Title:	**A Hybrid Effectiveness-Implementation Trial of Group CBT in Urban Schools**
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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
APRS	Academic Performance Rating Scale
CATS	CBT for Anxiety Treatment in Schools; A group CBT program for over anxious children
BDMC	The Biostatistics and Data Management Core
CBH	Community Behavioral Health
CBT	Cognitive Behavioral Therapy
CDI	Children's Depression Inventory
CFC	Content Fidelity Checklist
CHOP	Children's Hospital of Philadelphia
COTTAGe	Child & Adolescent OCD, Tic, Trich & Anxiety Group
CRS	Consultation Rating Scale
D&I	Dissemination and Implementation
EBP	Evidence-based Practice
FRIENDS	A group CBT program for over anxious children
GAD	Generalized Anxiety Disorder
GCBP	Group Cognitive Behavioral Therapy
GLM	Generalized Linear Models
IC	Independent Coders
IITC-ESMH	Index of Inter-professional Team Collaboration for Expanded School Mental Health
IRB	Institutional Review Board
KT	Knowledge Test
MASC-2	Multidimensional Anxiety Scale for Children
PA	Planned Adaptation
PI	Primary Investigator
REDCap	Research Electronic Data Capture
SAD	Separation Anxiety Disorder
SCARED	Screen for Child Anxiety Related Disorders
SRCM	Self-Report Coping Measure
SRS	Supervision Rating Scale
STS	School Therapeutic Services
SWPBIS	School-wide positive behavioral interventions and supports

TT	Train the Trainer (support strategy for the implementation of FRIENDS & CATS where Masters-level supervisors receive training by experts on conducting supervision)
TT+	Train the Trainer Plus (support strategy for the implementation of CATS where supervisors receive training and ongoing consultation by experts on conducting supervision)

ABSTRACT

Context: Unresolved psychological problems, such as anxiety, affect a significant number of our students and interfere with their ability to attend, actively participate, and prosper in school. This project will expand the capacity of selected mental health agencies to provide services in the participating schools through school therapeutic services (STS). The project will provide enhanced training in evidence-based behavioral health interventions to school-based mental health providers. The services will be implemented by STS Master's level therapists supervised by their mental health agency supervisors (Internal Support), who are in turn supported by the research team (TT) or external consultants (TT+).

Objectives: The purpose of this intervention study is to test the effectiveness of FRIENDS (a program for overanxious children) compared to an adapted version (CATS) and to compare the total cost between the interventions. The study also aims to compare support mechanisms: Train-the-Trainer (TT) to Train-the-Trainer Plus (TT+) for the implementation of CATS and to test mediators and moderators of type of support (TT vs. TT+) on therapist fidelity.

Study Design: This is a 3-arm, parallel group, Type 2 hybrid effectiveness-implementation trial in K-8 schools in Philadelphia over 5 years.

Setting/Participants: Schools within the School District of Philadelphia that have STS programs managed by mental health agencies are potentially eligible for participation. Schools (3-6 per agency) will be chosen for participation. Students who present excessive anxiety in grades 4-8 would be potentially eligible to participate in the interventions offered by the agencies' therapists in their school.

Study Interventions and Measures:
This study is designed to test: a) the effectiveness of an adapted version of a group cognitive behavioral therapy program (CATS) compared to the original version of this program (FRIENDS), and b) the effectiveness of two implementation strategies for CATS: Train-the-Trainer and Train-the-Trainer Plus. CATS is a shorter, more culturally sensitive, focused, and feasible CBT for anxiety in children than FRIENDS. CATS addresses one of the major barriers to implementation (intervention-context fit).

Therapists and supervisors will be randomly assigned to one of three conditions: a) FRIENDS with Train-the-Trainer implementation strategy (i.e., Masters-level supervisors receive training by experts on conducting supervision); b) CATS with Train-the-Trainer strategy; c) CATS using the Train-the-Trainer Plus strategy (i.e., supervisors receive training and consultation by experts on conducting supervision). Effectiveness will be measured by comparing A to B; Implementation will be measured by comparing B to C. Agency therapists will conduct all treatment groups in the schools.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Unmet need for mental health services remains extraordinarily high, especially among urban low-income children. Anxiety disorders in particular are highly prevalent among children in low-income, high-stress communities, and have been linked to academic and social problems and emotional maladjustment later in life. Schools in low-income urban communities present a context with great potential for implementation of psychosocial EBPs. Cognitive-behavioral therapy (CBT) is an EBP that has been found to be very effective in treating anxiety in various settings, including schools. Friends for Life (FRIENDS) is an efficacious group CBT protocol for anxiety. Unfortunately, CBT for anxiety is seldom employed in under-resourced urban schools, mainly because the treatment protocols are not tailored for the context or the population, existing behavioral health staff do not receive adequate training or support to allow them to implement the treatment with fidelity, and school districts do not have the resources to contract outside providers or consultants. Community Behavioral Health (CBH), a non-profit organization that manages Medicaid funds for the City of Philadelphia, has approached us for help to develop cost-effective implementation strategies for schools. The availability of a contextually relevant, feasible, and cost-effective evidence-based CBT protocol for urban schools designed to be implemented and supported by existing agencies would address existing gaps in services for children who might otherwise go without treatment.

1.2 Name and Description of Investigational Product or Intervention

1.2.1 Interventions implemented for anxious students by city agency therapists:

Friends for Life (FRIENDS): FRIENDS, a GCBT program, is an effective program for the prevention and treatment of anxiety disorders in children evidenced by a meta-analysis on school-based interventions for at-risk and clinically anxious youth. FRIENDS has been successfully implemented in several countries with children from diverse ethnic backgrounds. FRIENDS was developed based on the view that anxiety is a tripartite construct involving physiological, cognitive, and behavioral components.
Core components: Experts in CBT for childhood anxiety disorders have identified 5 essential components: psychoeducation, somatic management skills training, cognitive restructuring, exposure methods, and contingency management. The FRIENDS protocol consists of 10 weekly sessions and two booster sessions. We included the booster sessions in the regular protocol for a total of 12 sessions.

Adapted CBT for Anxiety Treatment in Schools (CATS): We conducted planned adaptations to the FRIENDS protocol based on our collective experience with the protocol and qualitative data (focus group and interviews). We followed procedures developed by Lee and colleagues, including surveying service providers and trainers regarding the appropriateness of FRIENDS for the target population. Changes were made to the language (idioms, metaphors, words), cultural fit (cultural values), methods (session length, number of sessions), activities (in-session practices), which resulted in additions and substitutions in these areas while maintaining the 5 essential components of the treatment. CATS is a briefer (8-session) and more engaging and culturally-sensitive protocol than FRIENDS.

1.2.2 Support Interventions (strategies) offered to city agency therapists implementing CATS

Train the Trainer (TT) by which agency supervisors are trained to conduct effective supervision, and then go on to train therapists.

Train the Trainer Plus (TT+) a modified train-the-trainer approach by which supervisors receive training plus extended consultation on conducting effective supervision.

