1. Title Page (Title, Principal Investigator and Team Members, Organization, Inclusive Dates of the Project, Federal Project Officer, Acknowledgment of Agency Support, and Grant Number)

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

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2. Structured Abstract (200-words maximum). Include five headings: Purpose, Scope, Methods, Results, and Key Words

Purpose: 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 and do not receive behavioral intervention.
Scope: The goal of the proposed study is to develop and test the integration of behavioral tools into the evidence-based mehealth.com software in order to improve access to behavioral treatment strategies, and ultimately improve outcomes for children with ADHD.
Methods: Using an iterative stakeholder-centered design approach, we developed the behavioral reward software. We assessed the acceptability and usability of this software through usability studies. Finally, we recruited 169 elementary school children with ADHD to participate in a randomized controlled trial to examine whether our intervention delivery impacts access to and integrity of behavioral treatments as well as its impact on patient outcomes.
Results: A prototype was developed and pilot tested using usability studies. The results of the randomized controlled trial suggest that use of this software did not lead to intervention-related improvements in children's functional impairment – other than one analyses that suggested that the intervention led to improvement in academic impairment.

Key Words: ADHD, behavioral treatment, ehealth

3. Purpose (Objectives of the study)

Though evidence-based guidelines recommend treating children with Attention Deficit Hyperactivity Disorder (ADHD) with a combination of pharmacological and behavioral strategies (American Academy of Pediatrics, 2011; American Academy of Child and Adolescent Psychiatry, 2007), the vast majority of children with ADHD (~90%) are treated with medication only (Epstein et al., 2014; Gellad et al., 2014). While medication results in significant reductions in ADHD symptoms, clinically significant ADHD-related functional impairments (e.g., academics) typically persist (Epstein et al., 2010; O'Connor, Garner, Peugh, Simon, & Epstein, 2015). The application of evidence-based behavioral interventions, either with or without concurrent pharmacological treatments, is an effective strategy for targeting specific domains of ADHD-related functional impairment such as noncompliance, social functioning, homework completion and materials organization skills (Chronis, Jones, & Raggi, 2006; DuPaul, Eckert, & Vilardo, 2012; Evans, Owens, & Bunford, 2013; Pfiffner, Villodas, Kaiser, Rooney, & McBurnett, 2013; Storer, Evans, & Langberg, 2014) (see Fabiano et al. (2009) for a meta-analytic review).

The factors that contribute to low rates of evidence-based *behavioral* treatment are complex and multifactorial. However, a significant contributing factor is that the majority of children with ADHD receive their ADHD care from pediatricians, not behavioral healthcare providers (Bernal, 2003; Zito et al., 1999). Primary care pediatricians generally do not have the resources to deliver behavioral treatments to their patients with ADHD (Horwitz et al., 2007) and report difficulties locating local referral sources for such services (Cunningham, 2009). Moreover, even for the minority of families who report using behavioral treatments, the integrity of these treatments is often poor (i.e., inappropriate behavioral targets) (Corkum, Bessey, McGonnell, & Dorbeck, 2015; Wright et al., 2015) and accordingly, children do not benefit (Fabiano & Pelham, 2003; Fabiano et al., 2010; MacKenzie, Fite, & Bates, 2004; Murray, Rabiner, Schulte, & Newitt, 2008; Noell, Gresham, & Gansle, 2002; Owens, Murphy, Richerson, Girio, & Himawan, 2008; Power et al., 2009; Vannest, Davis, Davis, Mason, & Burke, 2010; Vujonovic, Fabiano, Pariseau, & Naylor, 2013).

Using NIH-funding, we have developed, tested, and have begun to disseminate web-based software (www.mehealth.com) that assists pediatricians in providing evidence-based ADHD medication management by allowing parents, teachers, and pediatricians to regularly report on child symptoms, impairments, and side effects in order to enable optimization of medication for each child (Epstein, Langberg, Lichtenstein, Kolb, & Simon, 2013). Two randomized clinical trials of this software demonstrate that using this software significantly improves the quality of ADHD care delivered by community-based pediatricians (Epstein et al., 2011). Moreover, a recently concluded trial found that children with ADHD treated by pediatricians using this software had significantly more ADHD symptom reduction than children treated with usual care (Epstein et al., 2016). Dissemination of the mehealth.com software is already underway, with 861 pediatricians nationwide using the mehealth.com software to support their delivery of ADHD care to over 15,000 patients with ADHD. However, the current software functionality is limited entirely to medication management. Parents and teachers who use the mehealth.com software to complete behavioral ratings have repeatedly requested the integration of additional content to assist them in helping their child/student with ADHD. There is a clear need to expand the mehealth.com software to enable parents and teachers of children with ADHD to implement evidence-based behavioral strategies.

Consistent with AHRQ priority areas, this project will “discover, test, and spread a technique for health care practice improvement to improve health care quality, including accelerating the sustainable implementation of evidence-based practice.” Specifically, the primary goal of the proposed project is to develop and test the integration of behavioral tools into the evidence-based mehealth.com software in order to improve the access to and the integrity of evidence-based behavioral treatment strategies for children with ADHD. To accomplish this objective, we

propose the following specific aims:

1) Design, build, and integrate behavioral tools into the mehealth.com software using an iterative stakeholder-centered design approach whereby feedback will be obtained from all stakeholders (i.e., parents, teacher, and pediatricians) before, during, and after development of these tools;
2) Assess the acceptability of the integrated behavioral tools through qualitative methods (e.g., usability testing, focus groups);
3) Conduct a cluster-randomized controlled trial in community pediatric settings to test whether integration of the behavioral tools into the mehealth.com software:
    a) increases access to and rates of behavioral treatment;
    b) facilitates better integrity of behavioral interventions when implemented;
    c) improves functional impairment in children with ADHD; and
    d) generates higher satisfaction with ADHD care.

