Official Title of the study: **Web Based Tools to Improve Medication Continuity in Adolescents With ADHD**

NCT number: **NCT04173000**

Document name: **Study Protocol**

Date of the document: **2/21/2021**

ABSTRACT:

Medication is an efficacious treatment strategy for adolescents with attention-deficit/hyperactivity disorder (ADHD) (Chan et al. 2016), however use significantly declines during adolescence when the consequences of ADHD are most severe (e.g. dropping out of school, delinquency, etc.) (Visser et al. 2014). The Unified Theory of Behavior Change (UTBC) (Fishbein et al. 2001) has been proposed as a conceptual model to explain the mechanism underlying ADHD medication adherence and to guide the development of interventions to improve the continuity of treatment (Chacko et al. 2010). The UTBC is a well-established and empirically tested model that identifies factors that influence an individual's intention to perform a behavior as well as factors that influence whether a behavior is actually carried out (Fishbein et al. 2001). Indeed, our preliminary data support the relevance of pre-intention factors and implementation factors for medication continuity among adolescents with ADHD. For example, we found that a significant majority of adolescents intentionally stop taking medicine because they question the medicine's benefits (i.e., Expectations in model). We also found that adolescents who intend to take medicine experience a variety of barriers to taking it regularly, including deficient organizational and problem solving skills, inconsistent access to timely refills, and lack of daily routines to support continuity (Brinkman et al. 2012). For example, an adolescent may repeatedly forget to take their medicine.

Customizable interventions are available to address these factors. For example, pediatrician-supervised trials on and off medicine are recommended in ADHD practice guidelines (Pliszka 2007; AAP 2011) to shape *expectations* related to benefit vs. unwanted effects of continued medicine use. However, these rarely occur in practice, leaving adolescents to conduct impromptu experiments stopping their medicine and often experiencing a negative outcome before realizing that medicine is still needed (Brinkman et al. 2012). Forgetting to take medicine can be addressed by programming regular text message reminders, which may help make medicine taking more automatic.

Currently, no interventions target medication continuity for adolescents with ADHD. Our research team is well positioned to create an intervention that addresses each of the main UTBC factors influencing the intention and implementation of regular medicine taking. With NIH funding, we have developed web-based interventions that improve the care and outcomes for young children with ADHD (Epstein et al. 2011, 2016) and improve adolescent medication continuity for other chronic conditions (Hommel et al. 2013). Such an intervention would transform care for adolescents with ADHD and help prevent the alarming fall-off in effect size from medication efficacy studies to effectiveness in real world practice caused by poor adherence.

PURPOSE OF STUDY:

The primary goal of the proposed project is to test a multi-component intervention that systematically identifies and targets aspects of the UTBC model most relevant for each adolescent with poor ADHD medication continuity. Our central hypothesis is that our tailored intervention will support ADHD medication continuity, and ultimately improve outcomes for adolescents with ADHD.

BACKGROUND:

Statement of the problem

ADHD is the most common mental health condition of childhood (Perou et al. 2013) affecting 6.4 million children aged 4-17 years in the United States (Visser et al. 2014). Children

with ADHD experience impairments across a wide range of areas of functioning including academics, social relationships, and family functioning (Wehmeier et al. 2010). Fortunately, efficacious treatments for ADHD exist. Medications, either alone or in combination with behavior therapy, reduce ADHD symptoms and some areas of impairment (MTA 1999; Chan et al. 2016) and are recommended as a first-line treatment in clinical practice guidelines (Pliszka 2007; Wolraich et al. 2011). Medication use is quite common among children with ADHD, but use plummets after age 11 even though adolescents continue to demonstrate symptoms and impairment (Visser et al. 2014; Howard et al. 2016). Moreover, those who continue to take medicine take their medications inconsistently (i.e., only 50% of days covered with medicine; Molina et al. 2009).

Developmental influences

Changes during adolescence likley contribute to the decline in medication continuity. Most teenagers expect to have a voice in decisions that concern them. Collaborative decision making between parents and children is a part of normative development that precedes full decision-making autonomy (White 1996; Wills et al. 1996). Teen involvement in medical decisions may positively impact self-efficacy, satisfaction with medical care, adherence, and, ultimately, the transition to adult health care (McCabe 1996; White 1996; Wills et al. 1996; Walker et al. 2001; Schmidt et al. 2003; Miller et al. 2014). However, many parents are afraid to give their teen with ADHD a say in decisions about medicine because they believe it helps and worry that teen goals are short sighted (Brinkman et al. 2009; Brinkman et al. 2012). Many adolescents desire to stop taking medicine because they don't believe it helps or they don't like how it makes them feel. Some teens describe feeling 'zoned out' or less social, less creative, more irritable, or experience other somatic side effects (e.g. headache, etc.) (Knipp 2006; Meaux et al. 2006; Singh et al. 2010; Brinkman et al. 2012). Moreover, many teens are given the day-to-day responsibility for medication taking, and are increasingly without the safety net of parental supervision (Brinkman et al. 2012; Brinkman et al. 2016).

Impact of poor medication continuity

As a result of these developmental changes, teens with ADHD evidence low rates of medication continuity. Unfortunately, at the same time medication continuity declines, the outcomes of ADHD become increasingly consequential. For example, adolescents with ADHD are more likely than their peers to have fewer friends, drop out of school, use tobacco and illicit drugs, interact with the juvenile justice system, be treated for sexually transmitted infections, and have teen age pregnancies (Barkley et al. 2006; Molina et al. 2009; Bussing et al. 2010). Given that medicine has large effects on adolescent performance across a variety of domains (e.g. academic tasks, social skills, etc.) (Smith et al. 1998; Evans et al. 2001; Chan et al. 2016), poor medication continuity represents a significant public health problem. Because the vast majority of adolescents receive ADHD care from pediatricians in primary care practices (Albert et al. 2017), any intervention that will address this problem must be amenable to this setting. An intervention that improves medicine continuity during the transition from family- to self-management of a teen's mental health condition would transform care and outcomes by closing the gap between medication efficacy and effectiveness in real world practice.

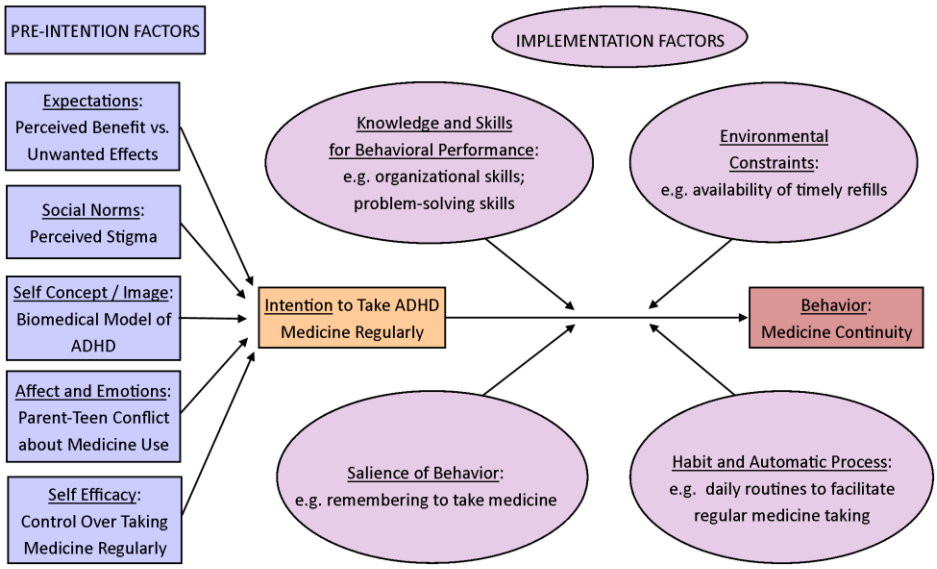
Mechanisms supporting medication continuity

Maintaining continuity of medication treatment among adolescents with ADHD is often difficult and influenced by heterogeneous factors. Indeed, different families have different needs at different times. A large body of basic behavioral science research has shown that behavioral change and maintenance of that change is best accomplished by addressing underlying mechanisms of change (i.e., beliefs about the pros and cons of the behavior, social norms and

influences, self-efficacy beliefs, and the degree to which any individual actually intends to adopt a behavior) (Armitage et al. 2000). Hundreds of studies have demonstrated that interventions must address these underlying mechanisms in order to reliably change behavior (Ajzen 1991; Jaccard et al. 1999; Fishbein et al. 2001; Rhodes et al. 2013). The UTBC (Fishbein et al. 2001) has been proposed as a conceptual model to explain the mechanism underlying ADHD medication continuity and guide the development of interventions to improve it (Chacko et al. 2010).