1.3 Findings from Non-Clinical and Clinical Studies

We pilot-tested FRIENDS with low-income urban children who were at risk or who met diagnostic criteria for an anxiety disorder. The treatment was part of a school-wide positive behavioral interventions and supports (SWPBIS) program (CDC, R18MN000003) in 2 K-8 public schools in Philadelphia. The development and implementation of these programs was based on the Public Health Approach. The proposed project will take place in similar schools. We interviewed the parents of 111 randomly selected children in order to assess mental health characteristics of the typical student attending the participating schools. On the Child Behavior Checklist, 28% of the children were rated within the borderline range or higher (T score > 60) on the Anxious/Depressed subscale and 9% were rated within the clinical range (T score > 70). The corresponding percentages for externalizing disorders were 29%, and 17%, respectively, indicating that the number of children at risk for anxiety is very similar to the number of children at risk for externalizing disorders.

Six graduate students in applied psychology and three counselors from each school were trained in and co led FRIENDS groups. The fidelity scores reflected the ability of graduate students and school counselors to implement the interventions with fidelity while receiving expert support. Six FRIENDS groups were conducted. All of the sessions were video recorded to assess content fidelity. Fidelity ratings were obtained from an independent coder (IC). Average fidelity to the FRIENDS manual across sessions and groups was 86%, considered moderate to strong fidelity. Of the 33 children who participated, only 10 (30%) children participated in all 12 sessions. Although only 30% of participants attended all originally scheduled sessions, 85% of participants received the entire content of the intervention. The procedure was for school counselors and project staff to review material with absent participants individually, or in groups of two, prior to the upcoming session. Following this procedure, 85% received all session content.

The findings from the pilot study are relevant for the proposed study because they show that: a) the prevalence of anxiety problems in the schools where the proposed project would take place is high; b) less than a third of the children participated in all 12 session, indicating that a briefer protocol would be more feasible in urban schools; c) counselors functioning as co-therapists with graduate students can deliver FRIENDS with relatively high levels of fidelity; and (d) the treatment led to reductions in diagnostic level and symptom severity.

Furthermore, in preparation for this project, we conducted qualitative interviews with 5 consultants from our current SWPBIS project (R01HD073430) and focus groups with school counselors implementing FRIENDS. A qualitative theme analysis (i.e., frequency of themes) about consultants' perceptions regarding context-fit of FRIENDS revealed that the protocol is too long, uses language and examples that are not congruent with the language and culture of low income, ethnically diverse children, and does not sufficiently emphasize teaching relaxation and exposure. Counselors thought the manual is "dry" and "boring" and

that it needs to be “tweaked” in order to increase children’s engagement. Counselors requested more optional activities to support main ideas in the manual.

1.4 Relevant Literature and Data

Anxiety disorders (i.e., Generalized Anxiety Disorder, Social Phobia, Specific Phobia and Separation Anxiety Disorder), affect up to 13% of the child population making them among the most common childhood conditions. Anxiety disorders are highly prevalent among inner city school children and often go unidentified and untreated. Children with these disorders are more likely than their peers to have problems with social, peer and parent-child relations, academic achievement school refusal and future socio-emotional adjustment. School factors, such as peer problems, academic pressures, and school violence, can contribute to and exacerbate symptoms.

Individual and group CBT (GCBT) have been shown to be highly effective for the treatment of anxiety in youth. GCBT requires fewer resources than individual CBT, such as one therapist treating several children at once, thus making it less expensive for use in under-resourced settings such as urban schools. GCBT for anxiety has successfully been employed in urban school settings by our team and others. FRIENDS, a GCBT program, is an effective program for the prevention and treatment of anxiety disorders in children as evidenced by a meta-analysis on school-based interventions for at-risk and clinically anxious youth. Also, our previous research demonstrates that FRIENDS is an effective protocol for use in urban public schools.

Public schools have become a common setting for the delivery of mental health services to children and may be the ideal context through which to narrow services disparities. The school is a convenient location where services can often be provided at little or no cost to families. Benefits of providing EBPs in schools include the ability to implement interventions in the very environment in which most symptoms are triggered and to incorporate protocol-specific interventions, with peer and teacher involvement, as needed for generalizability. EBPs for anxiety disorders enable overanxious children to overcome behavioral barriers to learning.

The most pressing challenge facing the mental health field is the dissemination and implementation (D&I) of EBPs: taking protocols that were developed in research settings and adapting them for specific community use. It has been estimated that it can take up to 17 years for new EBPs to make their way from research to practice. The delay is likely longer for child treatments in urban settings. The customary step-wise progression from clinical efficacy to clinical effectiveness in practice to implementation contributes to the long delay between the development of a treatment and its routine implementation in a community setting. Curran and colleagues have proposed three hybrid designs to galvanize the translation of efficacious treatments to enhance their public health impact. These research designs are thought to facilitate “more rapid translational gains, more effective implementation strategies and [yield] more useful information for decision makers. In the Type II design, effectiveness and implementation have equal importance. Type II effectiveness-implementation hybrid studies are most appropriate for treatments that have a strong record of efficacy and effectiveness, such as FRIENDS.

Treatments that are developed and tested for efficacy in highly controlled research settings often do not fit into “real world” contexts. As a result most effective treatments in health and mental health settings need to be adapted for new contexts. Unfortunately, in the adaptation process, there is a potential for some of the main components of the treatments to be altered, rendering them less effective than in their original form. Lee and colleagues developed planned adaptation (PA) to address the tension between “implementing

programs with fidelity and the need to tailor programs to fit the target population". PA orients the provider to the program and its theoretical orientation. A central tenet of PA is that adaptation must be conducted without altering the program's core components. PA helps the provider identify components of the program that can be modified, and provides a process for conducting adaptations and a direction on how to develop evaluation strategies. We applied PA to FRIENDS in order to make it more feasible for implementation in co-location settings with low-income urban children.

Substantial resources have been dedicated to the D&I of mental health EBPs. Key to that effort has been the identification of strategies for training community-based clinicians. Studies have shown that effective training models include initial workshops for therapists that are followed up with supervision, which often includes coaching and performance feedback. This was the strategy employed by our research team for an R01 study testing the effectiveness of consultation only vs. consultation plus coaching in the implementation of an EBP in public schools in the SDP. Another important challenge facing publicly funded mental health agencies is finding cost-effective strategies for supporting supervisors. Most community mental health agencies, where low-income urban children receive services, do not have the resources to pay for ongoing expert direct consultation for therapists who implement EBPs. As such, finding time- and cost-effective alternative strategies for supporting therapists would have a significant public health impact. An important feasibility question is, "Can internal clinical supervisors who are not familiar with EBPs provide effective supervision to therapists after participating in training workshops or do they need more extensive support?" A mostly self-sustaining system as previously described would likely be more practical and less expensive but perhaps lead to fewer positive child outcomes compared to a system where supervisors are provided extended consultation. Two alternative, and potentially cost effective, strategies are the cascade or train-the-trainer (TT) approach, by which agency supervisors are trained to conduct effective supervision, and then go on to train therapists; and a modified train-the-trainer approach by which supervisors receive training plus extended consultation (TT+) on conducting effective supervision. TT has been used with adult mental health populations. Two pilot studies using this approach have reported improved therapist knowledge and improved client behavior, but it is not known whether these findings could generalize to other settings or populations. TT+ has been used by Bruce Chorpita and colleagues with agency supervisors who support therapists in the implementation of modular individual CBT. Highlights of this approach include initial training, biweekly or monthly phone consultations with supervisors and a supervisor promotion review. This modified train-the-trainer approach has been found to lead to moderate outcome effect sizes.

