Title:	**Promoting Implementation of Behavioral Classroom Interventions for Children with ADHD in Urban Schools: A Pilot Test, Aim 3**
NCT #	NCT05489081
Protocol Date:	2/21/25

Title:	**Promoting Implementation of Behavioral Classroom Interventions for Children with ADHD in Urban Schools: A Pilot Test, Aim 3**
Short Title	Resource Package Pilot Test
Regulatory Sponsor:	
eIRB Number	22-019825
Protocol Date:	2/21/25
Amendment 1 Date: 7/26/22	Amendment 3 Date: 10/5/22
Amendment 2 Date: 8/31/22	Amendment 4 Date: 8/2/23
Amendment 5 Date: 2/21/25	

Study Principal Investigator: Gwendolyn Lawson
The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research
Office # 8291
2716 South St.
Philadelphia, PA, 19146
Phone: (267) 426-6612
email: lawsong@chop.edu

TABLE OF CONTENTS

ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse event
ADHD	Attention Deficit/Hyperactivity Disorder
AE	Adverse event
CHOP	Children's Hospital of Philadelphia
CRC	Clinical Research Coordinaor
EBP	Evidence-Based Practice
ID	Identification
IRB	Institutional Review Board
K	Kindergarten
PI	Principal investigator
SAE	Serious adverse event
SDP	School District of Philadelphia
SOP	Standard operating procedure

ABSTRACT

Context: Schools are an accessible and ecologically valid setting for children with symptoms of ADHD to receive evidence-based interventions to reduce symptoms and improve functioning. Behavioral classroom management interventions are well-established treatments for elementary-school age children with ADHD, but teachers use them at less than recommended frequency and fidelity. It is therefore important to develop and test implementation strategies in promoting teachers' use of behavioral classroom management interventions and in improving child outcomes.

Objectives: The primary objective is to pilot test the implementation strategy resource package that was developed in Aim 2 (IRB# 21-018638) of the larger study to demonstrate feasibility in a small-scale randomized Type 3 Hybrid Implementation Effectiveness Trial.

Primary endpoints include: 1) functional impairment, academic productivity, and the student-teacher relationship for two children with symptoms of ADHD per classroom, and 2) teacher implementation of evidence-based behavioral classroom management interventions. Secondary endpoints include child ADHD symptoms, student academic success, and homework performance.

Study Design: This study is a small-scale randomized controlled trial to test the feasibility and promise of an implementation resource package that was developed in Aim 2 (IRB# 21-018638) of the larger study. This is a hybrid implementation-effectiveness trial that includes collecting data on teacher (implementation) outcomes as well as student (effectiveness) outcomes. Participating teachers will be randomized to receive the resource package or support as usual.

Setting/Participants: The sample will consist of 30 K-5 teachers in the School District of Philadelphia (15 intervention, 15 control), and 60 students (2 nested within each classroom), nominated by their participating teachers based on concerns about inattention, hyperactivity, or impulsivity. Teachers will be randomized to condition, stratified on grade level (K-2 and 3-5) and school. Schools will be selected based on principal interest.

Study Interventions and Measures: The study intervention is teachers' receipt of an implementation resource package that was developed in Aim 2 of the larger study (IRB# 21-018638). Teachers in the intervention condition will receive the resource package after the completion of baseline measures. Additionally, the primary caregiver or legal guardian of participating children in both conditions will receive a small number of resources to support positive parenting interventions. These resources are not part of the intervention being tested, but rather are being offered to caregivers or legal guardians to thank them for their participation.

Measures used to assess child outcomes include: NICHQ Vanderbilt Assessment Scales, Student-Teacher Relationship Scale, Academic Performance Rating Scale (APRS), Direct Behavior Ratings Multi-Item Scale (DBR-MIS; Engagement and Disruptive subscales), and the Homework Performance Questionnaire – Parent Version.

The primary outcome measures are performance measured on the NICHQ Vanderbilt, Academic Productivity subscale of the APRS, and the student-teacher relationship. The secondary outcome measures are ADHD symptoms as measured on the NICHQ Vanderbilt, Engagement and Disruptive Direct Behavior Ratings, the Academic Success subscale of the APRS, and homework performance

Measures used to assess teacher implementation outcomes include: teacher report of appropriateness, acceptability, and feasibility; observed teacher use of behavioral classroom management interventions, using a modified version of the Student-Behavior Teacher Respones Observation Rating System. Additionally, the following measures of potential mediators of implementation will be collected: teacher intentions to implement behavioral classroom management interventions; teachers' attitudes, norms, and self-efficacy regarding behavioral classroom management interventions; barriers and facilitators to implementation, and the Self-Rated Habit Index.

SCHEDULE OF STUDY PROCEDURES – FOR TEACHERS

Study Phase	**Screening**	**Consent**	**Baseline Data Collection**	**Midpoint Data Collection**	**Endpoint Data Collection**
Impairment Rating Scale (Teacher Report)	x				
Review Inclusion/Exclusion Criteria	x				
Informed Consent/Assent		x			
Teacher Demographic Questionnaire (Teacher Report)			x		
Teacher Questionnaire about Intentions and Use of Behavioral Interventions (Teacher Report)			x	x	x
NICHQ Vanderbilt Assessment Scale (Teacher Report;)			x		x
Student-Teacher Relationship Scale (Teacher Report)			x		x
Academic Performance Rating Scale (Teacher Report)			x		x
Direct Behavior Rating (DBR) Multiitem Scale (Teacher Report)			x	x	x
Delivery of Resource Package to Teachers		x			
Classroom Observation using a modifited version of the SBTR			x	x	x
Adverse Event Assessment			x	x	x

SCHEDULE OF STUDY PROCEDURES – FOR CHILDREN AND CAREGIVERS/LEGAL GUARDIANS

Study Phase	Screening	Consent	Baseline Data Collection	Midpoint Data Collection	Endpoint Data Collection
Review Inclusion/Exclusion Criteria	x				
Informed Consent/Assent		x			
Parent/child Demographic Questionnaire (Parent Report)			x		
NICHQ Vanderbilt Assessment Scale (Parent Report)			x		x
Homework Performance Questionnaire – Parent Version (Parent Report)			x		x
Adverse Event Assessment			x	x	x

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Schools are an accessible[1] and ecologically valid[2] setting for children with ADHD to receive evidence-based interventions that reduce symptoms and improve functioning. Behavioral classroom management interventions are well-established treatments for elementary-school age children with ADHD[3]. Teachers' implementation of these practices is often lower than recommended guidelines[4.] It is important to understand and target both factors that promote teachers' intentions to implement EBPs, as well as those that promote their ability to act on their intentions.

We aim to Pilot test an implementation strategy resource package that was developed in Aim 2 (IRB# 21-018638) of a larger NIMH-funded study to demonstrate feasibility in a small-scale Type 3 Hybrid Trial. We will conduct a randomized clinical trial to pilot test the implementation strategy resource package for feasibility and promise. The ultimate goal of this study is to test theory-driven implementation strategies to increase the effective use of behavioral classroom interventions and therefore promote positive mental health outcomes for children with ADHD.

1.2 Name and Description of Investigational Product or Intervention

The Positive Behavior Management Toolkit is an implementation resource package developed in Aims 1 and 2 of the larger study. This resource package was informed by data collected in Aim 1 (IRB # 20-017250) and feedback from teachers and community stakeholders in Aim 2 (IRB # 21-018638). This package includes a variety of resources that aim to support teacher use of four evidence-based classroom behavior management

interventions for students with symptoms of ADHD, such as information sheets, short animated videos, reminder texts, and planning guides. The Toolkit includes teachers receiving the support of a "Toolkit Guide," who is a member of the study team. This support consists of the teacher meeting with the Toolkit guide biweekly for approximately 15-20 minutes to receive support in using the toolkit (e.g., setting goals, identifying relevant resources). The toolkit includes optional reminder texts and an invitation to follow the study Instagram account for additional resources. Teachers will choose to opt in or opt out of these resources at the time of enrollment. Participants may choose to follow the study instagram account in order to access resources as part of the toolkit. They are not required to do so.