The UTBC identifies two processes in behavioral change (see **Figure 1**). The first process focuses on 5 determinants of an individual's willingness, intention, or decision to perform a critical behavior (see pre-intention factors on left of **Figure 1**): 1) Expectations (also called expected-values) refers to an individual's perceived advantages and disadvantages of performing the behavior. For example, in the case of taking a medication, an adolescent might believe with varying degrees of certainty that a medication will help her/him pay attention at school, but s/he may also believe that these benefits may be outweighed by other negative consequences (e.g., side effects). 2) Social Norms include two components, a) the adolescent's perceptions about what their parents think s/he should do with respect to the behavior (i.e. taking medicine), and b) the adolescent's perceptions about whether his/her peers would also approve of and/or perform the behavior. Thus, the more stigma an individual feels about taking medicine for ADHD (Pescosolido et al. 2007), the less likely it is that s/he will decide to do so. 3) Self-concept and image considerations refer to an individual's concept of one's self and whether performing the behavior is consistent with or contradicts one's self-image, rendering the behavior more or less attractive. An individual who strongly feels that ADHD is a biomedical condition that requires biomedical treatment and s/he is the type of person who always takes action to improve their health will be more likely to take medicine for ADHD than one who does not (Leslie et al. 2007); 4) Affect and emotions refers to an individual's affective and emotional reactions to behavioral performance: individuals who have a strong negative emotional reaction to taking medicine because they equate it to a battle for control with their parents will be less inclined to regularly take medicine than if one feels like their parent involves them in decisions that impact them. Adolescent-parent conflict often flows from differences of opinion about the benefit of medicine with parents worrying that adolescents are short sighted in their goals and overestimate their competence compared to objective criteria (Owens et al. 2007; Brinkman et al. 2009). Conversely, adolescent involvement in decision making (e.g. sharing opinions, negotiating with parent) has been related to higher levels of treatment regimen adherence in chronic conditions like diabetes (Miller et al. 2014). 5) Self-efficacy refers to one's beliefs that s/he can perform the behavior, and how easy/difficult it is to perform the behavior. Thus, an adolescent who believes that s/he can easily take medicine regularly within their daily routines will be more willing to do so (i.e., higher self-efficacy beliefs

Figure 1: UTBC model adapted for Medication Continuity Among Adolescents with ADHD



will result in stronger behavioral intentions). Each of these five factors predicts variation in behavioral intentions or the decisions whether to perform specific behaviors.

The second set of four factors affect whether strong behavioral intentions are actually carried out (see implementation factors on right side of **Figure 1**). One variable pertains to the requisite knowledge and skills for behavioral performance - one may intend to take ADHD medicine regularly, but may subsequently find that s/he does not have the skills needed to take medicine every day. For example, some adolescents struggle to swallow pills. Adolescents may also lack the organizational and/or problem-solving skills needed to take medicine reliably. Another variable is the environmental constraints that may render behavioral performance difficult or impossible. For example, adolescents taking ADHD medicine are often dependent on their parent(s) to obtain medicine refills. This is often relevant because parents of adolescents with ADHD are more likely to have ADHD and/or depression (Chronis et al. 2003) which may interfere with their ability to support medication continuity by obtaining timely refills. Third, salience of the behavior is important so that the person does not forget to enact it. Even when salience is present, forgetting can be a challenge for adolescents with ADHD. Finally, habit and automatic processes may influence behavior. For example, by force of habit, a person who has developed a routine to help them to remember to obtain and take their medicine regularly will be more likely to sustain this behavior when competing intentions are activated and distractions are present.

We acknowledge that adolescent medication continuity is a complex phenomena and that no model can capture all of the factors and directionality that lead to medication continuity. Indeed, self-efficacy is likely influenced by past experiences managing pre-intention and implementation factors. In addition, Figure 1 fails to capture the important roles that parents and pediatricians play in supporting medication continuity. Regardless of these limitations, the UTBC conceptual model helps explain the mechanism underlying ADHD medication continuity and will help guide efforts to develop and test interventions (Chacko et al. 2010).

Pre-intention factors influencing ADHD medication continuity

We analyzed data from the Multimodal Treatment Study of Children with ADHD (MTA) to determine the prevalence of factors that impact adolescents' intentions to take medicine regularly (Brinkman et al. 2016). Twelve years after enrolling in the MTA, patients completed a survey reporting their age when they last stopped taking medicine for a month or more and their reasons for stopping. 94% of the sample (350/372) reported stopping, with a mean (SD) age of 14.2 (3.5) years when they last stopped taking medicine for ADHD. The most commonly endorsed reasons for stopping medicine related to questioning whether medicine was still needed or helped. Reasons related to side effect concerns were endorsed by a significant minority of adolescents (33-46%). The most commonly endorsed adolescent reasons for re-starting medicine related to recognition that medicine was helping at school or work (86%), with 45% of adolescents coming to realize that medicine was still needed after they had stopped taking it. For both stopping and restarting, the proportion endorsing some reasons differed by age range, with the overall pattern suggesting that parental involvement in stopping and restarting medications decreased with age. 98% of participants continued to have functional impairment after stopping medicine.

Implementation factors influencing ADHD medication continuity

We conducted focus groups with adolescents with ADHD (n=44) and parents (n=52) (Brinkman et al. 2009, 2012). Using an inductive approach to code transcripts and identify saturated themes, we elucidated a variety of barriers to medication continuity when adolescents intended to take medicine regularly. Some adolescents struggle with swallowing pills. Parental involvement in medication taking ranged from providing direct supervision, to reminders, to providing no supervision. Adolescent responsibility for medication taking increased with age and

maturity. However, many adolescents acknowledged that forgetting to take their medication was still an issue. Indeed, the organizational difficulties experienced by many adolescents with ADHD and their parents, who are at higher risk for ADHD themselves (Chronis et al. 2003), are a significant barrier to reliably obtaining refills before medicine runs out and taking medicine regularly. Moreover, parents often benefit from training on how to set goals, use behavioral contracts and rewards/consequences to encourage desired behaviors from their children with ADHD (Chronis et al. 2006), though these approaches have not been applied to ADHD medication continuity.