This current study has the potential to demonstrate that agency therapists and supervisors who have had little to no prior exposure to EBPs can implement an anxiety disorders EBP with fidelity. The use of group therapy can contribute to lowering services disparities in urban schools. Comparisons of the two implementation strategies (internal supervision with or without consultation for supervisors) would provide large urban mental health systems with data to make decisions about adoption of EBPs. The study is consistent with the goals of the Affordable Care Act in that it would generate information on implementation of effective practices that optimize delivery of mental health care to traditionally underserved communities.

1.5 Compliance Statement

This study will be conducted in full accordance with all applicable Philadelphia Department of Public Health Research Policies and Procedures and all applicable Federal and state

laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (when appropriate), and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia and Philadelphia Department of Public Health 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

This study is designed to answer two important questions:

1. Can publicly funded mental health therapists in urban schools successfully implement EBPs when supported by their own agencies or does successful implementation require external, expert support?

2. What is the comparative cost effectiveness of these different implementation strategies?

2.1 Primary Objective (or Aim)

The primary objectives of this study are:

- To compare pre- to post-treatment effectiveness of different CBT treatments (FRIENDS vs. CATS) and to compare the total cost between CATS and FRIENDS.

- To compare Train-the-Trainer (TT) to Train-the-Trainer Plus (TT+) for the implementation of CATS.

2.2 Secondary Objectives (or Aim)

The secondary objective is to test mediators and moderators of type of support on therapist fidelity.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a 3-arm, parallel group, Type 2 Hybrid (effectiveness-implementation) design. The three groups are:

A) FRIENDS with Train-the-Trainer (TT) implementation strategy (supervisors participate in training workshops on conducting supervision)

B) CATS with TT strategy

C) CATS using the Train-the-Trainer *Plus* (TT+) strategy (supervisors participate in training workshop and receive further consultation on conducting supervision).

The effectiveness part of the trial will compare A-B (different treatments); the implementation part of the trial will compare B-C (same treatment, different implementation strategies).

Agency therapists will conduct all treatment groups. At the outset of the study, therapists will be randomly assigned to condition (A, B, C).

3.1.1 Screening Phase

Student Screening: Students in grades 4-8 who are referred to the STS programs in the participating schools will be screened for signs of anxiety using the Screen for Child Anxiety Related Disorders (SCARED). The screening criterion is a total score $\geq$ 25 or elevated sub-scale scores (as noted by the scoring procedures) on the Screen for Child Anxiety Related Disorders (SCARED), completed by the student or a parent. This will become regular standard of care anxiety screening procedures for students in the STS Programs. In addition, STS agencies will also be trained and supported in screening students for traumatic life events using the Trauma History Questionnaire (THQ, caregiver and child report). This practice will also be encouraged to become regular standard of care. Referrals will be made to the research study team on the basis of the SCARED. For parents who are interested in having their children participate, their Therapist will share their contact information and SCARED/THQ scores with the research team after obtaining a parent signature to release information.

If a student meets screening criteria on the SCARED (as noted above), they will be referred to the study and research staff will ask parents /caregivers if they are interested in having their child participate.

Alternatively, STS Agencies may also refer students in grades 4-8 who are enrolled in or being evaluated for STS services to the study team. Upon referral, the study team may contact parents via telephone to obtain consent for screening procedures. With parental consent, the study team may conduct the SCARED Screener with students (in their school) in an effort to identify students who are eligible for participation in the study. If identified as eligible, the study team will contact the parent to further explain the study and schedule a consent meeting.

3.1.2 Phase I: Training of Supervisors & Therapists assigned to all 3 conditions

Members of the research team will conduct 1-2 days of training each year (i.e., 5 times over the course of the grant) for all new agency therapists (including alternates) and supervisors. Training of supervisors and therapists will take place at The Children's Hospital of Philadelphia (CHOP), at the site of a community agency, or at the school. Some of the training will be for supervisors only and some for supervisors and therapists together.

Supervisors will learn a competency framework for supervisors, strategies for identifying children who could benefit from the service (e.g., conducting in-service presentations to faculty on signs of anxiety in children), and how to use an online platform in the school/community setting (e.g., wireless access; using fidelity forms) to conduct, guide and track supervision sessions remotely. They will also be trained on the use of fidelity monitoring and conducting performance feedback with therapists. Supervisors will learn how to prepare therapists for each treatment session and how to conduct performance feedback using fidelity forms.

Therapists and supervisors will be trained in using a screening instrument (SCARED) for the identification of potential participants. They will be introduced to a competency model for CBT for anxiety, which delineates generic therapeutic competencies (e.g., professional practice), CBT competencies (e.g., relevance of theory and research), and specific CBT techniques for anxiety (e.g., managing negative thoughts). They will also learn about how to deal with implementation barriers (e.g., scheduling sessions, conducting exposure tasks).

Therapists and supervisors from the STS programs using FRIENDS (A) and the STS programs using CATS (B & C), will be trained separately for activities related to each protocol. Trainers will follow training procedures used in other EBP dissemination studies in nontraditional settings and other training strategies found to be effective (i.e., active learning such as modeling and role-playing). At the conclusion of the training, therapists and supervisors will be administered the Knowledge Test (KT) to measure knowledge of concepts taught during the training. Participants who score below 80% will be provided further training in the areas in which they scored low.

3.1.3 Phase 2: Therapist Implementation of EBP (FRIENDS & CATS) & Implementation of Support Strategies (TT vs. TT+)

STS therapists from the participating agencies will screen students who have been referred to the STS program and then refer students, who meet the screening criteria, to the research team. If the child has screened positive on either the parent- or child-form of the SCARED, then he or she is eligible to participate in the study. The research team will conduct further evaluations using rating scales to understand symptoms and impairment across different aspects of child behavior (e.g., depressive symptoms, coping skills, disruptive behavior, etc.). STS therapists will conduct treatment groups (FRIENDS or CATS) in the schools during lunch periods, or a non-academic period during the school day. Therapists will be expected to conduct FRIENDS or CATS groups with fidelity.

