Evaluation of a Remote Training Strategy for School Personnel

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ABBREVIATIONS AND DEFINITIONS OF TERMS

BASC-3	Behavior Assessment System for Children – 3rd Edition
BHS	Behavioral Health Staff
CATS	CBT for Anxiety Treatment in Schools
CBPR	Community-based participatory research
CC	Control Condition
CICO	Check-in/Check-out
CoP SBBH	Community of Practice on School-based Behavioral Health
CPP	Coping Power Program
EBPs	Evidence-based practices
EvsD	Engagement Versus Disaffection with Learning: Teacher Report
FRIENDS	Friends for Life
ISF	Interactive System Framework for Dissemination & Implementation
NCES	The National Center for Education Statistics
PaPBS	Pennsylvania Positive Behavior Support
PBIS	Positive Behavioral Interventions and Supports
RV	Remote Video
RV+	Remote Video plus Coaching
SAEBRS	Social, Academic, & Emotional Behavior Screener
SCARED	Screen for Child Anxiety Related Disorders
SDQ	Strengths and Difficulties Questionnaire

ABSTRACT

Context:

An increasing number of schools in rural settings are employing the multi-tier positive behavioral interventions and supports (PBIS) framework to improve school-climate. PBIS can also be used as a framework for the adoption and integration of evidence-based practices (EBPs) for children's mental health concerns. A key challenge is that school personnel need technical assistance (training plus ongoing consultation) in order to implement EBPs with fidelity. In urban and suburban schools, this support can be provided to school staff on site. However, providing ongoing on-site support is not feasible or sustainable in the majority of rural schools, due to their remote physical location. For this reason, video technology has been recommended for the training of behavioral health staff (BHS) in under-served rural communities.

Objectives:

The purpose of this study is to test the effectiveness of a remote training platform with BHS in schools serving rural communities.

Study Design:

This study is a pilot randomized controlled trial to compare implementation and student outcomes of three training strategies: Control Condition (CC), Remote Video (RV), and Remote Video plus Coaching (RV+).

Setting/Participants:

Participants will be school personnel with and without prior mental health training and students in grades 4-8 in schools serving rural communities who are deemed at risk for externalizing and internalizing mental health disorders. The pilot trial will be conducted in 24 schools (8 in CC, 8 in RV, and 8 in RV+). It is estimated that a total of 72 behavioral health staff (3 staff per school- 24 per arm) and 312 students (13 students per school - 104 per arm) will participate in this study. Additonaly, we estimate about 24 school administrators such as principals or assistant principals will approve school's participation.

Study Interventions and Measures:

This study is designed to test the effectiveness of initial training compared to remote video training and remote video training plus coaching to train BHS to implement EBPs. Each school will be randomly assigned to receive one of three training supports: (a) Initial training (CC) (b) Initial training, plus video (RV) or (c) Initial training plus video, plus remote coaching (RV+). BHS in the RV+ condition will receive consultation from a CHOP consultant regarding implementation of EBPs, whereas BHS in the RV condition will be given access to the asynchronous training video modules. Participants in all three conditions will receive treatment manuals for the interventions they have chosen. The EBPs to be implemented by the BHS include: Coping Power Program (CPP), CBT for Anxiety Treatment in Schools (CATS), and Check-in/Check-out (CI/CO). All BHS will conduct one CPP or CATS group with 5 students of similar developmental level (e.g., a group of 4th &

5th graders), and that each school staff in CI/CO will implement the intervention with 4 separate individual students of any eligible school grade.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Eighty-four percent of Mental Health Professional Shortage Areas are located in rural and frontier areas.[1] Children and adolescents in rural settings are less likely to receive services compared to their urban and suburban counterparts and even fewer are likely to receive evidence-based care.[2,3] Schools have become more involved in the delivery of mental health services and hold great potential for increasing access for children and adolescents. Innovations in training and service delivery are needed to improve mental health care quality and availability in rural schools.[4,5] Evidence-based practices (EBPs) can be incorporated into school-wide multi-tiered systems that are currently being used to improve school climate and safety. School-wide Positive Behavioral Interventions and Supports (PBIS), a service-delivery strategy based on the public health model is one example. [6-8] A growing number of schools in rural areas are employing PBIS. [9-12] Given the large service disparities for children in rural areas, offering EBPs through PBIS can improve access and lead to better long-term outcomes. [13]

PBIS is a multi-tiered framework for defining and organizing services, including mental health services. Emphasis is placed on teaching key behavioral expectations and routines to all students. Two key features of PBIS are its scalability and its compatibility with an array of mental health EBPs. Tier 1 strategies focus on preventing new cases of problem behaviors by using universal strategies such as effective instructional practices, classroom behavior management, and school-wide discipline. Tier 2 strategies focus on supporting children with, or at risk for, mental health disorders, and Tier 3 strategies offer individualized support for more severe cases. In urban schools, school-wide PBIS has been used to incorporate EBPs at Tier 2 and Tier 3.[14-16] Previous research has demonstrated that school personnel, with or without prior mental health training, can implement Tier 2 interventions with fidelity and clinical effectiveness if given adequate consultation support.[15,16,17,18] In urban and suburban schools, this support (training plus ongoing consultation) can be provided to school staff on site. However, providing ongoing on-site support is not feasible or sustainable in the majority of rural schools, due to their remote physical location. For this reason, video technology has been recommended for the training of behavioral health staff (BHS) in under-served rural communities. [19,20]

1.2 Name and Description of Intervention

1.2.1 Remote Video Training Strategy Development

We will use a remote training strategy to train BHS to implement EBPs to students in schools serving rural areas. We have obtained approval from the IRB for Phase 1 of this study (protocol ID: 20-017895). The remote video training strategy was developed during Phase 1 (years 1-2) of this 5-year grant using a community-based participatory research (CBPR) [21,22] approach to assess barriers and facilitators to participation in a remote training. We used an iterative development framework to build the training strategy. The framework, rapid prototyping, originally used for software development, [23,24] is based on a cyclic

process of analyzing data from users in order to improve successive prototypes. Applied to the development of psychosocial interventions, prototyping involves the creation of a "low fidelity" version of the intervention that contains key functions of interest in order to test a concept and facilitate rapid evaluation and feedback. [25] Following the evaluation of the early prototypes, a fully functional "high fidelity" prototype is created that is more similar to the final product and that offers fully interactive content.[26]

1.2.2 Asynchronous and Synchronous Trainings for Implementation of EBPs

Our online strategy, which will utilize WebEx video technology, will offer protected access to asynchronous training materials such as training "modules" that include didactic content, audio and visual examples, as well as treatment materials and resources, all of which can be viewed at the trainee's individual pace and convenience. The remote training strategy will also allow synchronous training and consultation for the implementation of EBPs by school staff supported by expert consultants, and communication between consultants and school personnel to coordinate services in a child-centered approach for student participants who are already receiving other services at school.