1.3 Relevant Literature and Data

Behavioral classroom management interventions are well-established treatments for elementary-school age children with ADHD[3]. These interventions require teachers to use evidence-based antecedent and contingency management practices, such as daily report cards,[5] specific and contingent praise[6], proactive reminders about rules[7], and consistent responses to rule violations[8]. Randomized trials of behavioral classroom interventions demonstrate that they decrease disruptive behavior symptoms and improve academic outcomes for children with ADHD[3].

However, teachers' implementation of these practices is often lower than recommended guidelines[4]. The small body of research examining barriers to teachers' use of evidence-based practices (EBPs) for children with ADHD has identified individual-level factors such as teachers' knowledge, attitudes, and attributions[9,10] as well as organizational-level factors such as school leadership[11]. Our preliminary work suggests that in the demanding context of under-resourced public schools, even when teachers *intend* to implement EBPs, they often struggle to do so[12]. It is therefore important that implementation strategies target both factors that promote teachers' intentions to implement EBPs, as well as those that promote their ability to act on their intentions.

This study aims to pilot test a resource package of implementation strategies, also referred to as a "toolkit" to support teacher use of behavioral classroom management interventions by targeting both teachers' intentions and their ability to act on positive intentions. This is a hybrid implementation-effectiveness trial[14] that includes data collection about both teacher (implementation) outcomes and child (effectiveness) outcomes.

To screen children for inclusion we will use the Impairment Rating Scale (IRS), [13] at screening. This scale assesses the child's functional impairment in specific areas of functioning that are known to be impaired in children with ADHD. The teacher IRS contains six domains (relationship with peers, relationship with teacher, academic progress, selfesteem, influence on classroom functioning, and overall impairment). The IRS has shown very good temporal stability and correlates with other impairment ratings and behavioral measures[13].

The outcome measures we will use in this study include: the Impairment Rating Scale (IRS),[13] Student-Teacher Relationships Scale,[14] Academic Performance Rating Scale,[15] NICHQ Vanderbilt Scale [16] and Homework Performance Questionnaire – Parent Version.[17]

To assess teachers' perceptions of their relationship with specific students, we will use the Student-Teacher Relationship Scale (STRS*).*[14] It generates three subscales (conflicts, closeness, dependency) and an overall total score. The STRS has shown adequate test-retest reliability (r = .89) and good internal consistency (alpha = .89).[14] The total score will be used as a primary outcome measure.

We will use the Academic Performance Rating Scale[15] which assesses teacher judgment of students' academic functioning. The Academic Success (i.e., academic achievement) and Academic Productivity (i.e., day-to-day performance) subscales have acceptable internal consistency (.72-.95), stability (.88-.95), criterion-related validity, and sensitivity to intervention.[18,19] Because the three impulse items have produced weaker psychometric properties we will not ask teachers to complete these three items. Teacher-reported Academic Productivity will be used as a primary outcome and teacher-reported Academic Success will be used as a secondary outcome.

We will measure parent and teacher report of ADHD symptoms and impairment for the two target students in each classroom at baseline and endpoint using the NICHQ Vanderbilt Scale. This scale assesses the frequency of inattention and hyperactivity/impulsivity symptoms. Parent-reported and teacher-reported performance will be used as primary outcome measures, and parent-reported and teacher-reported inattention and hyperactivity/impulsivity symptoms will be used as secondary outcome measures.

We will also collect teacher ratings of child behavior using Direct Behavior Rating Multi-Item Scales (DBR-MIS). For this study, teachers will rate behaviors in two domains: Engagement (5 items rating frequency of these behaviors on a 7-point scale from Never to Almost Always) and Disruptive Behavior (5 items rating degree to which each item is a problem on a 7-point scale from Not a Problem to Serious Problem). These domains of the DBR-MIS has shown acceptable factor loadings and internal consistency[20] and treatment sensitivity.[21]

We will use the Homework Performance Questionnaire – Parent Version[17] which assesses students' homework behavior during the past 4 weeks. Parents will complete this measure for target students in grades 1-5. The student self-regulation factor, which has shown strong psychometric properties,[17] will be used as a secondary outcome measure.

Additionally, we will measure acceptability of the intervention using the Acceptability of Intervention Measure (AIM),[22] which consists of four items (e.g., "[Intervention] is appealing to me") on a 5-point Likert scale. We will measure appropriateness of the intervention using the Intervention Appropriateness Measure (IAM),[22] which consists of four items (e.g., "[Intervention] seems suitable") on a 5-point Likert scale. We will measure feasibility of the intervention using the Feasibility of Intervention Measure (FIM) [22] which consists of four items (e.g., [Intervention] seems easy to use") on a 5-point Likert scale. These measures have shown acceptable reliability (alphas above .82) and test-retest reliability (Pearson correlations above .70).[13]

The last measure we will use to measure teacher implementation outcomes is a modified version of the Student Behavior-Teacher Response Observation Rating System (SBTR) [8] to measure observed teacher use of behavioral classroom management interventions at baseline, mid-point, and end-point. Specifically, the observer will record frequency counts of teacher use of the four effective practices directed to the target students. Additionally, following Owens et. al (2017), the observer will rate the global competence with which teachers implement the behavioral classroom management practices on a 10-point scale following each observation. For any implementation strategies that can be observed during a classroom observation (e.g., teacher use of a reminder system), we will also record frequency counts of the teacher's use of the implementation strategy.

We will also measure teacher baseline characteristics and hypothesized mechanisms of the implementation strategy, in order to determine whether the implementation strategy condition results in change in these hypothesized mechanisms.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (when appropriate), and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to pilot test the implementation resource package in a small randomized controlled hybrid effectiveness-implementation trial for initial evidence of feasibility and promise.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the whether the teacher use of the implementation resource package has effects on teacher implementation (i.e., frequency and competence with which teachers use 4 target behavioral classroom management interventions) and child outcomes (i.e., ADHD-related impairment, academic productivity, and the student-teacher relationship).

2.2 Secondary Objectives (or Aim)

The secondary objectives are to determine if teacher use of the implementation resource package has effects on ADHD symptoms, teachers' reatings of students' engagement and disruptive behavior, academic success, and homework performance.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Screening Phase

Participants will be recruited into two strata: K-5 teachers in participating schools, and children who are students of the participating teachers (two students per participating teacher).

Potential teacher participants will be screened using the protocol inclusion and exclusion criteria at participating schools. Children that are nominated by participating teachers will be screened for ADHD-related impairment through a modified version of the Impairment Rating Scale (completed without identifying information about the child) to confirm the presence of ADHD-related impairment.

Parental/guardian (must be child's legal guardian) permission (informed consent) will be obtained prior to child enrollment. When applicable, child assent will also be obtained.

3.1.2 Study Treatment Phase (start of the study intervention)

After teachers have enrolled, consented, and completed baseline self-report measures, informed consent (and assent if appropriate) will be obtained by the students' legal guardian and baseline teacher-report measures about the participating students will also be collected by child's primary caregiver or legal guardian. The study team will deliver the resource package to the teacher, which they will utilize in their teaching and behavior management practice over approximately 8-10 weeks. At the mid point of the study cycle, the study team may conduct a classroom observation and will collect mid point measures from the teacher. At the end of the study cycle, teachers and caregivers or legal guardians will complete endpoint measures.

