Evaluation of Organizational Skills Training (OST) Program for Upper Elementary Students

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ABBREVIATIONS AND DEFINITIONS OF TERMS

(ACES)	Academic Competence Evaluation Scales
(ADHD)	Attention Deficit Hyperactivity Disorder
(ADI)	Area Deprivation Index
(AEs)	Adverse Event(s)
(APR)	Academic Progress Report
(ASRS)	Autism Spectrum Rating Scales – Short Form
(BASC-3)	Behavior Assessment System for Children – third edition
(BDMC)	Biostatistics and Data Management Core
(CFR)	Code of Federal Regulations
(CHOP)	Children's Hospital of Philadelphia
(CHP)	Challenging Horizons Program
(CIRP)	Children's Intervention Rating Profile
(CLAS)	Child Life and Attention Skills
(CLS)	Child Life Skills
(COSS)	Children's Organizational Skills Scale
(COSS-P)	Children's Organizational Skills Scale- Parent version
(COSS-T)	Children's Organizational Skills Scale- Teacher version
(DAR)	Daily Assignment Record
(EF)	Executive Function
(GCP)	Good Clinical Practice
(HOPS)	Homework, Organization, and Planning Skills
(HPC)	Homework Problem Checklist
(HPQ-T)	Homework Performance Questionnaire- Teacher Version
(ICC)	Intra-cluster Correlations
(ICE)	Incremental cost effectiveness
(ICH)	International Conference on Harmonisation

(IRB)	Institutional Review Board
(LD)	Learning Disability
(NYU)	New York University
(OST)	Organizational Skills Training Program
(OST-C)	Organizational Skills Training Program – clinic-based version
(OST-S)	Organizational Skills Training Program – School version
(OTMP)	Organization, time management, and planning skills
(PALS)	Patterns of Adaptive Learning Scales
(PATHKO)	Parent and Teachers Helping Kids Organize
(PHI)	Protected Health Information
(REDCap)	Research Electronic Data Capture
(RtI)	Response-to-intervention
(SAEs)	Serious Adverse Events
(School Partner)	School counselor or identified school staff member agreeing to support study recruitment and implement the OST-S intervention.
(SD)	Standard Deviation
(TAU)	Treatment as usual (Control Condition)
(TEI-SF)	Treatment Evaluation Inventory- Short Form
(URP-IR)	Usage Rating Profile Intervention - Revised

TABLE 1. TIMELINE OF STUDY EVALUATION AND MEASUREMENT COMPLETION

Measures: *BOTH OST-S and TAU Conditions*	**Respondent:**	**Screening/ Eligibility**	**Pre-treatment/ Baseline**		**Post-treatment**	**5M Follow-up**	**12M Follow-up**
Measures of Proximal Student Outcomes							
Children's Organizational Skills Scale (COSS)–Teacher (COSS-T)	Teacher		X		X	X	X
Children's Organizational Skills Scale (COSS)–Parent (COSS-P)	Parent		X		X	X	X
Patterns of Adaptive Learning Scales (PALS) – Academic Efficiency Subscale	Student		X		X	X	X
Measures of Distal Student Outcomes							
Academic Progress Report (APR)	Teacher		X		X	X	X
Academic Competence Evaluation Scales (ACES) - Reading/ Language Arts & Mathematics Subscales ONLY	Teacher		X		X	X	X
Academic Grades	Study team		X		X	X	X
Student Homework Completion Survey	Teacher		X		X	X	X
Homework Performance Questionnaire – Teacher (HPQ-T)	Teacher		X		X	X	X
Homework Problem Checklist (HPC)	Parent		X		X	X	X
Measures of School and Participant Characteristics							
School Characteristics (e.g. subsidized lunch rate & participating grade level composition)	Study team	X					
Behavior Assessment System for Children, 3rd ed. (BASC-3)	Parent Teacher		X				
Autism Spectrum Rating Scales (ASRS) – Short Form	Parent				X		
Student Demographics & Medical History (ex: student grade level, special education status, ADHD symptoms, ADI)	Parent		X		X*	X*	X*
Demographics	Teacher School partner Trainer		X				
Survey of Current Organizational Supports for Students	Teacher				X		
Measures of Implementation Outcomes							
Measures of Intervention Fidelity (School Partner)	Study team		Throughout Duration of Study				
Measures of Stakeholder Engagement (School Partner, Student, Parent, Teacher)	Study team		Throughout Duration of Study				
Organization and Planner Checklists (observation)**	Study team		Throughout Duration of Study				
Measures of Adaptations, Feasibility, Usability, and Acceptability – *OST-S condition ONLY*							
Treatment Evaluation Inventory – Short Form (TEI-SF)	Parent				X		
The Children's Intervention Rating Profile (CIRP)	Student				X		
The Usage Rating Profile–Intervention–Revised (URP-IR)	Teacher School partner				X		
Survey of OST Adaptations and Supplementary Supports for Individual Students	School Partner				X	X	X
Survey of OST Adaptations and Supplementary Supports for Groups	School Partner				X		
Measures of Cost							
Labor – school staff and study team members	Study team School staff		Throughout Duration of Study				
Non-labor – supplies/materials	Study team		Throughout Duration of Study				

*A follow-up questionnaire will be administered to parents

**Adapted and used with permission, will be collected when feasible within a particular school and based on research team staff availability

ABSTRACT

Context: Although multiple factors influence school functioning, executive function (EF) deficits have been found to be a key predictor of academic achievement (Best et al., 2011). EF is a higher order cognitive ability associated with persistent goal-directed behavior (Best et al., 2009). Organization, time management, and planning (OTMP) skills are aspects of EF that are particularly associated with children's academic performance (Langberg et al., 2013). Organizational demands increase over the course of early schooling and are relatively high by 3rd through 5th grade. Poor OTMP skills during this period adversely impact academic functioning. In the late elementary school grades, as students are expected to become more organized, some students have difficulty learning these skills in spite of classroom supports provided by teachers, placing them at increased risk for academic failure (Abikoff & Gallagher, 2009).

Objectives: The purpose of this Goal 3 efficacy study is to conduct an evaluation of the Organizational Skills Training Program – School version (OST-S), a fully developed intervention for students in general education. The proposed study builds upon our research demonstrating the efficacy of a clinic-based version of the OST intervention (OST-C) in remediating OTMP skills deficits and improving academic functioning for 3rd, 4th and 5th graders with ADHD (Abikoff et al., 2013), and our recent pilot research demonstrating the feasibility and potential effectiveness of OST-S provided by end users ("school partners") for 3rd through 5th graders. It also builds upon research training school staff to implement evidence-based interventions with high fidelity (Eiraldi et al., 2014).

Study Design: This is a cluster-randomized controlled trial with a treatment as usual (TAU) control group.

Setting/Participants: Schools are located in Pennsylvania and New Jersey and include at least 20 urban and suburban schools serving a diverse population. Students (3rd to 5th grade) who are struggling the most with OTMP deficits and whose academic performance is negatively impacted by their OTMP deficits will be referred to the study team by their general education teachers.

Study Interventions and Measures: OST-S is a small group skills training intervention, with parents and teachers supporting children's use of new skills. The program manual includes strategies for training and coaching school staff, referred to as school partners, to effectively implement OST-S and guidelines to modify the program for implementation in diverse schools with diverse students. Each student session includes: (a) homework review to assess completion of between-session skills implementation; (b) skill-building activities, which include the use of modeling, shaping, guided practice, and reinforcement for organized behavior; and (c) activities to promote generalization of skills. Sessions address four organizational challenges: (a) tracking assignments, (b) managing materials, (c) managing time, and (d) planning for long-term assignments.

The study team will measure the following: intervention fidelity, stakeholder engagement, student OTMP skills, student academic self-efficacy, student academic outcomes, student characteristics, feasibility, usability, and acceptability of OST-S. In addition, the study team will track the interventions that are offered as treatment-as-usual in TAU schools. We will also complete a cost-analysis related to implementation of OST-S.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Although multiple factors influence school functioning, executive function (EF) deficits have been found to be a key predictor of academic achievement (Best et al., 2011). EF is a higher order cognitive ability associated with persistent goal-directed behavior (Best et al., 2009). Organization, time management, and planning (OTMP) skills are aspects of EF that are particularly associated with children's academic performance (Langberg et al., 2013). Organizational demands increase over the course of early schooling and are relatively high by 3rd through 5th grade. Poor OTMP skills during this period adversely impact academic functioning. In the late elementary school grades, as students are expected to become more organized, some students have difficulty learning these skills in spite of classroom supports provided by teachers, placing them at increased risk for academic failure (Abikoff & Gallagher, 2009).

Given the association between EF/OTMP skills and academic achievement, it is important that schools have effective interventions to address these deficits (Langberg et al., 2013; Janke et al, 2014; Knouse et al., 2014). Cognitive training interventions targeting EF have resulted in changes in children's performance on laboratory tasks of EF, but improvements have not generalized to academic performance (Rapport et al., 2013). In contrast, interventions targeting OTMP skills at home and school, which require EF abilities, have been found to be effective and to improve academic performance (Evans et al., 2014). Members of our investigative team (Abikoff and Gallagher), have developed an effective clinic-based organizational skills training intervention (OST-C) for 3rd through 5th grade students with ADHD who exhibit difficulties with OTMP skills, which improved children's academic performance with large effect sizes by both parent and teacher report (Abikoff et al., 2013).

1.2 Name and Description of Investigational Product or Intervention

1.2.1 Intervention Being Evaluated: Organizational Skills Training - School Version (OST-S)

Organizational Skills Training - School Version (OST-S) is a group skills training intervention, with parents and teachers supporting students' use of new skills. The program manual includes strategies for training and coaching school staff, referred to as school partners, to effectively implement OST-S and guidelines to modify the program for implementation in diverse schools with diverse students. The manual is based on the clinic-based OST intervention (OST-C) and was adapted in a pilot study conducted in New York City public schools. In the proposed project, a high level of implementation support (i.e., consultation and coaching) will be provided to promote intervention fidelity.

1.3 Findings from Non-Clinical and Clinical Studies

Organizational Skills Treatment, Clinic Version (OST-C). OST-C is a skills training intervention for 3rd to 5th grade students with ADHD and OTMP deficits. The program includes 20-21 individual child treatment sessions administered twice a week for 10 weeks. The majority of each session is spent in direct OTMP skills training with the child, with an opportunity for the child to explain their new skill to parents so parents are prepared to reinforce skills practice. Also, there are five therapist-teacher contacts; the first one occurs in person, and the remainder are by phone (Abikoff et al., 2013). Strong support for OST-

C's efficacy was reported in a large-scale (n=158), NIMH-funded RCT, which compared OST-C to a waitlist (WL) control group and a parent-training contingency management treatment that reinforced end-point performance (PATHKO; Abikoff et al., 2013). Compared to waitlist controls, the OST-C group showed significantly greater improvement in: (a) OTMP skills (ratings by teachers: Cohen's d =1.18, p<.0001; parents: d = 2.77, p <.0001; self: d =.69, p <.004); (b) academic functioning (d =.76, p <.0001); (c) academic proficiency (d =.42, p <.01); (d) homework performance (d=1.37; p <.001); and (e) percent of children no longer meeting OTMP criteria for study entry at post-treatment (60.1% in OST-C vs 3% in WL, p<.0001). The parent-training PATHKO treatment also resulted in significant improvements relative to waitlist controls. The treatment gains were sustained the following school year when evaluated by teachers who were blind to treatment condition. Importantly, improvements in children's OTMP skills mediated the effect of the intervention on children's academic functioning (Abikoff et al., 2014).