1.2.3 Benefits of a Remote Training Strategy

Advantages of web-based remote training include flexibility, accessibility, cost-efficiency, potential for both didactic and interactive learning, and consistency in quality. [20, 27] Remote online training allows for synchronous (i.e., interactive) supervision and feedback from a supervisor anywhere in the country (or the world). This allows for the trainee to be able to receive ongoing consultation or supervision on site without the time and cost of travel. [27-29]

Though findings are preliminary, remote technology-enhanced programs have been found to be acceptable and feasible in community settings. [30,31] Studies suggest that technology-based training methods, particularly when developed using the latest multimedia and interactive design formats, may be more effective than manuals alone and as effective as face-to-face training workshops in disseminating EBPs to community mental health professionals. [20,31-33]

1.2.4 Tier 2 Interventions

CBT for Anxiety Treatment in Schools (CATS): CATS is an adaptation of Friends for Life (FRIENDS). [34] The adapted protocol retains the core elements of evidence-based CBT for anxiety and the FRIENDS group format. We implemented planned adaptations to the protocol based on our collective experience with the protocol, two previous implementation studies, [17, 35] and focus groups and qualitative interviews with stakeholders. We followed procedures developed by Lee and colleagues [36] and Bernal et al. [37] regarding the appropriateness of FRIENDS for the target population. We conducted qualitative interviews with five consultants and six focus groups with school counselors who used FRIENDS. We made changes to the language (idioms, metaphors, words), cultural fit (cultural values), methods (session length [40 minutes], number of sessions [8 sessions]), and activities (in-session practices), which resulted in additions and substitutions in these areas, while maintaining the 5 essential components of the treatment. [38,39] This resulted in a briefer (8-session) and more feasible, engaging and culturally appropriate protocol for urban under-resourced schools than the original FRIENDS.

Coping Power Program (CPP): Coping Power Program is an evidence-based intervention designed for students with externalizing behavior disorders**.** CPP is comprised of twelve 45-minute sessions. This EBP has been shown to be effective at reducing aggressive behavior and substance abuse among aggressive boys, with gains maintained at one-year follow-up. [40] Growth curve analyses showed that CPP had linear effects for three years after intervention on reductions in aggressive behavior and academic behavior problems. [41]

Check-in/Check-out (CI/CO): CI/CO is a targeted, Tier 2 intervention for students at risk of developing externalizing and internalizing mental health disorders. [42,43] CI/CO is designed to provide immediate feedback (i.e., at the end of each class period) to students, based on the use of a daily report card. This feedback is developmentally sensitive. [42,43] CI/CO implementers meet individually with students for a brief 'check-in' in the morning and a brief 'check-out' in the afternoon. Research on the use of CI/CO has shown it to be effective in reducing externalizing and internalizing problems with elementary school students.[43,44,45] CI/CO will be offered to individual students for a variable period of time, depending on need.

1.3 Findings from Non-Clinical and Clinical Studies

We conducted a needs assessment and resource-mapping study in Pennsylvania schools that currently implement PBIS. According to the Pennsylvania Positive Behavior Support (PaPBS) Network, 171 elementary and middle schools in Pennsylvania are currently implementing PBIS with fidelity. We asked a member of each school leadership team at 85 schools, randomly selected from the pool of 171 schools, to complete an electronic survey about their school's PBIS program (e.g., How do the PBIS and mental health teams' function?). Participants completed the Survey on School Readiness for Interconnecting Positive Behavior Interventions and Supports and School Mental Health.[46] We collected 48 responses (56% response rate) from PBIS Leadership Team members. Schools were classified as being located in a suburb (40%), rural area (35%), town (15%), or city (10%).[47] Compared to non-rural schools (N = 31), rural schools (N = 17) showed a significantly higher Total Readiness [48] for interconnecting PBIS with mental health ($t = 2.34$, $p < .05$). Scores for all rural schools were within the "ready" range for interconnecting with mental health supports.[22] Also, rural schools reported having significantly more staff support for PBIS and school mental health programs, on average, compared to non-rural schools ($t = 2.49$, $p < .05$). Of the rural schools, all reported offering Tier 2 services, including 77% Social Skills Training, and 47% Check and Connect. None of the rural schools reported the use of manualized group-based mental health interventions or interventions for internalizing disorders. Approximately 65% of participants in rural schools reported receiving training, supervision/consultation for Tier 2; however, these implementers received initial training only (e.g., conferences, in-service professional development) with little ongoing or follow-up consultation or supervision. The study shows that rural schools have the capacity and readiness to implement Tier 2 mental health EBPs because all of them are already offering Tier 2 services. However, there is a clear need for training and consultation on manualized group and individual interventions for externalizing and internalizing mental health.

1.4 Relevant Literature and Data

1.4.1 Mental Health Services in Rural Schools

There is a pressing need to increase capacity to provide quality mental health services in rural schools. Rural areas have fewer and less well trained health care providers than non-rural areas. [2] Problems specific to mental health services in rural schools include staff turnover [23] and low levels of funding for mental health services. [50] Even though most rural schools have some school personnel with mental health training, the approach most schools take with regard to dealing with mental health problems is to assess and refer to an outside provider. Given the shortages of mental health providers in most rural communities, this option simply leads to children not being served. The second option taken by BHS in rural schools is to assess and treat students individually. However, given the high need for services, BHS in rural schools are not always able to see individual students for more than a brief period of time and many children in need of services never receive help. [47] . There is mounting evidence that school-based mental health programs can effectively address emotional and behavioral disorders. [51] A number of comprehensive school-wide prevention approaches have been found to have a positive effect on an array of behavioral, emotional and academic outcomes. One such approach is school-wide PBIS [52], a multi-tiered framework for defining and organizing practices and interventions. [53] One potential innovation to increase access to services is to incorporate EBPs into PBIS. [6-8] PBIS programs can also incorporate targeted group-based mental health EBPs for children at risk (Tier 2) and individualized EBPs for more severe cases (Tier 3). A growing number of schools in rural areas are employing PBIS at Tier 1. [9-12] However, rural schools are not able to provide Tier 2 support unless BHS are given adequate training and consultation on EBP implementation.