3.2 Allocation to Treatment Groups and Blinding

Teachers will be randomly assigned to group (Treatment, Comparison) stratified on grade level (K-2 and 3-5) and school. The study PI will produce the randomization lists. Children will be assigned to condition based on their teachers' randomization.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Subject Study Participation

The planned study duration per participant will be approximately 12-15 weeks, which includes screening, informed consent and baseline measures, delivery of resource package, mid point measures, and end point measures.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The total number of participants includes up to 30 teachers and up to 60 students (2 students nested underneath each teacher).

Participating teachers will be K-5 teachers in the School District of Philadelphia at a participating school.

Participating children will be a student in the class of a participating teacher, and will be screened by the teacher to confirm the presence of ADHD-related impairment.

It is anticipated that up to 30 teachers (from either the control or intervention conditions) will enroll in the supplemental post-participation interview. These participants are a subset of those in the main study and do not increase the number of projected enrolled teachers.

3.4 Study Population

3.4.1 Inclusion Criteria

Teacher Inclusion criteria

- A K-5 teacher at a participating school within the School District of Philadelphia
- Teach at a participating school
- Informed consent

Child Inclusion Criteria

- Is in a K-5 class of a participating teacher
- Nominated for participation by the participating teacher
- Identified by their participating teacher as displaying impairment related to inattention, hyperactivity or impulsivity
- Informed consent and assent if appropriate

Child Exclusion Criteria

- Special education classification of 'intellectual disability'
- Primary presenting concern of psychotic or autism specrum disorders
- Presents as in acute risk of harm to self or others, such that participation in the study is clinically inappropriate because the child warrants more intensive intervention

Parent/Legal Guardian Inclusion Criteria

- Parent or legal guardian of child
- Identifies as familiar enough with the child to fill out measures about the child
- Has mental capacity to provide consent for the participation of child in the study and for their own participation in the study

Caregiver Inclusion Criteria

- Has been referred by the legal guardian as the primary caregiver that can more accurately complete the measures about the child
- Has mental capacity to provide consent for the participation of child in the study and for their own participation in the study

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Teacher Enrollment and Consent

- A member of the study team will review the study procedures and consent form, and answer any and all questions with the teacher before obtaining informed consent.

4.2 Screening Child for Eligibility

- Teachers who have provided informed consent and enrolled in the study will nominate two students in their class who display inattentive, hyperactive, and/or impulsive behaviors.
- Without providing any identifying information about student, teachers will complete the Impairment Rating Scale for each of these nominated students (providing student initials only) to determine if they display impairment related to ADHD.
- If, based on this measure, the nominated student displays impairment related to ADHD, the teacher will then reach out to the students' parents to explain an overview of the study and ask if the parent consents to being contacted by the study team.
- If the parent agrees (by providing verbal or written permission to the teacher over the phone, email, or other class messaging system that teachers normally use to communicate with parents) to allow the teacher to give the study team the parent's contact information and to let the study team reach out to the parent, a member of the study team will reach out to the parent to invite the child to enroll. Informed consent will always be provided by the child's legal guardian.

4.3 Child Enrollment, Informed Consent, and Baseline Data Collection from Caregivers or Legal Guardians

- Informed Consent: A member of the study team will review the study procedures and consent form, and answer any and all questions with the guardian(s) before obtaining informed consent and assent (if appropriate).

- During phone and virtual consent meetings in which legal guardians or caregivers provide verbal consent and the study team documents verbal consent (i.e., they will not provide a signature) the study team will write a Note to File to note that the IRB waived the requirement for documentation of consent and issued an alteration of HIPAA for phone and virtual meeting consent procedures.

- When the legal guardian or participating children have Limited English proficiency, an interpreter (who will either be conferenced in by phone or present in the room with the study team and participate in person) will be present to interpret the

informed consent process. In all cases, the study team will obtain the interpreter's name and employee ID number and document it on the signature form. If the interpreter is present in person, they will sign the consent form. Because consent with legal guardians or participating children with LEP will always be obtained via documentation of verbal consent (i.e., they will not provide a signature) the study team will write a Note to File after each instance in which consent is obtained verbally to note that the IRB waived the requirement for documentation of consent and issued an alteration of HIPAA for phone and virtual meeting consent procedures.

- Administration of baseline measures:

Parent Baseline Measures: After informed consent is obtained, caregivers or legal guardians will complete the following baseline measures about their child: NICHQ Vanderbilt Scale and Homework Performance Questionnaire – Parent Version. If the legal guardian (who provides informed consent) notifies the study team that another primary caregiver is most familiar with their child, they can provide permission for the primary caregiver to complete questionnaires about the child on their behalf. Note that the informed consent form includes language explaining this.

- When legal guardians/ caregivers or participating children have Limited English proficiency, the following procedures will be in place for questionnaire completion at both baseline and endpoint:

  - Validated questionnaires will be offered in Spanish if the parent reads Spanish fluently. If the parent does not read Spanish fluently (i.e., reads/speaks a language other than Spanish or English), an interpreter (by phone or in person) will be used to support the parent in completing the questionnaires.

  - An interpreter (who will either be conferenced in by phone or present in the room with the study team and participate in person) will be used to support the parent in completing the demographic questionnaire.

4.4 Baseline Data Collection from Teachers and Delivery of the Resource Package

- Teachers will complete the following baseline measures about themselves and their classroom practice: Demographic questionnaire, Intentions Questionnaire, Self-Rated Habit Index, Barriers and Facilitators Questionnaire.

- Teachers will complete the following baseline measures about each enrolled student: NICHQ Vanderbilt Scale, Student-Teacher Relationship Scale, Academic Performance Rating Scale, and DBR Multi-Item scale (engagement and disruptive subscales).

- Classroom observation: We will use a modified version of the Student Behavior-Teacher Response Observation Rating System (SBTR) to measure observed teacher use of behavioral classroom management interventions and global competence.

- Delivery of resource package to teachers: Teachers will be given access to the resource package following baseline data collection and the informed consent and enrollment of the two students nested in their classroom.

4.5 Midpoint data collection

- Teacher-report measures: Teachers will complete the following self-reported measures: Intentions Questionnaire; Determinants of Intentions Questionnaire; Self-Rated Habit Index; Direct Behavior Rating subscales.

- Classroom observation: We will use a modified version of the Student Behavior-Teacher Response Observation Rating System (SBTR) to measure observed teacher use of behavioral classroom management interventions and global competence
- No data will be collected from parents at midpoint.

4.6 End-point data collection from teachers

Teachers will complete the following endpoint measures about each enrolled student: NICHQ Vanderbilt Scale, Student-Teacher Relationship Scale, and Academic Progress Report.

Teachers will complete the following endpoint measures about their classroom practice: Intentions Questionnaire; Determinants of Intentions Questionniare; Self-Rated Habit Index; Barriers and Facilitators Questionnaire.

Classroom observation: We will use a modified version of the Student Behavior-Teacher response Observation Rating System (SBTR) to measure observed teacher use of behavioral classroom management interventions and global competence.

4.7 End-point data collection from caregivers or legal guardians

Caregivers or legal guardians (the same caregiver or legal guardian that completed baseline measures for each child) will complete the following endpoint measures about their child: NICHQ Vanderbilt Scale and Homework Performance Questionnaire – Parent Version.

The same procedures will be in place for caregivers with LEP as outlined in section 4.3.

4.8 Optional follow-up meeting for teachers

At the end of their participation in the study, teachers will be offered 1-2 optional, brief follow-up meetings with a study staff member in case they have any remaining questions about the toolkit, which they are able to keep after their participation. These meetings will not constitute research and no data will be collected from these meetings.