Organizational Skills Treatment, School Version (OST-S). OST-S is an adapted version of OST-C, administered by school partners to students with OTMP deficits. Drs. Abikoff and Gallagher have developed this intervention in collaboration with the New York City Department of Education and have conducted an initial pilot study across three schools with a total sample size of 31. OST-S student group sessions were offered twice weekly for 9-10 weeks, with each session lasting 40 minutes. In addition, teacher consultation and parent collaboration were provided at the beginning of the program, with follow-up consultation occurring through written updates and periodic in-person contacts. Student groups were conducted by a guidance counselor as well as general and special education teachers. Findings based on within-group t-tests (Abikoff & Gallagher, 2016) indicated that OST-S resulted in significant reductions in students' OTMP deficits as measured by parent report (p<.001, d=.80) and teacher report (p<.001, d=.59), as well as significant reductions in parent-rated homework problems (p<.001, d=.88) and significant improvement in teacher-rated performance in academic subjects (p<.001, d=.62). Teacher ratings of program satisfaction were high (Mean = 5.83 on a scale of 1 to 7; 7 = very satisfied). Teachers indicated they would recommend the program to other teachers (Mean = 6.27). Parents also indicated they would recommend the program to a friend (Mean = 6.11). During the pilot, the OST-S manual and supporting materials were refined for use in this study.

1.4 Relevant Literature and Data

Executive Functioning (EF) is a multi-component cognitive process that encompasses the planning and execution of goal directed behavior over time (Best et al., 2009; Friedman et al., 2006). Longitudinal studies have confirmed that EF is a key predictor of academic functioning and adjustment (Best et al., 2011) in students with and without specific learning disabilities (Best et al., 2009) and in students with and without ADHD (Rinsky & Hinshaw, 2011). For example, EF in kindergarten predicts children's reading and math scores at the end of first grade (Monette et al., 2011) and EF deficits in middle childhood predict academic functioning in late adolescence (Rinsky & Hinshaw, 2011). The relationship between EF and academic performance is strongest when measuring children's EF in the real world via parent and teacher rating scales, rather than by children's performance on laboratory-based tasks (Waber et al., 2006).

OTMP skills are specific aspects of EF found to be associated with school performance. For example, among middle school students with ADHD, Langberg and colleagues (2013) found that planning skills and organization of materials were significantly linked to academic performance. These OTMP skills were significantly related to children's homework performance over and above the effect of ADHD symptoms. Consistent with this,

organizational problems such as failing to record homework assignments and not completing assignments on time were associated with teacher-reported learning problems in elementary and middle school (Power et al., 2006). Further, teachers reported lower achievement in children who misplaced assignments or took too long getting materials ready for class assignments (Langberg et al., 2011). Importantly, treatment-related changes in OTMP skills have been found to mediate changes in academic functioning (Abikoff et al., 2014; Pfiffner et al., 2013).

Increased recognition of the impact of EF on children's success in school has led to the development of methods to improve EF skills. The goal of broad-based EF interventions is to address the cognitive processes presumed to underlie EF impairments using cognitive training strategies (e.g., working memory training and computerized, lab-based tasks). If effective, EF training programs should result in "top-down" behavioral effects, leading to generalization and wide-ranging cognitive and behavioral improvements. Unfortunately, there is little support for this hypothesis from randomized controlled trials (Rutledge et al., 2012). These interventions have demonstrated benefits in performance on lab-based EF tasks but limited effects on academic performance (Rapport et al., 2013). Systematic research reviews suggest that the targets of intervention for children with EF deficits should instead be behavioral manifestations of EF deficits that are more directly related to school performance (Chacko et al., 2014; Rapport et al., 2013). Consistent with these recommendations, OST-C, a clinic-based intervention for students with ADHD, targets OTMP skills and has been demonstrated to significantly improve academic performance with large effect sizes by both parent and teacher report. Further, these improvements were maintained into the next school year when teachers were blind to children's treatment condition (Abikoff et al., 2013). The success of the OST intervention suggests that interventions including OTMP skills training, combined with methods to encourage generalization at school and home, hold promise as a potential treatment for the academic problems associated with EF deficits.

Several school-based programs have been developed to support students with OTMP skills deficits (see reviews by Storer et al., 2014 and Evans et al., 2014). Langberg and colleagues (2012) developed the Homework, Organization, and Planning Skills (HOPS) delivered by school mental health providers for middle school students with ADHD. An initial study indicated that HOPS participants demonstrated improvements in organizational skills and homework performance relative to a waitlist control group, but only by parent-report. This study demonstrated that it is feasible for middle school staff to deliver organizational skills interventions to students.

Evans and colleagues (2009) included an organizational intervention for middle school and high school students with ADHD as part of the Challenging Horizons Program (CHP). The organizational skills portion of the intervention addresses difficulties with tracking assignments and organizing materials and is conducted during a twice-weekly, year-long, after-school tutoring program. Studies evaluating the effectiveness of CHP have shown improvements in organizational skills, as well as a significant relationship between these changes and improvements in students' grades (Evans et al., 2011).

Pfiffner and colleagues (2007) developed the Child Life and Attention Skills program (CLAS), a 12-week, clinic-based group intervention for children with the inattentive subtype of ADHD. Parents are taught strategies for setting up routines and structures to help promote children's organization and time management skills, and children are taught social skills, as well as organization, time management, and planning skills. Results indicated that children's organizational skills improved as a result of the intervention. The CLAS program was modified into the Child Life Skills (CLS) program (Pfiffner et al., 2011), a school-based,

multimodal intervention for elementary school students in which school staff led the parent and child groups. In a pilot study, Pfiffner and colleagues (2013) found that the CLS program could be feasibly administered by school staff and demonstrated evidence of improving child outcomes, including OTMP skills. Furthermore, improvements in OTMP skills mediated the effects of the intervention on teacher-rated academic skills and parent-rated homework performance.

A limitation of existing research for students in grades 3 to 5 is that most programs have been developed and evaluated for students in middle and high school (Evans et al., 2011; Langberg et al., 2012). An exception is the multimodal intervention (CLS Program) developed by Pfiffner and colleagues (2011; 2013; 2014) for students in grades 2 to 5. The CLS Program is highly promising; it includes intensive parent training, classroom-based behavioral intervention, and 10 sessions of child social and daily living skills training, including organization skills training. Because of the multi-component nature of CLS, it is not possible to distinguish the effect of each component on children's OTMP skills and academic performance. In addition, the combination of social, daily living, and organizational skills training in 10 child sessions raises questions about whether the organizational skills component is sufficiently intense to reduce OTMP deficits. Finally, the CLS program includes a 10-session parent training program. Engaging parents in such an intensive program may not be feasible in many schools. Although parental involvement is critical for school success, it is important to identify feasible methods of involving families that can be applied across schools serving a diverse population of families.

Although the clinic-based OST intervention was designed for children with ADHD, it might not be feasible or acceptable to parents and school staff to evaluate and diagnose children with ADHD prior to enrolling them in OST-S. In fact, in accord with New York City Department of Education research regulations, which prohibit diagnosing students to determine study inclusion, students were not evaluated for ADHD during our recent school-based pilot of OST-S. As such, we have designed this study to address this feasibility concern. In addition, although deficits in OTMP skills are highly common among students with ADHD, they also occur among students with other disorders and without an identified disorder (Rinsky & Hinshaw, 2011). There is evidence that impaired organizational functioning occurs in approximately 50% of children with ADHD, 30% of children with LD, and 10-15% of students with no identified problems (Abikoff & Gallagher, 2009). Notably, organizational deficits have an effect on school adjustment and achievement in virtually all students (Best et al., 2011; Neuenschwander et al., 2012). As demands for independence increase, these deficits place children at increased risk for needing special education. In this project we will include all students in general education classrooms demonstrating OTMP deficits that may be impacting their academic functioning, regardless of diagnostic status. Our recently completed pilot study (See 1.3) demonstrated highly promising outcomes targeting students not assessed for ADHD.

School-based services provide an efficient and cost-effective means of addressing children's educational and mental health needs (e.g., Barrett & Pahl, 2006; Langberg et al., 2012). However, it often is difficult for school staff to provide evidence-based, manualized interventions in a high quality, consistent manner (Eiraldi et al., 2014). Successful implementation of school-based programs requires careful consideration of the training and supervision needs of school staff to ensure acceptable fidelity and participant engagement. For effective implementation, school staff, student, and systems variables should be addressed in the training process (Beidas & Kendall, 2010). Practice-based coaching models (e.g., Becker et al., 2013) are effective methods by which to support school staff in implementing evidence-based practices through ongoing professional development. When

used with school professionals, practice-based coaching, including direct observation and fidelity monitoring plus performance feedback, results in improved fidelity and quality of implementation of evidence-based interventions (e.g., Sutherland et al., 2015).

The proposed project includes a structured practice-based coaching model to support school staff, who are referred to as 'school partners,' in their implementation of the OST-S intervention. School partners will receive regular performance feedback and modeling of intervention strategies from coaches with the intent of maximizing fidelity and quality of OST-S implementation. The OST-S manual includes opportunities to modify procedures and supports so the coaching model is appropriately flexible in addressing the needs of diverse schools.

Intervention fidelity is a multi-faceted construct that includes content and process variables (Dane & Schneider, 1998; Power et al., 2005; Sanetti & Kratochwill, 2009). In monitoring fidelity, it is critical to consider the extent to which the steps in the manual are completed and whether those steps are delivered competently. As schools transition to response-to-intervention (RtI) models, intervention fidelity has become increasingly critical (Burns et al., 2008; Sanetti & Kratochwill, 2009). Without high fidelity, it is not possible to draw conclusions about the relationship between the intervention and student outcomes. Also, within RtI, implementation with high fidelity is required before decisions about students' eligibility for more intensive services (e.g., special education) can be made (National Association of State Directors of Special Education, 2008). Therefore, assessment of fidelity is a key component of implementation of interventions in school. In the proposed project, we will assess content and process fidelity and investigate how they are related to participant outcomes.

Treatments for student academic and behavioral deficits require engagement and high-quality implementation of strategies by participants. Engagement includes attendance, active participation in sessions, and adherence to recommended intervention practices (Power et al., 2005). Low engagement is common among parents and teachers and is related to worse outcomes (Dishion et al., 1992; Hinshaw et al., 2000). Engagement of children in skills training interventions and implementation of between-session practice is associated with improved child outcomes (Park et al., 2014). The OST-S intervention includes strategies to engage participants in the intervention. In addition, we will carefully monitor engagement and examine how it is related to outcomes.

1.5 Compliance Statement

This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, 21 CFR Parts 50, 54, 56, 312, 314 and 812 and the Good Clinical Practice (GCP): Consolidated Guideline approved by the International Conference on Harmonisation (ICH). 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 Children's Hospital of Philadelphia Institutional Review Board (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 this Goal 3 efficacy study is to conduct a cluster, randomized, controlled trial of OST-S, a fully developed, preventive intervention for students in general education.

2.1 Primary Objectives (or Aims)

The primary objectives of this study are:

- Determine the efficacy of OST-S with regard to improving **proximal student outcomes** (OTMP skills, academic self-efficacy) relative to a treatment as usual control group (TAU) at post-treatment, as well as 5-month and 12-month follow-up.

- Determine the efficacy of OST-S with regard to improving **distal student outcomes** (academic productivity and grades) relative to TAU at post-treatment, as well as 5-month and 12-month follow up.

2.2 Secondary Objectives (or Aims)

The secondary objectives of this study are:

- Explore whether reductions in student OTMP skills deficits and improvements in student academic self-efficacy mediate the effect of OST-S on students' academic outcomes.

- Investigate whether school partner implementation fidelity and participant engagement (student, parent, teacher) are associated with the effect of OST-S on student OTMP skills deficits.

- Investigate whether student grade level, special education status, and symptoms of ADHD, externalizing, internalizing problems, and symptoms of autism spectrum disorder moderate the effect of OST-S on student OTMP skills.

- Determine the costs associated with providing the OST-S intervention per group per school relative to student proximal (OTMP skills, self-efficacy) and distal (academic productivity and grades) outcomes.

- Investigate child in-session engagement in the OST-S intervention and the clinical factors associated with child engagement

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a cluster-randomized controlled trial with a treatment as usual (TAU) control group.

The study has two arms: OST-S and TAU. The study is designed to compare OST-S to what students typically receive in school to address their organizational skills deficits. School officials expressed concerns about participating in the study if identified students were not able to obtain OST-S and our study team also has ethical concerns about withholding intervention from students in schools assigned to the control group. Therefore,

students in control schools will receive OST-S as a “thank you treatment” after 12-month follow-up data are collected.