The problems of shortage of providers with appropriate training in EBP implementation and the common practice of assess-and-refer can be addressed via remote training of school personnel and by integrating mental health services into existing service delivery strategies. Remote video technology offers the potential to provide training and consultation for behavioral health staff in rural schools. Based on our reading of the relevant literature and our collective experience developing programs in the school setting, we propose that the development of a training approach for BHS in rural school settings ought to (a) include a training system for BHS to enhance knowledge and skill needed for implementation, (b) use remote video technologies, and (c) incorporate implementer and school context factors to increase the strategy's perceived feasibility, appropriateness and acceptability by stakeholders.

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.

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

Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective (or Aim)

The purpose of this study is to conduct a pilot randomiozed controlled trial comparing three training strategies: Control Condition (CC), Remote Video (RV), and Remote Video plus Coaching (RV+).

2.2 Secondary Objectives (or Aim)

The secondary objectives are the evaluation of implementation and student outcomes.

- To explore mediators and moderators of consultation support on behavioral health staff fidelity.
- To qualitatively examine school staff's perceived feasibility, appropriateness and acceptability of the support they received.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This study is a pilot randomized controlled trial. The three arms are: (a) Initial remote training (b) Initial remote training, plus video and (C) Initial remote training, plus video, plus remote coaching. Each school will be instructed to select CICO and one of the two group EBP protocols for use.

3.1.1 Pre-Trial Activities and Screening Phase

The Remote Training Strategy was developed during Phase 1 of this 5-year project using an iterative process (*Rapid Prototyping*) to develop the appropriateness, feasibility, acceptability and preliminary efficacy of the online training platform.

School Selection: The National Center for Education Statistics (NCES) subdivides rural and town school areas by their proximity to an urbanized area into fringe, distant, or remote locations.[47] Participant schools will be located in any of these three rural locations or town, remote area and/or the school will serve rural communities. We will invite 24 schools representing the 2 geographic locations (urban/rural) to participate in the pilot efficacy study. After receiving school approval to participate schools will be stratified based on the geographic location and a computer-generated block randomization list will be prepared to randomize the 24 schools in a 1:1:1 ratio to either RV, RV+ or CC (8 schools/arm) stratified by geographic locations (urban/rural). The block randomization with varying will ensure ensure equal number of schools in each arm and eleminate the predictability of schools'assignment.

Behavioral Health Staff Screening: Recruitment will begin with assistance from the school principal who may nominate school behavioral health staff to participate in the study. Additonally, the research staff will reach out to school behavioral health staff concurrently with the school principal. The research staff will speak with school staff by phone or via WebEx to clearly explain study procedures, as well as potential risks and benefits. BHS will be clearly informed of the voluntary nature of their participation and will receive ample opportunities to ask questions. A copy of the consent form will be provided to the BHS, and consent will be obtained electronically via REDCap.

Student Screening: Recruitment of child participants will begin with research staff assisting school behavioral health staff who will examine teacher nomination data for students in specific grades and classes in order to identify students for Tier 2 interventions. We will train BHS remotely on providing a brief in-service training to teachers tasked with nominating students on recognizing warning signs of excessive anxiety, depression, and disruptive behavior problems in children, and completing the screening measures. Following the remote training, BHS will ask teachers from specific grades or classes to nominate students. **First**, teachers will be asked to rank order students and then select the top three students with externalizing problems and the top three students with internalizing problems. **Second**, parents and teachers will complete the SDQ (paper or electronically) on these identified students. **Third**, parents and teachers will give the SDQ forms to the BHS member (when applicable). **Fourth**, BHS will scan the SDQ to CHOP staff to score. **Fifth**, students who score above the specified cut-off on the externalizing or internalizing dimension will be selected for the next step, which will require BHS to contact the parents and request that they complete the SCARED or to ask a teacher of the student to complete the SAEBRS. **Sixth**, children who score at least 25 or there is an elevated subscale for the SCARED or if the student score on the Social Behavioral subscale of the SAEBRS is 12 or less, they will be considered for participation in one of the groups or in CI/CO. **The research aspect of the project will begin at this point**. Children who meet inclusion criteria will be invited to participate in the study. Research staff will ask parents to provide consent for their child to participate in the intervention. The children wil also be asked to provide assent to participate in the intervention. Informed consent (parent) and assent (child) will be obtained by research staff prior to enrollment. Participating BHS will facilitate consent meetings with eligible children and their parents. A research staff member will join these meetings by phone or via a videoconference.

3.1.2 Phase 1: Training of Behavioral Health Staff

All initial trainings will be lead by research staff and will be conducted remotely via Webex. These initial trainings wil be recorded and made available to all participants to reference for the duration of their participation in the study.

Initial Red Flags and Screening Training: Research staff will train school staff from all conditions remotely on identifying “red flags” that a student is struggling with anxiety, anger, or other mood disorders and how this information can help Tier 2 Team members and teachers make informed referrals for the interventions. Study participants should use this information to hold a brief professional development with school staff to help guide their referrals. Additionally, participants will be taught about how the referral and screening

process operates, including who is responsible for each aspect of the process, how the screening measures are scored and what those scores mean. We will train BHS using strategies that have been proven effective, including the teaching of the theoretical approach used in the intervention, active demonstration and practice of skills, and coaching. [56,57]

Initial Evidence-Based Programs Training: Research staff will train school staff from all conditions remotely on the three EBPs. The three EBPs that schools staff will be trained on are Coping Power Program (CPP) [58] for externalizing behavior disorders, CBT for Anxiety Treatment in Schools (CATS) [59] for anxiety disorders, and Check-in/Check-out (CI/CO) [60] for externalizing and internalizing [61] disorders. Three separate trainings will be held to introduce participants to the interventions and provide an overview and understanding of each EBP.

Video Training Modules: We will offer protected access to asynchronous training materials to BHS in the Remote Video and Remote video plus coaching conditions. These trainings will include "modules" that are comprised of didactic content, audio and visual examples, as well as treatment materials and resources, all of which can be viewed at the trainee's individual pace and convenience. Participants will have access to the training modules via CHOP OPEN and they will be able to login using a unique username and password.

3.2 Study Duration, Enrollment and Number of Sites

Behavioral Health Staff: BHS will be asked to commit to participate in the study for one school year. The school the BHS works at will be randomly selected as a participating school for either years 1,2, or 3 of the study. BHS will be free to implement the EBPs outside the research project after their participation in the study has concluded.

Students: Students who are eligible, based on the SDQ, SCARED, and SAEBRS, and for whom consent/assent is obtained, will participate in the study for the time it takes them to receive one of the interventions. Participation includes receiving interventions consisting of CI/CO, CPP, or CATS. The interventions will consist of one 40-minute/class period intervention session conducted at school or two brief daily check-ins also conducted during the school day. Post-treatment data will be collected by a parent/caregiver and teacher using the BASC-3 and Engagement versus Disaffection with Learing Teacher Report (EvsD-Teacher). Students will be asked to complete the Behavior and Feelings Survey.