4.9 Optional post-participation interview for teachers

All teachers who complete participation will be offered the opportunity to participate an optional, supplemental, semi-structured qualitative interview after the post-treatment assessment timepoint. This interview will be conducted remotely (i.e., via a CHOP-approved video conferencing platform or telephone) or in person. For the qualitative interview data, participants' responses will be audio-recorded if the interview occurs in person or by telephone, or video and audio recorded via a CHOP-approved video conferencing platform. If conducted on a video conferencing platform, both video and audio will be recorded but only the audio file will be retained. The informed consent process and the interview will both be recorded. Additional information about these proccedures can be found in section 7.2.

4.10 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, AEs, or due to the following reasons: if it becomes clear that a higher level of care is warranted for the child due to severe symptoms or risk to self or others; or if either the teacher or student is absent from school for a significant amount of time (i.e. due to an illness, leave of absence, etc.) Additionally, students will be withdrawn from the study if their teacher withdraws. Data for students and teachers collected prior to their withdrawal will be retained. The Investigator or the Sponsor (if applicable) may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

After study participation is completed, the study team may reach out to parents/legal guardians of participating children to offer participation in other research opportunities. The study team will only contact parents/legal guardians who indicated willingness to be contacted in the future on the demographics survey. Outreach to these parents/legal guardians will occur by phone or email via the contact information that was provided during the study. The study team member who makes contact will be clear that their decision to participate in another study is completely voluntary and will not impact their participation in this study.

4.10.1 Early Termination Study Visit

Participating teachers who withdraw from the study prior to completion will not continue to receive resources related to the implementation resource package (e.g., support from the Toolkit Guide, text message reminders), although they will be permitted to retain access to paper and online resources that they previously accessed. If children/families withdraw from the study prior to its completion, the study team will no longer ask the child's teacher or parent to complete measures based on the student's performance or behaviors, and

classroom observations will no longer consider that child as a ‘target’ child. However, families will be permitted to retain access to resources they received through the study, the teacher may continue to receive the resource package and classroom observations may continue if the teacher remains enrolled in the study.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Screening child for eligibility

- In the screening phase, teachers will complete the teacher version of the Impairment Rating Scale (IRS) [13] regarding the two students they plan to nominate to screen the nominated students (providing student initials only) for impairment that commonly occurs with ADHD. This measure screens for impairment across six domains (relationship with peers, relationship with teacher, academic progress, self-esteem, influence on classroom functioning, and overall impairment), which teachers rate on a scale from 0 (no problem/definitely does not need treatment or special services) to 6 (extreme problem/definitely needs treatment or special services). The IRS has shown strong temporal stability, correlation with other impairment ratings, and ability to discriminate between children with and without ADHD[13]. Consistent with Fabiano et al. (2006), students will be screened as impaired if they receive a rating of 3 or greater in at least one IRS domain. If a student does not receive a rating of 3 or higher in at least one IRS domain, they will not be eligible for enrollment.

5.2 Efficacy Evaluations

5.2.1 Teacher Implementation Outcomes

- A member of the study team will utilize a modifited version of the SBTR during classroom observations at the baseline, midpoint, and end point to measure fidelity of teacher use of the behavioral classroom management interventions. Specifically, the observer will record frequency counts of teacher use of the four effective practices directed to the target students. Additionally, following Owens et al. (2017), the observer will rate the global competence with which teachers implement the behavioral classroom management practices on a 10-point scale following each observation.

Acceptability: Teachers will complete the Acceptability of Intervention Measure (AIM),[22] which consists of four items (e.g., "[Intervention] is appealing to me") on a 5-point Likert scale, regarding the resource package. Teachers will complete this measure at the end point.

Appropriateness: Teachers will complete the Intervention Appropriateness Measure (IAM), [22] which consists of four items (e.g., "[Intervention] is seems suitable") on a 5-point Likert scale, regarding the resource package. Teachers will complete this measure at the end point.

Feasibility: Teachers will complete the Feasibility of Intervention Measure (FIM),[22] which consists of four items (e.g., [Intervention] seems easy to use") on a 5-point Likert scale, regarding the resource package. Teachers will complete this measure at the end point.

5.2.2 Teacher Measures - Potential Mediators

Teacher Intentions Questionnaire: Teacher intentions to implement each of the four intervention components will be measured using a standardized 4-item questionnaire. The

items will use validated stems designed to probe provider intentions to use a specific practice (e.g., "Over the next month, how likely is it that you will praise these children for appropriate behavior at least as often as you correct their behavior?"). Teachers will be asked to complete these items "regarding students in your class who show elevated levels of inattentive, impulsive, or hyperactive behaviors." Additionally, teachers will be asked to complete these items regarding the participating children after the participating children have enrolled in the study.

Teacher Determinants of Intentions Questionnaire: Teachers will complete a questionnaire with validated, standardized item stems to report on their attitudes, norms, and self-efficacy for using behavioral classroom management interventions "regarding students in your class who show elevated levels of inattentive, impulsive, or hyperactive behaviors.".

Teacher Self-Rated Habit Index (SRHI): The SRHI is a 12-item scale that assesses the automaticity of a behavior, as well as its frequency of repetition and assimilation into one's self-identity.

Barriers and Facilitators Questionnaire. Teachers will report on the extent to which each of 10 potential barriers and 12 facilitators impact their use of behavioral classroom interventions.

5.2.3 Child Outcomes – Teacher Report

ADHD Symptoms and Impairment: Teachers will complete the NICHQ Vanderbilt Scale about participating children at the baseline and the end point. Teacher-reported performance will be used as a primary outcome measure, and teacher-reported inattention and hyperactivity/impulsivity symptoms will be used as secondary outcome measures.

Student-Teacher Relationship Scale: Teachers will complete the Student-Teacher Relationship Scale about participating children at the baseline and the end point. This scale assesses teachers' perceptions of their relationship with specific students. It generates three subscales (conflicts, closeness, dependency) and an overall total score. The total score will be used as a primary outcome measure.

Academic Performance Rating Scale: Teachers will complete the Academic Performance Rating Scale about participating children at the baseline and the end point. This scale assesses teacher judgment of students' academic functioning across two subscales: Academic Success (i.e., academic achievement) and Academic Productivity (i.e., day-to-day performance). The subscales are each measured by 8 items, rated on 5-point scales. Teacher-reported Academic Productivity will be used as a primary outcome measure and teacher-reported Academic Success will be used as a secondary outcome measure.

Direct Behavior Rating Multi-Item Scales (DBR-MIS): Teachers will complete the Direct Behavior Rating Multi-Item Scales for the domains of Engagement and Disruptive Behavior. They will complete these ratings at baseline, midpoint and endpoint. The average rating within domains will be used as secondary outcome measures.

5.2.4 Child Outcomes – Caregiver Report

ADHD Symptoms and Impairment: Caregivers or legal guardians will complete the NICHQ Vanderbilt Scale about participating children at the baseline and the end point. Caregiver-reported performance will be used as a primary outcome measure, and caregiver-reported inattention and hyperactivity/impulsivity symptoms will be used as secondary outcome measures. This scale is validated in English and Spanish.

Homework Performance: Caregivers or legal guardians will complete the Homework Performance Questionnaire – Parent Version at the baseline and end point. This scale assesses students' homework behavior during the past 4 weeks. Caregivers or legal guardians will complete this measure for participating students in grades 1-5. The student self-regulation factor, which has shown strong psychometric properties, will be used as a secondary outcome measure. This scale is validated in English and Spanish.