3.1.1 Screening Phase

School Selection: We have secured commitments from 20 schools. Schools will be matched on subsidized lunch rate and participating grade level composition (e.g., schools with participating grades of 3 and 4 versus schools with participating grades of 3,4, and 5) and randomly assigned to OST-S or TAU at a 1:1 ratio using a random number generator. Due to the nature of school-based research and the potential for school drop out after making a commitment to participate, it may be necessary to modify the ratio of school randomization assignment to OST-S or TAU if a school drops out of the study and an additional school is needed to meet participant recruitment goals. In a case such as this, this decision would be made by the principal investigators in consultation with the investigative team and documented as necessary.

Student Screening: For both OST-S and TAU schools, participating teachers in 3rd to 5th grade general education classrooms will receive a flyer or email correspondence including a brief description of the study and be asked to identify/nominate students from their class: (a) who are struggling the most with OTMP skills, (b) whose OTMP skill deficits are the students‘ primary concern (c) whose academic performance is negatively impacted by their OTMP deficits, (d) who are in general education classrooms (e) who do not have one to one student aids and (f) who have at least one parent who speaks English.

For each identified student, our school partner(s)/study team will ask teachers to fill out a short form (or electronic REDCap survey) indicating the extent to which the student’s difficulty with organizational skills negatively impacts academic performance. The teachers will then notify the school partner (and/or study team) of the students they have identified for the study. The school partner (or study team) will assign a screening ID number to each identified student (note: if referrals are obtained via an electronic REDCap Survey the screening ID number may be created automatically by REDCap). Any correspondence between the school partner and the study team during the screening phase with occur using students’ screening ID numbers.

If a student is determined to meet all study criteria, the school principal or administrator may wish to send a letter to the parent/guardian of students that a member of the school staff will be contacting them. The school partner will contact parent(s)/guardian(s) of identified students to introduce the study. Parent(s)/guardian(s) who express interest in the study and who agree to have their contact information (name, phone, email address) shared with the study team will then be contacted by the study team (via phone or email). If a primary adult caregiver (other than the parent and/or legal guardian) is involved the child’s care and school support, the family may also consider that caregiver participating in the study.

During that initial communication, a member of the study team will verify that the student meets eligibility criteria (as noted on the referral forms provided by the school) and schedule an in-person meeting with the goal of obtaining consent for study participation. (If due to logistical and/or scheduling constraints and/or by request of the school and/or family, the consent meeting may be conducted either over the phone or through a web-based HIPAA compliant video-conference software approved by CHOP). For each condition (OST-S and TAU) in each school, students will be recruited from multiple classrooms of the same grade levels when possible.

3.1.2 Training Phase: Training School Partners to Lead OST-S Groups

Training School Partners: School partners will be trained by the study team during an in-service to be facilitators for the small group OST-S sessions in participating schools. The procedures for training and providing ongoing consultation and coaching to school partners are based on our investigative team's previous experience training school staff to implement manualized, evidence-based interventions (Eiraldi et al., 2014) and on our experience during the pilot project for OST-S. These meetings may be conducted in-person, over the phone, or through a web-based HIPAA compliant video-conference software approved by CHOP (a combination of these modalities may also be used).

Prior to their first time participating in OST-S implementation, school partners will participate in a training (up to a maximum of 8 hours) that will include a detailed discussion of all of the major elements of OST-S, a detailed review of child group behavior management and intervention procedures (e.g., modeling, shaping, rehearsal with feedback, contingency management techniques), an overview of paperwork that they will need to complete, and an introduction to the consultation and coaching model used to support them during implementation of the group.

The in-service training will include didactic presentation, a review and discussion of videotaped examples of OST-S techniques and sessions, role-play, and guided practice techniques. The initial training will be repeated once a year for each school partner, as they prepare to conduct their first OST-S group for the year, with the length of training shortened when it is a refresher training for a school partner who was previously trained. This training may be conducted in-person, over the phone, or through a web-based HIPAA compliant video-conference software approved by CHOP (a combination of these modalities may also be used).

3.1.3 Implementation of Organizational Skills Training – School Version (OST-S)

Coached by the CHOP study team, trained school partners in the intervention condition will implement the OST-S intervention in their school with 3-4 students per group. OST-S will include 16 activities that will most often be administered in 16 sessions (typically two sessions per week) over the course of approximately 8 weeks. Sessions will be approximately 40 minutes in duration to align with typical class periods.

Typically, the OST-S intervention is delivered in-person, administered within a small classroom at the school. During the COVID-19 pandemic (or other circumstances that warrant the need), virtual learning may also be utilized for delivery of the OST-S intervention following the school's standard educational practice for engaging and instructing students (this includes any web-based or electronic platforms that the school would typically use in a virtual learning setting).

During the implementation of OST-S in the intervention condition schools, students in schools assigned to the TAU condition will only receive the standard support typically provided by school personnel (teachers and school partners) in their building. They will not receive any additional support from study team members in regard to organizational skill development.

3.1.4 Follow-up Phase

In addition to collecting baseline measures, outcome measures will be collected following completion of the 8-week OST-S Intervention. The study team will also collect outcome measures from students, parents and teachers at 5-months and 12-months from baseline.

Students, parents and teachers assigned to the TAU condition will provide outcome data at the same four time points (baseline, post-treatment (approximately 8 weeks from baseline], approximately 5-months from baseline and approximately 12-months from baseline).

At the discretion of a principal investigator or a co-principal investigator, measurement time points may be modified on a case-by-case basis due to the logistical and time constraints in collecting data from participants within a school-based setting (for example but not limited to snow days, holiday break, summer break, and unanticipated school programming.) The rationale for such modifications will be documented when applicable.

Data collection at baseline, post-treatment, 5-month, and 12-month follow-up may be collected either (1) in-person on hard-copy paper documents, (2) electronically through text/email links from REDCap to allow for off-site data collection or (3) in-person data collection utilizing an electronic tablet (that would be given to the participant) to access the REDCap link.

3.2 Allocation to Treatment Groups and Blinding

Refer to Section 8.1.1 (Randomization), and in regard to "Blinding" Paragraph 3.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

School Partners (OST-S & TAU Groups): Our intention is that one or two school partners from each participating school will work with our study team during the school's participation in the study (typically 4 years total); however, we recognize that school staffing might change over time. If school administrators request that we change the school partner from one year to the next, we will work closely with the school administrator and the new school partner to ensure that the new school partner receives the same initial training and support.

Students: Total participation for students assigned to either condition will span an estimated 12 months. After parent consent and student assent is obtained, participation in OST-S sessions will be approximately 8 weeks. Data will be collected at baseline, after the intervention period ends and approximately 5- and 12-months after baseline data collection. Participation in the study is complete after the 12-month follow up data are collected. Students assigned to TAU will have the opportunity to receive OST-S after 12-month follow-up data are collected, however this will not be considered a research procedure. No outcome data or recordings will be collected from the TAU students when they receive OST-S after their 12-month TAU control group participation period ends.

Parents/Legal Guardians/Caregivers and Teachers: Total duration of participation for parents/legal guardians/caregivers and teachers of participating students will mimic that of the students, noted above (12-month maximum).

Trainers: Total duration of participation for trainers will be the duration of their role as a study team trainer on this project.

3.3.2 Number of Study Sites / Total Number of Subjects Projected

The study will be conducted in at least 20 schools located in PA and NJ and include urban schools and suburban schools serving a diverse population. (It is possible that if a school drops out of the study that additional schools may need to be recruited to ensure that the study meets its enrollment goals. This would increase the number of schools to over 20

schools.) Schools will be randomly assigned to either OST-S or the control condition (TAU) (Refer to Section 8.1.1 for more details regarding participation).

The participants will include students in grades 3 thru 5 with organization, time management and planning (OTMP) skills deficits. We will enroll 3-4 students per grade level each year (3-4 students per group per school). Because we will hold 4 total groups at each school, the design targets, on average, 14 students per school over the course of the study. Therefore, we anticipate a total of 140 students from 10 schools in the OST-S group and 140 students from 10 schools in the TAU group. For every enrolled student, we anticipate one participating parent (280 parents). For every student, we will also enroll one participating teacher. It is possible that an individual teacher may participate with multiple students over the course of the study.

On average, participating schools include 3-4 classrooms per grade level. We plan to enroll students from two grade levels per school, although it is possible recruitment could include a third grade level. Additionally, there could be teacher turnover during the study, increasing the number of possible referring/participating teachers. Finally, because the 12-month follow up period will occur during the following school year for students in the study, an additional teacher will be enrolled for each student participant. Therefore, we estimate that up to 200 teachers will participate over the course of the study.

It is anticipated that we could enroll up to 40 additional school partners, with the expectation that we will have at least one school partner per school (20 total). We have projected the enrollment of 40 school partners to allow for potential school staff turnover within school buildings over the duration of the study.

It is also anticipated that up to 10 trainers will be enrolled as secondary research participants over the course of the study. The trainer will be a CHOP employee and study team member that will train and support the school partner in a participating school.

280 Student-Parent/Legal Guardian/Caregiver dyads +

40 School Partners +

200 Teachers +

10 Trainers =

530 Total Projected Participants.

3.4 Study Population

3.4.1 Inclusion Criteria for School Partners

School partners will be school staff (e.g., counselors, teachers) identified by the school principal who volunteer/agree to work with our study team to implement the OST-S program either in the intervention condition or as a complementary clinical service in the TAU condition.

3.4.2 Exclusion Criteria for School Partners

A school partner must be a school staff member other than the teacher of a participating student.

3.4.3 Inclusion Criteria for Teachers

Teachers will be school professionals at each participating school who refer students to the study team for potential participation, complete forms for students at baseline, post-

treatment, and 5- and 12-month follow-up. For students assigned to OST-S, teachers will participate in the teacher consultation portion of the intervention. It is likely that at least two teachers will participate for each student over the course of study participation as students will likely have progressed into the following grade for the 12-month follow-up data collection period.

3.4.4 Exclusion Criteria for Teachers

Teachers not willing to participate in the school partner-teacher consultation sessions (intervention condition only) will be excluded from the study.

No other exclusionary criteria apply, as a participating student's teacher is pre-determined by the school.

3.4.5 Inclusion Criteria for Students

Any student enrolled in grades 3 thru 5 in one of the participating schools who meets the following criteria.

1) First, students will be recommended by their general education teacher if the following are true: (a) students who are struggling the most with OTMP skills, (b) whose OTMP skill deficits are the students' primary concern (c) whose academic performance is negatively impacted by their OTMP deficits, and (d) who have at least one parent who speaks English.
2) Second, the teacher must rate the student's OTMP skills deficits as having a negative impact on academic performance (using items 39-42 of the COSS-T) by rating one of the four items $\geq$ 3 on 4-point scale.

Students with behavior and learning problems, including those classified with emotional/behavioral disorders and/or learning disabilities, will be included if it is determined that the students' disabilities are being addressed adequately in the current educational program. This determination will be made by the study team in collaboration with the student's teacher and the school partner.

3.4.6 Exclusion Criteria for Students

1) Students will be excluded if they are in a pull-out special education classroom for more than 50% of the day as the organizational demands for these students may differ from those students placed mostly in general education.
2) Students with a one-to-one aide will be excluded because the presence of an aide substantially alters how an organizational intervention is implemented.
3) Students from families in which both parents/guardians do not speak English will be excluded because the program has not yet been developed for non-English speakers.
4) Only one student per family will be included in the study.

3.4.7 Inclusion Criteria for Parents/Legal Guardians

One parent/guardian for each student enrolled in the study will complete forms for students at baseline, post-treatment and 5- and 12-month follow-up and will participate in the parent consultation portion of the intervention. Parents/guardians will consent prior to student enrollment in the study.

3.4.8 Exclusion Criteria for Parents/Legal Guardians

Parents/guardians of students not enrolled in the study will not be included. The enrolled parent/guardian must remain consistent throughout the study (for example, biological father cannot complete outcome measures, if biological mother is the consented participant).