Intervention development requires adolescent, parent, and pediatrician participation to ensure all needs are met

We have a strong record of success conducting ADHD research in partnership with primary care practices. 10 studies conducted by Drs. Brinkman and Epstein have involved 180 practices, 616 pediatricians, and 3011 families (Epstein et al. 2007; Epstein et al. 2008; Brinkman et al. 2009; Epstein et al. 2010; Brinkman et al. 2011; Epstein et al. 2011; Brinkman et al. 2012; Brinkman et al. 2013; Brinkman et al. 2016; Brinkman et al. 2016; Epstein et al. 2016). Dr. Brinkman developed and is testing an intervention to improve adherence among 118 children with ADHD ages 6-10 years cared for by 43 pediatricians. By engaging parents in the intervention development process for this study, we learned that the Vanderbilt ADHD Rating Scales (used by pediatricians around the country to monitor response to treatment) lack salience. Parents voiced a need to be able to track specific behaviors that were important for their child. As a result, we developed this capability in the intervention. In focus groups we've conducted in preparation for the proposed project, adolescents have voiced a similar need. Teens would like to be able to track outcomes that matter most to them and depend on their report. For example, parents and teachers have a perspective on how teens get along with peers, but only the teen can say whether they feel accepted by their peers or experience stigma. Teens we met with are eager to have their voice more fully integrated in the process of treatment monitoring.

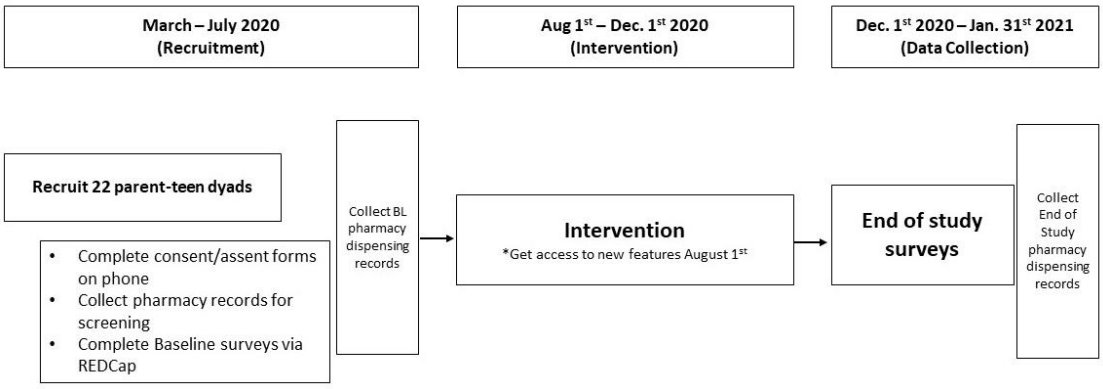
Leveraging a web-based intervention used by parents and pediatricians to efficiently conduct the proposed research and facilitate future dissemination

Dr. Epstein developed a web-based intervention (mehealth for ADHD) which enables community-based pediatricians to deliver higher quality ADHD care (Epstein et al. 2011) leading to children with significantly fewer ADHD symptoms (Epstein et al. 2016). Subsequently, partnerships with the American Academy of Pediatrics and American Board of Pediatrics helped spread use of the portal beyond practices that participated in research and now includes 17,412 patients cared for by 890 pediatricians in 659 practices across the US. These practices use the portal as a registry to manage their entire ADHD patient population. With pediatricians continuing to enroll patients on the portal as part of routine clinical care, opportunity exists to leverage this infrastucture to efficiently develop and test new interventions. The proposed research would fill a sizable gap as the current portal is focused exclusively on young school age children with ADHD and medication adherence has not been targeted nor improved. Specifically, while a randomized controlled trial testing the efficacy of the mehealth for ADHD web intervention demonstrated significant effects on children's treatment outcomes, there was not a significant intervention effect on medication adherence (i.e., 59% of days covered by children in the mehealth for ADHD portal group vs. 54% in the control group) (Epstein et al. 2016). Moreover, the portal is devoid of features for adolescents. In focus groups, pediatricians, parents, and adolescents have repeatedly requested such features.

STUDY DESIGN:

We will conduct a 4-month open label trial among adolescents with poor medication continuity (see **Figure 2**) to test whether the intervention engages the mechanism underlying medication continuity and improves outcomes. We will recruit 24 pediatricians from ~8 practices. Currently, 890 pediatricians are using the ADHD portal software nationwide to manage the care of 17,412 patients with ADHD. Therefore, there is a large group of eligible pediatricians from which to recruit. At the start of the school year, the enrolled families from each practice will receive access to the new features on their mehealth for ADHD account. We will recruit 20 adolescents with ADHD with poor medication continuity who receive care from one of these 24 pediatricians prior to the start of the open label trial. Because the medication experiment feature is not clinically relevant for adolescents taking a non-stimulant ADHD medication, and this is a key portion of the intervention, those who are taking non-stimulant medications will not be included. At the time of enrollment, families will complete consent and assent forms electronically via REDCap, and be sent baseline surveys to complete electronically. Before the intervention begins, we will verify the number of days covered with medicine based on dispensing data. Because medication use varies widely during the summer months and school holidays, the intervention will begin at the beginning of the school year to reduce variation in medication continuity based on time of year. The trial will end 4 months later. At that time, families will complete end of study measures, and pharmacy dispensing records will be obtained. End of study measures will also be completed electronically.

Figure 2:



DURATION:

This IRB protocol covers the second phase of the study during which we will test the medication continuity tools developed in collaboration with our stakeholders during the first phase of the study. Families will be enrolled in the study for approximately 10 months.

PROCEDURES:

Research Participant Recruitment and Obtaining Informed Consent

We will enroll 18 pediatricians from 14 practices who currently use the mehealth for ADHD portal to participate in the trial. The PI, Dr. Brinkman, or a co-investigator will visit with each of the practices and pediatricians prior to starting the research activities. At this meeting, the intervention components and requirements for pediatrician participation will be described in detail. Given that not all practices will be located in the Greater Cincinnati region, these meetings may take place over the phone or video conference. Pediatricians will be provided with a written description of what participation will entail, and will be asked to document their

informed consent. Consent will be recorded via RedCap using a study-specific consent form modeled after the eConsent demo on the RedCap Resource Center.

Each pediatrician will identify families who are using the ADHD web portal to care for a child (aged 11 to 15) to participate in the trial. Permission for research staff to contact families of children meeting eligibility criteria will be sought by members of the pediatrician's office by 1) sending a secure message to parents from their child's pediatrician on mehealth for ADHD, and/or 2) making a phone call to parents from a member of the pediatrician's staff (e.g., nurse) who will act as a research liaison and will use a script to describe the purpose of the study and ask parents if they would like to be contacted by a research team member with more information about the study. We will enroll a total of 22 parents and 22 children to participate in the intervention.

If a parent consents to be contacted about the study, the research liaison or CCHMC contact reference will provide the research team with patient contact information. Once the research team has received a parent's consent to be contacted, a research assistant will contact parents via phone to provide information and answer questions. Those who express interest will complete screening questions needed to assess eligibility criteria and to collect Medicaid status, race/ethnicity information, and medication continuity information that will be used to ensure a representative sample. If they are eligible, the research assistant will send interested parents a consent form and a link to the RedCap consent form via email, review the form with the parent, and complete a full informed consent for the study. If the parent does not have enough time to review the consent form and complete the consenting process, the research assistant will schedule a time to call back and do so. The consent form will include permission to access the child's pharmacy dispensing records in order to confirm eligibility. We will also explain the study to children (in language appropriate to them; see below) on these phone calls. We will review the content of consent form with the parent over the phone and the parent will record their consent and the child will record their assent on RedCap using a study-specific consent form modeled after the eConsent demo on the RedCap Resource Center. If child is not available at the time of the consent call with parent, their contact information and availability will be collected and assent will be collected later during a follow-up call at their convenience.