The mehealth.com software provides a unique opportunity to effectively disseminate evidence-based behavioral strategies to children being treated in pediatric settings – the vast majority of children with ADHD.

4. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Statement of the problem

The Center for Disease Control and Prevention's (CDC's) national survey on ADHD diagnosis and treatment patterns in the United States documented that 11% (6.4 million children) of children ages 4 – 17 years had been diagnosed with ADHD at some point in their lives, with 8.8% of all children currently diagnosed with ADHD (Visser et al., 2014). Children with ADHD experience significant impairments across multiple domains of functioning, including educational, interpersonal, and family functioning (DuPaul & Stoner, 2014; Efron et al., 2014; Wehmeier, Schacht, & Barkley, 2010; Wymbs et al., 2008). Fortunately, evidence-based treatments for children with ADHD exist(Evans, Owens, Mautone, DuPaul, & Power, 2014). Pharmacological treatment is by far the most commonly used treatment for ADHD(Visser et al., 2015; Visser et al., 2014). Pharmacological treatments clearly produce marked improvement in ADHD symptoms (e.g., improved attention, reduced hyperactivity)(Pliszka, 2007). However, ADHD symptom improvements do not translate into overall improvements in functional impairment (Currie, Stabile, & Jones, 2014; Epstein et al., 2010; O'Connor et al., 2015).

The other treatment strategy included in evidence-based treatment guidelines is behavioral treatment. Behavioral treatments for ADHD specifically target areas of functional impairment such as noncompliance, social functioning, homework completion and organization skills (Chronis et al., 2006; DuPaul et al., 2012; Evans et al., 2013; Pfiffner et al., 2013; Storer et al., 2014) and have been shown to be quite effective (i.e., effect sizes on functional impairment approach 0.61 [Cohen's d] (Vannest et al., 2010); see Fabiano et al.(2009) for a meta-analytic review). Given that pharmacological treatment primarily improves ADHD symptoms and behavioral treatments improve impairments, it is perhaps not surprising that combining these two treatment modalities is the most effective treatment option and is universally recommended (Chronis et al., 2006; Daly et al., 2007; Education, 2004; American Academy of Pediatrics, 2011; American Academy of Child and Adolescent Psychiatry, 2007). Combined treatment results in larger improvements than either modality alone (Conners et al., 2001). Further, it has been documented that when children are receiving behavioral treatment, lower doses of medication can be used (Fabiano et al., 2007; Pelham et al., 2014; Vitiello et al., 2001). Also, parents and teachers view behavioral treatments as highly acceptable (Corkum et al., 2015; Gage & Wilson, 2000; Liu, Robin, Brenner, & Eastman, 1991; Monastra, 2005; Power, Hess, & Bennett, 1995; Wilson & Jennings, 1996). Despite the acceptability and efficacy of behavioral treatments, either alone or in combination with medication, less than 25% of children with ADHD receive behavioral treatments (Epstein et al., 2014; Gellad et al., 2014). Hence, most children with ADHD are not receiving a critical modality of ADHD treatment - behavioral treatment - and thus remain functionally impaired.

Why don't children with ADHD receive evidence-based behavioral treatments?

Despite being regarded as a mental health disorder, the majority of children with ADHD are evaluated and treated by primary care physicians - generally pediatricians - rather than by mental health specialists (Bernal, 2003; Zito et al., 1999). Most pediatricians accept the evaluation and treatment of children with ADHD as being a core job responsibility(Stein et al., 2008). However, pediatricians are inclined to provide medication to children with ADHD but very rarely provide, facilitate, or refer children/families for behavioral treatments (Epstein et al., 2014; Gellad et al., 2014).

Fortunately, the reasons that the vast majority of children with ADHD treated by community-based pediatricians do not receive behavioral treatments are fairly well understood. First, pediatricians consistently report that they do not have the time or knowledge to deliver behavioral treatments to their patients with ADHD (Horwitz et al., 2007). Second, most communities lack access to effective and affordable behavioral treatment. For example, only

33% of pediatricians believe that behavioral treatments are readily accessible in their communities (Rushton, Fant, & Clark, 2004). This belief is supported by recent data from the Health Resources and Services Administration which concluded that more than four-fifths of US counties do not have enough mental health professionals to accommodate the need for mental health services (Services, 2012). Further, pediatricians are concerned that if they refer families, the behavioral treatments available will be low quality, unaffordable (Fiks, Hughes, Gafen, Guevara, & Barg, 2011) and will require long wait times (Horwitz et al., 2007). Third, parents of children with ADHD share these concerns, with 53% of parents reporting system barriers (e.g., insurance reimbursement) to receiving ADHD behavioral treatment (Bussing, Zima, Gary, & Garvan, 2003; Owens et al., 2002).

How can the accessibility and integrity of behavioral treatments be addressed?

It is clear innovative methods are needed to 1) *increase the accessibility* of behavioral treatments to children with ADHD as well as to 2) *improve the integrity* of treatment delivery of behavioral treatments. Realizing that pediatricians are likely to remain the primary mental health providers, many have argued that the best approach to improving mental health outcomes is to support primary care physicians in their delivery of mental health services (Geller & Muus, 1997; Geller, 1999). One promising method for providing this support is through the use of technology. In fact, the US government has promoted the use of technology to address health care disparities through both American Recovery and Reinvestment Act funding initiatives and mandates within the recent Patient Protection and Affordable Care Act which specifically proposes the meaningful use of technology to improve health care for all citizens (Public Law 111-148; March 23, 2010).