3.4.9 Inclusion Criteria for Adult Caregiver

A primary adult caregiver (other than the parent or legal guardian) may participate in the study if that caregiver is involved with communication and support of the child in school. This caregiver would be a participant with the authorization from the parent/legal guardian. This adult would complete forms for students at baseline, post-treatment, and 5- and 12-month follow-up (in lieu of the parent/legal guardian) and will participate in the parent consultation portion of the intervention. Adult caregivers will consent at the time of student enrollment in the study. They cannot consent for student enrollment in the study. They will only consent for their own participation in the study.

3.4.10 Exclusion Criteria for Adult Caregiver

Adult caregivers not enrolled in the study will not be included. The designated adult who is completing measures for the study must remain consistent throughout the study. That adult may be the parent, legal guardian, or adult caregiver. The adult caregiver will be excluded if he/she does not speak English because the program has not yet been developed for non-English speakers.

3.4.11 Inclusion Criteria for Trainer

Trainers are individuals employed at Children's Hospital of Philadelphia and are study team members designated to train a school partner in a participating school in the OST-S Intervention. This individual will also support the school partner in Consultation and Coaching throughout the delivery of the intervention.

3.4.12 Exclusion Criteria for Trainer

A trainer would be excluded if they do not consent for be a secondary research participant.

4 STUDY PROCEDURES

4.1 Student Screening / Referral Process

For both the OST-S and the TAU conditions, recruitment will be conducted in 3rd, 4th, and/or 5th grade general education classrooms. Based on the grade level targeted for a particular school, all teachers who educate students at that grade level will be offered a description of the study, including a specification of the roles for teachers. Teachers will be informed that they will be asked to participate in screening, outcome assessment, and consultation conducted by the school partner. Participating (consenting) teachers will be asked to identify students from their class using the inclusion (Section 3.4.5) and exclusion (Section 3.4.6) criteria outlined above. For each identified student, our school partners will ask teachers to fill out a short form indicating the extent to which the student's difficulty with organizational skills negatively impacts his/her academic performance. This form may be completed on either a hard-copy paper document or via an electronic survey link from REDCap.

The school partner or study team will determine whether the student meets study criteria. The school partner will contact the family of potentially eligible students by phone to introduce the study. Families who express interest in the study and who agree to have their

contact information (phone number/email address) shared with the study team will then be contacted by the study team. During that initial contact, a member of the study team will verify that the student meets eligibility criteria (as noted on the referral forms provided by the school). The study team will then schedule an in-person meeting with the parent(s)/guardian(s)/caregiver and student with the goal of obtaining written consent from the parent and assent from the student for study procedures, collecting baseline measures and conducting the initial parent consultation meeting. An adult caregiver may also be enrolled in the study with the permission of a parent/legal guardian. (If due to logistical and/or scheduling constraints and/or by request of the school and/or family, the consent meeting may be conducted either over the phone or thru a web-based HIPAA compliant video-conference software approved by CHOP.) If the family provides consent, a member of the study team will inform the student's teacher of the parent and student's enrollment in the study.

4.2 Training Phase: Training School Partners to Lead OST-S Groups

The **initial training** of school partners is described above in section 3.1.2.

Following the initial training, school partners will receive weekly or twice weekly **consultation and coaching** to support high fidelity implementation of OST-S. Consultation and coaching may be conducted in-person, over the phone, or through a web-based HIPAA compliant video-conference software approved by CHOP (a combination of these modalities may also be used). The frequency/duration of meetings as part of Consultation and Coaching will also take into consideration if a school partner has already been trained in and run the OST-S intervention in a prior year(s) of participation. If this is the case, the frequency/duration of these meetings may be adjusted from what is detailed below.

Consultation sessions (approximately 20 minutes per week) will be designed to prepare the school partner for the upcoming group session (e.g., review of key components of intervention during the session, plan for encouraging active involvement of student participants). Coaching sessions (approximately 20 minutes per week) will include a detailed review of the previous session with performance feedback for the school partner. Additional consultation and coaching may be provided during the weeks when parent and teacher meetings take place.

As indicated above, all OST-S sessions (student group and teacher and parent contacts) will be video and/or audio recorded, and the study team trainer will view the videos and listen to the audio to identify examples of effective implementation and areas for improvement. During the coaching session, the study team trainer will review brief segments of the video and/or audio (i.e., examples of effective and ineffective implementation) with the school partner and provide specific performance feedback regarding the extent to which OST-S program components were delivered accurately and competently (i.e., to encourage high rates of content and process fidelity). In addition, the study team trainer and school partner will discuss and practice strategies to address implementation difficulties and address concerns about individual students that may arise. Consultation and coaching sessions between the study team trainer and school partner will be videotaped (and may be audio recorded separately as a back-up method) used in supervision of the study team trainer.

School partners assigned to the TAU condition will not receive any training until the second year of participation after 12-month follow-up data have been collected.

4.3 Intervention Implementation

TAU Control Condition*:* As noted previously, students enrolled in the TAU condition will only receive support from their teachers and school staff that they would typically receive if not enrolled in this study.

Table 2. Participants in TAU Control Condition:

YEAR	STUDENTS/PARENTS	SCHOOL PARTNERS	TEACHERS
1	Research Participants: Providing data at 4 time points	**Collaborator**: Support recruitment **Research Participant:** Complete Demographic Form;	**Collaborator**: Support recruitment **Research Participant:** Complete Demographic From;
2	Recipient of Free, Clinical Intervention; no data collected; no recordings.	**Collaborator**: Implement Clinical Intervention as a Professional Development Experience; no data collected **Research Participant**: Complete Demographic Form if new to study;	**Collaborator:** Participate in Clinical Intervention as a Professional Development Experience; no data collected **Research Participant:** Complete Demographic Form

*It is anticipated that teachers in Years 1 and 2 will be different people.

OST-S Condition*:* OST-S is a small group skills training intervention, implemented by the trained school partner, with parents and teachers supporting students' use of new skills. Each small group session includes: (a) homework review to assess completion of between-session skills implementation; (b) skill-building activities, which include the use of modeling, shaping, guided practice, and reinforcement for organized behavior; and (c) activities to promote generalization of skills.

Sessions address four organizational challenges to students: (a) tracking assignments, (b) managing materials, (c) managing time, and (d) planning for long-term assignments.

Procedures to promote parent and teacher involvement and student skills generalization. Once parental consent and student assent are obtained, the school partner will meet with the parent (ideally in-person but phone or web-based video software typically used by schools to engage with families virtually may also need to be utilized). The purpose of the initial meeting between the school partner and parents is to explain OST-S in more detail, increase parent investment in participation, and ensure that parents understand their role in the intervention. The school partner and parent will collaboratively identify goals for the student related to OTMP skills (e.g., bringing home needed papers, writing down homework), and the school partner will explain how OST-S can be helpful in addressing those goals. Furthermore, the school partner will schedule 1 additional meeting, approximately 30-minutes in duration. The meetings will ideally be held in-person, but could be done by phone or web-based video software (typically used by schools to engage with families virtually) if it is not possible to meet in person. We could also allow for an email exchange if necessary. During these meetings (or contacts with the parent), the school

partner will review OST-S strategies and collaboratively design home-based methods for parents to prompt, monitor, and reinforce the skills students have learned. At the initial parent meeting, parents will be given a manual that provides specific guidelines to them about how to promote the implementation of their student's OTMP skills. These parent meetings will be audio and/or video recorded. If there is only an email exchange, the email will be printed and coded as study data in place of the video/audio recording.

Also, after parent consent is obtained, the school partner will arrange a meeting with the student's teacher (ideally in-person but phone or web-based video software typically used by schools to engage with families virtually may also be utilized). For feasibility purposes, this meeting might occur individually with teachers or in a group format for all of the teachers of students involved in the group. The purpose of the meeting is to review the goals of OST-S, encourage teacher buy-in, introduce the use of positive behavior supports to encourage skill change, and collaboratively plan for use of OST-S strategies in the classroom (e.g., Daily Assignment Record). After the initial meeting, the school partner will schedule 1 additional 15-minute consultation session with the teacher to review student's progress toward goals and discuss implementation of OST-S strategies in the classroom (ideally in-person but phone or web-based video software typically used by schools to engage with each other virtually may also be utilized). School partners will give teachers handouts after each student session to inform teachers about session content and tips for integrating OST-S strategies into the classroom. These teacher meetings will also be video and/or audio recorded and evaluated by the study team as implementation fidelity data.

The goals of the parent and teacher-mediated components are to: (a) address generalization challenges by promoting student use of OTMP skills at school and home, and (b) increase students' academic self-efficacy.

Table 3. Participants in Intervention (OST-S) Intervention Condition:

YEAR	STUDENTS/PARENT	SCHOOL PARTNERS	TEACHERS
1	**Research Participants:** Participate in recorded OST-S Intervention & provide data at 4 time points	**Research Participant:** Implement recorded OST-S Intervention with Students, Parents and Teachers; Complete Demographic Form and additional measures; Support Recruitment	**Research Participants:** Participate in recorded OST-S Intervention & provide data at 4 time points; Support Recruitment

Students, School Partners and Teachers in the **Intervention Condition are all Research Participants as their participation in the intervention is recorded and evaluated for study outcomes.

4.4 Subject Completion/Withdrawal

Students, parents and school personnel may withdraw from the study at any time without prejudice to their care, education or employment. They may also be discontinued from the study at the discretion of the investigators for lack of adherence to the study and/or development of exclusionary criteria.

If a school partner, withdraws from the study, there will be no impact on his/her employment. The study team will work with the school administration to identify another school partner to provide the intervention in the school building.

If a teacher withdraws from the study, the student and parent may continue their participation. The teacher data moving forward will be missing, but the student will not be subsequently withdrawn.

If a parent chooses not to participate/engage in parent consultation sessions but still consents to his/her student's participation, the student and teacher may continue.

If a student is withdrawn (or withdraws) from the study, his/her parent and teacher will also be withdrawn. Of note, a student may choose to withdraw from the small group sessions, but still decide to complete the questionnaires at the remaining time points. In this case, the student would not be withdrawn from the study but rather documentation would be made that the student declined to continue to participate in the small group sessions, but was willing to still complete measures at remaining time points. In this case, the student's teacher and parent would also be asked to continue to complete study measures at the remaining time points if they are willing.

Students will be withdrawn from the study if they develop exclusionary criteria during the study. Student well-being will be monitored by the study team trainer in collaboration with the school partner throughout participation in the study. If any adverse events occur that require clinical intervention during the course of study participation, the study team trainer, and/or Dr. Nissley-Tsiopinis, the clinical supervisor, will hold an individual Adjunct Services and Attrition (ASAP) session following the protocol outlined in the Multi-modal treatment of ADHD (MTA) study (Abikoff et al., 2002). If the investigators become aware of any serious, related adverse events after a participant completes or withdraws from the study, the event will be recorded in the study files.

5 STUDY EVALUATIONS AND MEASUREMENTS

The table on Page vi (*Table 1. Timeline of Study Evaluation and Measurement Completion*) summarizes the sections to follow with detailed descriptions of the study evaluations and measurements. Phone, text, and email are means of communication that may be utilized to get in touch with families and school staff members to schedule meetings for data collection. The study team may communicate with the subject via text after the subject provides their permission for this method of communication.

5.1 Screening Measures (Students)

Teachers will be asked to complete a short form to indicate the extent to which the student's difficulty with organizational skills negatively impacts the student's academic performance. The teacher must rate the student's OTMP skills deficits as having a negative impact on academic performance (using items 39-42 of the COSS-T) by rating one of the four items $\geq$ 3 on 4-point scale (COSS-T; Abikoff & Gallagher, 2009). The study team has obtained a waiver of consent to conduct this screening procedure.

5.2 Measures of Proximal Outcomes and Mediators – OTMP Skills and Student Academic Self-efficacy

Measures will be completed at baseline, post-treatment, and at 5-month and 12-month follow-up.

Children's Organizational Skills Scale*, Parent (COSS-P) and Teacher (COSS-T) Versions.* The COSS-P and COSS-T (Abikoff & Gallagher, 2009) will be used to assess OTMP functioning at home and school. COSS total scores have good discriminant validity and are sensitive to treatment effects (Abikoff et al., 2013; Pfiffner et al., 2013). Each COSS version uses a 4-point rating scale (1=*Hardly ever or never to* 4=*Just about all of the time*). Although the COSS yields three subscale scores, only the total score will be used to reduce the number of measures in the analyses.