5.2.5 Supplemental Teacher Interview

Teachers of both conditions will be offered the opportunity to complete a one-time, audio-recorded, **qualitative interview after the post-treatment assessment timepoint**. This interview will include questions related to perceptions of effectiveness, acceptability, feasibility, and usability of the resource package. The interview will be conducted once and take approximately 30 minutes to complete. Teachers will be asked to participate (i.e., not children or teachers) as long as they have completed their participation in the study.

STATISTICAL CONSIDERATIONS

5.3 Primary Endpoint

The goal of this pilot study is to examine the feasibility and promise of the implementation strategy resource package. This is a Hybrid Implementation-Effectiveness study[23], with outcomes of interest at the level of the teacher (implementation outcomes) and child (effectiveness outcomes).

At the level of teacher (implementation) outcomes, the primary outcomes are the frequency of observed teacher use of behavioral classroom management interventions and global competence as rated on the modified Student Behavior Teacher Response rating system, as well as teacher-reported acceptability, appropriateness and feasibility.

At the level of child (effectiveness) outcomes, the primary outcomes are changes in child functional impairment measured on the Vanderbilt, the Academic Productivity subscale of the APRS, and the student-teacher relationship.

5.4 Secondary Endpoints

Secondary endpoints at the level of child (effectiveness) outcomes include: change in ADHD symptoms, the Academic Success subscale of the APRS, Direct Behavior Ratings in the domains of Engagement and Disuptive Behavior, and change in homework performance.

5.5 Statistical Methods

5.5.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

5.5.2 Efficacy Analysis

We will use descriptive statistics to examine teacher-reported acceptability, appropriateness, and feasibility. We then will examine whether the intervention and control groups differ on baseline teacher and student outcomes.

To compare teacher use of the four behavioral classroom management strategies between the implementation strategy and control group, we will estimate means and standard deviations (SD)of observed teacher use of the four strategies and teacher global competence ratings. Similarly, to compare child-level outcomes between the groups, we will estimate means and SDs of child primary and secondary outcomes. We will examine baseline and post-intervention scores, as well as change scores. We will compute effect sizes by calculating the difference in change scores for the intervention versus control group between post intervention and baseline and dividing this amount by the pooled standard deviation of the baseline score for intervention and control[24].

Additionally, we will examine change in the measure of teacher intentions and teacher-reported implementation barriers, and explore the extent to which the data are consistent with the conceptual model for mediation[25]. These analyses will determine whether there is

preliminary evidence to support changes in specific barriers as plausible mechanisms for the implementation strategy.

5.6 Sample Size and Power

This is a pilot study with the goal of examining the feasibility and promise of the implementation strategy resource package and generating pilot data for a future R01 submission.

Given this goal, we plan to recruit 30 teachers and 60 children to provide acceptability, feasibility, and appropriateness data, and some preliminary effectiveness data (though the latter is not central to the successful completion of the project). Given the randomized control design, approximately 15 teachers will be randomized to the implementation strategy condition and 15 to the control condition. The sample size is not based on a power analysis but is rather the pilot randomized control trial is included as a training exercise, given that the focus of the K23 award is on training for career development. The pilot trial will determine the feasibility of the outcome measures and will provide preliminary effectiveness data for the subsequent R23 application. All other statistics will be descriptive, on acceptability, feasibility, and appropriateness of the implementation strategy resource package.

SAFETY MANAGEMENT

6.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

6.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that do not meet prompt reporting requirements will be summarized in narrative or other format and submitted to the IRB at the time of continuing review (if continuing reviews are required), or will be tracked and documented internally by the study team but not submitted to the IRB (if continuing reviews are not required).

All AEs (including serious AEs) will be noted in the study records and on the case report form with a full description including the nature, date and time of onset, determination of non-serious versus serious, intensity (mild, moderate, severe), duration, causality, and outcome of the event.

6.3 Definition of a Serious Adverse Event (SAE)

An SAE is any adverse experience that results in any of the following outcomes:

- death,
- a life-threatening event (at risk of death at the time of the event),
- requires inpatient hospitalization or prolongation of existing hospitalization,
- a persistent or significant disability/incapacity, or
- a congenital anomaly/birth defect in the offspring of a subject.

7 STUDY ADMINISTRATION

7.1 Treatment Assignment Methods

7.1.1 Randomization

Teachers will be randomly assigned to group (Treatment, Comparison) stratified on grade level (K-2 and 3-5) and school. The study PI will produce the randomization lists. Children will be assigned to condition based on their teachers' randomization.

7.1.2 Blinding

This study does not include blinding.

7.1.3 Unblinding

N/A

7.2 Data Collection and Management

All data and records generated during this study will be kept confidential in accordance with Institutional policies. The PI, members of the study team, and other site personnel will not use such data and records for any purpose other than conducting the study. The following steps will be taken to maintain confidentiality: (1) all paper data will be transferred in a locked bag and be kept at a locked site; (2) participant identity will be de-identified using numbers keyed to a master list; (3) de-identified data will be entered directly into files that will be password protected; (4) all project staff will be trained in the importance of confidentiality, and will promise in writing to protect participant confidentiality; and (5) if the results of the study are published and/or shared with community partners, data which might reveal the identity of any particular participant will be disguised.

No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes). If data from the study is shared, the investigators will share with recipients that they must follow the CoC.

For teachers who consent to the post-participation qualitative interview, participants' responses will be audio-recorded through a HIPAA-secured video platform that is CHOP-approved. Participants' responses will be audio-recorded in person or by telephone, or video and audio recorded via a video conferencing platform. If conducted via video conferencing, both video and audio will be recorded but only the audio file will be retained. The informed consent process and the interview will both be recorded.

The audio files will also be password-protected and temporarily saved on the Principal Investigator's password-protected research drive on a password-protected computer. Transfer of audio files from the audio device to the Principal Investigator's computer will occur directly from the audio-recording device. In the drive on the password-protected computer, audio files will be labeled according to participants' unique study ID numbers, and no identifying information will be used to label the files. Audio files are unlikely to include any identifiying

information unless the participant states their name or the interviewer addresses the participant by name.

Audio files of the interviews will then be transcribed by the research team or an outside vendor and checked for accuracy, at which point the digital files will be destroyed upon termination of the study by the IRB. Audio recordings may be sent to an outside professional transcription agency, ADA Transcription located in Mt. Holly, New Jersey via uploading the audio files on their secure site. ADA Transcription is CHOP-approved and a BAA will be in place. All files are securely stored, transmitted, and encrypted. The agency will remove all identifying information from the transcripts and destroy their copy of the audio files after transcription is complete. Transcribed interview data will be coded using participants' unique study ID numbers. Any interviewer field notes taken during the observation and/or interview will be coded using only the participants' unique study ID numbers, and stored in the Principal Investigator's locked cabinet in their CHOP office until the point of transcription. The transcribed interview and interviewer field note data will be stored in password-protected files on the study network drive/ Audio files of telephone-based informed consent for study procedures will be stored in password-protected files on the Principal Investigator's office computer and retained for 6 years to comply hospital policy.

7.3 Confidentiality

1. Confidentiality: Names will be collected regarding participants (teachers and students) across baseline data collection, mid-point data collection, and end-point data collection, in order to link data across instruments. Participants (teachers and students) will be assigned a unique study ID number after consenting to study procedures. A member of the study team will record the participant name in a separate, password-protected REDCap database that will be used as a master list linking names and study ID numbers. The following steps will be taken to maintain confidentiality: (1) all paper data will be stored in a HIPAA lockable bag for transportation of papers and will be kept at a locked site; (2) participant identity will be de-identified using numbers keyed to a master list; (3) de-identified data will be entered directly into files that will be password protected; (4) all project staff will be trained in the importance of confidentiality, and will promise in writing to protect participant confidentiality; and (5) if the results of the study are published and/or shared with community partners, data which might reveal the identity of any particular participant will be disguised. Additionally, we will not be collecting any information from students education records.