Administrators: School principals and/or administrators will be asked to complete a qualitative interview about their experience with the project.. The interview will occur at the end of the academic year and their participation will last the time it takes to complete the interview

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

We will conduct the pilot trial in 24 schools (8 in Control Condition, 8 in Remote Video, and 8 in Remote Video plus Coaching. We anticipate enrolling 24 administrators (1 per school), 72 behavioral health staff (3 from each school; 24 in CC, 24 in RV, 24 in RV+) and 312 students (104 in CC, 104 in RV, 104 in RV+). We expect that each school will have one staff member with prior mental health training (e.g., school counselor). This staff member will be expected to implement one of the group-EBPs. The two other staff will be tasked

with implementing CICO, as this intervention can be implemented by school staff without prior mental health training. [62,63] We estimate that each school staff will conduct one CPP or CATS group with 5-6 students of similar developmental level (e.g., a group of 4th & 5th graders; 144 students total), and that each school staff in CICO will implement the intervention with 6 individual students of any school grade (144 students total).

3.3 Study Population

3.3.1 Inclusion Criteria

Administrator: Any school principal or assistant principal from participating schools implementing PBIS.

Behavioral Health Staff: Any counselor, social worker, or teacher from participating schools implementing PBIS who work with students in grades 4-8.

Students: Inclusion of students to receive a Tier 2 intervention is as follows:

- attending one of the participating schools
- being in grades 4-8
- identified by the Tier 2 team as not responding to Tier 1 intervention, thus needing Tier 2 support
- scoring ≥ 1 SD above the mean on the Emotional Symptoms or Conduct Problems scales of the Strength and Difficulties Questionnnaire (SDQ) [54] completed by a parent or a teacher

The cut-off score level for the SDQ is appropriate for identifying students at risk for a behavioral/mental health disorder[54,55]. We limit participation to students in grades 4-8 because the group EBPs are appropriate for this age group.

3.3.2 Exclusion Criteria

Administrator: School staff who are not principals or assistant principals.

Behavioral Health Staff: School staff who are not part of the PBIS team and who do not work with students in grades 4-8.

Students: Students who do not meet screening or group participation criteria will not be included in the study. Students with a history of intellectual disability or serious developmental delays according to school records will not be included because they would be unlikely to benefit from the interventions used in the study. Students with a history of psychotic or autistic spectrum disorders as reported by parents will not be included.

Subjects that do not meet all 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 Screening and Consent Procedures

Please refer to Section 3.1.1 for detailed description of Screening and Consent Procedures.

Teachers will assist with screening procedures by completing screening measures for potentially eiligible students in their class. Teachers are not considered study participants.

4.2 Phase 1: Training of Behavioral Health Staff

4.2.1 Initial Synchronous Trainings

Research consultants will conduct a synchronous (live) training workshop at the beginning of each year via a video-conferencing platform (Webex) for behavioral health staff. BHS will be instructed on the use of data to identify and assign students at risk for behavioral and emotional disorders into Tier 2. The BHS will also be taught a competency framework for mental health and PBIS[77,78] strategies for enhancing school personnel knowledge of mental health "warning signs" among students, and how to access the online materials. The training related to "warning signs" will be conducted in order to help BHS identify students who could benefit from the interventions.

BHS will be instructed to use training manuals and will be trained on the use of a mental health screening instrument (SDQ)[54] and a multi-axial parent rating scale (Behavioral Assessment System for Children, Third Edition (BASC-3)[68] and other instruments used in the study. BHS will be introduced to a competency model for CBT[79] . They will also learn about how to deal with implementation barriers (e.g., scheduling sessions, conducting exposure tasks)[80]. Training content and procedures will be based on adult learning characteristics (e.g., propensity to learn from experience, capacity to reflect on performance and apply knowledge, and selfmotivation)[81,82].

4.2.2 Guided Video for Remote Video and Remote Video plus Coaching

Following the initial training workshop and after BHS have identified students for interventions, BHS in the RV and RV+ conditions will be given access to the training videos. The videos will be made available through CHOP OPEN that has the ability to measure how many times each video has been accessed by the BHS and for how long. Each participant will be given access to the videos that correspond to the interventions that they plan to use. All Tier 2 implementers in RV and RV+ will be given access to videos that address general topics (e.g., how to use data to identify students for participation; dealing with implementation barriers).

4.3 Phase 2: Implementation of EBPs

We expect that each school will have one staff member with prior mental health training (e.g., school counselor). This person will be expected to implement one of the group-EBPs. The two other staff members will be tasked with implementing CI/CO, as this intervention can be implemented by school staff without prior mental health training.[63, 68] We estimate that the staff member with mental health training will conduct one CPP or CATS group with 5-6 students of similar developmental level (e.g., a group of 4th & 5th graders; 144 students

total), and the other implementers will lead CI/CO and will implement the intervention with 6 individual students of any school grade (144 students total). Following the initial live training, BHS will be instructed to conduct targeted screenings with the grade group they would like to select for participation in the study.

Research consultants will provide technical assistance to support behavioral health staff. The three EBPs that schools will use for Tier 2 are the Coping Power Program (CPP) [58] for externalizing behavior disorders, CBT for Anxiety Treatment in Schools (CATS) [59] for anxiety disorders, and Check-in/Check-out (CI/CO) [60] for externalizing [61] disorders. CPP and CATS will be implemented in group format with students of similar developmental level (e.g., 4th & 5th or 7th & 8th grade together) during the lunch or free period. BHS could also use CI/CO for individual students who do not meet inclusion criteria for CPP or CATS. Each school will be instructed to select CI/CO and one of the two CBT protocols for use.

4.3.1 Remote Consultation for Remote Video plus Coaching

BHS will receive a study-purchased audio recorder to use to record the student groups.They will be instructed to upload the recording to OneDrive. Research team consultants will provide synchronous consultation to BHS in the RV+ condition via Webex. The consultation will have two main components: (a) session preparation (CPP/CATS) or review and planning (CICO) and (b) coaching.

Session Preparation: Session preparation for CPP and CATS will consist of (a) discussing referrals to the groups; (b) conducting a step-by-step walkthrough of the session objectives, (c) reviewing the CBT principles behind the treatment components for that session; (d) encouraging adherence and the use of active learning strategies; (e) problem-solving barriers to implementation and helping implementers reflect on past challenges (e.g., attendance problems, organizational barriers, materials/resources) in order to successfully implement the next session with appropriate adaptations as needed; and (f) enhancing BHS's use of empathy and positive reinforcement through modeling. Research consultants for CICO will (a) review the school's CICO implementation manual and (b) provide feedback and suggestions for program implementation.