In response to these governmental mandates, technologically-based and telehealth interventions have increased rapidly across the US (Institute of Medicine, 2012). While many of these online interventions offer some form of professional support, many are self-guided and involve merely interaction with a web-based interface. Though early technological intervention research demonstrated the advantage of supported types vs. self-guided web-based interventions (Richards & Richardson, 2012), several recent studies using more interactive interfaces have demonstrated that self-guided technological-interfaces are as effective as supported technological interventions (Berger, Hammerli, Gubser, Andersson, & Caspar, 2011; Dear et al., 2015; Furmark et al., 2009; Leykin, Muñoz, Contreras, & Latham, 2014). Moreover, some of these web-based self-guided interventions produce similar treatment effect sizes to clinician-delivered interventions (Carlbring, Westling, Ljungstrand, Ekselius, & Andersson, 2001; Proudfoot et al., 2004), and have similar levels of satisfaction as traditional face-to-face interventions (Spence, Holmes, March, & Lipp, 2006). To date, effective self-guided web-based cognitive-behavioral interventions have been developed and demonstrated to be efficacious for several disorders, which similar to ADHD have established evidence-based treatments. These include interventions for social phobia (Berger, Caspar, et al., 2011), OCD (Wootton, Dear, Johnston, Terides, & Titov, 2014), depression (Berger, Hammerli, et al., 2011) and insomnia (Lancee, van den Bout, van Straten, & Spoormaker, 2013).

The development of behavioral interventions for children with ADHD (e.g., daily report cards, token economies) which involve the development and refinement of appropriate behavioral goals, defining the monitoring schedule, monitoring performance, and deriving effective rewards can all be facilitated through web-based algorithms and interfaces. Specifically, we propose to develop web-based software that allows multiple users (e.g., parents, teachers) to work collaboratively to develop behavioral goals, monitoring schedules, and reward plans. Program routines, called wizards, will guide parents and teachers though a series of customized steps to develop and implement behavioral treatments for home and/or school. A software wizard or setup assistant is a type of user interface that presents a sequence of dialog boxes that lead the user through a series of steps towards goal completion. Wizards

can prompt parents and teachers to identify and prioritize behavioral targets, aid in the collection of baseline data on behavioral targets, and assist with the creation of rewards and reward schedules. Moreover, a web-based platform allows for online data capture and graphing of children's performance, providing a simple way for parents to track progress towards behavioral performance goals. Also, the wizard will be programmed to ensure that behavioral targets, monitoring schedules, and rewards are realistic and evidence-based. Further, the wizard can provide suggestions for improving the integrity of the intervention (e.g., frequency of monitoring, saliency of reward, level needed for goal attainment), when adequate progress is not being made. A major advantage of such online behavioral tools is that they remove the need for a pediatrician to implement the behavioral treatments and do not require referral to a mental health professional when access is limited due to cost, transportation issues, scheduling difficulties, or a shortage of mental health providers.

Clinical significance of this project

Medications alone do not normalize behavior in terms of functional impairment (Epstein et al., 2010). Even after effective treatment with medication, children with ADHD continue to struggle academically and have difficulty getting along with peers, siblings, parents, and relatives. In fact, of the more than 15,000 children currently registered on the mehealth.com software and receiving medication, 83% continue to have at least one domain of clinically significant impairment based on parent- and teacher-ratings. Remediating these functional impairments is imperative, especially since functional impairment is the primary reason that families present for treatment (Becker, Chorpita, & Daleiden, 2011; Gordon et al., 2006).Moreover, integrating behavioral tools into the mehealth.com software directly addresses multiple reasons for the low rates and poor implementation of behavioral treatments in community-based settings. By targeting these mechanisms, we will ultimately improve child outcomes by facilitating the widespread dissemination of behavioral treatments that directly target functional impairments in children with ADHD.

5. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Our objective was to develop and test the integration of behavioral tools into the evidence-based mehealth.com software in order to improve access to behavioral treatment strategies, ensure the integrity of these treatments, and ultimately improve outcomes for children with ADHD. Towards this objective, we first designed, built, and integrated behavioral tools into the mehealth.com software and then assessed the acceptability of this software through qualitative methods (e.g., usability testing, focus groups). We engaged a team of parent, teacher, and pediatrician stakeholders who collaborated with us on the design, content, and usability of the behavioral tools. Once the tools were finalized, we recruit 169 patients to participate in a randomized controlled trial to examine whether our intervention delivery impacts access to and integrity of behavioral treatments as well as its impact on patient outcomes. We collected information about ADHD care, patient outcomes (i.e., functional impairment), and consumer satisfaction with ADHD care at baseline, 6-months, and 12-months using phone interviews. Hierarchical mixed models compared rates of behavioral treatments, patient outcomes, and consumer satisfaction across the intervention and control groups.

Stakeholder Panel

Five pediatricians volunteered to be involved in intervention development activities. These pediatricians currently use the mehealth.com software to organize their delivery of ADHD care. These pediatricians were selected because they serve a diverse range of patients both in terms of setting (e.g., urban, rural, suburban) and the percent of Medicaid patients they serve. The pediatricians helped us recruit 5 families to serve as stakeholders. Those five families helped us recruit 5 teachers that served as stakeholders.

