Purpose
The purpose of this study is to explore whether using an online patient portal plus a Care Manager is more effective than using an online portal alone in managing care for children with ADHD. Doctors at The Children's Hospital of Philadelphia currently use the online patient portal to help gather information from parents and teachers on ADHD symptoms, treatment, and medication side effects. The Care Manager is a person who meets with participants during the study to discuss their child's ADHD care. The Care Manager communicates with the child's doctor and teacher to communicate a parent's goals and preferences for their child's ADHD care.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention-Deficit/Hyperactivity Disorder</td>
<td>Behavioral: Care Manager Other: ADHD Portal</td>
<td>Phase 3</td>
</tr>
</tbody>
</table>

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment
Official Title: Communication to Improve Shared Decision-Making in Attention-Deficit/Hyperactivity Disorder

Resource links provided by NLM:
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Further study details as provided by Children's Hospital of Philadelphia:

Primary Outcome Measures:
- Change in Vanderbilt Parent Rating Scales (VPRS) [Time Frame: Baseline to 9 months]
  [Designated as safety issue: No]
The VPRS is a public domain tool that consists of forms completed by the child's parent and includes 18 items corresponding to the DSM-5 ADHD symptom criteria, 8 performance items, and 12 items assessing side effects. The VPRS items are scaled on a 4-point Likert rating ("never" to "very often"), and the scales used in this study will be restricted to the 18 ADHD symptom items and the 8 Performance Items, excluding further questions regarding medication. Scores will help measure ADHD Symptoms.

Secondary Outcome Measures:
- Change in Vanderbilt Teacher Rating Scales (VTRS) [Time Frame: Baseline to 9 months]
  [Designated as safety issue: No]
The VTRS is a public domain tool that consists of forms completed by the child's teacher and includes 18 items corresponding to the DSM-5 ADHD symptom criteria and 8 performance items. The VTRS items are scaled on a 4-point Likert rating ("never" to "very often"), and the scales used in this study will be restricted to the 18 ADHD symptom items and the 8 Performance Items. Scores will help measure ADHD Symptoms and be compared to parent's VPRS scores.

- Change in Goal Attainment Scale (GAS) [Time Frame: 3 months to 9 months]
  [Designated as safety issue: No]
The GAS is a 5-point Likert scale that assesses the degree to which parents' goals (obtained from the ADHD Preferences and Goals Instrument) are attained from none to completely.

- Treatment Initiation [Time Frame: Baseline]
  [Designated as safety issue: No]
Using responses from the Services Assessment for Children and Adolescents (SACA), we will determine (yes/no) whether participants were receiving educational, mental health, or medications for ADHD.

- Treatment Adherence [Time Frame: 3 Months to 9 months]
  [Designated as safety issue: No]
Using responses from the Services Assessment for Children and Adolescents (SACA), we will determine (yes/no) whether participants were receiving educational, mental health, or medications for ADHD during the study period.
• Changes in School Performance [ Time Frame: Baseline to 9 Months ] [ Designated as safety issue: No ]
School Performance is a 6-item Healthy Pathways measure of child- (age 8-12) and parent-reported school performance.

• Changes in Student Engagement [ Time Frame: Baseline to 9 Months ] [ Designated as safety issue: No ]
Student Engagement is a 6-item Healthy Pathways measure of child- (age 8-12) and parent-reported engagement in school over the past 4 weeks.

• Changes in Teacher Connectedness [ Time Frame: Baseline to 9 Months ] [ Designated as safety issue: No ]
Teacher Connectedness is a 7-item Healthy Pathways measure of child- (age 8-12) reported connectedness with teachers over the past 4 weeks.

• Changes in Peer Relationships [ Time Frame: Baseline to 9 Months ] [ Designated as safety issue: No ]
Peer Relationships is a 7-8-item PROMIS measure of child- (age 8-12) and parent-reported relationships with peers over the past 7 days.

• Changes in Family Relationships [ Time Frame: Baseline to 9 Months ] [ Designated as safety issue: No ]
Family Relationships is a 9-item PROMIS measure of child- (age 8-12) reported relationships with other family members over the past 4 weeks.

Other Outcome Measures:

• Proportion with Disclosure of Private Health Information [ Time Frame: 3 Months to 9 Months ]
[ Designated as safety issue: Yes ]
The proportion of study participants who report disclosures of their private health information to individuals outside of the research team.

Estimated Enrollment: 300

Study Start Date: March 2016

Estimated Study Completion Date: October 2018

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

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: ADHD Portal</td>
<td>Other: ADHD Portal</td>
</tr>
<tr>
<td>In this arm, the ADHD Portal will be</td>
<td>The ADHD portal is a web-based platform that permits access to parts of the</td>
</tr>
<tr>
<td>used alone as an electronic</td>
<td>hospital's electronic health record. The portal permits (1) capture and sharing of</td>
</tr>
<tr>
<td>communication tool. The ADHD portal is</td>
<td>patient data.</td>
</tr>
<tr>
<td>considered standard of care at our</td>
<td></td>
</tr>
<tr>
<td>institution for</td>
<td></td>
</tr>
</tbody>
</table>
Communicating information between clinicians, teachers, and parents.