Coaching: Coaching for CPP and CATS will consist of (a) goal setting, [65] (b) self-reflection, [66] and (c) performance feedback. [67] BHS will be told that they are expected to reach high fidelity when implementing the intervention. Then, implementers will be asked to reflect on the previous session (e.g., "How do you think you did during the last CPP/CATS session? What do you think went right? What do you think did not go well?"). Finally, the consultant will use audio clips from the previous session that contain examples of well-executed implementation objectives and brief audio clips that contain ineffective or less than optimal execution of objectives. The consultant will also discuss how the implementer handled student behavior in session, including overall level of participation and enthusiasm, and disruptive or withdrawn behavior. The audio clips will be contained in a OneDrive server uploaded by implementers. All consultation procedures will be detailed in a consultation manual. Coaching for CICO will consist of (a) providing performance feedback to the CICO coordinator and data analyst about their program (e.g., use of data to refer students to CICO, student progress monitoring) and (b) problem solving implementation barriers.

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 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. 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 Measures

Screening for Tier 2: The Strengths and Difficulties Questionnaire plus Impact Supplement (SDQ).[54] The SDQ is a 25-item, 3-point scale questionnaire used to assess the psychological adjustment of children and youth, ages 4-17. [54] The SDQ has excellent psychometric properties as a screening instrument for behavioral and emotional problems. [54] We will use the scores on the Conduct Problems and Emotional Problems [62] scales plus impact supplement scores (impairment) for screening students for Tier 2.

The Screener for Child Anxiety Related Disorders (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.

The Social, Academic, and Emotional of Behavioral Risk Screener (SAEBRS): is a 19-item, psychometrically sound screening instrument for assessing emotional and behavioral risk. The SAEBRS is completed byschool staff using a 4-point Likert scale. We will use the "Social Behavior" subscale of the SAEBRS to determine eligibility for CPP and CICO.

5.2 Demographic Information

Demographic information for students will be collected at baseline from a parent. Demographic information for BHS will be collected via a REDCap survey following consent to participate.

Demographic information for administrators will be collected via a REDCap survey following consent to participate.

5.3 Implementation Fidelity

Content Fidelity to Tier 2 Group CBT (CPP & CATS). The Content Fidelity Checklist (CFC) reflects each activity component of the session agenda of the treatment protocols. Raters use a yes/no response scale to indicate whether or not the implementer covered a particular component. All GCBT sessions will be audio-recorded. 100% of sessions will be

coded by the first coder and approximately 20% of sessions will be randomly selected and coded by the second coder. Interrater reliability will be evaluated using Kappa coefficients[69]

Process Fidelity to Tier 2 Group CBT (CPP & CATS). Process fidelity will be assessed via an adapted version of the rating system developed by Lochman and colleagues. [70] Ten items are rated on a scale of 0 to 4, with 0 being "Not At All" and 4 being "Very Often". Ratings are given on the extent to which school staff members delivered the intervention in an orderly fashion, using active learning strategies. etc. Exploratory factor analysis (EFA) yielded two factors on the 10-item scale. We will use the average *Total* and factor scores for analysis. 100% of sessions will be coded by the first coder and approximately 20% of sessions will be coded by the second coder. Interrater reliability will be evaluated using ICC.

Content Fidelity for CI/CO. Content fidelity for CI/CO will be assessed via the CI/CO Implementation Guide Fidelity Checklist (IGFC). The CI/CO IGFC is completed by the consultant (research staff) after school teams submit their completed CI/CO Implementation Guide. The IGFC is completed once and measures both the content and quality of the customized manual components for each school. The CI/CO IGFC/Content Measure is a 26-item measure of CI/CO customization of the following CI/CO components: (a) staff roles and responsibilities, (b) CI/CO process logistics, (c) daily progress report, (d) motivation system, (e) fading and self-monitoring procedures, (f) staff training procedures, and (g) data collection and progress monitoring procedures. Each item is scored according to completion status as “yes,” “no,” or “not applicable.” The CI/CO IGFC/Content Measure will be scored by recording the frequency of “yes” scores over the frequency of “yes,” and “no” scores.

The CI/CO IGFC/Quality Measure, or part 2 of the IGFC/Content Measure, is also completed by the consultant (research staff) once teams submit their completed CI/CO Implementation Guide. The IGFC/Quality Measure is a 14-item measure of the quality of, or degree to which, team responses in customizing their respective CI/CO Implementation Guides are comprehensive, clear, feasible. Measurement entails examining team responses to items related to the (a) implementation roles and responsibilities, (b) implementation process, (c) motivation system, (d) fading and self-monitoring, (e) training/orientation of staff, mentors, students and families, and (f) data entry and progress monitoring. The IGFC/Quality Measure will be scored by recording a score of 0-3 for each item depending on whether or not the team response meets the criteria for being comprehensive, clear, and feasible (with 1 point awarded for each).

Process Fidelity to CI/CO. Process fidelity for CI/CO will be assessed with the Check-In/Check-Out Fidelity Checklist, a measure of the daily implementation of CI/CO. The CI/CO Fidelity Checklist is completed by the consultant (research staff) on a monthly basis after collecting the completed Daily Progress Report (DPR) student forms for each student involved in CICO. The Check-in/Check-Out Fidelity Checklist is an 11-item form that indicates whether or not students received daily CICO feedback based on the occurrence of the following: (a) student identification, (b) feedback date, (c) recorded goal, (d) behavioral expectations rated by the teacher for each period, (e) the number of daily points earned out of the number of possible points, (f) an indication of whether or not the goal was met, and (g) the signature of the teacher/mentor. The 11 items will be scored as “occurred” or “did not occur.” The Check-In/Check-Out Fidelity Checklist will be scored by recording occurrence over occurrence-plus-non-occurrence and multiplying the decimal by 100.

Adoption Inventory (AI). The AI will track the number of times each intervention is used per school, per condition. This information will be collected one time at the end of the intervention via a REDCap survey.

Dosage Inventory (DI). The DI is an Excel tracking sheet exported from the website hosting the video modules listing the number of times and length of time each video module is accessed by BHS.

Penetration Inventory (PI). The PI will list EBP penetration at the student level (students receiving EBPs at Tier 2). This information will be collected one time at the end of the intervention via a REDCap survey.

5.4 Student Outcome Measures

Parent, teacher, and student measures will be collected at pre-treatment and post-treatment of the pilot trial to assess changes in mental health symptoms and academic engagement.