Prototype Development

We developed our behavioral tools using an iterative stakeholder-centered design approach. The iterative patient-centered design consisted of two phases: development and usability. We gathered our stakeholders via in-person meeting or phone conferences on a monthly basis. We (1) briefly discussed the behavioral tools and/or examine prototypes; (2) encouraged an unstructured discussion about the intervention materials; and (3) lead a group discussion centering around pre-determined questions about the intervention (e.g., Do you use reward systems with your children?, If yes, what types of rewards do you use?). At the outset, stakeholders were asked about features they would like to see in the behavioral tools. The research team and software programmers worked on prototyping features (e.g., selection of target behaviors, collection of baseline data) and the interface (e.g., drop down of potential target behaviors, online wizard of rewards). Stakeholders then interacted with the tools and provided feedback. We elicited and incorporated the perspectives of our stakeholders to iteratively refine the software until a functional prototype was ready for evaluation.

Usability Studies

We then conducted usability testing with the prototype. We collaborated with our stakeholders to determine what questions need to be addressed during usability testing. We then recruited an additional 5 families and 5 teachers. We enrolled these families and teachers to participate in usability studies to better understand the human factors of the behavioral tool software. Selected families and teachers first tested the software. Importantly, children with ADHD were included in these visits as their input will be important for the development of specific tools including the reward system. Research team members directly observed and audio-recorded as patient families and teachers interacted with the prototype while “thinking aloud.” This method, which is a type of cognitive interview, can uncover unanticipated problems with the user interface as well as potential solutions (Van den Haak & Schellens, 2004).

Information obtained through this methodology was shared with the stakeholders who reviewed user feedback and informed the revision of the software.

Following revisions to the wizard, we recruited an additional 10 families and their teachers to participate in the usability study where they interacted with the mehealth.com software at home and school for a 3 week period (including a one week baseline period). We periodically contacted families and teachers via phone during their use of the prototype if it looked like they are having difficulty using the prototype. Following 3 weeks of use of the prototype, we asked users open-ended questions about the usability, acceptability, and perceived usefulness of the software and intervention. When evaluating an intervention that is intended for widespread adoption, it is essential to determine not only whether the intervention works, but also if it is perceived as 1) feasible to implement and 2) of acceptable quality.

Randomized Controlled Trial

We recruited participants from two sources. The first source was pediatric offices where we worked with 9 physicians and their practice staff to recruit patients with ADHD. The second source was patients seen at our Center for ADHD at Cincinnati Children's Hospital Medical Center. All children had to be 1) in grades K-6; 2) diagnosed with ADHD; 3) if currently being prescribed ADHD medication, ensuring they have been on a stable medication/dosage for 1 month; and 4) still experiencing ADHD-related impairment at school as evidenced by a score of 3 or higher on any item related to academics or school on the parent or teacher Impairment Rating Scale.

Our goal was to recruit 150 patients with ADHD. We exceeded that goal and recruited 169 patients for the study. To do so, we approached 297 families across our recruitment sources. 56 of these did not meet our inclusion criteria. An additional 45 were unresponsive to our attempts to contact them. 196 consented to participate. Of those 196, 27 did not complete the baseline survey which was necessary for randomization. As a result, 169 families were randomized to either the intervention or control group.

Baseline teacher surveys were collected on 151 of those 169 families. Families were randomly assigned to either receive 1) immediate access to the integrated behavioral tools on the mehealth for ADHD portal (see description in Results), or 2) wait-list control group whereby they will receive access to the integrated behavioral tools on the mehealth for ADHD portal after 1 year.

At 6-, and 12-months post-baseline, research assistant contacted parents and teachers and administered measures related to behavioral tool implementation, patient outcomes (i.e., functional impairment), and consumer satisfaction. These surveys were administered using online surveys (REDCap) but research assistants also administered these surveys by phone if parents were not responsive to online administration or indicate that they prefer phone administration. The following measures were collected at baseline, 6-month, and 12-month timepoints:

Rates of behavioral treatment: We will conduct a service utilization interview (Services Use in Children and Adolescents-Parent Interview; SCA-PI (Jensen et al., 2004)) at baseline, 6- and 12 months. This 20-minute phone interview will be administered to parents at baseline to capture children's ADHD service use across mental health, primary care, school, and community settings. The SCA-PI is a reliable instrument for assessing mental health and related services use (Hoagwood et al., 2004). Data from the baseline SCA-PI will be used to determine if behavioral treatments were implemented and whether mental health professionals were involved in setting up and monitoring its use. Moreover, we will ask parents to complete questions on the Services Assessment for Children and Adolescents-Parent Report (Horwitz et al., 2014) related to parents' perception of need for services and barriers to receipt of services at each assessment point. At post-baseline assessment points for children treated by

intervention providers, we additionally will be able to query the mehealth.com database to determine whether the family used the behavioral tools.

Children's functional impairment: While we do not expect to observe large behavioral treatment-related effects on ADHD symptoms based on previous research demonstrating smaller effects of behavioral treatment on ADHD symptom outcomes (Sibley, Kuriyan, Evans, Waxmonsky, & Smith, 2014), we do hypothesize moderate changes in functional impairment among patients being treated by pediatricians in the intervention group. Hence, functional impairments are our primary child outcome measure. The Impairment Rating Scale (IRS; Fabiano et al., 2006)) was selected in order to provide a standardized measure of ADHD-related functional impairment. The IRS consists of 4 items included on both the parent- and teacher-report versions, including peer relations, academic progress, self-esteem items as well as an overall severity/impairment rating. The parent-report version also has items assessing sibling relations, parent–child relations, and impact of the child's behavior on the family, whereas the teacher-report version has items assessing teacher-child relations and classroom functioning. Items are rated on a scale ranging from 0 (no impairment) to 6 (extreme impairment). The IRS demonstrates excellent temporal stability and evidence of convergent and discriminant validity (Fabiano et al., 2006) and is sensitive to treatment effects (Evans, Langberg, Raggi, Allen, & Buvinger, 2005; Evans, Serpell, Schultz, & Pastor, 2007). Parents and teachers will complete their respective versions of this scale over the phone at baseline, and 6-and 12-months post-baseline.