Inclusion/Exclusion Criteria

Inclusion Criteria: Participants for the study must meet all of the following criteria:

a. Consent: The family must provide informed consent by parents or legal guardians
b. Assent: Children must provide assent to participate in the study
c. Ages 11-15
d. Treated for ADHD by pediatrician
e. First prescribed ADHD medicine more than one year prior to enrollment
f. Have < 80% of days covered by ADHD medicine in the past year of treatment (based on pharmacy dispensing records)
g. Filled at least one prescription for a stimulant medication in the past year

Exclusion Criteria: Participants will be excluded from the study if they meet any of the following criteria:

a. Poor understanding level: The participant and parent cannot understand or follow instructions given in the study.
b. Have ≥ 80% of days covered by ADHD medicine in the past year of treatment (based on pharmacy dispensing records)

Intervention components targeting UTBC pre-intention factors

1. **Education** (Targeting **adolescent and parent** expectations, self-concept, affect and emotions)

The intervention delivers education about relevant topics (e.g. the etiology of ADHD; how medicine works; the importance of medication titration, how to mitigate side effects and minimize dosing regimen complexity, and how adolescents, parents, and doctors can work together to titrate medicine, conduct a trial on/off, and discourage diversion).

2. **Pediatrician supervised medication management** (Targeting **adolescent and parent** expectations, self-concept, affect and emotions).

Overview: Pediatricians can play a critical role supporting medication management and continuity of treatment, if they have the right information and teens and parents are actively engaged in the process. When teen and parent responses to the assessment battery suggest that the teen may benefit from additional titration or a trial on/off medication, the teen and parent will all be alerted to the recommendation. Adolescents and parents will be guided through a series of customized steps using program routines, called wizards. A software wizard is a user interface type that presents a sequence of dialog boxes that lead the user through a series of steps towards goal completion. Wizards will prompt patients and parents to identify, prioritize, and discuss behavioral targets to monitor during titration or trial on/off medicine.

Medication titration: Dosage adjustment and/or titration of a medicine with a different chemical ingredient will be recommended to optimize effectiveness when a teen/parent indicate they are interested in trying a new medication or dose. Parents and adolescents who express interest in changing medicine or dose will be directed to make an appointment with their pediatrician to discuss what the best option is for the family. Videos that describe different medication/treatment options will also be available for the parents and adolescents.

Pediatrician supervised trial on/off optimal dosage: A structured trial on/off medicine will be recommended when teen/parent responses to the assessment battery indicate uncertainty about whether medicine is still needed because the teen appears to be thriving. The intervention delivers training on how to conduct a high quality trial on/off medicine will include the ADHD clinical practice guideline recommendations (Pliszka 2007; AAP 2011) that differentiate these trials from the common clinical practice of stopping medication during summer or holiday breaks from school (e.g., best when there are few transitions or demands [mid school year], avoid at beginning of any school year, especially at the start of junior/senior high school, discontinue medication for 2-4 weeks, monitor target outcomes). The trial on/off medicine is designed to reduce ambivalence about medicine (i.e. document improvement among teens that still benefit) which may motivate self-directed changes to support medication continuity. Of note, trials on/off non-stimulant medication have limited utility given that atomoxetine and guanfacine take 4-6 weeks before maximal response is achieved and guanfacine can't be abruptly stopped due to risk of rebound hypertension (Froehlich et al. 2013). Accordingly, pediatricians will advise each family regarding the value of conducting an on/off trial in each situation.

Symptom & side effect monitoring: The mehealth for ADHD intervention enables the tracking of ADHD symptoms, medicine side effects, and other outcomes that are important to adolescents and parents. In addition, adolescents and parents can construct their own measures using a structured approach with examples to ensure that adolescents and parents can translate what matters most to them into a measure that can be tracked over time. For example, an adolescent could decide to record the presence of a relevant side effect (e.g. irritability) on a daily basis. A parent could decide to track the time spent completing homework every night. Adolescents and parents can report on their chosen outcomes via an internet survey that has been optimized for completion on a mobile screen. The system provides reminders to adolescents and parents to rate targeted outcomes by cell phone text messages. At the conclusion each titration or trial on/off medicine, the pediatrician, adolescent and parents

will regroup to discuss what was learned using a report generated by mehealth for ADHD to visualize the outcome data that was collected. The intervention also includes a tool that will enable parents and/or adolescents to indicate side effect(s) that are problematic for them. The tool will guide them through solutions that may mitigate the side effect(s) they are experiencing from their ADHD medication.

3. **Stigma** (Targeting **adolescent and parent** social norms)

Videos normalizing ADHD and medication taking: There are hundreds of videos available on YouTube related to ADHD (Kang et al. 2016). Some videos share information about successful people with ADHD. Other videos feature celebrities talking about how medication helps them manage ADHD. Yet other videos, like TED talks, feature adolescents and adults discussing how they have made sense of ADHD and have been successful managing ADHD symptoms. Other videos discourage diversion of ADHD medicine. The intervention includes links to videos that may help adolescents normalize ADHD and medication taking and discourage diversion.

Intervention components targeting UTBC implementation factors

4. **Organizational interventions: Refill reminders; visual cues, pill taking reminders** (Targeting **adolescent and parent** habits and automatic processing, and environmental constraints)

The portal enables parents and/or adolescents to schedule reminders for when to request a refill from the pediatrician's office. Adolescents and parents will also be oriented to strategies such as use of visual cues embedded within their daily routine to take medicine (e.g. putting pill bottle next to toothbrush, etc.). Adolescents will be able to schedule daily text message reminders to take medicine.

5. **Monitoring medication taking** (Targeting **adolescent, parent, and pediatrician** salience)

After receiving their text message reminders to take their medication, adolescents will be sent a second text message asking if the dosage was taken with response options of Yes/No. This will enable tracking of medication to inform a feedback loop for self-monitoring. Tracking results will be displayed graphically to make it easy to assess trends over time relative to interventions that have been implemented to improve medication continuity.

Measures to characterize the sample

1. Demographics: Adolescents, parents, and pediatricians will report on age and race/ethnicity. Parents will also report on child insurance status, and their own level of education and mental health history.
2. Technology Use Survey: Adolescents and parents will complete this 30-item phone survey from the Pew Research Center's Internet & American Life Project (PewResearchCenter 2011). Items query respondents about use of various types of devices (e.g. desktop, tablet, smartphone, etc.), internet connections (e.g. cable modem, etc.), and activities (e.g. internet browsing, emailing, texting, downloading apps, etc.).
3. Vanderbilt ADHD Parent Rating Scale: (VADPRS) (Wolraich et al. 2003) has subscales for Inattention and Hyperactivity/Impulsivity. In addition, a symptom count score can be derived for DSM-IV items and includes a subscale to assess parents' perceptions of youth school and social functioning.
4. ADHD Self-Report Scale: The ASRS is a self-report measure of the 18 DSM ADHD symptoms (Kessler et al., 2005). Items reflect symptoms of inattention and hyperactivity-impulsivity, and in this study all items will be rated by teens on a 4-point scale (0 = never; 3 = very often) consistent with the parent- and teacher-completed VADRS.