Mental health symptoms. The BASC-3 [55] is a 138-item, 4-point, Likert-type rating scale for assessing parental report of child mental health functioning, standardized for ages 2.5 to 18 years. The BASC-3 has excellent psychometric properties. [55] The BASC-3 (*Aggression, Conduct Problems,* and *Anxiety* scales) will be administered at pre- and post-treatment for children who participate in CPP, CATS or CICO. Parents will complete the paper and pencil version of the BASC-3[55] over the phone with a research assistant or they may complete electronically. When this measure is administered to Spanish proficient parents, the research assistant will call language services to connect to an interpreter and the measure will be completed by phone.

Student academic engagement. The Engagement versus Disaffection with Learning: Teacher Report (EvsD) [71] will be completed by teachers for all children receiving Tier 2 interventions. This is a 20-item, four-point instrument with four sub-scales: (a) *Behavioral Engagement*, (b) *Emotional Engagement*, (c) *Behavioral Disaffection,* and (d) *Emotional Disaffection*. The survey will be completed by hand or electronically via REDCap survey. We will use the average score for each of the four scales at pre- and post-participation in CPP, CATS or CICO.

Externalizing and Internalizing Problems: Children will complete The Behavior and Feeling Survey-Your Report (YFS-SR). The YFS-SR is a brief (10 items) measure of internalizing and externalizing problems rated on a 5-point scale. The YFS-SR has excellent psychometric properties and it is sensitive to change.[50] The YFS-SR provides three scores (Internalizing, Externalizing, Total). The measure will be completed at pre- and post-treatment for children who participate in group CBT or CICO.

5.5 Remote Training Strategy Feedback

Perception of Training Support. Qualitative Interview. We will conduct semi-structured qualitative interviews with BHS and administrators in each condition. These interviews will be audio-recorded and conducted over the phone or via Webex and should last approximately 30 minutes in length. Teachers will not be interviewed. We will seek to interview one administrator at each school. We will utilize purposive sampling with BHS,

focused on variation in interventions implemented and levels of experience. In interviews with administrators, we will utilize an interview guide designed to understand existing Tier 2 programs at their school as well as their perceptions of the training support's feasibility, acceptability, appropriateness, and usability. In interviews with BHS, we will utilize an interview guide that seeks to elicit views and perspectives about the perceived feasibility, acceptability, appropriateness, and usability of the training support they received. The audio recorded interviews will be transcribed by ADA transcription services. We will conduct a thematic analysis of these data and compare across conditions.

6 STATISTICAL CONSIDERATIONS

The statistical analysis plan (SAP) will be updated and finalized before the data base lock. The SAP will provide comprehensive descriptive information of the statistical analysis plan, including approaches for summarizing primary and secondary endpoints at baseline and post treatment. All statistical analyses will be performed using SAS®, 73version 9.4 or higher

6.1 Primary and SecondaryEndpoints

The primary endpoints related to school staff implementing the interventions are measures of content and process fidelity. Primary endpoints related to student outcomes are pre-to-post changes in student mental health symptoms (measured by Behavior Assessment System for Children- 3rd Edition (BASC-3),[55] which include Aggression, Conduct Problems, Anxiety, and Academic engagement measured by Behavioral Engagement, Emotional Engagement, Behavioral Disaffection and Emotional Disaffection.

Secondary endpoints are: the mediators and moderators effects of consultation support on behavioral health staff fidelity and the qualitative examination of school staff's perceived feasibility, appropriateness and acceptability of the support they received.

6.2 Statistical Analysis

Prior to statistical comparison between groups (RV, RV+, and CC), all pertinent variables collected for the pilot study will be reported by groups and presented as mean, standard deviation, median, minimum, maximum and the 95% confidence intervals for continuous variables, while frequencies and proportions will be used for categorical variables. Continuous data measures will also be checked for normality and outliers. Non-normally distributed continuous data variables will be examined and transformed "normalized" if needed using appropriate transformation functions. Outliers not found to be in error will be kept in the analysis. Since the school is the randomization unit, BHS and student characteristics (Demographic and other potential confounders will be compared between the two groups using the two independent samples t-test or the non-parametric Wilcoxon signed rank test) to identify pre-treatment differences between the two groups. If the two groups are found to be statistically different in a pre-measured outcome, the pre-measurement(s) will be included in the subsequent analyses as a covariate using analysis of covariance (ANCOVA).

6.3 Statistical Methods

Data will be analyzed using an intent-to-treat approach, wherein each participant (BHS or student) will be kept in the arm to which the school was randomized, regardless of treatment

received. In addition to creating pre/post change scores and analyzing the data using t-tests (or the Wilcoxon signed rank test), a mixed-effects model will be explored for analyzing the pre/post repeated-measures endpoints related to student academic engagement and mental health symptoms. A student-level random effect will be included and modeled using the unstructured covariance matrix to account for within-subject dependence due to repeated measurements. The models will include study arm (RTS or CC) and time of measurement (pre/post) as fixed effect. Arm x Time interaction effects will be included in the model as well. This modeling approach will allow us to compare pre-to-post changes and the extent to which these changes differ across study arms. For the purpose of generating statistical estimates for an anticipated phase 3 larger scale study, the nested nature of students within the school as well as BHS within the school will be explored using a hierarchal mixed effect multilevel model. Furthermore, we will explore marginal models using generalized estimating equations (GEE; [74,75]), which will produce robust estimates that adjust for clustering at the school level. Although SAS PROC MIXED will not remove participants with post-missing data from the analysis, missing data will be kept to a minimum. As a sensitivity analysis, we will impute the potential missing data using the maximum likelihood method for imputation. [76]

For the mixed-methods analyses (survey and semi-structured interview data about perceived appropriateness, feasibility, and acceptability of the training and consultation procedures, and BHS's opinions about the support they received), we will use the same data analytical approach described in IRB Protocol # 20-017895.

The statistical analysis related to the secondary aims to examine the mediators and moderators effects of consultation support on behavioral health staff fidelity will utilize PROCESS[85] a modeling tool freely-available for SPSS and SAS. The many features of PROCESS integrate many existing functions and published statistical tools for analyzing mediation and moderation. The SAS software [83]; and the SPSS software [84] will be utilized for data analyses. The qualitative examination of school staff's perceived feasibility, appropriateness and acceptability of the support they received will be in NVivo and analyzed thematically.