Demographics: We will ask parents to report on race/ethnicity, socioeconomic status, and level of education.

Parental motivation: The Parent Motivation Inventory (Nock & Photos, 2006) is a 25 item scale that assesses parent motivation for treatment. The measure has good psychometric properties and has been shown to predict treatment adherence (Nock & Photos, 2006).

Treatment acceptability: Parents will complete the ADHD Knowledge and Opinions Scale (Bennett, Power, Rostain, & Carr, 1996) that queries parents about their acceptability, feasibility, and perceived competence of implementing psychosocial treatment. Items are summed in each of these domains to provide estimates of these constructs (Bennett et al., 1996).

In summary, of those 169 families, 141 (83.4%) parents completed surveys at the 6-month data collection point and 126 parents (74.6%) completed surveys at the 12-month data collection point. We collected teacher data at baseline, end-of-the school year, 6-month, and 12-month time points. We were able to collect at least 1 post-baseline survey for 123 (72.8%) participants. Moreover, we were able to collect multiple (2-3) post-baseline surveys from 118 (69.8%) participants.

Post-RCT Follow-up Interviews

In response to some of the qualitative feedback we have received from parents and teachers on the 6- and 12-month consumer satisfaction surveys, we conducted more extensive interviews with parents and teachers who expressed difficulty with using the software. We used those parents/teachers and reviewed their experience with the software to identify shortcomings and brainstormed strategies for improving the software. We then incorporated some of the strategies by modifying the software accordingly.

6. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Prototype Development

We initially met with our stakeholders individually and interviewed them about what they would like to see in behavioral tools. Monthly focus groups were held with the parents and teachers. These focus groups with parents and teachers initially talked about project goals, reviewed their roles as stakeholders, and began to query them about what they'd like to see in behavioral tools. In monthly meetings, the stakeholders guided us in the development of the software functionality. For the sake of demonstration, we will describe one piece of the software development and the stakeholder involvement. Because the selection of target behaviors and rewards for meeting behavioral targets are central to the creation of any behavioral program, one of our first goals was to figure out how parents and teachers might select target behaviors and rewards. In collaboration with research team and using a variety of behavioral how-to guides, we identified a comprehensive list of potential home-based and school-based target behaviors and a list of potential home-based and school-based rewards that might be used as part of the behavioral tools. Each list had approximately 30-40 behaviors/rewards. Our parent and teacher stakeholders were quick to point out that an interface that just provided a long list of behaviors and/or rewards would be overwhelming to end-users. Because there is no existing taxonomy for target behaviors or rewards, we chose to use our stakeholders to help us create such a taxonomy. In our monthly focus groups with parents and teachers, we asked parent and teacher stakeholders to do the following: 1) Amend our lists of target behaviors and rewards with any missing target behaviors and rewards that they have used in their own experience; 2) Perform a card sort task using OptimalSort web-based software by placing the behaviors and rewards into categories; and 3) Label the different card sort categories that they identified so we could learn how parents and teacher referred to these clusters of behaviors and rewards. The research team than used analytics from the OptimalSort web-based software to derive a taxonomy for home- and school-based target behaviors and rewards. During subsequent focus groups with parents and teachers, we had them explore the taxonomies using interactive PowerPoint software. The taxonomies were revised both in terms of content and labeling based on stakeholder feedback. We now have a set of four taxonomies (home-based behaviors, home-based rewards, school-based behaviors, school-based rewards) on which to build an interface that can be used by end-users to select behaviors and rewards for the target child.

As a result, a prototype was developed. In brief, a video describing the benefits of DRCs resides on the child's homepage. Pediatricians can click a link to recommend the use of the DRC to a family. Alternatively, parents or teacher can initiate the DRC tool for their child/student. After accepting use of the DRC tool, the child's teacher is prompted to identify the child's behaviors they would like to target with the DRC. An automated wizard will lead the teacher through a series of steps to identify a list of problem behaviors, narrow the list to 1-3 behavioral targets, identify a schedule for tracking each behavioral target, and invite other teachers to track behaviors. Teachers then track the frequency of those behaviors over the course of a single week to establish a baseline frequency for each behavior. After one week of baseline data collection, computerized algorithms derive behavioral goals that are specific, measurable, attainable, relevant, and time-limited. Once behavioral goals are derived, a behavioral grid is generated that includes the monitoring intervals suggested by teachers and behavioral monitoring begins. Teachers can record the child's performance directly into the online system, or they can opt to receive texts at the end of each interval and enter whether the child met the behavioral goal via SMS or they can print out the behavioral grid, record on the printed version, and enter the data online at a convenient time later. Before monitoring begins, the automated wizard prompts the family (and teacher) to develop a daily reward system for the child. An effective daily reward system includes multiple reward levels. An online wizard guides

users through reward selection and modifying selected rewards for a 3-level reward system (e.g., green level = 1 hour of video games; yellow level = ½ hour of video games; red level = no video games). 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. If a behavioral goal is being consistently met or consistently not being met, the teacher is prompted to modify the goal accordingly.