The agency supervisors will be expected to conduct supervision with therapists. Supervisors will provide one 50-minute supervision session for each treatment session the therapist conducts (12 for FRIENDS, 8 for CATS). The session is divided into group preparation (i.e., discussing referrals, preparing for upcoming session, engaging in problem solving around implementation barriers), and coaching (i.e., performance feedback). Prior to the first session, project staff uploads video-recorded samples of effective implementation of the main components of the treatments, as recorded during a previous implementation of FRIENDS. Periodically, the supervisor encourages therapists to watch the video clips at their convenience. Also, prior to the session, the supervisor will watch a recording of the previous session and select clips for discussion. During the coaching portion of the session, the supervisor will ask for self-reflection of previous sessions and provide performance feedback. Then, the supervisor will provide the therapists with (a) fidelity data and (b) video clips bookmarked from the previous session showing effective and ineffective implementation of FRIENDS/CATS.

Simultaneously, TT and TT+ will be implemented by the research team to support the agency supervisors in supporting their therapists.

If substantial time (45-90 days) has lapsed between training and the start of intervention, Supervisors will be offered a booster training session after the original training in the weeks before starting their group. The purpose of the booster session is to review key points from the training (e.g., conducting performance feedback) and to answer questions about any aspect of the supervision process. This subsequent training opportunity for agency

supervisors (on how to be effective supervisors to the implementing therapists) will be conducted remotely, or in person.

Supervisors in TT+ (Group C) will receive 8 consultation sessions in the first year using the online platform. The consultation sessions will center on helping the supervisor conduct supervision, and will include performance feedback, implementation fidelity, problem solve implementation barriers and will answer supervisors' questions about the supervision manual. We will monitor whether supervision with therapists takes place regularly for the expected length of time and whether therapists implement the treatments with fidelity. This information will be obtained from group fidelity scores.

Supervisors will be instructed to supervise therapists based only on what they have learned in the consultation sessions.

3.2 Study Duration, Enrollment and Number of Sites

3.2.1 Duration of Study Participation

Agency Supervisors: There is no time limit placed on the duration of participation for agency supervisors. They may continue working with the research team for the duration of the study (5 years) or as long as their agency remains involved in the study or as long as they remain employed by the participating agency.

Agency (STS) Therapists Implementing EBP Interventions: Therapists are asked to commit to participate in the study for one school year. After the initial year, the study team would prefer to train a new therapist in an effort to minimize the effects of differences in therapist experience and therapist dropout on outcomes (yearly therapist dropout in the agencies is 25%). However, based on agency need and staff consideration, therapists can participate in additional years at the study team's discretion. This will be determined on a case-by-case situation. Therapists will be free to continue to implement the intervention groups outside the research project after participation in the study has concluded.

Students: Students who are determined to be eligible, based on the SCARED, and for whom consent/assent is obtained, will participate in a 30 minute baseline data collection session and then in the intervention which will consist of 12 (FRIENDS) or 8 (CATS) 40 minute (or one-class period) intervention sessions, conducted at school. They will also participate in a similar post-treatment data collection session once the intervention (12 or 8 sessions) is completed. Parents of the students participating in the intervention will also participate in two 30-minute data collection sessions (completion of the CBCL, CDI, and MASC-2, see section 5.2 below).

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

The study will be conducted in a minimum of 36 (potentially up to 41) public K-8 schools within the School District of Philadelphia and in collaboration with community mental health agencies, contracted by CBH, in the City of Philadelphia. However, not every school will participate during every project year. It is anticipated that schools will participate in 2 project years.

We expect there to be a minimum of 36-41 agency supervisors (one per school at all times). However, there is a 17% drop-out rate of supervisors across agencies. Therefore, depending on supervisor turnover, the number of enrolled supervisors will be comparable. If

all therapists participate once per school year, we'd expect to enroll 90 agency therapists (1 therapist per school (n=18), per year of the study (n=5) = 18x5 = 90). However, given that therapists may run a second intervention group, we could end up with fewer therapists than expected. Yearly therapist drop out in the agencies is 25%. Therefore, depending on therapist turnover within the agencies, the number of enrolled therapists will also be comparable.

Each of the participating mental health agencies will make available extra supervisors and therapists to serve as alternates in case a supervisor or therapist drops out of the study or terminates employment with the agency for any reason. Alternate supervisors and therapists will be invited to attend the initial trainings. If a supervisor/therapist moves to another school within the same study arm, s/he will be allowed to remain in the study and will be treated as a returning supervisor. Supervisors/therapists in conditions A and B who move to a school assigned to a different study arm can participate in the project pending PI review. Supervisors/therapist in condition C who move to a new school assigned to condition A or B will not be allowed to continue in the study due to potential condition contamination. They will be counted as drop outs.

Given agency structure and high staff turnover rate, consented therapists and supervisors may switch roles in an additional study year dependent on randomized study arm. Similar to procedure stated above, any therapist or supervisor that switches a role in the study in condition A or B can participate in any other condition. If the participant is in condition C, then they can only participate in condition C regardless of a change in school or agency during the duration of the study.

We expect each of the therapists to run one intervention group each per year and we expect each group to be composed of 4-6 eligible and consenting students. Therapists can run a second group if time permits but is not expected for participation. Therefore, we expect to enroll 360 students in the intervention sessions.

Given that some referred students will not meet inclusion criteria and that some will not consent or not attend group, we expect that we will need to consider 426 referred students to yield 360 participating students (based on a 15% attrition rate).

3.3 Study Population

3.3.1 Inclusion Criteria

1) Mental Health Agencies: Any CBH supported agency with 2 or more clinical supervisors implementing STS Programs in Philadelphia K-8 Schools.
2) Supervisors: Any participating agency clinician with a Master's degree or higher in a mental health field, as indicated by the agency and confirmed by self-report on the Staff Demographic form.
3) Therapists: Any STS therapist with a Master's degree or higher who provides services in one of the 18 participating schools.
4) Students: Any student enrolled in grades 4-8 in one of the participating schools, who enrolled in the STS program in their school and who meets study screening criteria. The screening criterion is a total score $\geq$ 25 or elevated sub-scale scores (as noted by the scoring procedures) on the Screen for Child Anxiety Related Disorders (SCARED) completed by the student or a parent.

3.3.2 Exclusion Criteria

1) Mental Health Agencies with less than 2 clinical supervisors and those not implementing STS programs within the School District of Philadelphia.

2) Student, supervisors, or therapists not involved in STS.

3) Students with Special Education classification of "Intellectual Disability."

4) Students with current school refusal (>15 missed days of school in current semester), a history of psychotic or autistic spectrum disorders as reported by school or agency staff at the time of referral and confirmed by parent/legal guardian at the time of baseline data collection.

5) Students who present with diagnoses that make participation in the study clinically inappropriate in that they warrant more intensive, outpatient or potential inpatient intervention, (i.e., severe, current, major depressive disorder, PTSD, or bipolar disorder) or who present as in acute risk to themselves or others during screening process or baseline data collection.

*Students meeting criteria in #2, #3 & #5 above will be excluded from participation because they would be unlikely to benefit from GCBTS.

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

4 STUDY PROCEDURES

4.1 Student Screening / Referral Process

Note Section 3.1.1.