Patterns of Adaptive Learning Scales – Academic Efficacy Subscale (PALS). The 5-item Academic Efficacy subscale of the PALS (Midgley et al., 1998) will be used to evaluate students' perceptions of their competence in completing their classwork. Items are rated on a 5-item scale from 1 = not at all true to 5 = very true.

5.3 Measures of Distal Outcomes – Academic Outcomes

Measures will be completed at pre- and post-treatment, and at 5-month and 12-month follow-up.

Academic Progress Report (APR; Abikoff et al., 2013). The APR is a teacher-report measure that assesses proficiency in seven academic subjects relative to standard expectations (1=Well below standard expected at this time of year; 3=At standard; 5=Well above standard). The sum of ratings across seven academic subjects is the unit of analysis. Reliability is acceptable (alpha = .84), and this measure is sensitive to OST treatment effects (Abikoff et al., 2013).

Academic Competence Evaluation Scales (ACES; DiPerna & Elliott, 2000). The ACES is a teacher-report scale that assesses the academic competence of students in kindergarten through grade 12. The Reading/Language Arts and Math subscales of this measure will be used. Alpha coefficients and test-retest correlations for these subscales have been shown to be above .90. The average of these subscale scores will be used in the analyses.

Academic Grades. We will obtain student report card grades for students in OST-S/TAU. We will calculate students' grade point average based on report card grades.

Homework Survey: Teachers will be asked to complete one question related to the percentage of homework assigned (in the school year to date) that they student has turned-in.

Homework Performance Questionnaire – Teacher Version (HPQ-T). The HPQ-T assesses students' homework behavior during the past 4 weeks. Each item is rated on a five-point scale. The 9-item Student Self-Regulation factor will be used in the analyses. This factor has been demonstrated to have strong psychometric properties (Power et al., 2014).

Homework Problem Checklist (HPC). The HPC is a 20-item parent-report measure that assesses student homework performance. The psychometric properties of this instrument have been shown to be acceptable (Power et al., 2006), and the HPC was sensitive to

treatment effects in the OST-C study (Abikoff et al., 2013). The total HPC score will be used in the analyses.

5.4 Implementation Outcome Measures

Measures of Intervention Fidelity. To ensure treatment components are delivered as intended, numerous treatment fidelity procedures will be implemented during each group. The procedures are based on those used in the OST-C study. Process fidelity procedures will be based on strategies used by Dumas and colleagues (2001) to train school staff. To assist with monitoring school partner process and content fidelity, checklists for each OST-S group session and parent and teacher meeting will be used. Checklists will be used in two ways. First, school partners will be encouraged to use the content and process fidelity checklists as a guide during sessions. Second, all student small group sessions will be video and audio recorded, and parent and teacher consultation meetings will be video and/or audio recorded. The study team trainer will observe each video (student group sessions) and listen to each video/audio (parent and teacher consultation meetings) and code content and process fidelity for use in consultation and coaching meetings. A separate member of the Intervention Core team who is not directly involved with a school, will watch 50% of the videos for each group that are selected at random and code content and process fidelity for use as research data. A member of the Intervention team supervisory staff will function as the 'Gold Standard' coder and will code a randomly selected 25% of the videos, which are selected for content and process coding for use in calculating the reliability of the coding. When challenges are encountered in administering the intervention, portions of these videos may be viewed by the Intervention Core team (Nissley-Tsiopinis, Abikoff, Gallagher) during weekly meetings. The Intervention Core will determine how best to address the situation in a manner that is consistent with the original intervention. Dr. Nissley-Tsiopinis will watch videos of consultation and coaching sessions as needed to provide supervisory feedback on the study team trainer's implementation of the consultation and coaching procedure.

Fidelity content items will specify what to do during sessions and will be rated on a scale from 0 to 1 (0 = not implemented; 1 = implemented). These ratings yield a fidelity index, and represent the extent to which OST-S content is covered in each session. Process items for OST-S sessions (e.g., encouraging all persons to participate), will be rated on a scale from 0 to 4 (0 = rarely; 4 = all or almost all of the time; Dumas et al., 2001).

Measures of Stakeholder Engagement. Several measures of school partner, parent, student and teacher engagement in the program and adherence with procedures outside of sessions will be used. Research assistants will make note of student attendance and arrival time at each OST-S session. Also, using a measure used in the OST-C study (Abikoff et al., 2013) and based on their observation of the student session videotapes, study team members who are not directly involved with a group will watch the videos of a randomly selected 50% of student small group sessions per intervention group and listen to a randomly selected 50% of audiotapes of each parent and teacher consultation session and complete ratings for each group participant regarding the extent to which the student: (a) was engaged in in-session activities, (b) appeared to understand the new skill, and (c) was able to implement the new skill effectively. A second study team member will independently complete the same ratings for 25% of student group session and parent and teacher consultations selected for coding. Agreement between the study team coders will be calculated as a measure of the reliability of these ratings. At the conclusion of each session, OST-S homework assignments will be given. For example, students will be asked to write down their assignments daily in their new Daily Assignment Record (DAR). At the beginning

of the following session, RAs will collect all OST-S homework assignments. These assignments will be scored for completion and accuracy using the procedure developed by Drs. Mautone and Power (Clarke et al., 2013). The scoring system for student OST-S homework assignments has been adapted so that it provides a more useful index of student success in acquiring OTMP skills.

In addition, school partners will record parent attendance at parent consultation sessions and will indicate the extent to which the parent: (a) was engaged in discussions during the consultation, and (b) appeared to understand consultation content. A similar process will be used for teacher consultations. Furthermore, parents and teachers will generate permanent products (e.g., daily assignment record, home behavior chart). Students will be asked to bring those permanent products to the student group sessions and those permanent products will be collected and scored using the procedures developed by Drs. Mautone and Power (Clarke et al., 2013) to assess parent and teacher engagement in the generalization components of the program. If students forget to bring these permanent products to the student session, school partners will ask for them and make copies of them during parent and/or teacher consultations.

Measures of Behavioral Change (Intervention Condition Only). Organization and Planner Checklists (Evans et al., 2009; Sadler et al., 2011) will be used to assess how well students organize their academic materials and record their assignments in their planner. These checklists have been developed for middle and high school students with ADHD, and we have adapted them for use with elementary students. The criteria on the checklists are behaviorally defined. Scores for "Organization" and "Planner" are calculated by determining the percentage of criteria met (Sadler et al., 2011). Study staff will be trained to complete these checklists during the intervention group sessions. (*Please note: this measure will ONLY be collected when feasible within a particular school and based on research staff availability.)*

5.4 Measures of School and Participant Characteristics

School Characteristics (as noted in Table 1.) will be collected by the study team about participating schools. This information will largely be obtained from publicly available data sources including (https://nces.ed.gov/ccd/schoolsearch/).**Teacher and parent ratings on the Behavior Assessment System for Children – third edition** (BASC-3, Reynolds & Kamphaus, 2015) will be used to assess child behavioral functioning. The BASC-3 has impressive psychometric properties. This measure will be given at baseline to characterize the sample and derive an index of ADHD, aggression, and internalizing problems for examination of potential moderation effects. If this measure is unable to be collected at baseline, an attempt will be made to collect it at a subsequent timepoint.

Parent ratings on the Autism Spectrum Rating Scales (ASRS)-Short Form (Goldstein, S. & Naglieri, J.,2012) – The ASRS Short Form is a 15-item scale designed to differentiate children with an Autism Spectrum Disorder from those in the general population, and those with other clinical disorders. High scores suggest that many behaviors associated with the Autism Spectrum Disorders have been observed. Parents are asked to evaluate how often they observed specific behaviors in the child in areas such as socialization, communication, unusual behaviors, behavioral rigidity, sensory sensitivity, and self-regulation. T-scores of 59 or less are within the normal range and usually suggest the absence of an autism spectrum condition. T-scores between 60 and 75 are generally considered above average or "at-risk" and indicate the presence of mild impairments in this area and the possible

presence of a mild autism spectrum disorder. T-scores of 76 or higher indicate severe impairments in this area and suggest that the child should be evaluated further for the presence of an autism spectrum disorder.

Parents/legal guardians/caregivers will be asked to complete this measure at post-treatment to reduce the burden on parents at the time of baseline data collection. If the measure is unable to be collected at post-treatment (aka approximately 8-weeks after baseline), it will be collected at either the 5-month follow-up or 12-month follow-up time-point. This measure will only be administered to the parent once about the student during the duration of study participation.

Survey of Current Organizational Supports for Students – This measure was developed by the investigative team. This measure will be administered to teachers (per student) to assess the current level of organizational supports being provided to students in their school environment (other than the OST-S intervention). This measure will be administered to teachers at post-treatment ONLY. If this measure is unable to be collected at post-treatment, an attempt will be made to collect it at a subsequent timepoint.

Student Demographic Information – To characterize the sample, demographic information will be obtained from school records, teacher report, and parent/legal guardian/caregiver report. Specifically, we will collect information about special education status, amount of special education services being offered, IEP goals, services being provided to address organizational problems, school counseling services, medication status, and current organizational, supervision, and homework systems in place at school and home. An area of deprivation index (ADI) which reflects a geographic areas level of socioeconomic deprivation will also be determined for participants to aid characterizing the samples socioeconomic status (Kind et al., 2018). A follow-up questionnaire will be administered to parent/legal guardian/caregiver at post-treatment, 5-months, and 12-months to obtain information about utilization of services during the intervention and follow-up periods.

School Staff Demographic Form – School partners and teachers will complete a demographics questionnaire to collect information regarding staff members' educational experience and background, to help characterize the school staff sample, as well as to collect information regarding about TAU organizational skills interventions offered in TAU by their schools.

Trainer Demographic Form – Trainers will complete a demographic form to collect information regarding trainers' educational experience and background.

5.6 Measures of Adaptations, Feasibility, Usability, and Acceptability of OST-S

Adaptations to OST-S made by school partners in providing additional support to students at the group or student level will be assessed by the following measures.

Survey of OST Adaptations and Supplementary Supports for Individual Students – This measure was developed by the investigative team. This measure will be collected from school partners (per student) at post-treatment, 5-month follow-up, and 12-month follow-up. The measure is designed to capture when school partners contribute extra supports above and beyond what is outlined in the treatment manual for them to provide to students in the Organizational Skills Training School-based program (OST-S).

Survey of OST Adaptations and Supplementary Supports for Groups – This measure was developed by the investigative team. This measure will be collected from school partners at post-treatment (per group). The measure is designed to capture when school partners prepare/provide additional supports for students beyond that outlined in the treatment manual as they implement the Organizational Skills Training School-based program (OST-S).

Feasibility and usability will be assessed by monitoring of intervention fidelity, participant engagement, and adherence.

The Treatment Evaluation Inventory – Short Form (TEI-SF), a 9-item measure, will be used to assess parents' views of treatment acceptability (Kelley et al., 1989).

The Children's Intervention Rating Profile (CIRP), a 7-item measure, will be adapted to assess student's perceptions of acceptability (Witt & Elliott, 1985).

The Usage Rating Profile–Intervention–Revised (URP-IR), a 29-item measure, will be adapted (with permission) to assess multiple factors that may influence the usage of the OST-S intervention in a school-based setting – for example: acceptability, understanding, home school collaboration, feasibility, system climate, and system support (Chafouleas, Briesch, Neugebauer, & Riley-Tillman, 2011).

5.7 Cost Analysis Measures

Main cost item for the OST-S is the time spent by school partners, trainers/consultants, and experts from the investigative team on intervention activities which may be collected using time diaries. Costs for the OST-S group may include: (a) initial training time of the study team trainers; (b) initial training time of the school partners; (c) subsequent supervision time of study team trainers; (d) subsequent consultation and coaching time provided to the school partners; (e) school partner implementation of OST-S groups with eligible students (including consultation with parents and teachers to promote generalization); and (f) consultant (post-doctoral fellow) time necessary to maintain relationships with participating schools and support ongoing implementation of the OST-S program. For each component, two main types of costs will be calculated: (1) cost of physical materials used for training and interventions and (2) costs associated with time spent for training, supervision, and intervention implementation (Blonigen et al., 2008).