Usability Studies

For Phase I of usability testing, we had parent-child dyads and teachers who had not been involved in prototype development interact with the prototypes. We used a "think aloud" approach whereby participants spoke aloud as they interacted with the prototype thereby providing us with feedback regarding whether they understood what they were being asked to do on each web page. We conducted the usability studies in an iterative fashion. Each round, we invited 2 parent-child dyads and 2 teachers to interact with the prototype. Each session was conducted separately in order that we could obtain the maximum amount of information from each participant. These sessions were recorded and relevant feedback was abstracted from each session. After each round, we summarized all of the participants' feedback, met with the research team and the programmer to resolve issues that arose during the usability sessions, and modified the prototype accordingly. Solutions have ranged from modifying the instructions to changing the functionality of the interface. We conducted three rounds of usability studies for the first phase. For each subsequent round, there were significantly less issues raised by participants. However, we did have to make more modifications to the prototype than we expected. In particular, we had to cycle through a variety of instructional text and instructional videos for the prototypes in order to decide what instructional method was most likely to be understood by users. After the initial round of usability studies, we were under the impression that more instructional text and more videos were necessary to ensure that users fully understood what their task was on each page. However, during the next round of usability studies, we found that users tended not to read the extended text and tended not to watch the videos. Hence, we finally converged on a strategy that involved a set of brief, bulleted instructional text and rather than using videos, using a forced set of steps with examples that allowed users to better understand what was being asked of them. By the final round of phase 1 usability studies, both parent-child dyads and teachers understood all the steps and the research team and stakeholders were pleased with the prototypes.

For phase 2 of usability testing, nine families with children with ADHD and teachers used the behavioral tools to develop a daily report card to be used for school-based behavioral monitoring and home-based rewards. We asked families and teachers to set up a home-school behavioral reward system using the software prototype. Moreover, we asked families and teachers to continue to interact with the mehealth.com software at home and school for a 3 week period (including a one week baseline period). All 9 teachers successfully used the online behavioral selection wizard to select 2-3 target behaviors for the child. All 9 teachers also were able to successfully input 1-week of baseline data on daily rates of the target behaviors into the online system in order that reasonable behavioral goals (e.g., raises hand before talk with no more than 2 violations) could be created for the child. Teachers received automated reminders during intervals when they were to rate whether the child achieved their behavioral goals. Over the 2 weeks of use after baseline data collection, teachers inputted ratings on 90.4% of days that they were supposed to input data. Moreover, on the days that they entered data for the child, 99% of intervals were completed by the teacher. Parents and their children were asked to set up a reward hierarchy using the online reward selection wizard. All 9 parent-child dyads successfully set up this reward hierarchy. Following 3 weeks of use of the prototype, we met with parents, teachers, and children to ask open-ended questions about the usability,

acceptability, and perceived usefulness of the software and intervention. Questions focused on if the software was perceived as 1) feasible to implement and 2) of acceptable quality. We also asked about obstacles that users found in using the behavioral tools on the mehealth.com software and whether they would recommend these tools to a friend/colleague. The feedback from parents and teachers was largely positive and included the following selected qualitative statements:

- **Selected teacher comments**
  - *"interface was simple and easy to use"*
  - *"easier and more successful than trying to do on paper"*
  - *"saw immediate changes in child's behavior"*
  - *"would definitely use with my students with ADHD"*
- **Selected parent & child comments**
  - *"like reward options and suggestions for rewards"*
  - *"setting up system was easy"*
  - *"liked getting feedback every day rather than only when child has a bad day"*
  - *"child was motivated by the system"*

In response to some of the Phase 2 usability feedback, we decided that we needed to have some instructional videos interspersed throughout the software targeting parents, teachers, and children in order to will assist users with making sure that they understand the features of the software. We used a video animation company to develop of a set of 4 instructional videos for the behavioral tools software. These were embedded within the behavioral tools software.

Randomized Controlled Trial

Table 1 summarizes sociodemographic information for the 169 families that participated in the randomized controlled trial.

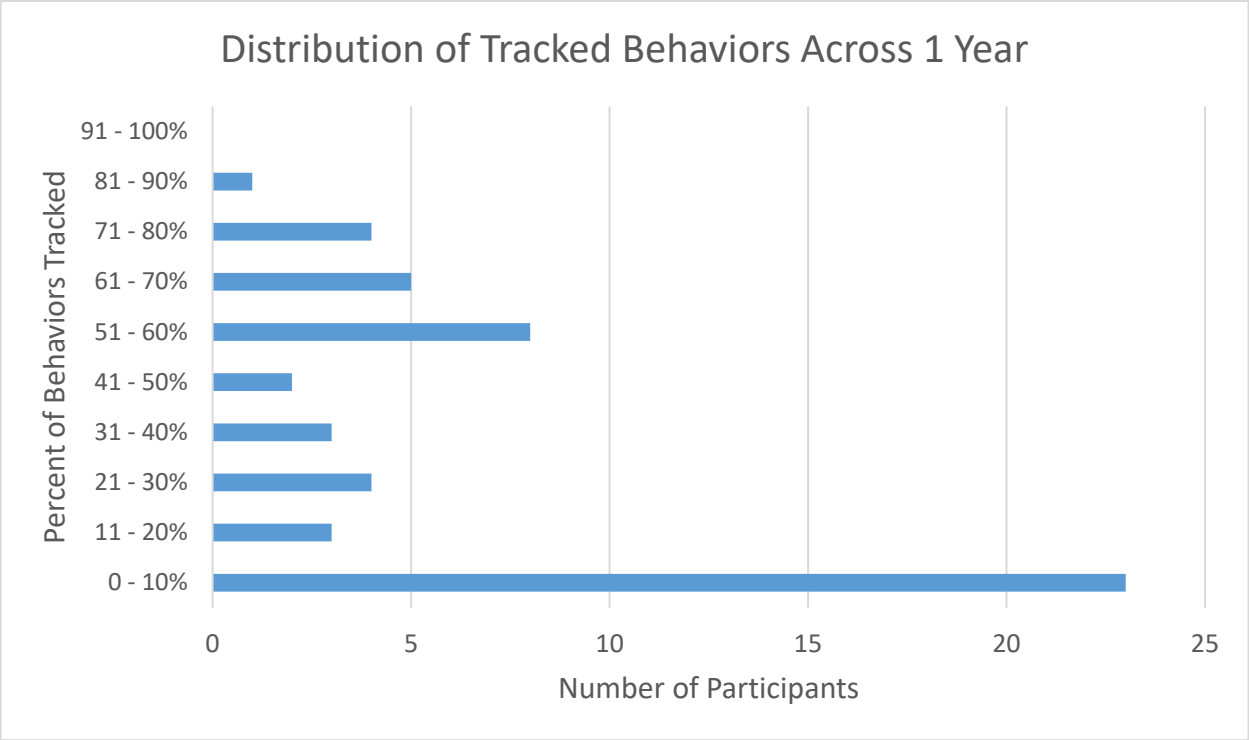
Table 1. Demographics for analytic sample of participants (N = 169).