5. Pittsburgh Side Effects Rating Scale: (Pelham et al. 1993) is a 13-item measure that allows adolescents and parents to report whether ADHD medicine side effects were none, mild, moderate, or severe.
6. The Columbia Impairment Rating Scale (CIS) Parent and Child Versions (Appendix Q & R): The Columbia Impairment Rating Scale (CIS) assesses impairment in behavioral, emotional, interpersonal, and task-related functioning. Behavioral functioning includes problems with behavior at home and school; emotional impairment involves feeling nervous or sad; interpersonal impairment taps problems in relationships with peers, siblings, parents, and other adults; and task-related functioning includes problems with schoolwork and involvement in leisure activities. Parents reported how much of a problem each of these areas of impairment was for their child on 13 items using a 7-point scale ("No problem" to "Extreme problem"). The CIS has shown high internal consistency, excellent test–retest reliability, and good validity when correlated with a clinician's score on the Children's Global Assessment Scale.
7. COVID-19 Adolescent Symptom and Psychological Experience Questionnaire (CASPE): The COVID-19 Adolescent Symptom and Psychological Experience (Ladouceur, 2020) is an adolescent and parent report of the psychological impacts of the pandemic. Items assess negative affect and changes in caregiver employment or income due to COVID-19.
8. Remote and In-Person Learning during COVID-19: This is a 25-item measure that allows parents to report on adolescent engagement in remote, blended, and in-person learning during COVID-19. Two items were used from the Home Adjustment to COVID-19 Scale (HACS) (Becker et al., 2020) to assess parent confidence and challenges experienced when assisting with remote learning.

Outcome measures

9. Fidelity to intended use of intervention components: For each adolescent and parent, we will calculate the proportion of intervention components completed relative to the components that were recommended by the portal based on adolescent/parent responses to the assessment battery. For intervention components that are used once (e.g. trial on/off medicine), we will identify a portal data element to characterize intervention component completion. For intervention components that are used more than once (e.g. refill reminders, pill taking reminders, etc.), we will define "intended use" of the feature as use for at least 2 months since research suggests that, on average, it takes 2 months to develop a new habit (Lally et al. 2010). Mehealth for ADHD will capture and report on these data elements to characterize fidelity to the intended use of intervention components for each adolescent and parent.
10. Pre-intention factors of UTBC influencing medication continuity (Appendix G & H): Our measurement strategy for the adolescent and parent pre-intention factors closely follow well-developed procedures (Ajzen et al. 1981). We will use standard scales that have been used in hundreds of previous studies using the UTBC and closely related basic science theories. For example, an item to assess social norms would be ''Most of the people who are important to me think I should take ADHD medicine regularly.'' Responses are on a 7-point scale from strongly agree (+3) to strongly disagree (-3). The internal consistency of items within each construct is good ($0.7 \leq \text{alpha} \leq 0.9$) (Steele et al. 2005; Bentley et al. 2009; Cornelio et al. 2009; Boyko et al. 2011). For this study, we will assess pre-intention factors (i.e. expectations, social norms, self-concept/image, affect and emotions, and self-efficacy) framed around the behavior of ''taking ADHD medicine regularly" following published methods (Francis et al. 2004) and informed by our prior qualitative research (Brinkman et al. 2009, 2012).

11. Behavioral Intentions (Appendix I & J): Teen and parent intention for teen to take ADHD medicine regularly will be measured using the standard measure of intention from the UTBC (Ajzen and Fishbein, 1981).
12. Implementation factors of UTBC influencing medication continuity (Appendix K & L): These factors will be measured using the Adolescent and Parent Medication Barriers Scales (AMBS and PMBS) (Simons et al. 2007; Simons et al. 2010). Adolescents and parents respond using a 5-point Likert-like scale from ‘‘strongly disagree’’ to ‘‘strongly agree’’ to report perceived barriers to medication taking. Both the adolescent scale (17-items) and parent scale (16-items) have strong internal consistency for total score and the four factor-analytically derived subscales: ‘Disease frustration/adolescent issues’, ‘Regimen adaptation/cognitive’, ‘Ingestion issues’, and ‘Parent reminder’. For criterion-related validity, adolescents classified as non-adherent had significantly higher barrier scores than those classified as adherent. In prospective validation studies, the adolescent-perceived barriers of ‘Disease frustration/adolescent issues’ and parent-perceived barriers of ‘Regimen adaptation/cognitive issues’ were associated with poorer adherence to medication taking (Simons et al. 2010).
13. Medication Continuity: We will calculate the percentage of days covered with medicine based pharmacy dispensing records and verified by parent report of ADHD service use using the reliable Services for Children & Adolescents – Parent Interview (Eaton Hoagwood et al. 2004). This measures ADHD service use, including office visits and medication use. We have successfully obtained pharmacy dispensing records via parental permission for 95% (155/164) of subjects across 2 studies (R01 MH074770, K23 MH083027) (Brinkman et al. 2013; Brinkman et al. 2016). Pharmacy dispensing records provide an objective, unobtrusive, reliable measure that is a well-accepted proxy for medication consumption (Steiner et al. 1997) that was significantly correlated with the more expensive and invasive Medication Event Monitoring System (MEMSCap™) which uses a microprocessor in the medication container cap to record the day and time of each vial opening (Farley et al. 2003).
14. Medication Diversion: Self-report of giving away, trading, or selling ADHD medicine to someone for whom it was not prescribed will be collected via a confidential web-based survey used in past population-based studies of middle/high school students. (Boyd et al. 2007; McCabe et al. 2011a).
15. Client Satisfaction Questionnaire (CSQ) (Attkisson et al. 1982) is an 8-item unidimensional measure of client satisfaction with services. Psychometric properties, operating characteristics, and coefficient alpha (.93) are very strong for this measure which we will collect from adolescents and parents.
16. Decision Making Involvement Scale (DMIS) (Miller et al., 2012): is a 30-item scale to measure adolescent involvement in a decision. The five subscales are: “Child Seek” (child asks for an opinion or information from parent), “Child Express” (child expresses an opinion or information to parent), “Parent Seek” (parent expresses advice or opinion to child), “Parent Express” (parent expresses advice or opinion to child), and “Joint/Options” (negotiation or brainstorming between parent and child). We will collect this measure from adolescents and parents.

DATA ANALYSIS

Hypothesis testing:

Each hypothesis examines part of the mechanism underpinning intervention impact on medication continuity.

Hypothesis #1*: Adolescents will use greater than 80% of relevant intervention components.* For each subject, we will calculate the proportion of ***recommended*** intervention components that were utilized by the subject during the study intervention period. The mean and 95% confidence interval (CI) will be computed to give a range estimate of the fidelity measure. To evaluate our hypothesis, we will utilize the computed CI to determine if 80% or greater is a plausible value, such that if the CI includes a value of 80% or greater we will reject the null hypothesis. We will also examine the temporal distribution of use for each of the recommended components.

Hypothesis #2*: Use of the intervention components will be related to improvements in the targeted UTBC factors.* Using a generalized linear model, we will test whether the intervention addressed the UTBC factors (i.e., pre-intention factor scales and ABMS/PBMS total and subscale scores). Model predictors will include a fixed effect indicator of time point (baseline or end of study). A significant effect of time point in the expected direction would indicate UTBC factor improvement.

Hypothesis #3*: Medication continuity will be higher at the end of the study compared to the baseline period.* We will compare the percentage of days covered with medicine using a paired t-test. In exploratory analyses, we will compare this cohort's percentage of days covered at end of study with the percentage of days covered in a control group that is accruing as part of another study (IRB# 2020-0236).

Hypothesis #4: *Pre-post changes in UTBC factors will be related to increases in medication continuity.* We will calculate the change score for each relevant UTBC factor (end of study minus baseline) and the change score for medication continuity (end of study minus baseline). We will model the association between change in UTBC factor scores (independent variable) with change in medication continuity (dependent variable) using generalized linear model. A significant effect of change in UTBC factor scores (beta coefficient) in the expected direction would indicate changes in UTBC factor scores were associated with medication continuity improvement.

Exploratory analyses:

We will conduct descriptive analyses to characterize rates of diversion at baseline and end of study using a McNemar's test to see if rates differ. We will summarize responses to the client satisfaction questionnaire descriptively as this may facilitate future dissemination.