Intervention and training/consultation times will be derived from administrative records of OST-S session times and student attendance, and diaries completed by interventionists, trainers/consultants, and experts, during four, 1-week periods throughout the trial.

6 STATISTICAL CONSIDERATIONS

6.1 Main Study Analysis

6.1.1 Study Aims

Aims 1 and 2: Effect of Intervention on Proximal and Distal Outcomes. Linear mixed effects models with random intercepts and slopes for school (the cluster), and fixed effects for intervention, time, and time-by-intervention interaction (the estimate of interest) will be applied. Random effects account for inter-school variation in the effect of the intervention over time.

Aim 3: Mediation Effects. This aim explores the effect of potential mediating variables (M; OTMP skills, self-efficacy) on the effect of the intervention (A) on student academic outcome (Y). Our goal is to understand the mechanism of change in student performance due to the planned intervention. In this context, we will examine two levels of mediation: school-level average organization skills associated with school-level academic performance, and student-level organization skills and performance.

Aim 4: Association Between Fidelity/Engagement and Outcomes: To determine whether fidelity and engagement are associated with outcomes, we will describe the impact of these factors on outcomes, with special attention to variation in outcomes across schools. These associations will not benefit from randomization (fidelity and engagement are post randomization interim process endpoints). For that reason, our assessments will be largely descriptive and qualitative, and will include assessment during the follow-up periods.

Aim 5: Effect Modification: Aim 5 explores potential moderating variables (i.e., gender, grade level, family SES, special education status, and severity of ADHD, externalizing and internalizing behaviors). Because these potential effect modifiers vary within the unit of randomization (school), these contrasts are essential within-cluster comparisons with good statistical power (see below). Effect modification can be estimated using the mixed effects and longitudinal models outlined previously.

Aim 6: Cost and Cost Effectiveness. We will estimate the incremental costs and incremental cost effectiveness (ICE) of OST-S. An ICE ratio will be constructed for each outcome measure with effects that differ significantly from the control group. The ICE will be determined based on differences in direct costs and will be calculated based on differences in mean costs for each condition, divided by the mean difference in outcomes (e.g. ratings of organizational skills and academic performance).

In many OST-S schools, the same school partner will provide intervention during both years of participation. In addition, we expect that many teachers who receive consultation during the first time will be involved again the second time. It is possible that school partners and teachers will be more effective in implementing OST-S later in the study than earlier, which could have some effect on outcomes. Our team will perform sensitivity analyses to determine whether response to intervention in OST-S schools differs for students enrolled earlier versus later in the study.

We anticipate that some of the students in the study will be medicated for ADHD. Medication status did not moderate outcomes for students included in study of OST-C (Abikoff, et al., 2014). During baseline, post-treatment, and follow-up assessments, we will obtain information about student medication status. In the analyses, we will explore whether medication status has an effect on outcomes.

6.1.2 Primary Endpoint

The primary endpoints are student OTMP skills and student academic self-efficacy, measured at post-treatment, 5 months from baseline and 12 months from baseline and compared between the intervention condition and the TAU condition.

6.1.3 Secondary Endpoints

The secondary endpoints are student academic productivity, homework, and academic grades.

6.1.4 Sample Size and Power

Number of students and statistical power. It is anticipated that a total of 140 students will participate in the OST-S group and 140 in a treatment as usual (TAU) control group.

Primary Objectives and Secondary Objectives Involving Academic Outcomes:

As is customary, our estimates are in standard deviations (SDs; effect sizes). We examined power assuming 20 schools, inclusion of 3-4 students per grade level across two grade levels (3.5 students per school), and randomization at the school level. The design targets on average 14 students per school, or 280 total. To allow for 15% loss to follow up at the student level, we assume 120 students per arm. Each student will have data collected at 4 time points: baseline, post-treatment, 5-month follow-up, and 12-month follow-up. For analysis, we will use all available data until the time of dropout. For power calculations, we assumed conservatively a baseline measure and one follow up per student.

We accounted for the reality that longitudinal measures at the student level increase power and clustering of students within schools decreases power. We assumed three relatively modest correlations of outcome measures within student over time: 0.5, 0.6 and 0.7, which correspond to SDs of change of 1.0, 0.8, and 0.6 for a 1 SD cross sectional difference. Correlations of 0.5 lead to no increase in power from the design, and correlations of 0.6 and 0.7 correspond to approximately 10% and 20% increases in power. To account for clustering, we assumed intra-cluster correlations (ICC)=0.01, typical in school-based trials (Office of Behavioral and Social Sciences Research, NIH: http://esourceresearch.org/tabid/384/Default.aspx). We also used ICC=0.038. This ICC value corresponds to variation across schools on the order of 0.4 SD of the distribution of outcome scores, or the equivalent to a range of means across schools of 1.6 SDs, a modest degree of inter-cluster variation. The design effects of these assumptions are 1.03 (small) and 1.11 (modest), to be expected with a relatively small number of students per school, and correspond to a reduction in the effective sample size of 3-11%.

Power calculations were performed using PASS 11 (Hintze, 2011; www.ncss.com), which demonstrated 90% power to detect a change in outcomes equivalent to 0.5 or greater in cross-sectional SDs, assuming at least 12 students per school and model correlation of these scores within student over time (corr=0.7), and assuming an ICC of 0.038 (a relatively large degree of variation across schools). A change equivalent to 0.5 cross-sectional SDs in outcome scores and 12 students per school is still detectable (power>0.85) if the correlation within students over time is 0.7 and the ICC across schools is 0.038. Larger effects can be detected with greater power. These power estimates apply to both OTMP skills and academic outcomes using intervention as a binary outcome in an intent-to-treat analysis. Based on the pilot study of OST-S, we expected effect sizes for outcomes to be in the 0.6 to 0.8 range. These power calculations are likely conservative; inclusion of covariates might actually improve power.

6.1.5 Secondary Objectives

Mediation effects. For this Aim, we rely on our own simulations as well as two programs in the R package. We assumed 220 evaluable students across 20 schools, and a design effect of 1.1. In brief, David Kenny's program "PowMedR" (Kenny 2016) suggests that power is adequate to detect an effect size of 0.3 SD for both the effect of treatment (A) on the mediator (M) and the effect of M given A on Y (conditional effect of OTMP on outcome). Likewise, the R package "medssp" (Vittinghoff 2015) suggests adequate power (> 0.8) to detect effect sizes of 0.4 jointly and separately for both the association of A and M (effect of intervention on OTMP skills) and OTMP skills on academic performance (association of M and Y). Our own simulations, conducted using Stata v 14.1, to determine power to rule out a direct effect (of the intervention on outcomes not mediated by OTMP skills) suggest that only a large direct effect can be ruled out at conventional levels of statistical significance using the planned sample. 95% confidence intervals of results of all analyses will reflect post hoc power.

Association between fidelity/engagement with OST-S, child clinical factors, and outcomes. Descriptive and qualitative analyses will be used, so power calculations were not conducted.

Moderation effects. Power to detect an interaction of treatment (A) and a modifier with 25% prevalence was estimated to be greater than 85% assuming a main effect of treatment of 0.5 SD and design effects from the clustering of students within school in the range noted previously noted, for an interaction effect of 0.67 SD. Owing to the absence of software for testing interaction effects, these estimates are based on our simulations conducted using Stata v 14.1. While these estimates continue to reflect the clustered (by school) design, the design effect in practice for the interaction of an across-cluster (intervention) and a within-cluster (student characteristic) variable tends to be much lower than for a main effect (intervention only). We choose a binary moderator for this calculation, and 25% prevalence, to be somewhat conservative. Prevalence of some moderators (e.g., inattention) are likely to approach 50%.

Descriptive methods will be used to examine costs and cost effectiveness. As such, power calculations were not conducted.

6.2 Preliminary Analysis to Respond to Project Officer

6.2.1 Goals of Preliminary Analyses

Our study team has identified three primary goals to address the question of whether OST-S is having its intended effect to address the request of the project officer. The goals of the preliminary analyses are contained within the original study aims and do not represent new aims.

1. **Determine whether OST-S may be effective in improving proximal outcomes (students' organization, time management, and planning [OTMP] skills) relative to a treatment as usual, waitlist control group (TAU-WL) at post-treatment.**
   This goal is included within study Aim 1. We will examine only the primary study outcome, students' OTMP skills, assessed by parent and teacher ratings on the Children's Organizational Skills Scale (COSS-P, COSS-T), and we will examine outcomes only at post-treatment (not follow-up).

2. **Determine whether there may be a differential effect of OST-S on OTMP skills as a function of student grade level (3rd to 5th grade).**
   This goal was included as an original study aim. It is especially important to examine this goal because there is good reason to believe 3rd graders may not respond as well to OST-S as older students. It is also important to examine this goal because by chance (due to randomization) the year impacted by COVID included mostly 4th and 5th graders, whereas the years before this included more younger students. Therefore, our sample of 175, which was designed to be evenly distributed across the grades, currently underrepresents 5th graders (Grade 3 – *n* = 64; Grade 4 – *n* = 72; Grade 5 – *n* = 39).
3. **Determine whether there may be a differential effect of OST-S on OTMP skills as a function of the resource level of schools (low, middle, or high subsidized lunch rate).** This goal was included as an original study aim. It is important to examine this goal because prior research has suggested that schools with fewer resources (high subsidized lunch rates) might not do as well in implementing such interventions given the multiple stressors their staff face. That being said, fidelity implementation data suggests that our school partners generally are implementing the intervention with high quality regardless of school subsidized lunch rate.

6.2.2 Statistical Plan for Preliminary Analyses

The study team, led by our statisticians, will compute descriptive statistics (mean, standard deviation, and 95% confidence interval) for change scores from baseline to post-treatment on the COSS-P and COSS-T in raw score format (mean item score). Descriptive statistics will be computed for each of the two arms of the study (OST-S, TAU-WL), as well as each grade-level subgroup (Grade 3, 4, 5) and school resource-level subgroup (low, middle, high subsidized lunch rate) within each arm. These descriptive statistics will be highly valuable in determining whether there is a signal of overall OST-S effectiveness, differential effects for grade-level subgroups, and differential effects for schools with low, middle, and high subsidized lunch rates. The study team will evaluate whether the lower limit of 95% confidence intervals is above 0, which would be suggestive of a significant difference. In addition, the difference in mean change scores between study conditions will be divided by the standard deviation of the control group (TAU-WL) standard deviation of change scores to provide a rough estimate of effect size for the entire sample, each grade-level subgroup, and each school subsidized lunch rate subgroup. Further, descriptive statistics will be computed to characterize the OST-S and TAU-WL conditions with regard to child sex, grade level, and school subsidized lunch rate subgroup.

In addition, we will determine whether there is a difference between intervention conditions with regard to the proportion of students who demonstrate a small, medium, and large degree of change in the expected direction from baseline to post-treat, as well as the proportion of students who demonstrate no change and change in the oppositive direction. Degree of change on each measure (COSS-P and COSS-T) will be computed for each participant by subtracting baseline score from post-treatment score and dividing by the standard deviation of change scores for the condition to which the participant was assigned (OST-S vs. TAU-WL). Similar to guidelines established by Cohen (1988), effect sizes (ES) approximating .20 will be considered small; ES approximating .50 will be medium; and ES approximating .80 or higher will be large. We will conduct these analyses with all students in OST-S and TAU-WL as well as with subgroups based on grade level and subsidized lunch rate. **Because we did not include a plan to examine the proportion of students**

responding to each condition in the original analytic plan, we are including a request for these analyses in this amendment.