	Demographic Characteristics of Sample		
Demographic Variable	Control n = 84	Intervention n = 85	Overall N = 169
Relationship to Child			
Mother	74	77	151
Father	5	3	8
Grandparent	2	3	5
Other relative	0	1	1
Other	3	1	4
Child's Primary Residence			
Two parent home	67	68	135
Single parent home	13	16	29
Other	3	1	4
N/A	1	0	1
Marital Status of Parents			
Married	61	62	123
Single	12	10	22
Divorced	9	9	18
Separated	1	3	4
Widowed	1	0	1
N/A	0	1	1

	Demographic Characteristics of Sample		
Demographic Variable	Control n = 84	Intervention n = 85	Overall N = 169
Highest Level of Education (Mother)			
Any post-graduate work	31	25	56
Four-year college graduate	20	27	47
Two-year college or technical school graduate	6	13	19
Some college	15	10	25
High school graduate or equivalent	10	8	18
More than 8th grade, but not a high school graduate	0	2	2
N/A	2	0	2
Highest Level of Education (Father)			
Any post-graduate work	18	12	30
Four-year college graduate	19	28	47
Two-year college or technical school graduate	9	6	15
Some college	11	17	28
High school graduate or equivalent	22	16	38
More than 8th grade, but not a high school graduate	1	1	2
Don't know	1	4	5
N/A	1	1	2
Child's Age (M, SD)	8.95 (1.707)	9.23 (1.669)	9.09 (1.689)
Child's Gender			
Male	55	61	116
Female	29	24	53
Child's Ethnicity			
Not Hispanic or Latino/a	81	83	164
Hispanic or Latino/a	3	2	5
Child's Race			
White	73	73	146
Black or African American	9	10	19
American Indian or Alaskan Native	0	1	1
Native Hawaiian or Pacific Islander	0	0	0
Asian	0	0	0
More than one race	4	4	8
Don't know	1	0	1
Refused	1	0	1
Child's Grade Level			
Kindergarden	5	3	8
First	13	11	24
Second	14	17	31
Third	19	14	33
Fourth	14	14	28
Fifth	14	16	30
Sixth	4	8	12
Seventh	1	2	3

Demographic Characteristics of Sample			
Demographic Variable	Control n = 84	Intervention n = 85	Overall N = 169
Child's Main Source of Insurance			
Private	63	70	133
Public	20	13	33
Other	1	2	3

85 families were randomized to receive the intervention during the RCT. Of those, 61 families have initiated use of the online behavioral intervention to date. Of those who initiated use, 88% used the system to focus on home behaviors, 10% focused on school behaviors, and 2% focused on both home and school behaviors. The adherence of participants regarding their usage of the behavioral rewards system to track behaviors across the year (i.e., the percentage of days that behaviors were tracked is displayed in the Figure below.



Among those that used the behavioral reward system, 122 different behaviors were tracked. The top 10 behaviors and the number of families that tracked those behaviors is shown below:

Behavior	count
Manages frustration appropriately (does not have temper tantrums)	47
Keeps hands and feet to self	38
Follows parents directions	34
Interacts respectfully with parents/adults (does not fight or argue with parents/adults)	34
Turns in completed homework	34
Manages frustration appropriately (does not whine/complain, not irritable)	32
Interacts nicely with siblings/peers (does not fight or argue with siblings/peers)	31
Completes morning routine in timely manner	26
Remains on task during classwork	24
Tells the truth (does not lie)	21

We conducted hypothesis testing to assess whether there were intervention effects. In particular, we tested the following hypotheses:

Hypothesis #1*: Families of children with ADHD who had access to the behavioral treatment tools on mehealth.com will receive behavioral treatments at significantly higher rates as compared to children who did not have access to mehealth.com-integrated behavioral tools.*
Analyses**:** Using data regarding use of behavioral treatment from baseline, 6-, and 12-month SCA-PI interviews, we conducted analyses with Group (Intervention vs. Control) and Time (baseline, 6-, and 12-months) variables in the analyses. A Group x Time interaction term would indicate whether intervention effects are present.