Power and Sample Size:

We are adequately powered for our exploratory analysis of Hypothesis #3. The study would require a sample size of 18 for each group (i.e. a total sample size of 36), to achieve a power of 80% and a level of significance of .05 (two sided), to detect a difference in means between the intervention and the control groups of 15.7% (i.e. 66.2% vs. 50.5%) on the percentage of days covered with medicine assuming a pooled standard deviation of 16.5. Due to the low intra-class correlations observed in previous studies of ADHD medication continuity (ICC = 0; Brinkman et al. 2018), the analyses will not account for the nesting of patients within physicians. We will recruit 44 patients (22 in this cohort and 22 in control group from 2020-0236) to ensure that 36 are retained for this analysis. A retention rate of 80% (36/44) is conservative in light of the 12-month retention rate of 92% achieved by Dr. Hommel in his current trial.

Scientific Rigor:

Our open label trail is an appropriate design to initially examine whether the intervention engages the mechanism underlying medication continuity and therefore warrants further testing in a future larger trial. Our preliminary data strongly supports the importance of the problem, intervention targets identified, and the feasibility of the approach in our hands.

FACILITIES

Cincinnati Children's Hospital is the performance site for this study.

POTENTIAL BENEFITS

Although we cannot guarantee a benefit to any individual participating pediatrician, adolescent, or parent, the intervention components we propose to integrate into the ADHD web portal are theory- and evidence-based strategies with significant support from the research and clinical literature. Thus, families have the potential to benefit from state-of-the-art treatment. Benefits of the study outweigh any potential risks because our interventions are likely to improve care and outcomes for children who receive them.

POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES, AND PRECAUTIONS

There is minimal risk to the participants in this study other than a potential for invasion of privacy. Because confidential information about study participants will be available to study staff, procedures to safeguard the confidentiality of this information are required. Given the sensitive nature of some of the teen-reported outcome measures (e.g. ADHD medication diversion), we will apply for a Certificate of Confidentiality that will allow collection of these measures but will protect this information from being divulged to other parties. Additionally, several safeguards will be put in place. All data collected on pediatricians, adolescents, and parents will be assigned a unique code that will be linked to identifying information. The master coding sheet that will link the information will be kept in the study coordinator's office under lock and key. In addition to assuring confidentiality of the research data, it is also critical that the confidentiality of the patient's clinical information is protected in mehealth for ADHD. The HIPAA regulations and their application to this product will be clearly defined to ensure compliance within their guidelines. Mehealth for ADHD was designed with a procedure for encrypting and storing the data in such a manner to only allow pediatricians to view identifiable data. This design employs a key-based encryption structure. This method does require extra security information to be maintained by the parties who are encrypting the data. For example, parties needing access to the data are assigned a "key" that is used to encrypt and decrypt the data in addition to a user ID. Such a key will be maintained by the PI and kept under lock and key. Implementation of additional methodologies to keep the confidential information off the server will be implemented including such methodology as ensuring the CCHMC server is secure (i.e., firewalled).

Data from this study may be submitted to the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. If participants consent to have their information shared in the data repository, all personal information about research participants such as name, address, and phone number will be removed and replaced with a code number. Participants may decide at any point that they do not want to share their information to the NIMH data repository. If a family consents to have their data shared, the information required to create their deidentified code number will be collected during the phone screen by a member of the research team.

PROTECTION OF VULNERABLE POPULATION

Because children are being invited to participate in the study, the following procedures will be followed to avoid issues related to coercion or undue influence. First, study staff will review the consent form with participating children, in language appropriate for their intellectual functioning and developmental levels, and ask whether or not the child agrees to participate.

Similarly, they will be told that they can opt not to participate or answer any questions which they do not want to answer at any time. This will be re-iterated whenever necessary.

RISK/BENEFIT ANALYSIS

The risks to participants are minimal and unlikely, largely stemming from the possibility of loss of confidentiality. We have instituted provisions to minimize this risk and will assure participants of the voluntariness of their participation and their right to withdraw participation at any time. We will also take appropriate steps to safeguard confidentiality. We would suggest that this study falls under the "Minimal Risk" category.

ALTERNATIVES

Participation in the present study is completely voluntary. The alternative to participation in the study is to choose not to participate in the study.

DATA SAFETY & MONITORING

Intervention development will design and optimize the prototype intervention. Physicians, adolescents, and parents who agree to participate will receive access to mehealth for ADHD that has been enhanced with new intervention components. Given that the risks to participants are minimal, there does not appear to be the need for an external monitoring board. Rather, the Drs. Brinkman (PI) and Epstein (co-I) will assume primary responsibility for the ongoing monitoring of the data and safety of the study, and will provide reports of this with annual renewal application to the IRB and annual progress report to the sponsor. Both are experts in ADHD management, ADHD research, and have experience conducting community-based research such as that proposed in this application. Dr. Brinkman has medical expertise related to pharmacotherapy of children with ADHD to address study-related medical issues. All research staff will complete education in the protection of human research subjects.

Drs. Brinkman and Epstein will continuously evaluate the project's performance, safety, and need to stop. Performance will be monitored by examining subject recruitment, comparison with targeted recruitment retention, protocol adherence, and quality of data collection procedures. This will primarily be accomplished in weekly staff meetings attended by Drs. Brinkman and Epstein.

Drs. Brinkman and Epstein will be available at all times to address any safety issues. Any serious adverse events will be determined by Drs. Brinkman and Epstein and reported to the IRB within 24 hours, specifying the nature of the event and outcome, if related to the study and if anticipated or not. If a serious adverse event as a result of participation in the study occurs, recruitment will be immediately discontinued until the serious adverse event has been reported to the IRB and the IRB has deemed it appropriate for the study to continue.

COST OF PARTICIPATION

There will be no costs to the subject for participating in this study.

PAYMENT FOR PARTICIPATION

Each parent/adolescent dyad will be compensated $50 for each survey completed during the trial for a total of $100 throughout the intervention. We will pay $250 per enrolled pediatrician at each practice to reimburse office staff members such as a nurse or office manager for identifying eligible subjects and obtaining their consent to be contacted by the

research team. All payments will be made upon completion of each survey battery. ClinCards will be used for all payments.

REFERENCES

Ajzen, I. (1991). "The theory of planned behavior." Organ. Behav. Hum. Decis. Process. **50**: 179-211.

Ajzen, I. and M. Fishbein (1981). Understanding attitudes and predicting social behavior. Englewood Cliffs, NJ, Prentice Hall.

Albert, M., P. Rui, et al. (2017). Physician office visits for attention-deficit/hyperactivity disorder in children and adolescents aged 4–17 years: United States, 2012–2013. NCHS data brief. Hyattsville, MD, National Center for Health Statistics. **269**.

American Academy of Pediatrics. (2011). "Implementing the key action statements: An algorithm and explanation for process of care for the evaluation, diagnosis, treatment, and monitoring of ADHD in children and adolescents." Retrieved May 8, 2017, from Addhttp://pediatrics.aappublications.org/content/suppl/2011/10/11/peds.2011-2654.DC1/zpe611117822p.pdf.

Armitage, C. J. and M. Conner (2000). "Social cognition models and health behaviour: A structured review." Psychology and Health **15**: 173-189.

Attkisson, C. C. and R. Zwick (1982). "The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome." Eval Program Plann **5**(3): 233-237.

Barkley, R. A., M. Fischer, et al. (2006). "Young adult outcome of hyperactive children: adaptive functioning in major life activities." J Am Acad Child Adolesc Psychiatry **45**(2): 192-202.