Descriptive statistics will be computed separately in three samples, First, using an intent-to-treat approach all enrolled participants will be examined. Second, using a per protocol approach most of the participants involved in the study during the COVID-19 shutdown in the spring, 2020 will be excluded from the sample. The only participants affected by COVID-19 who will be included are those for whom the duration of time between the collection of the COSS-P and/or COSS-T was $\geq$ 8 weeks (56 days) and the collection of post-treatment data for the COSS-P and/or COSS-T data occurred within 3 weeks (21 days) of the first date of shutdown (March 16). Third, using a per protocol approach two groups of participants will be excluded: (a) those participants affected by COVID-19 described earlier in this paragraph, and (b) those participants in the OST-S arm for whom COSS-T data were collected after the fourth intervention session (note: study team persisted with efforts to collect data in order to minimize missing data), because the initial sessions are believed to be critical for intervention success. **In our original statistical analysis plan, we planned to conduct intent-to-treat analyses, but we did not include a plan to conduct per protocol analyses. We are requesting an amendment to conduct per protocol analyses, as indicated.**

These exploratory descriptive analyses will be conducted on one occasion and a report will be sent to the IES project officer. By conducting the analyses in this way, our team is adhering to the approved IRB protocol. We will not conduct any statistical analyses in addition to those outlined above. To minimize bias in conducting these descriptive analyses, the deidentified data set needed for these analyses will be exported from REDCap by a study coordinator and will only include information about study arm (which will be deidentified), grade-level subgroup, school subsidized lunch subgroup, child sex, COSS-P and COSS-T raw scores at baseline and post-treatment, and sample subgroup (intent-to-treat, per protocol excluding most participants affected by COVID-19, and per protocol excluding most participants affected by COVID-19 and those in the OST-S condition with delayed collection of COSS-T data). A study statistician will conduct the analyses using the data set with deidentified study arms, and he will report findings to the study coordinator who will indicate the identity of the study arms for interpretation of findings.

If these exploratory analyses reveal there is a signal indicative of a main effect of intervention condition and/or an interactive effect of intervention condition and grade level and/or an interactive effect of intervention and school subsidized lunch rate subgroup, power calculations will be performed to determine the sample size needed to conduct tests of significance for the three study goals outlined above, which are the most important study aims. We will not perform power calculations again to conduct complex mediation analyses, which require a relatively large sample size. We will base power calculations on the same assumptions outlined in the original statical analysis plan, including an expected effect size of .50 and attrition of 15%.

This is a one-time request to provide summary statistics to the project officer for the purpose of obtaining a financial supplement. **If we obtain a supplement from the funding agency, we plan to submit another amendment to the IRB to clarify aims, update power calculations, and modify the statistical analyses plan.**

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

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

7.2 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 are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

The randomization of the recruited 20 schools to either the OST-S or TAU will be based on first & second year recruitment of schools to the interventions. The ten schools that agreed to start the program in the first year of the study will be randomized first and a randomization list (LIST1) will be created. Prior to randomization, we will pair schools based on grades (3 only; 3 and 4; and 3, 4 and 5) and percentage of students with subsidized lunch programs (subsidized lunch percentages ranged from 8% to 100%). Within each of the 5 pairs, each school will be randomized to receive one of the two interventions. This will result in five schools receiving OST-S and another 5 schools receiving the TAU intervention.

During the second year of recruitment, a new 10 schools will be randomized using the method described above (LIST2). This will result in additional five schools receiving OST-S and another 5 schools receiving the TAU intervention. Therefore, a total of 10 schools will be in the OST-S intervention and another 10 schools in the TAU. The randomization design sought to balance relatively few schools two characteristics: one categorical (grade levels) and one continuous (% subsidized lunches).

Due to logistical issues related to recruiting larger number of schools (i.e., 40 schools instead of 20), more staffing and limiting funding, and in order to maximize the number of students per school, the same schools will be recruited again during the third and fourth schooling years and will receive the same intervention assignment based on their first year or recruitment. So by default, during the second phase of recruitments, schools will know their intervention assignment ahead of time. We will examine whether or not such a situation biases the effect of intervention by comparing same outcomes obtained in year 1 verses year 2 by the two intervention arms.

Due to the nature of school-based research, if a school drops out of the study prior to enrollment of students or after a single year of participation, the study team will pursue the participation of an additional school to support participant recruitment in a subsequent year of the study. In this case, the number of participating schools would be over 20 schools. In addition, it may be necessary to modify the ratio of school randomization assignment to

OST-S or TAU if a school drops out of the study and additional schools are needed. In a case such as this, this decision would be made by the principal investigators in consultation with the investigative team and documented as necessary.

8.2 Data Collection and Management

The data collection and management plan is consistent with CHOP Policy A-3-6: Acceptable Use of Technology Resources that defines the requirements for encryption and security of computer systems.

- Identifiable data will be collected as part of this study. This data includes full names/initials, date of birth, address, telephone number, e-mail addresses. However, participants will be identified by numeric code only. This precautionary step allows for the electronic transfer of data without using data encryption techniques. At each stage of data collection and maintenance, measures are taken to ensure that all identifying information is taken out of data archives, and any hard copies of data that could identify participants are stored in locked file cabinets with restricted access, and that data files are password protected. Participant identification numbers are used that do not reveal the identity of participants (e.g., no use of birth dates, initials, social security numbers, etc). Only members of the research team will have access to the data. If the results of this study are presented at scientific meetings or published in professional journals, they will not contain information that could be used to identify parents, teachers, students or school partners.

- Hard data will be kept in a locked file cabinet with restricted access in the Roberts Center for Pediatric Research. Digital video and audio recordings (containing participant identifiers) will be transferred from the devices and stored to a CHOP computer network drive and analyzed by study team members for the coding of integrity/fidelity. After audio/video recordings are saved to the CHOP network space, the recordings will be deleted from the digital device. After all analyses are complete, the files will be destroyed and personal identifiers will not be retained with the data. All computerized study databases for questionnaire data will be kept on a secure Windows NT server located at one of the hospital's research buildings. This server is also protected by a firewall to reduce the risk of unauthorized access to study information.

- Data (video and audio recordings of both training sessions and consultation sessions) will be shared with co-investigators (external to CHOP) using a secure, web-based, HIPAA compliant collaboration platform known as Box.com (provided by CHOP). Data will be uploaded to Box.com solely for the purpose of collaboration and consultation to ensure that the intervention is implemented as intended, according to the clinical manual. The data will be removed from Box.com once reviewed and discussed with study team members. Please refer to Form DCC (attached to the eIRB application) for details regarding data sharing with external collaborators.

- Hard-copy paper data collected as part of this study will be entered (data entry from CRFs or uploaded from Excel files) and stored using REDCap (Research Electronic Data Capture) database, a secure web-based software database supporting clinical and translational research databases. When data are unable to be obtained in-person, electronic links will be sent to participants via email/text via REDCap surveys. The database will be password-protected, stored, and backed up on a daily basis by CHOP's Research Institute. REDCap provides data management functionality; including

automated export procedures for seamless data downloads to Excel and commonly used statistical packages (SPSS, SAS, Stata, R). The database will incorporate range checks and between-variables consistency checks to ensure quality control. The system will signal the presence of questionable or potentially incorrect items. After data cleaning and quality assurance procedures are completed, pertinent sets of data will be converted into SAS format for statistical analysis. The Biostatistics and Data Management Core (BDMC) of the Research Institute will provide expertise in REDCap database design and implementation, randomization, and statistical analysis under the direction of the study's biostatistician.

- The process for obtaining e-consent thru REDCap will be reviewed and approved by the REDCap Team. These electronically signed consent forms will be printed out from REDCap and stored with paper consent forms in locked filing cabinets in the Roberts Center for Pediatric Research.

- REDCap will be utilized to send e-consent links and/or survey links to participants via email as well as via text message (via an integrated text messaging option through a company called Twilio (www.twilio.com). Twilio will be used to send survey links, i.e. "Click this link to open our survey," which then opens the survey in Safari or any other browser on a participant's mobile device. The participant then fills out the REDCap survey within their browser, exactly as if they received the invitation by email. Links will only be sent via text message with prior permission from the participant (otherwise the default method, e-mail, will be utilized).

- Data for the "Behavior Assessment System for Children (BASC) – third edition" is collected from parents and teachers at baseline. This measure may be administered on paper or thru an electronic link provided directly by the publisher, Pearson. If completed online thru Pearson, parents/teachers will be providing PHI directly to Pearson. PHI will be removed from the source data prior to data analysis. Applicable participant consent forms will include Pearson as a party that may have access to participant data. Pearson software is required to score this measure so that the data can be analyzed in a meaningful way. In addition, the Pearson software requires that participants complete all items in this measure. This is a permanent setting in the software that the study team is not able to modify. Parents and teachers will be informed that this measure will require all items to be entered to be completed. Parents/teachers will still have the option to not complete the measure if they are not comfortable answering any of the questions.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

All identifiable information that is obtained from participants (e.g., names on the signed consent form or on rating scales) will be obtained through collection of paper records or electronic links generated thru REDCap. Information obtained on paper will be entered into REDCap using a student ID number. All data will be coded within the REDCap database. Only one electronic file at the CHOP site will hold the link between the student's ID number and their name. The files linking identifiers (PHI) will be retained for a minimum of 6 years

post the data collection phase. The identifiers will be retained for this duration to comply with CHOP's data retention policy (A-3-9).

All print data will be housed in locked filing cabinets with restricted access at the Roberts Center for Pediatric Research at CHOP. At the end of the study, signed consent forms will be housed in locked filing cabinets separate from the ID coded data. All data that are transported to and from the school buildings and the research offices will be transported in HIPAA-compliant lockable bags. Families and school staff will be informed that research data are confidential and cannot be shared with participants; research data will not become part of the student's educational record. All data that are analyzed and presented will be de-identified.

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

The PI (Dr. Power) and Co-PIs (Drs. Nissley-Tsiopinis and Mautone) assume overall responsibility for monitoring the integrity of data collection and the safety of the interventions. The investigative team, which will most often meet monthly, will oversee all aspects of the study, monitor progress in meeting recruitment goals, and address methodological issues as they arise. The PI (Dr. Thomas Power) will chair this team. Members of the investigative team will include the Co-PIs (Drs. Jenelle Nissley-Tsiopinis and Jennifer Mautone) and Co-Investigators (Drs. Abbas Jawad, Russell Localio, Zuleyha Cidav, and Richard Gallagher). Dr. Howard Abikoff will be a consultant to this team. The research staff will attend these meetings. The study will include three core areas, which have been designed to ensure the study achieves its goals and data are collected in an unbiased manner. The **Intervention Core**, directed by Dr. Nissley-Tsiopinis, will address all intervention training, supervision, and implementation activities. This team, including the post-doctoral fellows and Drs. Gallagher and Abikoff, will most often meet weekly (although Drs. Gallagher and Abikoff will attend less frequently). The **Evaluation Core**, directed by Dr. Mautone, will address all data collection, management, and analytic activities. This team, including Drs. Power, Jawad, Localio, and Cidav, as well as the research staff, will most often meet bi-weekly (although Drs. Power, Jawad, Localio, and Cidav will attend less frequently). The **School Engagement Core**, directed by Dr. Power, will focus on recruiting schools and maintaining their engagement throughout the study. This team, including the Co-PIs and fellows, will most often meet on a monthly basis.

Safety of Student Participants: Student participants will be under the care of a school partner who is supported by a consultant/coach (study team trainer) for the duration of their participation in the study. The consultant/coach will have the support of a licensed psychologist. School partners will monitor students' behavior and response to the intervention through communication with them. School partners will closely monitor participants throughout the course of the study. In all cases, if a school partner or study team member has any concern about a student's emotional state at any point, immediate action will be taken to provide appropriate care. If a family is interested in other treatments, we will work with them to identify appropriate referrals in the community.

8.4.2 Risk Assessment

Risks are not greater than minimal. There are no known physical or legal risks to participating in the study interventions.

The following steps will be taken to protect against risk: First, all study personnel and all school-based personnel who will be involved in participant recruitment will receive initial

training and ongoing supervision in areas related to ethical conduct, confidentiality protection, and other topics of human participant protection.

Second, only identified school personnel will make initial contacts with parents so as to protect parents/students from being known to the investigators prior to agreeing to participate in the study. Paper records will be stored in a locked file cabinet with restricted access at the Roberts Center for Pediatric Research.

Third, students, teachers, school partners, and parents will be told that they do not have to answer any question that makes them feel uncomfortable.

Fourth, careful monitoring of family conflict and teacher stress and the provision of psychological consultation if families or teachers become destabilized will minimize the risk of the student, parent, teacher, and family-school interventions.