6.4 Sample Size and Power

The proposed pilot study aims to collect data and estimate effect sizes measuring the effect of RV and RV+ when compared to the CC. Although, this pilot study is not powered to test for specific hypotheses regarding effect sizes, the sample size estimates were based on data obtained from our recently completely NIH funded study, [15,77] we estimated that a total of 72 BHS (24 per arm) and 312 students will participate in this study. With 24 BHS per arm, a two-sided 95% confidence interval in mean differences in content fidelity (CF) and process fidelity (PF between) RV or RV+ vs. CC will be produced. The minimum distance from the mean difference to the limits (margins of error) will equal to 9.3 (CF) and 0.35 (PF) with the estimated pooled standard deviations equal to 16 and 0.6 respectively. It is anticipated that 104 students per arm will be recruited (total = 312).Assuming a uniform attrition rate of 15%, a total of 268 evaluable students will be included in the final statistical analysis. With 89 students in each of the three study arms, a two-sided 95% confidence interval for mean differences in pre/post changes in student mental health symptoms and academic engagement between the two arms ((RV or RV+) vs. CC) will equal to 2.4 with estimated

pooled standard deviation equal to 8. Sample size justification was reported using PASS 13 software. [78]

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.

If a participant becomes more symptomatic (based on parent/child report or clinical judgment), without resolution for at least four weeks, the study treatment provider will review the participant's clinical status with the project team and PI. Concerns about deterioration will trigger an evaluation conducted by school's behavioral health staff and then discussion with the PI regarding whether discontinuation from the study is in the best interests of the child. Such participants will be removed from the study and treated openly with appropriate clinical care.

In cases where concern about danger to self or others is identified, the behavioral health staff – with consultation with CHOP consultants, as needed – will conduct further assessment of the child's mental status and decide on a course of action. If the assessment leads to the conclusion that the child is at risk for suicide, the behavioral health staff will work with the family to take the child to the emergency room for evaluation and treatment. If the child returns to school after visiting the emergency room and it is determined that an outpatient, school-based level of care is appropriate, he or she may continue to participate in study interventions. If it is determined that a higher level of care is appropriate, the child will be withdrawn from the study and will receive the higher level of care.

If previously undocumented sexual or physical abuse is discovered during eligibility assessment, behavioral health staff at the schools will implement standard procedures for notifying the State social welfare authorities (per state law and standard procedure in the respective school district), and defer further evaluation if needed until the child has been released from agency review. If state involvement is identified or mandated at any point during the study, the child may or may not be continued in treatment depending on what is in the best interests of the child. This decision will be made by the PI and treating counselor at the site in coordination with the child's legal guardians and state/local authorities. If the child returns to school after receiving emergency services, he or she will continue to participate in interventions in the school setting.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

The 24 invited schools will be recruited from 2 geographic locations (urban/rural). Schools will be stratified based on the geographic location and a computer-generated block randomization list will be prepared to randomize the 24 schools in a 1:1:1 ratio to either RV, RV+ or CC (8 schools/arm) stratified by geographic locations (urban/rural). The block randomization with varying will ensure ensure equal number of schools in each arm and eleminate the predictability of schools'assignment. It is estimated that a total of 72 behavioral health staff (3 staff per school- 24 per arm) and 312 students (13 students per school- 104 per arm) will participate in this randomized parallel groups pilot study.

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 BHS, or parents/students.

- Hard data will be kept in locked file cabinets at the Roberts Center for Pediatric Research. 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 maintained for 6 years in accordance with CHOP policy A-3-9, then 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.

- Remote data collection will only take place via secure video chat platforms and/or the telephone. Study team members will record the data onto paper CRFs in the

same manner as in-person data collection, and no digital video or audio recordings will be created.

- 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 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 kept in a locked file cabinet in the secure lab space; (2) rating scales will be collected using REDCap (3) subject identity will be de-identified using alphanumeric codes keyed to a master list; (4) de-identified data (i.e., no names or other possible identifiers) will be entered directly into a database that will be password protected; (5) all computerized study databases for questionnaire data will be kept on a secure CHOP server located at one of the hospital's research buildings which is password and firewall protected to reduce the risk of unauthorized access to study information; (6) all project staff will be required to complete training in research protocol and Human Subjects safety and privacy before starting, and will promise in writing to protect subject confidentiality; (7) only trained research staff will have access to the data; and (8) if the results of the study are published in scientific journals or presented at scientific meetings, data which might reveal the identity of any particular subject will be disguised. Subjects and their families 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 used for future study without first obtaining IRB approval. 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 management, and the safety of the interventions. The PI will inform each member of the research team of his or her responsibility in this area and will also meet weekly with the team to monitor all efforts. This includes the external consultants who have the responsibility of training the behavioral health staff in each school, and the research team who has the responsibility for informed consent procedures and data collection and management activities. All adverse events will be reported immediately to the IRBs at CHOP.

8.4.2 Risk Assessment

Risks are not greater than minimal. There are no known physical or legal risks to participation in the study. The experimental study protocol is designed to identify and remediate depression, anxiety, and disruptive behavior; however, it is possible that participation in the study may exacerbate some children's emotional and/or behavioral difficulties. Children's emotional and behavioral difficulties normally fluctuate over the course of a school year. We do not expect that this study will pose any additional risk to study participants compared to non-participants. In the event that a parent, child, or teacher becomes distressed as a result of study participation or present potential safety concerns (e.g., suicidal thoughts or behaviors), Dr. Eiraldi licensed psychologist, will work to stabilize the situation and address any outstanding concerns or needs.

Potential Risks Associated with Assessment. Child assessments will be administered by school behavioral health staff who have had training in depression, anxiety, and disruptive behaviors. Participants could develop mild to moderate emotional discomfort or frustration associated with completing questionnaires. Participants will be allowed any breaks during data collection that are needed. Parents and children may experience a loss of privacy as a result of providing information about the child's mental health history during the assessment. Parents and children will be reminded about confidentiality, the secure storage of study data, and authorized data sharing via a signed release of information. Teachers, some of whom may feel uncomfortable providing personal information about the child, will be provided a copy of the parent and child's authorization for the release of confidential data.

Given the time required for recruitment and assessment of study participants, it is possible that eligible participants may experience a waiting period of up to two months between the point of assessment and the start of study interventions. Research staff will work with behavioral health staff and parents to identify appropriate care, especially in cases where the presenting symptoms require immediate attention. Their school counselor or other behavioral health providers in the school may serve some children. Other children may require a referral to a community provider, which the behavioral health staff will facilitate in consultation with research staff.

Potential Risks Associated with Group Interventions. One risk associated with the selected interventions, as with all therapeutic interventions, is that they might not be

effective for every participant that enters treatment. If following the course of any of these treatments, no improvement in symptoms (based on post-intervention measures) is noted, if deterioration is noted during treatment (based on self-report, parent- or teacher-report, or clinical judgment), or a family member is interested in further treatment for the child, we will work with families and behavioral health staff to identify appropriate referrals in their community. Participants may experience at least some subjective distress during treatment. 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, the PI will withdraw him or her from the study and clinical recommendations in the best interest of the child will be made on a case by case basis. Should clinical need arise (e.g., need to address clinical worsening, address parent concerns, prevent premature termination), the research team will support the behavioral health staff to schedule in-person parent meetings. Should there be concerns regarding the child's symptoms that cannot be addressed in the context of these treatments, we will work together with the family to identify appropriate next steps including the option to seek services from other providers.