At the beginning of each project year, we will offer each participating school an in-service training for teachers and/or behavioral support staff on recognizing warning signs of excessive anxiety in children. Following the in-service, STS therapists will ask teachers to refer any child showing signs of anxiety to the STS program. Either students or parents will be asked to complete the SCARED and THQ for identified students. These are regular standard of care screening procedures, so we will not collect these data for research purposes. If a student meets screening criteria (a total score $\geq$ 25 or elevated sub-scale scores as noted by the scoring procedures on the SCARED completed by the student or a parent), the STS therapist will refer the family to the research team. The study team may also assist in collecting the SCARED Screener from students, in cases where parental consent is obtained. In these cases, the THQ will only be collected if the student is eligible and the parent/child consents/assents to the full study.

4.2 Intervention Implementation (For Students)

Families (students and caregivers) who consent to participate in this intervention, will be enrolled in one of two programs (FRIENDS or CATS, depending on their school's randomization), over the course of several weeks. The students will participate in the program during lunch or a non-academic period during the school day. The programs will be implemented by the student's school-based STS Therapist. Refer to section 1.2.1 for a description of the programs.

Hectic periods of the year when student absenteeism and class trips are more common (1st and 4th Quarters) as well as several class breaks, including winter holidays (approximately 10 days), snow days, Spring Break (1 week) and state mandatory testing of students (2 weeks) will interrupt group sessions. We plan for the interventions to take place primarily during the 2nd and 3rd quarters to eliminate major interruptions in the 1st and 4th quarters. We acknowledge that interruptions might affect the interventions differently, partly because one of the interventions is longer than the other (8 vs. 12 sessions). We were not able to locate a measure that would capture these factors. However, differences in length will be analyzed by adding up the number of days dedicated to instruction for each school when groups are held and divide it by 5. We will then add up the weekly average for each subsequent week and divide it by 8 (CATS) or 12 (FRIENDS). This will give us an index of instruction time for each treatment, which we will then compare and use in covariate analysis.

4.3 Implementation of Support Strategies

Throughout the duration of the program, implementing therapists will engage in regular supervision with their agency supervisor. Depending on randomization, the research team will support the agency supervisors through the implementation of TT or TT+ (refer to section 3.1.3 for a description of "supervision" and TT vs. TT +).

4.4 Subject Completion/Withdrawal

Subjects 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 Investigator for lack of adherence to the study and/or development of exclusionary criteria. Student participants will be removed from the study if they develop exclusionary criteria during the trial (e.g. Bipolar Disorder I, acute suicidality, psychotic symptoms, etc) or if it is determined that the intervention group is not age/developmentally appropriate based on the grade level of the majority of enrolled students. As examples, acutely suicidal participants would be excluded from study participation, as would participants who require medical attention for a severe medical illness. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the study files.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening Measurements (Students)

Potential student participants will be screened using the SCARED. The SCARED is a 41-item questionnaire used to screen for children with anxiety disorders, using five sub-scales and a Total Score. It has excellent psychometric properties and has been used in community settings as a screening instrument for anxiety disorders. Therapists will ask students or parents to complete the SCARED if referred to or enrolled into STS Programs.

STS agencies will also be encouraged to collect information about Traumatic Life Events using the Trauma History Questionnaire (THQ). The THQ is a 23-item self-report measure for children that examines experiences with potentially traumatic events such as crime, general disaster, community violence, and sexual and physical assault using a yes/no format. For each event endorsed, respondents are asked to respond "yes" or "no" if they have experienced or witnessed the event. The THQ is used in research and clinical settings and is available in English and Spanish.

For parents who consent to the sharing of this information, the study team will collect this information, as well as the SCARED. However, the THQ will not be used as a screening tool. Students will be referred to the study solely on the basis of the SCARED.

5.2 Treatment Efficacy Evaluations (Information Collected *about* the Students enrolled in FRIENDS or CATS)

Multidimensional Anxiety Scale for Children (MASC-2). The MASC-2 is a 50-item rating scale for the assessment of anxiety symptoms in children. The MASC 2 has strong psychometric properties and is sensitive for measuring treatment effects. We will use the Total Anxiety score on the parent and child forms.

Self-Report Coping Measure for Elementary School Children (SRCM). The SRCM is a 34-item self-report measure with good psychometric properties that is used to assess children's coping strategies (Seeking Social Support, Self-Reliance/ Problem-Solving, Distancing, Internalizing, and Externalizing). The Total score for the SRCM will be used in outcome analyses.

Children's Depression Inventory – 2nd Edition (CDI-2). The CDI-2 is a child self-report 27-item instrument that measures the cognitive, affective and behavioral signs of depression. The CDI has high internal consistency, moderate retest reliability, and correlates with measures of related constructs such as self-esteem, negative cognitive attributions, and hopelessness. We will use the Total CDI score.

Child Behavior Checklist (CBCL). Completed by parents, this 118-item multi-axial rating scale provides a measure of children's (ages 6-18) internalizing and externalizing difficulties, as well as social and academic competencies. Good psychometric properties have been reported. We will use the Anxious/Depressed Somatic Complaints, Rule-Breaking Behavior and Aggressive Behavior scales in outcome analyses.

Engagement versus Disaffection with Learning: Teacher & Student Report. This is a 20 item teacher and student report measure which includes four sub-scales: Behavioral Engagement, Emotional Engagement, Behavioral Disaffection and Emotional Disaffection. Validity of scores is supported by findings that teacher reports are correlated with student reports, with in vivo observations in the classroom, and with markers of self-system and social contextual processes. As such, these measures capture important features of engagement and disaffection in the classroom.

*All measures noted above are validated / standardized.

5.3 Implementation Outcome Measures

All treatment sessions (across groups A, B and C) will be video recorded. Implementation will be measured by coding twenty-five percent of sessions by 2 Independent Coders (IC's). IC's will be Master's level research staff members or advanced doctoral students in Psychology who have been trained to a reliable standard. Coder reliability will be checked quarterly. Kappa coefficients will be computed; a minimum of .85 will be required for each code. Retraining will be conducted should rater agreement fall below .85. For the qualitative content analysis. Coding differences of within 1 point between the 2 ICs will be considered an agreement. We will report the average score between the two ICs. If the difference is greater than 1 point, a third IC will independently rate the session and the average of the three ICs will be reported. The IC's will code the videos using the measures below (and attached to section 12 of the eIRB application):

- Content fidelity (how well therapists delivered the content as originally intended by the treatment developers), which is our main fidelity measure, will be assessed

using the Content Fidelity Checklist (CFC). The CFC will reflect each activity component of the session agenda or outline of the original and adapted treatment protocols. Raters will use a yes-no response scale to indicate whether or not an STS therapist covered a particular component.