Fifth, school partners, families and teachers will be informed that when information about the study is disseminated, no information that could identify the student, family, or school will be included.

Finally, parents, teachers, school partners, and students will also be informed that participation is voluntary. If they choose to take part in this study, they may stop at any time during the study. If they choose not to take part in the study, there will be no negative impact on their educational services or health care services provided by CHOP (students and families) or employment with the participating school districts (teachers and school partners).

8.4.3 Potential Benefits of Trial Participation

This study will contribute to be available interventions that schools have to address organizational challenges of students by determining the efficacy of the school-based version of a very effective clinic-based intervention, the Organizational Skills Training intervention. This will improve schools' ability to improve organization, time management and planning skills among students in grades 3 to 5, before they face the increased demands of middle school. There is a lack of such interventions for students in late elementary school in spite of the increased organizational expectations and independence at these ages. Families and teachers participating in the intervention are likely to benefit from the targeted interventions to improve organizational and academic functioning.

8.5 Risk-Benefit Assessment

The risks associated with this study are minimal and generally no greater than the risks of receiving care in the community.

8.6 Informed Consent/Assent and HIPAA Authorization

8.6.1 Waiver of Consent for Student Screening

A waiver of consent has been obtained for school personnel to screen students. The screening procedures noted in section 3.1.1 and 4.1 involves no more than minimal risk to the student. The screening is conducted by school personnel involved in the existing care of the student and support and management of his/her school-related challenges. The process of screening students or identifying those struggling with OTMP skills in an effort to better support them will become part of school standards. No contact information about students or families collected as part of screening will be released to the study team without

parental permission/expressed interest in this study. Screening students for participation in this study does not adversely affect their rights and welfare, nor could they practicably be identified for this beneficial program without an identified OTMP skill deficit.

8.6.2 Consent for Student/Parent/Legal Guardian (and Caregiver if applicable) Dyads

After a student is identified and meets study criteria, the school partner will contact the family to gauge interest in the study. If families are interested, the school partner will ask permission to share family contact information (phone and email address) with the CHOP research team. If the family agrees, then a member of the research team will contact the family to explain the study and obtain written informed consent from the parent/legal guardian and assent from the student. If the family provides consent, a member of the research team will inform the student's teacher of the family's enrollment in the project. The family and teacher will be informed that they have the right to withdraw participation in the study at any time.

If another adult caregiver (other than a parent/legal guardian) is a primary caregiver of the child and supports the child with schoolwork and communication with the school, he/she may be enrolled as a research participant (with permission from the parent/legal guardian). This adult would only be consenting for his/her own participation in the research study. This adult could not consent for the student's participation in the research study as that is needed from the parent/legal guardian. The caregiver's role as a research participant would include completion of a demographic form, completion of outcomes measures, and participation in parent meetings which may be audio recorded.

Study procedures as well as potential risks, benefits and treatment alternatives will be described to families at the time participation in the study intervention is sought. No student will be asked to participate if demonstrably unwilling, even if his or her parent wishes it. Students and their parents will be clearly informed of the voluntary and confidential nature of their participation, that treatment services will be provided in the school setting, and of their right to terminate their participation at any time without penalty. Ample opportunity will be provided for them to ask any questions they may have of study team. If the family agrees to participate, the consent form will be signed. The PI will retain copies of the signed consent and assent forms, and parents will be given a copy of these forms (either hard-copy or provided electronically thru e-mail).

If the study team has exhausted all possible ways to meet a parent for the consent process in-person and it is just not feasible, the study team member will discuss the ICF with the parent over the phone (or a web-based HIPAA compliant video conference platform provided by CHOP) and answer any questions they may have about the study. Afterward, if the parent/student is interested in participating, the parent may return a copy of the signed consent form to the team member via fax or mail/email.

Written informed consent may also be obtained electronically through REDCap. The parent/legal guardian would receive a link to a secure REDCap portal in which they will be asked to enter their name, their child's name, and the date to indicate their consent. The provision of the parent/legal guardian name and child's name will associate the informed consent document with the participant. The REDCap portal will contain the complete informed consent document with the exact same text as the paper consent copy. The study team will email a copy of the completed electronic consent form to the family, with the instruction to either save or print a copy of this form. These electronically signed consent

forms will be printed out from REDCap and stored with paper consent forms in locked filing cabinets in the Roberts Center for Pediatric Research.

Electronic signature for an informed consent document for caregivers may also be obtained via the procedure detailed above if it is not possible to meet with the caregiver in person or obtain via email/fax. In this case, the caregiver will receive a link to a secure REDCap portal in which he/she will be asked to enter his/her name and the date to indicate his/her consent.

Once parental consent is obtained/documented via fax/email or REDCap, student assent will be obtained either in-person by a study team member in the school, via the phone or thru a web-based HIPAA complaint video conference software provided by CHOP. No study procedures will take place in the time between obtaining documentation of consent from the parent/legal guardian and obtaining student assent.

Students or families who are in need of treatment, but do not qualify for this study or decide not to participate will be provided with appropriate treatment referrals, in collaboration with the school partner.

8.6.3 Verbal Consent for School Partners and Teachers in the Intervention Condition

Consent for the participation of school partners and teachers in the intervention condition of this study will be obtained verbally. Teachers will be provided with an information sheet either in-person, via email or via a REDCap link, outlining what their participation will entail (completion of questionnaires and implementation of /participation in recorded intervention sessions). A consent letter will be provided either in-person, via email or via a REDCap link to school partners that outlines their participation. Teachers and school partners will be given the same opportunity as families to ask questions and make an informed decision regarding their involvement. If it is not possible to have an in-person meeting with a teacher and/or school partner, a direct email to the teacher/school partner will provide contact information (phone/email) of the study team should they have any questions/concerns. Consent will be obtained by study team members, which will include Co-Investigators, Post-Doctoral Fellows, Research Coordinators, Research Assistants, and other research team members. Refusal to participate will not affect their employment at the participating school or their relationship with CHOP.

8.6.4 Verbal Consent for School Partners and Teachers in the TAU Control Condition

Consent for the participation of school partners and teachers in the TAU condition of this study will be obtained verbally. Teachers will be provided with an information sheet either in-person, via email or via a REDCap link, outlining what their participation will entail (completion of questionnaires). A consent letter will be provided either in-person, via email or via a REDCap link to school partners that outlines their participation. Teachers and school partners will be given the same opportunity as families to ask questions and make an informed decision regarding their involvement. If it is not possible to have an in-person meeting with a teacher and/or school partner, a direct email to the teacher/school partner will provide contact information (phone/email) of the study team should they have any questions/concerns. Consent will be obtained by Study Team Members, which will include Co-Investigators, Post-Doctoral Fellows, and other study team members. Refusal to

participate will not affect their employment at the participating school or their relationship with CHOP.

8.6.5 Verbal Consent for Trainers

Trainers are study team members as well as secondary research subjects. Trainers will be provided with an information sheet outlining what their participation, as a research subject, will entail – completion of demographic questionnaire, use of audio recording data of consultation and coaching sessions with school partner for research purposes, and use of fidelity checklist data for research purposes. All of these procedures are detailed in the prior protocol sections.

Informed Consent of trainers will be obtained verbally. Trainers are employed at CHOP and will not be paid for their participation as a secondary research participant. A waiver of documentation of consent is being requested for these participants. Verbal consent will be documented internally by the study team. A study team member other than a principal investigator will obtain verbal consent to prevent coercion.

Given that these participants are research study team members providing a service as a part of this study, the audio recording and completion of fidelity checklists will not be voluntary. Completion of fidelity checklists and audio recording is a widely accepted, standard practice in the delivery of a behavioral intervention to monitor adherence to an intervention manual. These checklists and recordings will be used in the clinical supervision of trainers when applicable.

The use of the fidelity checklist data and audio recordings for research purposes (beyond use in clinical supervision) will be voluntary. Completion of the demographic form for research purposes will also be voluntary. Participants will be given time to ask questions and make an informed decision regarding their completion of the demographic questionnaire and use of the "data" from the fidelity checklists and audio recordings for research purposes. The fidelity checklists, audio recordings, and demographic form (used for research purposes) will not have a negative impact on the trainer's employability at CHOP. If a trainer declines participation as a secondary research participant, the fidelity checklists and audio recordings will ONLY be used for purposes of clinical supervision. This data would not be analyzed for research purposes.

8.7 Payment to Subjects/Families

Parent/Legal Guardian/Caregiver Stipends. All parents/legal guardians/caregivers completing measures will be given a stipend of $30 for completing assessment forms at each time point. Forms will be collected at four time points: baseline, post treatment, 5-month follow-up and 12-month follow-up.

Student Compensation. Student participants will receive small prizes (valued at $2 or less) for actively participating in study sessions and for completion of measures at four time points: baseline, post-treatment, 5-month follow-up and 12-month follow-up.

Teacher Stipends. Teachers of participating students will be given a stipend of $30 per student for completing assessment forms at each study assessment time point. Forms will be collected from all participants at baseline, post-treatment, 5-month follow-up, and 12-month follow up.

School Staff Buyout Time. For their work collaborating with us in conducting the OST-S groups, school partners' time will be bought out so that the school can pay for replacement staff during this time. Our budget calculations assume that for each OST-S group, a school partner will work with us 4 hours a week during the 8 weeks of the OST-S group, running two group sessions a week, preparing for the group, consulting with teachers and parents and meeting with study team trainers for consultation and coaching. In addition, we are assuming that each year they run groups, school staff will spend up to 8 hours in training during the weeks prior to running the first of the two groups. We have also allocated 4 hours per group for both OST-S and TAU groups to compensate the time that they spend assisting in the eligibility assessment and consent process (contacting families).

School Partner Stipends. In addition to school staff buy-out, school partners in both conditions will be compensated $50 for their effort is assisting with student recruitment of two OST-S groups (up to 4 students each) (contacting families, collecting referral forms from teachers, and collaborating with CHOP staff). The stipend will be provided to the school partner each year after the eligible students are enrolled for that particular school year. If two school partners assist with the recruitment of students each school partner will receive $25 for assistance in recruiting one OST-S group (up to 4 students).

In addition, a stipend of $25 will be provided to the school partners in both conditions at each of the 4 data collection time points to compensate them for assisting CHOP staff in collecting data from teachers, parents, and students within the school per OST-S group. This often requires additional time and effort on behalf of the school partner to coordinate student and teacher schedules in collaboration with CHOP staff. The stipend will be provided to the school partner after all data from a time point for the OST-S group has been collected (i.e. baseline, post-treatment, 5 Month, and 12 Month.)

For school partners who are in a school assigned to the OST-S Condition only, school partners will be compensated $50 per group at two different times during the delivery of the OST-S intervention (mid-intervention and at the end of the intervention). This compensation is for the assistance of the school partner for data collection for research purposes that occurs during the OST-S groups.

School partners will also be reimbursed (nontaxable) for travel expenses in the case that they have to travel to a location (other than their own school) for the initial in-service training as described above in Section 3.1.2

Stipends for all participants will be issued on an electronic bankcard that functions like a debit card. Participants will be informed that their personal information to register the card will be shared with the bank institution.

Trainers will not be compensated for their role as a secondary research participant.

9 PUBLICATION

We will disseminate information to researchers and practitioners in school psychology, school mental health, special education, and clinical child psychology through conference presentations and publications in peer-reviewed journals. Conferences targeted include National Association of School Psychologists, Council for Exceptional Children, Association

for Behavioral and Cognitive Therapies, and Advancing School Mental Health. Journals to target include Journal of School Psychology, School Psychology Review, School Mental Health, Advances in School Mental Health Promotion, Exceptional Children, and Journal of Special Education. Further, the investigators are frequently asked to present to school districts. We will highlight the results of this study in these presentations. In addition, a summary of study results will be posted on the "Resources" section of the CHOP ADHD Center website, as well as on the NYU Child Study Center "About Our Kids" website. Lastly, in collaboration with CHOP Public Relations, we will publicize the results to parents, teachers, and intervention providers through press releases and notifications on the CHOP Facebook page and Twitter feed.

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