2. Questionnaire data will be collected by paper forms and/or via a secure REDCap survey link to complete these questionnaires electronically on participants' own devices or devices of research team members. The REDCap databases are password protected, accessible only to members of the study team, and only contain participant ID numbers and questionnaire responses. Paper forms will be de-identified (i.e., labeled with unique study ID number), kept in a locked file cabinet, and only accessible and/or analyzed by trained research staff. Data from paper forms will be entered into a secure REDCap database, labeled with unique study ID number.

3. Security: Copies of only coded data (i.e., with participant unique study ID, questionnaire responses,) will be downloaded from the REDCap for data analysis purposes. These data will be stored in password-protected files on the Principal Investigator's office computer, in a secure server for research. No identifying data from the separate, password-protected REDCap dataset that contains the master list linking the participants' identifying information and their unique study ID number will be downloaded, and the database will only be accessible on the secure, password-protected REDCap serverAs noted above, any files from audio recorders will be transferred directly from the audio recorder to the password-protected computer, consistent with CHOP IT security procedures. Any recordings on the audio recorder will be deleted from the recording device immediately after they are uploaded to CHOP computer. Uploads of audio files to the ADA Transcription site for transcription purposes will also be encrypted. ADA Transcription has been vetted by CHOP and is compliant with all CHOP technology transfer policies.

4. Anonymization, de-identification or destruction: All identifiers that are stored in the separate, password protected REDCap database master list will be retained for 6 years and then destroyed, consistent with CHOP Hospital Policy. The coded data will be retained indefinitely through password-protected files on the secure research server and on the REDCap platform.

5. If participants choose to follow the study Instagram as part of their engagement with the toolkit, their username will be available to others who follow the account, who may be able to infer study participation. This information will be explained to teachers as part of the consent process.

No identifiable data will be used for future study without first obtaining IRB approval or determination of exemption. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

7.4 Regulatory and Ethical Considerations

7.4.1 Data and Safety Monitoring Plan

The Principal Investigator (Dr. Lawson) will assume overall responsibility for maintaining oversight over data integrity and security and subject safety. The PI will meet on a weekly basis with members of the core research team to monitor data collection and safety. For additional details about procedures to ensure data confidentiality, security, and anonymization, please see section 7.2 and 7.3. All adverse events will be reported to the CHOP IRB and the NIMH.

7.4.2 Risk Assessment

Teachers: There are no known physical or legal risks to teachers for participating in the study; study participation poses minimal risks to subjects. Use of the resource package and

completion of questionaires does not confer greater than minimal risks for participating teachers. There are minimal risks related to confidentiality and breach of privacy in collecting these instruments from participants. Participation in the study will have no impact on teachers' employment at the School District of Philadelphia and their supervisors will not be aware of their individual responses in the questionnaires. These risks will be addressed through maintaining a coded REDCap database for electronic data, maintaining coded interview notes and audio-recordings, and keeping a separate REDCap database with the subjects' identifying information and unique study IDs. For further information please see the plan for safeguarding these data, described above in section 7.2 and 7.3.

Using the resource package and/or completing questionnaires could potentially be stressful or anxiety-provoking for participating teachers. The content of the questionnaires and interviews will not pertain to teachers' health, mental health or other sensitive information. Nevertheless, it is possible that participating teachers may find it uncomfortable to reflect on their teaching practices and use of the resource package. To reduce these risks, participants will be reminded that participation in the questionnaires are voluntary, and that they may choose to refrain from answering any questions and may stop the questionnaire at any time.

Children and Families: There are no known physical or legal risks to participating in the study; study participation poses minimal risks to subjects. Child involvement in the proposed study involves: a) the child's caregiver(s) receiving brief resources related to positive parenting (for children in both treatment and control groups); b) the child's teacher receiving the implementation strategy resource package to support positive behavioral interventions in the classroom (for children in the treatment group); and c) the collection of teacher and parent report data regarding child behavior and learning (for children in both treatment and control groups). The study therefore involves minimal risk to children and their families. However, it is possible that children and their families may experience:

- The risk of discomfort or distress from questionnaire content or from learning of study findings
- The possibility of breached confidentiality by disclosure of personal information
- The risk that the intervention may have some iatrogenic effect.

There is the possibility that answering certain questions on parent-report measures about demographics and homework performance may cause caregivers some discomfort. To reduce these risks, participants will be reminded that participation in the questionnaires are voluntary, and that they may choose to refrain from answering any questions and may stop the questionnaire at any time.

The proposed teacher-report measures include a number of sensitive items related to children's behavior and learning. A breach of confidentiality may cause embarrassment and distress. Therefore, precautions will be taken to minimize the likelihood of a breach of confidentiality (see sections 7.2 and 7.3).

Finally, there is a small chance that the proposed intervention may have negative consequences. The majority of evidence suggests that behavioral classroom management interventions are effective in improving child outcomes. However, it is possible that they

may have negative effects for certain children in certain contexts. To protect against this risk, I will monitor outcomes and potential adverse events, as described in below, to identify any iatrogenic effects of the intervention.

7.4.3 Potential Benefits of Trial Participation

Direct benefits for participating teachers include receiving the implementation strategy resource package. Teachers randomized to the treamtment group will receive the full implementation strategy resource package during the course of the study. Teachers randomized to the control group will receive access to any paper documents and websites in the resource package (but not any coaching support) after their participation in the study ends.

Direct benefits to participating children and their families include access to brief resources regarding positive parenting support for families of children in both conditions. Benefits also include the potential that their teachers' use of the reasource package may result in positive outcomes on the childrens' symptoms, impairment, academics, and/or student-teacher relationship. Indirect benefits include the possibility that the resource package, if found to be feasible and promising, may be more widely distributed and accessible to other teachers and students.

7.4.4 Risk-Benefit Assessment

The benefits of this project outweigh the minimal participant risks associated with study procedures.

7.5 Recruitment Strategy

Schools will be recruited to participate in the study based on principal interest. We will document principal approval to recruit in their school for the study using the form required by the School District of Philadelphia's Research Review Committee. Teachers at participating schools will be invited to participate by a member of the study team by email, phone, text (when a teacher has provided their phone number and provided verbal or written permission to receive texts), or in person. Additionally, flyers may be posted within school buildings or distributed by email, in which teachers who are interested in participating, or have additional questions, can scan the QR code on the flyer and fill out a brief redcap survey to share their contact information with the study team. A brief informational video may be shared with staff, so that interested teachers can contact the study team. The study team may also share videos with teacher testimonials (i.e. videos in which teachers share their experience using classroom management practices or trying out the teacher toolkit) that were created in an earlier phase of the study (IRB# 21-018638) via email or disseminating the video to school leaders as a way of sharing information about the toolkit and participation in the study. These videos will be submitted for the IRB's review in an IRB amendment prior to their use for recruitment; if this amendment is not approved, they will not be used for recruitment. Teachers will be approached after the IRB and RRC proposals are approved, during the 2022-2023 or 2023-2024 school years. Principals who have agreed to participate will provide contact information regarding teachers to be approached for

participation. Children will be nominated for participation by their teachers (see Section 4.3).

7.6 Informed Consent/Assent and HIPAA Authorization

7.6.1 Screening

There is no screening process for teachers, but there is a screening procedure for child participants. When teachers have provided informed consent, they will then be asked to complete a screening process to screen for potential child participants that are nested in their class. Teachers will be asked to nominate two students with inattentive, hyperactive, or impulsive behavior without providing the child's name or identifying information at this time. Teachers will be asked to complete the Impairment Rating Scale for each of these two students (providing only the childrens' initials) as a screening tool to determine if the nominated students meet inclusion criteria.