- Process fidelity (delivering treatment content while actively engaging clients in therapy and doing it with a sense of competence) will be measured using an instrument based on a 12-item measure developed by John Lochman and colleagues (e.g., Counselor stops to clarify material; counselor's tone is warm and positive; stimulated discussion; stopped to clarify material) rated on a 5-point scale ranging from "not at all" to "very often." We will use the total score (Overall Process Fidelity). This measure has excellent internal psychometric properties.

Each supervision/consultation session will also be audio/video-recorded. After each session, supervisors will complete the Supervision Rating Scale (SRS) and the consultants (TT+) will complete the Consultation Rating Scale (CRS). Our team developed both measures. The SRS and CRS measure supervision/consultation content and process as detailed in the training manual (e.g., preparing for next session; Demonstrated empathy and provided positive reinforcement).

The supervisions/consultation sessions will also be coded for interruptions and session length. Service interruption is defined as the degree to which therapists are fully available for supervision and treatment sessions. We will derive three scores averaged over the total number of sessions: a) Projected length of the session in minutes minus time spent on interruptions (e.g., answering a phone call, talking about unrelated topics); b) Number of interruptions; c) Total number of supervision / consultation and treatment sessions per group.

To measure differences between support strategies (TT vs. TT+), agency supervisors (12) and therapists (60) in all groups, including participants who did not complete a treatment group but were consented and trained to participate, will be interviewed regarding their perception of the appropriateness and acceptability of the support they receive. A study staff member will conduct open-ended, semi-structured interviews about the process, feasibility and acceptability of the type of support they receive. Interviewers will follow a script to ask questions of supervisors and therapists (e.g., *"How acceptable is the level of support you received for the implementation of the FRIENDS protocol?"; "Was the supervision you received from your agency's supervisor appropriate for running groups with children?"; "Was the consultation you received from the research team appropriate for preparing you to conduct supervision with STS therapists?"*) These interviews will be conducted at the end of each academic year, or once the treatment groups have completed. Qualitative methods will be used because there are currently no psychometrically validated measures that address these areas.

To evaluate potential mediators and moderators of type of support on implementation fidelity, we will use the Index of Inter-professional Team Collaboration for Expanded School Mental Health (IITC-ESMH). The IITC-ESMH is a 26-item measure rated on a 5-point Likert-type scale (1=never to 5=always) designed to measure four organizational constructs: Reflection on Process; Professional Flexibility; Newly Created Professional Activities; Role Interdependence. The measure has excellent psychometric properties. We will use the Total Score in mediator analyses. All school staff members who participate in referring students to the STS programs will be invited to participate in the completion of this measure. For those school staff members who are not study participants, an information

sheet will be provided to them explaining their participation in the completion of this measure.

An additional measure of mediator and moderators of type of support will include a measure of intention, specifically therapists' intention to conduct treatment sessions and participate in supervision. These data will be used to 1) test for differences between the conditions. This is an important secondary outcome because high intentions to use specific evidence based practices are necessary but not sufficient for therapists do use evidence-based practices. These data will also 2) explain why child outcomes do (or don't) differ: Intentions of therapist→ therapist behavior → child outcomes. We will measure therapists' intentions for each condition after training, and two more times during treatment.

6 STATISTICAL CONSIDERATIONS

Variables pertinent to the study aims will be examined for skewed distributions and/or not meeting the assumptions of normality. For such variables, an appropriate method for variable transformation will be selected and applied to stabilize outcomes and their variances and to approximate the normal distribution. The geometric mean, the log transformation and the Box-Cox transformation are examples of such functions. In addition, we will consider non-parametric tests such as the Mann-Whitney test for comparing pre/post changes between two independent groups. Continuous variables will be summarized and described using means, medians, ranges, and standard deviation. Categorical data will be presented by frequencies and percentages. All summaries will be presented by pre and post intervention and by groups. Since randomization was done at the school level, the potential for imbalances at pre-measurements between students who will be part of FRIENDS or CATS groups are anticipated. We will first determine whether student's related demographics, diagnostic, mental health, academic functioning, and therapists' level of experience are balanced in both conditions. We will account for any differences in the analysis by including such variables as covariates.

6.1 Primary Endpoint

Effectiveness between treatment groups (FRIENDS and CATS) will be tested by calculating the 95% confidence limits (the width of the limit =|4.20|) for the differences in symptom severity, impairment, and academic competence (child outcomes) from pre to post between children receiving FRIENDS and children receiving CATS. If the calculated differences are within the 95% limit, then we will conclude that the two interventions have an equal impact or effect on child outcomes. If any of the differences in child outcomes is/are larger than the upper limit, then we will conclude that one intervention is better than the other. The limit of |4.20| was chosen based on the distribution of the reported mean effect sizes associate with FRIENDS.

Qualitative interviews with supervisors and therapists (perceived acceptability of support strategies) will be audio-recorded, transcribed and entered into NVivo 10.0 for coding and analysis. For each interview, a codebook (of common themes related to the appropriateness and acceptability of the support they received) will be developed and trialed by three coders based on an initial reading of the transcripts, and revised through discussions and subsequent transcript reviews. Coders will meet regularly to compare coding and revise the codebook. This will yield a stable set of qualitative codes that will be used to code the transcripts. Two independent coders will then code all of the transcripts. This iterative process will be continued until consensus is reached and saturation occurs. Coder reliability will be checked quarterly using the inter-rater reliability function in NVivo.

Kappa coefficients will be computed; a minimum of .85 will be required for each code. Retraining will be conducted should rater agreement fall below .85. In order to aid with interpretation of results, IE's will randomly select an additional 35% of the interviews and code them, as a measure of inter-rater-reliability. We will conduct a structured content analysis for perceived acceptability and appropriateness. The unit of analysis is each interview. We will create a case-by-variable matrix from the codes. The matrix will have an interviewee identifier number, type of support (i.e., TT, TT+), school, agency, subject demographic information, and codes. The code cells will contain the number of times the participant emitted words or phrases pertaining to perceived acceptability and appropriateness of the support they received. Once acceptability and appropriateness are defined for each interview, percentages for acceptability (% acceptance) and appropriateness (% appropriate) out of the total number of words will be calculated. Comparison of % acceptance and % appropriate between TT, TT+ will be conducted using the Wilcoxon sum rank test.

Datasets from the REDCap and NVivo databases will be combined using the statistical software SAS. Each session will be considered to be a "case" in the qualitative database and will be assigned a unique identifying number that will link it (anonymously) to the quantitative database and individual session information such as fidelity scores.

To measure the differences of implementation between therapists whose supervisors receive TT vs. TT+, means of content fidelity will be calculated with its 95% Confidence interval. Similar analysis will be done regarding process fidelity.

6.2 Secondary Endpoints

Costs will be assessed by use of generalized linear models (GLM). Links and families for the GLM will be empirically fit to the data using diagnostic tests including the Modified Parks test, Pregibon-Link test, Hosmer-Lemeshow test, and Pearson's correlation test. Measures of effectiveness will be derived from the "clinical" analysis of the trial data. Standard errors will be derived from a nonparametric bootstrap. Point estimates for the cost-effectiveness ratios will be based on the point estimates for the difference in costs and outcomes. Confidence intervals for the cost-effectiveness ratio as well as an acceptability curve will be derived using the point estimates of the differences, their standard errors, and the correlation between the differences. Acceptability curves will allow agency administrators to judge whether the gains in children's outcomes/fidelity are sufficient to justify any increases in cost.