Intent-to-treat analyses that included all children assigned to the intervention and control groups (n=169) indicated no intervention effect (estimate = -.02, p=.97). We interrogated this analyses further by conducting a sub-analyses whereby we excluded all participants in the intervention group who never activated the behavioral reward system software. There continued to be no intervention effect (estimate =.11, p=.82).

Hypothesis #2: *Children with access to the mehealth.com enhanced with behavioral tools will have fewer areas of parent- and teacher-rated functional impairment than children without access to the behavioral tools.*
Analyses: The primary dependent measures for measurement of child outcomes was the IRS total score as rated by parents and teachers. These analyses evaluated whether growth curves using baseline, 6-, and 12-month data are different across the two groups. For all analyses, our primary hypothesis predicting improved outcomes for children in the intervention group was tested by examining the Group x Time interaction effect.

Intent to treat analyses and sub-analyses excluding participants in the intervention group who never activated the behavioral reward system software are included in the table below.

IRS item	ITT analyses estimate	p	Exclude no activation estimate	p
Relationship with other children	0.016	0.82	0.01	0.89
Relationship with siblings	0.126	0.13	0.138	0.12
Relationship with parents	-0.03	0.64	-0.018	0.82
Academic impairment	-0.128	0.04	-0.12	0.07
Self-esteem	-0.088	0.17	-0.069	0.29
Impact on family	0.02	0.78	0.027	0.69
Overall severity	0.004	0.93	0.023	0.67
Number of areas of impairment	-0.103	0.26	-0.12	0.22
Mean impairment	-0.077	0.64	-0.065	0.72

As can be seen in the table, the only intervention effect that was detected was reduced academic impairment in the intervention group compared to the control group in the intent-to-treat analyses. However, that effect was reduced to non-significance when we excluded those participants in the intervention group that did not activate their account in the sub-analyses. Intervention effects were not detected on any other IRS outcomes. Moreover, a similar set of analyses was conducted examining the teacher ratings and no intervention effects were observed on any of the teacher IRS ratings.

Hypothesis #3: *Families treated for ADHD by pediatricians with access to the mehealth.com enhanced with behavioral tools will have experience higher satisfaction with ADHD treatment compared to families treated for ADHD by pediatricians without access to the behavioral tools.*
Analyses**:** The dependent measure for these analyses will be parent satisfaction from the consumer satisfaction measure. One question asked about parent's overall level of satisfaction with the behavioral reward software. Another question asked whether parents would recommend the behavioral reward software to other parents.

Regarding overall level of satisfaction, 59% of families reported being either Very Satisfied, Satisfied, or Slightly Satisfied with the behavioral rewards software. Another 31% responded being Neutral. Finally, 10% responded being Dissatisfied.

Regarding recommending the behavioral reward software to others, 69% said they would Slightly Recommend, Recommend, or Strongly Recommend the software to other parents. 28% reported being Neutral. Only 1 family responded that they would Not Recommend the behavioral rewards software to other parents.

Post-RCT Follow-up Interview Results

We conducted 11 post-RCT follow-up interviews with parents. As a result of these interviews, we have learned about some shortcomings of the software. Briefly, we have learned that parents and teachers had difficulty understanding purpose of the baseline data collection and found this process to be burdensome. We continue to work on modifying the software so that instead of including a baseline data collection period, it will allow parents and teachers to estimate rates of behavior rather than collect baseline data and we have altered the algorithms to quickly titrate and adjust behavioral goals based on the child's performance on their behavioral goals over the first couple weeks of the program. In addition, we learned that parents found the online selection of dates and times for being notified for inputting whether the child met their behavioral goals to be confusing. We have problem solved a simpler interface

for inputting these days of the week for parents and are working on implementing this modification.

Conclusions

Our team strongly feels that the behavioral rewards software that was developed with the input from stakeholders and two rounds of usability testing was a robust tool that had the potential to assist parents and teachers with the development and implementation of behavioral reward systems. Nevertheless, the results of the randomized controlled trial suggest that use of this software did not lead to intervention-related improvements in children's functional impairment – other than one analyses that suggested that the intervention led to improvement in academic impairment.

We believe that similar to most behavioral intervention studies that implementation and adherence to behavioral intervention among those in the intervention group likely led to our lack of finding intervention effects. Indeed, adherence to behavioral interventions is difficult. Prior research studies in this area generally find that parents have difficulty maintaining behavioral interventions with their children. Perhaps our goal of trying to get parents to maintain the behavioral intervention over the course of an entire year was too ambitious. Had we the opportunity to conduct this study again, we likely would shoot for a shorter intervention period (e.g., 3 months) with measurement of outcomes after this briefer intervention period.

Significance & Implications

Despite the lack of intervention effects, we do believe that this behavioral reward software that was developed during the course of this study and modified as a result of this study is a viable intervention option for families with children with ADHD. As noted above, parent's adherence over the 1-year intervention period was moderate. However, this adherence data can also be viewed as encouraging. Indeed, approximately one-third of parents who initiated the intervention were adherent to the intervention over 50% of the time of the course of a year. That is an impressive metric for maintaining a behavioral intervention. The goal of future research should be to figure out how to either identify families that did not initiate or had low adherence to the intervention and devise strategies for engaging those families. Note that this is a universal problem for getting families to engage with behavioral intervention – whether done in-person or electronically.

As stated, we believe that the intervention developed in this study has unique potential for wide-spread dissemination. We have integrated the behavioral reward system into mehealth.com, which is used by health care providers across the United States to aid in ADHD care.

7. List of Publications and Products (Bibliography of Outputs) from the study. Follow the AHRQ Citation Style Format at https://www.ahrq.gov/funding/grant-mgmt/refstyle.html.

None.