 days)]
   average nightly across 5 nights

Secondary Outcome Measures:
1. inhibitory control [Time Frame: measured before and after sleep - about 12 hrs]
   measured with the Go/NoGo task
Eligibility Criteria

Information from the National Library of Medicine

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, Learn About Clinical Studies.

Ages Eligible for Study: 6 Years to 9 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
- A subset of children were required to have an ADHD diagnosis

Exclusion Criteria:
- diagnosis of intellectual disabilities or developmental delay
- current diagnosis of history of sleep disorder
- uncorrected hearing or visual impairments

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03446716

Locations

United States, Massachusetts

University of Massachusetts
Amherst, Massachusetts, United States, 01003

Sponsors and Collaborators

University of Massachusetts, Amherst
National Institutes of Health (NIH)
National Heart, Lung, and Blood Institute (NHLBI)

Investigators

Principal Investigator: Rebecca Spencer, PhD  University of Massachusetts, Amherst

Study Documents (Full-Text)

Documents provided by Rebecca Spencer, University of Massachusetts, Amherst:
Study Protocol and Statistical Analysis Plan  [PDF] February 20, 2018

More Information

Responsible Party: Rebecca Spencer, Associate Professor of Psychological and Brain Sciences, University of Massachusetts, Amherst