6.3 Sample Size and Power

Number of students and statistical power. It is anticipated that a total of 284 (142 students per treatment protocol) will complete the proposed study. The published reported effect size of FRIENDS has been estimated to equal 0.56 (cohen's *d*). In testing for equivalence of FRIENDS and CATS, using two one-sided tests with sample sizes of 142 in FRIENDS and 142 in CATS achieves 88% power at a 5% significance level when the true difference between the means is 0 (null hypothesis), the standard deviation of the differences in means is assumed to be 11, and the equivalence limits are
-4.20 and 4.20.

Number of therapist and statistical power. To compare TT to TT+ for the implementation of CATS (H2a), with 30 therapists in TT and 30 in TT+ achieve 86% power to detect a

difference of 8% between the null hypothesis that both group means are 80% (content fidelity) and the alternative hypothesis that the mean of group TT is 80% with estimated group standard deviations of 10 and 10 (an estimated effect size=.8) and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test. Similarly, group sample sizes of 30 and 30 achieve 84% power to detect a difference of 0.7 in process fidelity between the null hypothesis that both group means are 4 and the alternative hypothesis that the mean of group TT+ is 4.7 with estimated groups standard deviations of 0.9 and 0.9 (an estimated ES= .78) and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test.

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.

For students enrolled in the treatment sessions: Careful baseline screening will be conducted to identify participants whose risk for potential adverse effects are elevated were they to utilize the study treatment. If a participant becomes more symptomatic (based on parent/child report or agency/clinician judgment), the STS provider will review the participant's clinical status with the project team and PI. Concerns about deterioration will trigger an evaluation by the STS Therapist and then discussion with the PI regarding whether discontinuation from the study is in the best interest of the student. Such participants will be removed from the study and treated openly with appropriate clinical care.

In the event that suicidality is noted during the course of the eligibility evaluation or during participation in the study, CHOP evaluator will communicate finding to STS therapist to ensure that this information is incorporated into their standard care of practice. CHOP evaluator will also inform on-call CHOP-based licensed clinical provider to ensure any other potential safety measures that may need to be put in place to provide appropriate care, including but not limited to informing parents, STS staff, and other professionals involved with the child's mental health care. If CHOP staff learns or observes of any changes in a child's mental health status that would affect their eligibility status while participating in treatment groups, the child may be withdrawn from the study at the discretion of the PI. All eligibility decisions will be made in collaboration with the STS team.

The procedures of reporting adverse events include immediately notifying their supervisor and the PI and following procedures to maintain participant safety. Study therapists will have the PI's cell phone number and beeper or cell phone contact information for their clinical supervisor. Children and guardians will also be given emergency contact information should they require assistance or in the case of an emergency.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

Selection and Randomization of schools, therapists and supervisors to intervention conditions:

At least thirty-six schools (potentially up to 41) from mental health agencies will participate in this study. Computerized randomization lists will be generated with random assignment of schools (and therefore, the schools' therapists and supervisors of the agencies participating in this study) to Condition A (FRIENDS/TT), B (CATS/TT), or C (CATS/TT+) with the goal of exposing all agencies to each of the three conditions over the course of the study.

Schools will be stratified according to their size (greater than 625 students (yes/no)). Therefore, a list of 18 schools (including their therapists) will be randomly assigned to the treatment groups and will participate in year 1 of the study (Randomize 1). Schools listed in Randomize 1 will also be used in year 2 while recruiting new therapists and their supervisors (potentially repeat supervisors). We expect this to add 6 new therapists (and their supervisors), per intervention condition, to the study. Schools spanning elementary and middle school grades will run interventions with middle school grades in year 1 and elementary grades in year 2.

From the remaining 18 schools (not randomized yet), a stratified new randomization list will be generated for year two and to be used again in year four (Randomize 2) of the study. As a result, a group of six new therapists and their supervisors (potentially repeat supervisors) per intervention will be recruited for year 3 and a new group of six therapists and their supervisors will be recruited for year 4. Schools spanning elementary and middle school grades will run interventions with middle school grades in year 3 and elementary grades in year 4.

For the 5th year, from the original list of 36 schools using the same stratified randomization method, a new randomization list of schools (Randomize 3) will be generated to recruit a new group of 18 therapists and their supervisors (6 per treatment group). Therefore, a new group of 18 therapists per year (a total of 90 therapists) will participate in this study. Each therapist will participate only one time in this study. In schools spanning elementary and middle school grades, the study conditions will be evenly distributed across grade levels.

The three randomization lists may result in assigning the same supervisors to different treatment groups. This may result in modifying the intervention effect due to the supervisor's knowledge gained by participating in a previous different treatment arm. Therefore, working with the agencies, we will make sure that supervisors will stay in the same support condition (i.e.: A or B; C) they were originally assigned using randomize 1 and randomize 2.

New schools will replace dropped schools by matching stratification variables (size and type).

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 alphanumeric 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 agency staff members.

- Hard data will be kept in a locked file cabinets at the Roberts Center for Pediatric Research. Digital video and audio recordings (containing participant identifiers) will also be stored in locked file cabinets at CHOP. The files will be transferred and stored to a CHOP computer network drive and analyzed by study team members for the coding of integrity/fidelity scoring. 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 collected as part of this study will be entered (data entry from CRFs or upload from Excel files) and stored using REDCap (Research Electronic Data Capture) database, a secure web-based software database supporting clinical and translational research databases. 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 staff expertise in REDCap database design and implementation, randomization, and statistical analysis under the direction of the study's biostatistician.

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.

The following steps will be taken to maintain confidentiality: (1) the interview protocols and case record forms will be transported from schools to the research offices at CHOP in HIPAA compliant lockable bags and kept in a locked file cabinet in a locked office; (2) subject identity will be de-identified using numbers keyed to a master list; (3) de-identified data will be entered directly into files that will be password protected; (4) all project staff will be trained in the importance of confidentiality, and will certify in writing to protect subject confidentiality; and (5) if the results of the study are published, data which might reveal the identity of any particular subject will be disguised. Subjects and their families also will be informed about the limits of confidentiality, e.g., in cases of danger to self or others or when previously undocumented physical or sexual abuse is discovered. No identifiable data will be retained or used for future studies. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

The PI (Dr. Eiraldi) will assume overall responsibility for monitoring the integrity of data collection and the safety of the interventions. The PI will meet on a weekly basis with members of the core research team, which has responsibility for data collection and supervising the STS clinical supervisors who will also oversee data collection conducted by STS therapists. The purpose of the meeting will be to monitor and ensure data collection and safety. Each member of the research team will be informed of his or her responsibility to ensure the integrity of data collection and the safety of children and families participating in the study. All adverse events will be reported immediately to the IRBs at CHOP, the City of Philadelphia and the Philadelphia School District and to NIMH. The IRB at CHOP will inform NIMH about actions taken in response to the reporting of adverse events.