Becker SP, Quach ET, Dvorsky MR, et al. (2020). Home adjustment to COVID-19 scale (HACS). Cincinnati, OH.

Bentley, B., T. A. Lennie, et al. (2009). "Demonstration of psychometric soundness of the Dietary Sodium Restriction Questionnaire in patients with heart failure." Heart Lung **38**(2): 121-128.

Boyd, C. J., S. E. McCabe, et al. (2007). "Prescription drug abuse and diversion among adolescents in a southeast Michigan school district." Arch Pediatr Adolesc Med **161**(3): 276-281.

Boyko, J. A., J. N. Lavis, et al. (2011). "Reliability of a tool for measuring theory of planned behaviour constructs for use in evaluating research use in policymaking." Health Res Policy Syst **9**: 29.

Brinkman, W. B. and J. N. Epstein (2016). Reasons why teens with ADHD stop and/or re-start taking medicine. Pediatric Academic Societies' Annual Meeting. Baltimore, MD.

Brinkman, W. B., H. Sucharew, et al. (2013). Predictors of medication continuity in children with ADHD Pediatric Academic Societies' Annual Meeting. Washington D.C.

Brinkman, W. B., H. Sucharew, et al. (2016). Predictors of medication continuity in children with ADHD. Pediatric Academic Societies' Annual Meeting. Baltimore, MD.

Brinkman, W. B., J. Hartl Majcher, et al. (2013). "Shared decision-making to improve attention-deficit hyperactivity disorder care." Patient Educ Couns **93**(1): 95-101.

Brinkman, W. B., J. Hartl, et al. (2011). "Physicians' shared decision-making behaviors in attention-deficit/hyperactivity disorder care." Arch Pediatr Adolesc Med **165**(11): 1013-1019.

Brinkman, W. B., R. Baum, et al. (2016). "Relationship Between Attention-Deficit/Hyperactivity Disorder Care and Medication Continuity." J Am Acad Child Adolesc Psychiatry **55**(4): 289-294.

Brinkman, W. B., S. N. Sherman, et al. (2009). "Parental Angst Making and Revisiting Decisions About Treatment of ADHD." Pediatrics **124**: 580-589.

Brinkman, W. B., S. N. Sherman, et al. (2012). "In their own words: adolescent views on ADHD and their evolving role managing medication." Acad Pediatr **12**(1): 53-61.

Bussing, R., D. M. Mason, et al. (2010). "Adolescent Outcomes of Childhood Attention-Deficit/Hyperactivity Disorder in a Diverse Community Sample." J Am Acad Child Adolesc Psychiatry **49**(6): 595-605.
Chacko, A., J. H. Newcorn, et al. (2010). "Improving medication adherence in chronic pediatric health conditions: a focus on ADHD in youth." Curr Pharm Des **16**(22): 2416-2423.
Chan, E., J. M. Fogler, et al. (2016). "Treatment of Attention-Deficit/Hyperactivity Disorder in Adolescents: A Systematic Review." JAMA **315**(18): 1997-2008.
Chronis, A. M., B. B. Lahey, et al. (2003). "Psychopathology and substance abuse in parents of young children with attention-deficit/hyperactivity disorder." J Am Acad Child Adolesc Psychiatry **42**(12): 1424-1432.
Chronis, A. M., H. A. Jones, et al. (2006). "Evidence-based psychosocial treatments for children and adolescents with attention-deficit/hyperactivity disorder." Clin Psychol Rev **26**(4): 486-502.
Cornelio, M. E., M. C. Gallani, et al. (2009). "Development and reliability of an instrument to measure psychosocial determinants of salt consumption among hypertensive patients." Rev Lat Am Enfermagem **17**(5): 701-707.
Eaton Hoagwood, K., P. S. Jensen, et al. (2004). "Reliability of the services for children and adolescents-parent interview." J Am Acad Child Adolesc Psychiatry **43**(11): 1345-1354.
Efron, D., F. C. Jarman, et al. (1998). "Child and parent perceptions of stimulant medication treatment in attention deficit hyperactivity disorder." J Paediatr Child Health **34**(3): 288-292.
Epstein, J. N., D. Rabiner, et al. (2007). "Improving attention-deficit/hyperactivity disorder treatment outcomes through use of a collaborative consultation treatment service by community-based pediatricians: a cluster randomized trial." Arch Pediatr Adolesc Med **161**(9): 835-840.
Epstein, J. N., J. M. Langberg, et al. (2008). "Community-wide Intervention to Improve the Attention-Deficit/Hyperactivity Disorder Assessment and Treat-ment Practices of Community Physicians." Pediatrics **122**: 19-27.
Epstein, J. N., J. M. Langberg, et al. (2010). "Attention-deficit/hyperactivity disorder outcomes for children treated in community-based pediatric settings." Arch Pediatr Adolesc Med **164**(2): 160-165.
Epstein, J. N., J. M. Langberg, et al. (2011). "Use of an Internet portal to improve community-based pediatric ADHD care: a cluster randomized trial." Pediatrics **128**(5): e1201-1208.
Epstein, J. N., J. M. Langberg, et al. (2013). "The myADHDportal.com Improvement Program: An innovative quality improvement intervention for improving the quality of ADHD care among community-based pediatricians." Clin Pract Pediatr Psychol **1**(1): 55-67.
Epstein, J. N., K. J. Kelleher, et al. (2016). "Impact of a web-portal intervention on community ADHD care and outcomes." Pediatrics **138**(2): 1-9.
Epstein, J. N., K. J. Kelleher, et al. (2017). "Specific Components of Pediatricians' Attention-Deficit/Hyperactivity Disorder (ADHD) Medication-Related Care Predict ADHD Symptom Improvement." J Am Acad Child Adolesc Psychiatry Apr 4, 2017. Retrieved Apr 4, 2017, 2017, from https://doi.org/10.1016/j.jaac.2017.03.014.
Evans, S. W., W. E. Pelham, et al. (2001). "Dose-response effects of methylphenidate on ecologically valid measures of academic performance and classroom behavior in adolescents with ADHD." Exp Clin Psychopharmacol **9**(2): 163-175.
Farley, J., S. Hines, et al. (2003). "Assessment of adherence to antiviral therapy in HIV-infected children using the Medication Event Monitoring System, pharmacy refill, provider assessment, caregiver self-report, and appointment keeping." J Acquir Immune Defic Syndr **33**(2): 211-218.