And family treatment preferences and goals, (2) monitoring of ADHD symptoms, treatment receipt, and side effects, and (3) assessing goal attainment. The system prompts for completion of periodic check-in surveys (bi-weekly to 3 months) with parents and teachers. Within the portal, preferences and goals for ADHD treatment are measured using the ADHD Preference Goal Instrument (PGI) (Fiks et al., 2012). Parents are encouraged to consult with their children when completing the tool.

Experimental: ADHD Portal plus Care Manager

In this arm, the ADHD Portal will be combined with the Care Manager. Clinicians, teachers, and parents will use the ADHD Portal as in the ADHD Portal arm. In addition, clinicians, teachers, parents, and any external mental health providers will interact with a Care Manager, who will have access to information contained in the ADHD Portal.

Behavioral: Care Manager

The CM is an individual responsible for communicating and coordinating ADHD care. The CM establishes rapport with families and communicates with them weekly to every 3 months to assess treatment use, identify new concerns, and help problem-solve. The CM also communicates with the patient's ADHD care team (pediatrician, teacher, mental health providers) to clarify family goals, communicate information, and coordinate treatment.

Other: ADHD Portal

The ADHD portal is a web-based platform that permits access to parts of the hospital's electronic health record. The portal permits (1) capture and sharing of patient and family treatment preferences and goals, (2) monitoring of ADHD symptoms, treatment receipt, and side effects, and (3) assessing goal attainment. The system prompts for completion of periodic check-in surveys (bi-weekly to 3 months) with parents and teachers. Within the portal, preferences and goals for ADHD treatment are measured using the ADHD Preference Goal Instrument (PGI) (Fiks et al., 2012). Parents are encouraged to consult with their children when completing the tool.

**Detailed Description:**

Fragmentation in health care and poor communication across systems adversely impact engagement and adherence to treatment by children with ADHD and their families. Fragmentation of services for ADHD impairs communication and collaboration between families and primary care providers, mental health providers, and educators, and leads to suboptimal outcomes for children. Prior studies have documented that little communication and coordination exist among providers across different systems despite calls for better system integration.

Fragmentation in communication between providers has the potential to impair shared decision-making. To promote shared decision-making, we have developed an electronic health record (EHR)-linked portal to collect
information from parents, teachers and clinicians on children's ADHD symptoms and treatment-related preferences and goals. We have also developed an ADHD Care Manager intervention manual.

Approximately 300 participants will be enrolled for this study. Participants will be randomly assigned to use either the EHR portal alone, or the EHR portal plus a Care Manager. For those assigned to the EHR portal plus Care Manager, the Care Manager will meet with families at the beginning of the study to confirm their treatment preferences and goals, provide additional education on ADHD treatment, and distribute handouts on common concerns among ADHD patients and families. The Care Manager will contact families weekly to every 3 months by phone, email, or in-person as needed to assess treatment use, identify new concerns, and assist families with problem-solving. Using the portal or other means, the Care Manager will also communicate with pediatric clinicians, mental health providers, and teachers to clarify family treatment preferences and goals and address emerging treatment issues. Participants will complete surveys that will assess ADHD symptoms, goal attainment, patient-reported outcomes, patient and family engagement and treatment initiation and adherence.

Eligibility

Ages Eligible for Study: 5 Years to 12 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

• Aged 5 through 12 years old
• Receiving Attention-Deficit/Hyperactivity Disorder (ADHD) treatment from participating practices
• ADHD or Attention Deficit Disorder (ADD) diagnosis code, International Classification of Diseases (ICD) code ICD-10-CM F90.9 or F90.0, listed in the problem list or recorded at an ambulatory visit in the past year.
• Parental/guardian permission (informed consent) and if appropriate, child assent.

Exclusion Criteria:

• Autism spectrum disorder, ICD-10-CM F84.0
• Conduct disorder, ICD-10-CM F91.1
• Psychosis, ICD-10-CM F29
• Bipolar disorder, ICD-10-CM F31.9
• Suicide attempt, ICD-10-CM T14.91, or suicide ideation, ICD-10-CM R45.85
• Children and/or their parents/caregivers are non-English speaking

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: NCT02716324

Contacts

Contact: James P Guevara, MD MPH 2155901130 guevara@email.chop.edu
Contact: Maritza Pedlar, MPH 2155902993 pedlarm@email.chop.edu
Locations

United States, Pennsylvania

The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania, United States, 19104

Sponsors and Collaborators

Children's Hospital of Philadelphia
Patient-Centered Outcomes Research Institute

Investigators

Principal Investigator: James Guevara, MD MPH  Children's Hospital of Philadelphia

More Information

Publications:

Responsible Party: Children's Hospital of Philadelphia

ClinicalTrials.gov Identifier: NCT02716324  History of Changes

Other Study ID Numbers: IRB 15-012456

Study First Received: March 10, 2016

Last Updated: March 17, 2016

Health Authority: United States: Institutional Review Board

Keywords provided by Children's Hospital of Philadelphia:
Attention-Deficit/Hyperactivity Disorder  Children
Shared-Decision Making  Parents
Care Manager  Teachers

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Mental Disorders Diagnosed in Childhood
Hyperkinesis  Nervous System Diseases