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.

Potential Risks Associated with Assessment. Masters level clinicians, Bachelors and Masters level research staff and undergraduate research staff will collect rating scales from parents, children and teachers for screening, to determine eligibility and to assess treatment outcomes. Children, parents and teachers could develop mild emotional discomfort or frustration associated with filling out questionnaires. In the event that a child, parent or teacher becomes upset or irritated as a result of filling out the questionnaire, the clinicians or research staff collecting the data will try to determine the reason for the discomfort and provide any assistance that the informant might need. If an informant expresses a desire to not complete the questionnaire, clinicians and research staff will no longer ask the informant to complete the questionnaire.

Potential Risks Associated with FRIENDS. There are no known physical or legal risks to participating in the study. One risk associated with the treatments, as with all therapeutic interventions, is that it might not be effective for every participant that enters treatment. If, after participation in the original or CATS treatment, no improvement in symptoms is noted,

or, if deterioration is noted during treatment (based on self-report, parent-, child-, teacher-report or clinical judgment), or if a family is interested in further treatment, we will work with them to identify appropriate referrals. This will include the option to work with a clinician, either at the Department of Child and Adolescent Psychiatry and Behavioral Sciences (DCAPBS) of the Children's Hospital of Philadelphia or at Child & Adolescent OCD, Tic, Trich & Anxiety Group (COTTAGe) at the University of Pennsylvania, Department of Psychiatry. Participants may experience at least some subjective distress during treatment, and their reactions will be closely monitored and addressed therapeutically. In the unlikely event that a child manifests unusually high levels of distress, suggesting prohibitive side effects or intolerance of treatment, he or she will be withdrawn from the study by the PI and clinical recommendations in the best interest of the child will be made on a case by case basis. In-person parent meetings will be scheduled as needed should clinical need arise (e.g., address clinical worsening, address parent concerns, prevent premature termination).

Potential Risks to STS Therapists and Clinical Supervisors. There are no known physical or legal risks for STS therapists and clinical supervisors to participating in the study. One potential risk might be related to the video recording of treatment and supervision sessions. Therapists might be apprehensive about being video-recorded while conducting treatment sessions with children and therapists and supervisors might feel apprehension about being video-recorded while participating in supervision. In a current study we are conducting, school-based therapists did not object to and did not report any apprehension about being video recorded while conducting groups and receiving consultation from members of the research group. Supervisors and therapists will be told that the video-recordings will be used for research purposes only and that they will not be shared with agency or school administrators. If a therapist or supervisor raises strong concerns about being video recorded either before or after consenting to participate in the study, we will not insist on having them participate or allow them to drop out of the study.

8.4.3 Potential Benefits of Trial Participation

Student participants in this study will benefit from receiving an evaluation, continuous monitoring and treatment for anxiety. Information from this study will directly benefit participants by guiding appropriate treatment design and planning. It will be of general benefit as it will add to the body of knowledge concerning the types of training supervision school-based therapists need in order to be able to provide services with high levels of fidelity and acceptability. Thus, benefits to participants are direct (amelioration or elimination of symptoms) and indirect (helping to evaluate the effectiveness of levels of support provided to school-based therapists). If parents express interest in additional treatment for behavioral health concerns outside of current STS services at the end of study participation, a list of community behavioral health providers will be distributed. The child's STS team will also be informed of the parents' expressed wish for additional services.

8.5 Risk-Benefit Assessment

8.6 Recruitment Strategy

In collaboration with CBH (during the grant proposal and start-up phases), the research team has identified the participating mental health agencies. Each agency will facilitate school selection as described in Sections 3.2 & 8.1.1. Supervisors and therapists from the agencies who are embedded within the selected schools will be approached for participation. However, participation is voluntary, so if a supervisor or therapist does not

consent to participate, we will ask a different supervisor/therapist (already in the school) to participate. All student recruitment will be based upon school/STS referrals as noted in Sections 3.1.1. Parents of students who meet screening criteria and who have indicated an interest in our program, will be contacted via telephone by a team member about the study.

8.7 Informed Consent/Assent and HIPAA Authorization

Informed consent (parent) will be obtained by the PI or research team prior to intervention treatment. Student assent will also be obtained. In all cases, study procedures, as well as potential risks, benefits, and treatment alternatives will be clearly explained to both the parent and the child in a language understandable to each.

Study procedures as well as potential risks, benefits and treatment alternatives will be described to subjects 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 research staff. 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. If the study team has exhausted all possible ways to meet a parent for the consent process and it is just not feasible, the study team member will discuss the ICF with the parent over the phone 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 STS or CHOP team member via fax or email. Once parental consent is obtained/documented via fax/email, student assent will then be obtained in-person by a study team member in the school. No study procedures will take place in the time between obtaining documentation of consent and obtaining student assent. Children 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.

All treatment sessions are video recorded for fidelity monitoring. Parent consent for videotaping will be obtained using the CHOP Consent and Release for Recording and Filming, so that the videos may be used for the training of future staff members and education purposes, potentially outside of CHOP (i.e.: presentations to professional and/or medical boards).

Consent for the participation of supervisors and therapists in this study will be obtained verbally. They will be provided with a consent letter, outlining what their participation will entail, and will be given the same opportunity as families to ask questions and make an informed decision regarding their involvement. Consent will be obtained by Research Staff Members, which will include Co-Investigators, Post-Doctoral Fellows, and other research staff. Refusal to participate by a supervisor or STS therapist will not affect their employment at the participating mental health agency.

8.8 Payment to Subjects/Families

The agencies providing the treatment will bill Community Behavioral Health (CBH) for services (i.e., fee for service) related to treatment provided for this study.

Therapists will be provided a $37 stipend for each supervision session attended with their supervisor. Therapists can also receive an extra $18.50 stipend per half-hour of “prep time” (e.g., preparation to run group, preparation for supervision, etc.) Therefore, therapists can receive up to a maximum of $74 per session implemented, for which he/she prepared to implement and engaged in supervision with his/her supervisor.

Supervisors will be reimbursed at a rate of $42 per hour of time invested in the project. This will include the one hour supervision session conducted with their implementing therapist (as is existing standard of practice via agency requirement), any time spent preparing for supervision), and for those supervisors enrolled in Condition C, any consultation session he/she participates in with the CHOP study team.

Parents will receive $10 for completing baseline measures (pre-intervention time point) and $10 for completing outcome measures at post.

Teachers will receive $10 for completing measures pre-intervention and $10 for completing outcome measures at post.

Students will receive small gifts (e.g., pencils, notebooks, small toys) as reinforcement for participating and reaching certain goals in group sessions.

9 PUBLICATION

Describe the plans for publication. If the CHOP investigator will not have access to the complete trial data, describe how publication will proceed.

10 REFERENCES

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