Fishbein, M., H. C. Triandis, et al. (2001). Factors influencing behavior and behavior change. Handbook of Health Psychology. A. Baum, T. A. Revenson and J. E. Singer. Mahwah, NJ, Lawrence Erlbaum Associates**:** 3-16.
Francis, J., M. P. Eccles, et al. (2004). "Constructing questionnaires based on the theory of planned behaviour: A manual for health services researchers." Retrieved Jun 5 2016, 2016, from http://openaccess.city.ac.uk/1735/.
Froehlich, T. E., S. V. Delgado, et al. (2013). "Expanding medication options for pediatric ADHD." Curr Psychiatr **12**(12): 20-29.
Gollwitzer, P. M. and P. Sheeran (2006). "Implementation Intentions and Goal Achievement: A Meta-analysis of Effects and Processes." Advances in Experimental Social Psychology **38**: 69-119.
Greenhill, L. L., J. M. Swanson, et al. (2001). "Impairment and deportment responses to different methylphenidate doses in children with ADHD: the MTA titration trial." J Am Acad Child Adolesc Psychiatry **40**(2): 180-187.
Hagger, M. S., A. Luszczynska, et al. (2016). "Implementation intention and planning interventions in Health Psychology: Recommendations from the Synergy Expert Group for research and practice." Psychol Health: 1-26.
Hemming, K., T. P. Haines, et al. (2015). "The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting." BMJ **350**: h391.
Hommel, K. A., E. Hente, et al. (2013). "Telehealth behavioral treatment for medication nonadherence: a pilot and feasibility study." Eur J Gastroenterol Hepatol **25**(4): 469-473.
Hommel, K. A., M. Herzer, et al. (2011). "Individually tailored treatment of medication nonadherence." J Pediatr Gastroenterol Nutr **53**(4): 435-439.
Howard, A. L., N. J. Strickland, et al. (2016). "Progression of impairment in adolescents with attention-deficit/hyperactivity disorder through the transition out of high school: Contributions of parent involvement and college attendance." J Abnorm Psychol **125**(2): 233-247.
Jaccard, J., H. A. Litardo, et al. (1999). Social psychological models of behavior. Social psychology and cultural context. J. Adamopolis and Y. Kashima. Newbury Park, Sage.
Kaplan, B. J., R. A. Steiger, et al. (2010). "Successful treatment of pill-swallowing difficulties with head posture practice." Paediatr Child Health **15**(5): e1-5.
Knipp, D. K. (2006). "Teens' Perceptions about Attention Deficit/Hyperactivity Disorder and Medications." The Journal of School Nursing **22**(2): 120-125.
Ladouceur, C.D. (2020). COVID-19 Adolescent Symptom & Psychological Experience Questionnaire.
Lally, P., C. H. Van Jaarsveld, et al. (2010). "How are habits formed: modelling habit formation in the real world." Eur H Soc Psychol **40**: 998-1009.
Leslie, L. K., D. Plemmons, et al. (2007). "Investigating ADHD treatment trajectories: listening to families' stories about medication use." J Dev Behav Pediatr **28**(3): 179-188.
McCabe, S. E., B. T. West, et al. (2011a). "Medical misuse of controlled medications among adolescents." Arch Pediatr Adolesc Med **165**(8): 729-735.
Meaux, J. B., C. Hester, et al. (2006). "Stimulant medications: a trade-off? The lived experience of adolescents with ADHD." J Spec Pediatr Nurs **11**(4): 214-226.
Miller, V. A. and A. F. Jawad (2014). "Relationship of Youth Involvement in Diabetes-Related Decisions to Treatment Adherence." J Clin Psychol Med Settings.
Molina, B. S., S. P. Hinshaw, et al. (2009). "The MTA at 8 years: prospective follow-up of children treated for combined-type ADHD in a multisite study." J Am Acad Child Adolesc Psychiatry **48**(5): 484-500.
MTA Cooperative Group (1999). "A 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder. Multimodal Treatment Study of Children with ADHD." Arch Gen Psychiatry **56**(12): 1073-1086.

Newcorn, J. H., C. J. Kratochvil, et al. (2008). "Atomoxetine and osmotically released methylphenidate for the treatment of attention deficit hyperactivity disorder: acute comparison and differential response." Am J Psychiatry **165**(6): 721-730.
Owens, J. S., M. E. Goldfine, et al. (2007). "A Critical Review of Self-perceptions and the Positive Illusory Bias in Children with ADHD." Clin Child Fam Psychol Rev **10**(4): 335-351.
Pai, A. L., J. Rausch, et al. (2012). "System for integrated adherence monitoring: real-time non-adherence risk assessment in pediatric kidney transplantation." Pediatr Transplant **16**(4): 329-334.
Pelham, W. E., Jr., C. Carlson, et al. (1993). "Separate and combined effects of methylphenidate and behavior modification on boys with attention deficit-hyperactivity disorder in the classroom." J Consult Clin Psychol **61**(3): 506-515.
Perou, R., R. H. Bitsko, et al. (2013). "Mental health surveillance among children--United States, 2005-2011." MMWR Surveill Summ **62 Suppl 2**: 1-35.
Pescosolido, B. A., B. L. Perry, et al. (2007). "Stigmatizing attitudes and beliefs about treatment and psychiatric medications for children with mental illness." Psychiatr Serv **58**(5): 613-618.
PewResearchCenter. (2011). "Apps and Adult SNS Climate." Retrieved May 31, 2013, from http://pewinternet.org/Shared-Content/Data-Sets/2011/August-2011--Apps-and-SNS-Climate.aspx.
Pliszka, S. (2007). "Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder." J Am Acad Child Adolesc Psychiatry **46**(7): 894-921.
Rhodes, R. E. and G. J. de Bruijn (2013). "What predicts intention-behavior discordance? A review of the action control framework." Exerc Sport Sci Rev **41**(4): 201-207.
Schmidt, S., C. Petersen, et al. (2003). "Coping with chronic disease from the perspective of children and adolescents--a conceptual framework and its implications for participation." Child Care Health Dev **29**(1): 63-75.
Simons, L. E. and R. L. Blount (2007). "Identifying barriers to medication adherence in adolescent transplant recipients." J Pediatr Psychol **32**(7): 831-844.
Simons, L. E., M. L. McCormick, et al. (2010). "Medication barriers predict adolescent transplant recipients' adherence and clinical outcomes at 18-month follow-up." J Pediatr Psychol **35**(9): 1038-1048.
Singh, I., T. Kendall, et al. (2010). "Young People's Experience of ADHD and Stimulant Medication: A Qualitative Study for the NICE Guideline." Child and Adolescent Mental Health **15**(4): 186-192.
Smith, B. H., W. E. Pelham, et al. (1998). "Dosage effects of methylphenidate on the social behavior of adolescents diagnosed with attention-deficit hyperactivity disorder." Exp Clin Psychopharmacol **6**(2): 187-204.
Steele, S. and D. Porche (2005). "Questionnaire development to predict mammography intention among women in southeastern Louisiana." J Nurs Meas **13**(1): 23-37.
Steiner, J. F. and A. V. Prochazka (1997). "The assessment of refill compliance using pharmacy records: methods, validity, and applications." J Clin Epidemiol **50**(1): 105-116.
Tian, J. H., Z. X. Lu, et al. (2014). "Effectiveness of directly observed treatment of tuberculosis: a systematic review of controlled studies." Int J Tuberc Lung Dis **18**(9): 1092-1098.
Visser, S. N., M. L. Danielson, et al. (2014). "Trends in the parent-report of health care provider-diagnosed and medicated attention-deficit/hyperactivity disorder: United States, 2003-2011." J Am Acad Child Adolesc Psychiatry **53**(1): 34-46 e32.
Walker, N. E. and T. Doyon (2001). "'Fairness and reasonableness of the child's decision:' a proposed legal standard for children's participation in medical decision making." Behav Sci Law **19**(5-6): 611-636.

Wehmeier, P. M., A. Schacht, et al. (2010). "Social and emotional impairment in children and adolescents with ADHD and the impact on quality of life." J Adolesc Health **46**(3): 209-217.
White, F. A. (1996). "Parent-adolescent communication and adolescent decision-making." Journal of Family Studies **2**: 41-56.
Wills, T., E. Blechman, et al. (1996). Family support, coping, and competence. Stress, coping, and resiliency in children and families. Mahwah, N.J., L. Erlbaum Associates**:** 107-133.
Woertman, W., E. de Hoop, et al. (2013). "Stepped wedge designs could reduce the required sample size in cluster randomized trials." J Clin Epidemiol **66**(7): 752-758.
Wolraich, M. L., W. Lambert, et al. (2003). "Psychometric properties of the Vanderbilt ADHD diagnostic parent rating scale in a referred population." J Pediatr Psychol **28**(8): 559-567.
Wolraich, M., L. Brown, et al. (2011). "ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." Pediatrics **128**(5): 1007-1022.