This screening procedure will occur either during an in-person, phone, or virtual consent meeting. A HIPAA authorization is not necessary prior to screening since the teacher will not be providing the students' names or identifying information.

Once teachers have consented to the study, nomimated two students, and completed the screening measure for those two students, if the nominated student screens for impairment related to ADHD, the teacher or another school staff member will contact the nominated students' parents/guardians to give a brief overview of the study and see if they are interested in participating. If the family expresses interest in participating, informed consent for the child (and when appropriate, assent) will happen in one of two ways:

1. If the family gives verbal permission to the teacher to relay their contact information to the study team, the study team will ask the teacher for the families' contact information. The study team will then reach out to the family by phone to provide more information about the study and see if they would like to provide informed consent during that call or schedule a separate meeting to do so. See section 7.6.2 for a description of this consent meeting.

7.6.2 Main Study

Teachers: After the study team obtains contact information for teachers (see 8.5), potential participating teachers will be approached by the PI or another member of the study team in person, by phone, or by email to be offered the opportunity to participate in the study. Additionally, some teachers at participating schools may reach out to the study team by phone or email if they see a recruitment flyer or video that was provided to the school by the study team. In a meeting that may occur by phone, on a secure video platform, or in person, study personnel will explain the nature of the study, including its procedures and potential risks and benefits, and will allow potential subjects the opportunity to ask any questions. They will be informed that their participation is voluntary and that they may decline participation at any time.

The informed consent meeting with teachers will occur either over the phone, on a secure video platform, or in person. The consent documents attached in the IRB application Section 12.01 (3.0) is the final format of the electronic consent form that will be used in this study (e.g., the final, stamped .pdf documents will be uploaded as an image to REDCap). The study team will work with the REDCap admiministrative team to ensure the electronic consent is appropriately obtained.

Teachers will be provided withtheir unique eConsent form on REDCap that outlines what their participation in this phase of the study will entail, and will be given the opportunity to ask questions and make an informed decision regarding their involvement. Prior to enrolling in the study and completing baseline questionnaires, participants will provide informed consent by signing the eConsent form electronically.

- If the consent meeting occurs in person, teachers will provide informed consent by signing a paper consent form during the meeting or signing electronically via REDCap eConsent either on the study staff member's computer, or on their own computer (the study team will email teachers the link to their eConsent form). When teachers provide consent via signed paper consent form, the study team will store the signed consent form in a HIPAA compliant lockable bag for safe transport to the office, where it will be stored in a locked cabinet. Note that for teachers, no health information will be collected.
- When the consent meeting occurs in a virtual meeting format or over the phone, the study team will email the participant their unique survey link to their REDCap eConsent form during the consent meeting and teachers will electronically sign the eConsent form in REDCap from their computer If the meeting occurs in a virtual meeting format, the video platform software used for the meeting will be on the CHOP approved vendor list. If the consent meeting occurs over the phone, participants will still provide consent via the eConsent form in REDCap, which will be sent to them during the phone conversation.

Children and Families: When the study team obtains consent and assent a memer of the study team will meet with the child's legal guardian. This meeting may occur by phone, on a secure CHOP-approved video platform, or in person. Study personnel will explain the nature of the study, including its procedures and potential risks and benefits, and will allow the parent/guardian of the potential child participant the opportunity to ask any questions. They will be informed that their participation is voluntary and that they may decline participation at any time. They will be provided with a copy of the consent form (either a paper copy, an electronic copy attached to an email, or a link to REDCap eConsent form) that outlines what their participation in this phase of the study will entail, and will be given the opportunity to ask questions and make an informed decision regarding their involvement. The consent form that may be emailed as an attachment or provided as a paper copy is the same consent form that is used in the REDCap eConsent. In cases where the legal guardian provides verbal consent, the study team will provide them a copy of the consent form for their records by mailing a paper copy or sending an electronic copy attached to an email, although they will not sign it. Because all LEP subjects will be consented via documentation of verbal consent, we will not be using the REDCap eConsent process. If consent meetings occur in person, LEP participants will sign the paper copy of the consent form. For phone or virtual consent

meetings, will email the consent form to the participant in an email attachment for their records but will obtain and document verbal consent. Please note that the consent form that would be sent in the attachment is the same consent form that would be used on REDCap econsent.

Prior to enrolling in the study and completing baseline questionnaires, participants will provide informed consent in one of three ways: 1) by signing a paper consent form during an in-person meeting, 2) signing the eConsent form via REDCap during a virtual or phone meeting (which the study team will email to them) or 3) providing verbal consent during a phone or virtual meeting in which the study staff member documents verbal consent. The consent documents attached in the IRB application Section 12.01 (3.0) is the final format of the electronic consent form that will be used in this study (e.g., the final, stamped .pdf documents will be uploaded as an image to REDCap). The study team will work with the REDCap admiministrative team to ensure the electronic consent is appropriately obtained.

When it is appropriate to obtain assent, this will occur in one of two ways. If the child is present at the consent meeting with the parent/guardian, the study staff member will conduct the assent process with the child and obtain their verbal assent. The study staff person will then document assent by signing the documentation of verbal assent document. If the child is not present at the initial consent meeting, the study team will schedule a separate time to obtain assent from the child in-person. If the study staff completes the verbal assent process with the child in-person the child can also sign the assent form if they want to. When participants provide consent via signed paper consent form, the study team will store the signed consent form in a HIPAA compliant lockable bag for safe transport to the office, where it will be stored in a locked cabinet. If the child is not present at the caregiver consent meeting, the parent/caregiver may complete questionnaires prior to assent. If the child then declines assent, data from those questionnaires will not be used.

For eligible students in foster care where parental rights (either a birth parent or legal guardian) have not been terminated, consent for the child to participate must be obtained by the birth parent or legal guardian, according to the consent plan noted above. However, if consenting parent identifies foster parent as the “primary care taker,” he/she may complete pre-post measures on behalf of the consenting parent. If the parent/legal guardian who provides informed consent for the child identifies that a different caregiver knows the child better and refers the study team to this other caregiver to complete measures about the child, a separate consent process will occur to obtain consent of the caregiver who will be filling out the questionnaires. In these cases, the legal guardian will document on the consent form that we have permission to contact the caregiver. The study team will then reach out to the caregiver by phone or email to conduct the consent process for the caregiver and to complete the measures. Caregivers will provide informed consent for their own participation completing measures about the child. They will do this by either signing a consent form or providing verbal consent, that will be documented on a documentation of verbal consent form, in a meeting that will occur by phone or on a CHOP-approved virtual platform. There is a separate consent form that will be used for caregivers who are not the child’s legal

guardian, as their sole role in the study will only be to complete questionnaires about the child (i.e., they are not consenting the child to the study).

For eligible students in foster care where parental rights have been terminated, a DHS Officer must provide consent for the child's participation, according to the consent plan noted above. However, primary care taker may complete pre-post measures on behalf of DHS, given the relationship to the child.

Children who are 12 or will turn 12 within the expected timeframe of the study (i.e., within 12 weeks of enrollment) will be asked to provide assent (see proposal for waiver of assent below).

7.6.3 Individuals with Limited English Proficiency

In situations where the parent/legal guardian of a child has limited English proficiency, we will utilize an interpreter for the consent process. If the consent meeting is occurring by phone or virtually, the interpreter will join by phone. If the consent meeting is occurring in person, the interpreter will either join by phone or in person.

