Improving ADHD Behavioral Care

Though the most effective treatment for children with Attention Deficit Hyperactivity Disorder (ADHD) consists of combined medication and behavioral strategies, the vast majority of children with ADHD are treated with medication only. One reason for the low rates of behavioral treatment is that primary care pediatricians, not mental health professionals, are responsible for treating the vast majority of children with ADHD. The investigators have developed, tested, and are beginning to disseminate web-based software (mehealth for ADHD) that has been shown in randomized clinical trials to improve the quality of ADHD medication care delivered by pediatricians. The goal of the proposed study is to develop and test the integration of behavioral tools into the evidence-based myADHDportal.com software in order to improve access to behavioral treatment strategies, and ultimately improve outcomes for children with ADHD. The automated algorithms and decision rules the investigators have developed for creating and monitoring the behavioral tools ensure that behavioral treatments like daily report cards and token economies are delivered in a manner that is consistent with the evidence-base. The investigators are conducting a cluster randomized controlled trial in community pediatric settings to test whether integration of the behavioral tools into the myADHDportal.com software (1) increases rates of behavioral treatment; (2) facilitates better integrity of behavioral interventions when implemented; (3) improves functional impairment in children with ADHD; and (4) generates higher satisfaction with ADHD care. By continuing to expand the functionality of the myADHDportal.com software, the investigators are increasing patients' access to evidence-based care. This is especially critical for rural and underserved communities who have no or limited access to evidence-based mental health services. Moreover, by putting these behavioral tools in the hands of parents, teachers, and pediatricians, the investigators are making it more likely that children will receive a high quality of care that includes both medication management and behavioral strategies, thereby improving the overall treatment outcomes of children with ADHD.
**Study Design**

**Study Type:** Interventional (Clinical Trial)

**Estimated Enrollment:** 150 participants

**Allocation:** Randomized

**Intervention Model:** Parallel Assignment

**Masking:** Single (Outcomes Assessor)

**Primary Purpose:** Treatment

**Official Title:** Improving ADHD Behavioral Care Quality in Community-Based Pediatric Settings

**Estimated Study Start Date:** August 21, 2018

**Estimated Primary Completion Date:** August 31, 2020

**Estimated Study Completion Date:** August 31, 2020

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Experimental: mehealth portal with integrated behavioral tools</td>
<td>Patients in this arm will continue to use the mehealth for ADHD web-based software for ADHD care but will also have access to a module that allows parents and teachers to develop and implement behavioral interventions such as daily report cards online.</td>
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<tr>
<td>Other: Behavioral tools integrated within mehealth for ADHD software</td>
<td>Integrated functionality within the mehealth for ADHD software allows parents and teachers to set up and deliver behavioral interventions such as daily report card systems and home-based program such as star charts. Automated wizards lead parents and teachers through the process of selecting target behaviors and setting up reward schedules. Baseline data is gathered online and algorithms derive a set of behavioral goals for the child. Thereafter, parents or teachers record the child's performance directly into the software. Once behavioral monitoring begins, parents and teachers receive daily email or text communications from mehealth for ADHD alerting them to the daily rewards earned by their child. Finally, online algorithms exist that detect how a child is doing in meeting behavioral goals and prompt users to modify goals accordingly.</td>
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<tr>
<td>Other: mehealth for ADHD</td>
<td>The mehealth for ADHD software has multiple functionalities including 1) online training regarding the American Academy of Pediatrics (AAP) ADHD guidelines; 2) an ADHD workflow wizard that guides pediatricians through the creation of an efficient office workflow to deliver quality ADHD care; 3) online collection of parent- and teacher-report ADHD rating scales for the assessment of ADHD as well as monitoring response to medication treatment; 4) integrated algorithms that automatically score rating scales in real time and provide pediatricians with assessment and treatment reports as well as immediate warnings; 5) a communication feature that allows parents, teachers, and pediatricians to communicate with each other; 6) an online pediatrician &quot;report card&quot;; and 7) a Plan-Do-Study-Act wizard</td>
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mehealth portal with no integrated behavioral tools
Patients in this arm will continue to use the mehealth for ADHD web-based software for ADHD care but will wait one year before getting access to the behavioral intervention features.

Other: mehealth for ADHD
The mehealth for ADHD software has multiple functionalities including 1) online training regarding the American Academy of Pediatrics (AAP) ADHD guidelines; 2) an ADHD workflow wizard that guides pediatricians through the creation of an efficient office workflow to deliver quality ADHD care; 3) online collection of parent- and teacher-report ADHD rating scales for the assessment of ADHD as well as monitoring response to medication treatment; 4) integrated algorithms that automatically score rating scales in real time and provide pediatricians with assessment and treatment reports as well as immediate warnings; 5) a communication feature that allows parents, teachers, and pediatricians to communicate with each other; 6) an online pediatrician "report card"; and 7) a Plan-Do-Study-Act wizard that allows pediatricians to select a practice behavior to improve based on their report card and guides them through the creation of small tests of change to improve their office systems.

### Outcome Measures

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**Primary Outcome Measures:**

1. Rates of behavioral treatment [Time Frame: 12 months after randomization]

   Parent-report of implementation of behavioral interventions on the Services Use in Children and Adolescents Parent Interview

**Secondary Outcome Measures:**

1. Quality of behavioral treatments [Time Frame: 12 months after randomization]

   Codings of the appropriateness of behavioral targets and rewards based on parent report of the behavioral interventions on the Services Use in Children and Adolescents Parent Interview

2. Children's impairment levels [Time Frame: 6 months after randomization]

   Parent- and teacher-ratings of school-related impairment items (range 0-6; higher scores indicate worse outcome) on the Impairment Rating Scale

3. Family satisfaction with ADHD treatment [Time Frame: 12 months after randomization]

   Parent ratings on the ADHD Knowledge and Opinions Scale (True/False scale; total score derived from total number of correct answers; range: 0-15)
Eligibility Criteria

Ages Eligible for Study: 5 Years to 12 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Inclusion Criteria:
• child in grades K-5
• child has been diagnosed with ADHD by pediatrician or other mental health professional
• child's ADHD care is currently being managed by pediatrician
• if child is being prescribed ADHD medication, is currently on a stable dosage of medication
• child is experiencing impairment at school as evidenced by a rating of 3 or higher on parent- or teacher-ratings of "academic progress" or "problems in classroom" and on the Impairment Rating Scale.

Exclusion Criteria:
• parent does not have access to a computer or smartphone

Contacts and Locations

Contacts
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Sponsors and Collaborators
Children's Hospital Medical Center, Cincinnati
Agency for Healthcare Research and Quality (AHRQ)

More Information

Responsible Party: Jeff Epstein, Professor, Children's Hospital Medical Center, Cincinnati
ClinicalTrials.gov Identifier: NCT03628781 History of Changes
Other Study ID Numbers: R18HS024690 ( U.S. AHRQ Grant/Contract )
First Posted: August 14, 2018 Key Record Dates
Last Update Posted: August 15, 2018
Last Verified: August 2018

Individual Participant Data (IPD) Sharing Statement:
   Plan to Share IPD: No

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

Keywords provided by Jeff Epstein, Children's Hospital Medical Center, Cincinnati:
Behavioral intervention