ADHD/Me Bibliotherapy Study

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. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03620344

Recruitment Status: Recruiting
First Posted: August 8, 2018
Last Update Posted: August 8, 2018
See Contacts and Locations

Sponsor:
Children's Hospital Medical Center, Cincinnati

Information provided by (Responsible Party):
Children's Hospital Medical Center, Cincinnati

Study Description

Go to Brief Summary:
Attention-deficit/hyperactivity disorder (ADHD) is one of the most common neurodevelopmental disorders of childhood. It affects approximately 8% of school aged children and is characterized by persistent symptoms of inattention and/or hyperactivity/impulsivity. Typical ADHD assessments primarily involve interviewing the parents and gathering rating scales from parents and teachers. Feedback regarding diagnosis, clinical conceptualization, and treatment recommendations is usually provided by the clinical staff to the child's parents in the absence of the child. Hence, the ADHD diagnosis and repercussions of that diagnosis are often left unexplained to the child. Research has shown that bibliotherapy is an effective educational tool that can be used to help parents discuss ADHD diagnosis and treatment with their child. The aim of this study is to conduct a randomized trial in which tools for parents who are getting their elementary-aged (7 to 10-year-old) children evaluated for ADHD are explored. The evaluations (N=60) will be conducted at the Center for ADHD at Cincinnati Children's Hospital Medical Center (CCHMC) in Cincinnati, OH. Half of the families (n=30) will be randomly assigned to the intervention group, where they will be provided with the child-focused "ADH-Me!" book during the feedback session, and the remaining half will not receive it. All participants will receive a booklet with general information about ADHD and a list of recommendations from the clinicians. Approximately 3 months after their feedback sessions, follow-up surveys will be conducted via telephone to question the parents and children about their ADHD knowledge, as well as about whether they had followed up on the clinicians' recommendations. It is hypothesized that providing families with the ADH-Me! book will increase families' knowledge about ADHD and facilitate the family following up on treatment recommendations.

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<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
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<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Other: ADH-Me Book and ADHD Informational Brochure</td>
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<td></td>
<td>Other: ADHD Informational Brochure Only</td>
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Study Design

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Study Type: Interventional (Clinical Trial)

Estimated Enrollment: 60 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Supportive Care

Official Title: The Effect of Bibliotherapy on Parent and Child Knowledge of ADHD and Treatment Follow-up

Estimated Study Start Date: August 13, 2018

Estimated Primary Completion Date: June 30, 2019

Estimated Study Completion Date: June 30, 2019

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Arms and Interventions

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<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Experimental: ADH-Me Book</td>
<td>Families in both conditions will be told that they are receiving additional reading materials to help them and their child better understand the ADHD condition and the available options for treating ADHD. Families in both groups will receive the &quot;Understanding ADHD: Information for Parents About ADHD&quot; brochure. Families assigned to this condition will also receive the ADH-Me! book. Written by a pediatrician and health literacy expert, ADH-Me! is an accessible, rhyming narrative that describes an empathetic journey from the perspective of a child learning to live and succeed with ADHD. The book is intended to help families know what to expect from diagnosis through all stages of treatment, while attempting to foster love and support.</td>
</tr>
<tr>
<td>Sham Comparator: No ADH-Me Book</td>
<td>Families in both conditions will be told that they are receiving additional reading materials to help them and their child better understand the ADHD condition and the available options for treating ADHD. Families in both groups will receive the &quot;Understanding ADHD: Information for Parents About ADHD&quot; brochure.</td>
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Outcome Measures

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Primary Outcome Measures:
1. ADHD Knowledge and Opinion Survey - Revised [Time Frame: 3 months after ADHD evaluation feedback session]

The knowledge portion of the AKOS-R, which consists of 15 true/false items, was modified by the research team for the 7 to 10-year-old children that will participate in this study. The overall readability of the survey was reduced from a 6th grade to a 4th grade level.

Secondary Outcome Measures:

1. Decision-Making Involvement Scale - Parent Report [Time Frame: 3 months after ADHD evaluation feedback session]

The DMIS is a 30-item measure completed by parents that was developed to assess the degree to which children and adolescents (ages 8 to 19 years) are involved in decisions having to do with their chronic illness management.

2. Decision-Making Involvement Scale - Youth Report [Time Frame: 3 months after ADHD evaluation feedback session]

The DMIS is a 30-item measure completed by children that was developed to assess the degree to which children and adolescents (ages 8 to 19 years) are involved in decisions having to do with their chronic illness management.

Eligibility Criteria

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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: 7 Years to 10 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- English speaking
- Meet ADHD criteria based on ADHD evaluation

Exclusion Criteria:

Contacts and Locations

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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): **NCT03620344**

**Contacts**

Contact: LaShonda Waters, Psy.M.  513-636-8387  lashonda.waters@cchmc.org

**Locations**

**United States, Ohio**

Center for ADHD, Cincinnati Children's Hospital Medical Center  
Contact: LaShonda Waters, Psy.M  513-636-8387  lashonda.waters@cchmc.org  
Principal Investigator: Jeffery N Epstein, Ph.D.

**Sponsors and Collaborators**

Children's Hospital Medical Center, Cincinnati

**More Information**

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Responsible Party: Children's Hospital Medical Center, Cincinnati

ClinicalTrials.gov Identifier: **NCT03620344**  
History of Changes

Other Study ID Numbers: 2017-4815

First Posted: August 8, 2018  
Key Record Dates

Last Update Posted: August 8, 2018

Last Verified: August 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Plan Description: No plan to share.

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity  
Attention Deficit and Disruptive Behavior Disorders  
Neurodevelopmental Disorders  
Mental Disorders