7.6.4 Waiver of Assent

We propose a waiver of assent (without a waiver of parental permission) for children under 12 who will not turn 12 within the time range that they are participating the study, under 45 CFR 46.408. Because child participants will not be actively participating in any aspect of the research study and children under 12 do not have the capacity to understand the implications of interventions focused on teachers, children under 12 have a limited capability to be consulted on the topic of providing assent. Furthermore, the intervention holds out a prospect of a direct benefit important to the well-being of the children and is available only in the context of the research.

7.7 Payment to Subjects/Families

7.7.1 Payments to parent for time and inconvenience (i.e. compensation)

For children who participate, the primary caregiver or legal guardian who completes measures will be compensated $30 for their time (approximately 15-25 minute) completing questionnaires about their child (including demographic questionnaires and the Homework Performance Checklist-Parent Version) at baseline and following completion of the project period (total possible compensation: $60). Payment to caregivers or legal guardians will come in the form of a ClinCard.

7.7.2 Payments to subject for time, effort and inconvenience (i.e. compensation)

Teachers will be compensated $30 for their time (approximately 20-30 minutes) completing self-report questionnaires and $20 for their time (approximately 10-20 minutes) completing each of the two teacher-report questionnaires at baseline and following completion of the project period (for a total possible compensation of $70 at each of these two time points), as well as $30 for completing self-report and teacher-report questionnaires at mid-point (approximately 20-30 minutes). Participants may choose to complete all or some of the measures. Additionally, teachers will be compensated $10 for completing the screening

measures to screen potential child participants and $10 for their time spent contacting the parent/guardian for each student (up to 5 students) to explain the research study. Thus, the total possible compensation for typical participation (during which 2 sets of of parents/guardians are contacted) is up to $200 per teacher, although compensation could up to $230 per teacher if parents/guardians for 5 students are contacted. We will attempt to compensate participants at the time the steps are completed. For example, participants will receive compensation for an interview or measure completion on the day of the visit. Payment to teachers will come in the form of a ClinCard.

Teachers who take part in the post-participation interview will receive $30 for their time conducting the interview. This payment will be issued on the same ClinCard provided to teachers for the completion of measures or via an electronic gift card.

7.7.3 Reimbursement for travel, parking, and meals

Caregivers or legal guardians who travel to the school or another location in order to attend a consent meeting or complete measures will be compensated $5 per trip in order to reimburse any travel expenses.

8 PUBLICATION

We intend to present the results of this project at national conferences and to publish project results in peer-reviewed journals.

9 REFERENCES

1. Farmer, E.M., Burns, B.J., Phillips, S.D., Angold, A. & Costello, E.J. Pathways into and through mental health services for children and adolescents. *Psychiatr. Serv*., **54**, 60-66 (2003).
2. Evans, S.W., Langberg., J.M., Egan, T., & Molitor, S.J. Middle school-based and high school-based interventions for adolescents with ADHD. *Child Adolesc. Psychiatr. Clin. N. Am., **23***, 699-715 (2014).
3. Evans, S. W., Owens, J. S. & Bunford, N. Evidence-based psychosocial treatments for children and adolescents with Attention-Deficit/Hyperactivity disorder. *J. Clin. Child Adolesc. Psychol.* **43**, 527–551(2014).
4. Martinussen, R., Tannock, R. & Chaban, P. Teachers' reported use of instructional and behavior management practices for students with behavior problems: Relationship to role and level of training in ADHD. *Child Youth Care Forum* **40**, 193–210 (2011).
5. Owens, J.S., et al. Incremental benefits of a daily report card intervention over time for youth with disruptive behavior. Behav. Ther., **43**, 848-861. (2012).
6. Cook, C.R., et al. Evaluating the impact of increasing general education teachers' ratio of positive-to-negative interactions on students' classroom behavior. *J. Posit. Behav. Interv*., **19**, 67-77. (2017).

7. De Pry, R.L., & Sugai, G. The effect of active supervision and pre-correction on minor behavioral incidents in a sixth grade general education classroom. *J. Behav. Educ.,* **11**, 255-267. (2002).
8. Owens J.S. et al. Using multi-component consultation to increase the integrity with which teachers implement behavioral classroom interventions. A pilot study. *School Ment. Health*, **9**, 218-234. (2017).
9. Blotnicky-Gallant, P., Martin, C., McGonnell, M. & Corkum, P. Nova Scotia teachers' ADHD knowledge, beliefs, and classroom management practices. *Can. J. Sch. Psychol.,* **30**, 3–21. (2015).
10. Elik, N., Weiner, J. & Corkum, P. Pre-service teachers' open-minded thinking dispositions, readiness to learn, and attitudes about learning and behavioural difficulties in students. *Eur. J. Teach. Educ.,* **33**, 127-146. (2010).
11. Hershfeldt, P. A., Pell, K., Sechrest, R., Pas, E. T. & Bradshaw, C. P. Lessons learned coaching teachers in behavior management: The PBIS *plus* Coaching Model. *J. Educ. Psychol. Consult.,* **22**, 280–299. (2012).
12. Lawson, G.M. et al. The best of intentions: What predicts teachers' intentions to use and observed use of praise
13. Fabiano, G. A. et al. A practical measure of impairment: psychometric properties of the impairment rating scale in samples of children with attention deficit hyperactivity disorder and two school-based samples. *J. Clin. Child Adolesc. Psychol.,* **35***,* 369–385 (2006).
14. Pianta, R. C. (2001) Student-teacher relationship scale; Professional manual. (Psychological Assessment)
15. DuPaul, G. J., Rapport, M. D., & Perriello, L. M. Teacher ratings of academic skills: The development of the Academic Performance Rating Scale. *Sch. Psych. Rev.* **20**, 284-300. (1991).
16. Wolraich M.L., Lambert W., Doffing M.A., Bickman L., Simmons T., Worley K. Psychometric properties of the Vanderbilt ADHD diagnostic parent rating scale in a referred population. *J Pediatr Psychol.* **28**, 559-567. (2003).
17. Power, T. J., Dombrowski, S. C., Watkins, M. W., Mautone, J. A. & Eagle, J. W. Assessing children's homework performance: Development of multi-dimensional, multi-informant rating scales. *J. Sch. Psychol.,* **45**, 333–348 (2007).
18. Fabiano, G. A. et al. Enhancing the effectiveness of special education programming for children with Attention Deficit Hyperactivity Disorder using a daily report card. *Sch. Psychol. Rev*. **39**, 219 (2010).
19. Murray, D. W., Rabiner, D., Schulte, A., & Newitt, K. Feasibility and integrity of a parent-teacher consultation intervention for ADHD students. *Child Youth Care Forum*, **37**, 111-126. (2003).
20. Daniels, B., Briesch, A.M., Volpe, R.J., Owens, J.S. Content validation of Direct Behavior Rating Multi-Item Scales for assessing problem behaviors. *J. Emot. Behav. Dis.*, **29**, 71-82. (2021).
21. Hustus, C.L., Owens, J.S., Volpe, R.J., Briesch, A.M., & Daniels, B. Treatment sensitivity of Direct Behavior Rating Multi-Item Scales in the context of a Daily Report Card intervention. *J. Emot. Behav. Dis.*, **28**, 29-42. (2020).
22. Weiner, B. J. *et al.* Psychometric assessment of three newly developed implementation outcome measures. *Implement. Sci.* **12**, (2017).

23. Curran, G. M *et al.* Effectiveness-implementation Hybrid Designs Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact. *Med Care*, **50**, 217-226 (2012).
24. Morris, S.B. Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods.* **11**, 364-386. (2008).
25. Hayes, A. F. & Rockwood, N. J. Regression-based statistical mediation and moderation analysis in clinical research: Observations, recommendations, and implementation. *Behav. Res. Ther*. **98**, 39–57 (2017).