Please refer to Section 7.2 for procedures related to suicidal ideation.

Dr. Eiraldi, a licensed psychologist, will provide the team with on-call support to address any potential safety concerns, including suicidal ideation or behavior and concerns about abuse or neglect.

8.4.3 Potential Benefits of Trial Participation

We believe that this study will result in the development of a feasible and effective strategy for the training of behavioral health staff in schools serving rural communities. Linking PBIS with state-of-the-art mental health supports and having well trained behavioral health staff in underserved schools would likely lead to improvement in the behavioral health and academic productivity of students who would otherwise not have access to evidence-based care. Both of these would be important contributions to public health in rural school settings

8.5 Recruitement Strategy

Recruitment of schools will be selected from the existing pool of schools that participated in phase one of the grant (IRB number 20-017895). If necessary additional schools will be selected that are eligible if the school is implementing PBIS and serves rural communities.

Recruitment of BHS may begin with assistance from the school principal or an additional school staff member. The principal and school staff member may nominate school staff to participate in the study. Additonally, the research staff will reach out to school behavioral health staff concurrently with the school principal.

Recruitment of child participants will begin with research staff assisting school behavioral health staff who will examine teacher nomination data for students in specific grades and classes in order to identify students for Tier 2 interventions. The study team will approach the family of referred students via phone call, email and/or text message. After five unsuccessful attempts at contact, a recruitment letter may be distributed to families by the school. We will train BHS remotely on providing a brief in-service training to teachers

tasked with nominating students on recognizing warning signs of excessive anxiety, depression, and disruptive behavior problems in children, and completing the Strengths and Difficulties Questionnaire (SDQ). Following the remote training, BHS will ask teachers from specific grades or classes to nominate students. **First**, teachers will be asked to rank order students and then select the top three students with externalizing problems and the top three students with internalizing problems. **Second**, parents and teachers will complete the SDQ on these identified students. **Third**, parents and teachers will give the SDQ forms to the BHS member. **Fourth**, BHS will scan the SDQ to CHOP staff to score. **Fifth**, students who score above the specified cut-off on the externalizing or internalizing dimension will be selected for the next step, which will require BHS to contact the parents and request that they complete the SCARED or to ask a teacher of the student to complete the SAEBRS. **Sixth**, children who score at least 25 or there is an elevated subscale for the SCARED or if the student scored on the Social Behavioral subscale of the SAEBRS is 12 or less, they will be considered for participation in one of the groups or in CI/CO. **The research aspect of the project will begin at this point**. Children who meet inclusion criteria will be invited to participate in the study. Research staff will ask parents provide consent for their child to participate and the child will provide assent to participate in the intervention. Informed consent (parent) and assent (child) will be obtained by research staff prior to enrollment. Participating BHS will facilitate consent meetings with eligible children and their parents. A research staff member will join these meetings by phone or via a videoconference.

8.6 Informed Consent

8.6.1 Behavioral Health Staff

Behavioral health staff will be provided with a public survey link from REDCap to review the IRB approved verbal consent form. After reviewing the consent form they will be prompted to enter their email address to receive a copy of the consent form and the following statement will be included in REDCap, “By clicking “next” you agree to participate in Project CARE”. Consent will be documented electronically via survey completion. If consent is not documented within 5 business days after distribution, the study team will contact BHS via email or phone to discuss any questions or concerns they have. The consent form will clearly explain study procedures, potential risks and benefits, and the voluntary nature of their participation. A copy of the consent form will be provided to the BHS, and consent will be obtained electronically via REDCap.

8.6.2 School Administrators

School administrators will consent for the school’s participation in the study, the demographics survey, and participation in the qualitative interview. The consent procedures for school administrarors will follow the same method as consent for BHS. Administrators will be provided a public survey link from REDCap to review the IRB approved verbal consent form. After reviewing the consent form they will be prompted to enter their email address to receive a copy of the consent form and the following statement will be included in REDCap, “By clicking “next” you agree to participate in Project CARE”. Consent will be documented electronically via survey completion. If consent is not documented within 5 business days after distribution, the study team will contact administrators via email or phone to discuss any questions or concerns they have. The consent form will clearly explain

study procedures, potential risks and benefits, and the voluntary nature of their participation. A copy of the consent form will be provided to the administrators, and consent will be obtained electronically via REDCap.

8.6.3 Parents and Students

Once a family has been identified by BHS, they will be approached by the study team to verbally consent for screening procedures. Study staff will speak with parents by phone for the verbal screening consent and email them a copy of the screening consent form for their records. Students will be contacted by phone or WebEx with a BHS member to verbally assent to screening procedures. Verbal screening consent and assent will be documented by the study team using the verbal consent/assent signature blocks. After the child has been screened and determined to be eligible, the family will meet with research staff again to verbally consent for the main study.

Informed consent (parent) and assent (child) will be obtained by research staff prior to enrollment. Participating BHS will facilitate consent meetings with eligible children and their parents by either scheduling an appointment to go over the consent process or by giving research staff the parents' phone number with permission from the parents. The research staff will explain the study procedures, as well as potential risks, benefits, and treatment alternatives to both the parent, and child in a language understandable to each. No child will be asked to participate if demonstrably unwilling, even if his or her parent wishes it. Children and 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 the professional staff. If the family agrees to participate, parents will provide verbal consent and children will provide verbal assent. Informed consent and assent will be documented by research staff at the conclusion of the consent meeting. Families will be sent a copy of the consent and assent forms via email or by mail**.** Consent and assent will be documented using the verbal consent/assent signature blocks. Children who need treatment but do not qualify for this study or whose family decides not to participate will be provided appropriate treatment referrals. Treatment referrals will occur without disclosure of PHI.

8.6.4 Individuals with Limited English Proficiency

Once a family has been identified by BHS, they will be approached by the study team to verbally consent for screening procedures. Study staff will call language services to speak with an interpreter and once the connection with the interpreter is established, study staff will proceed with reviewing the screening consent form with the Spanish proficient parent. Study staff will speak with parents by phone for the verbal screening consent and email them a copy of the screening consent form for their records.Verbal screening consent will be documented by the study team using the verbal consent signature block.

Informed consent will be obtained by study staff prior to enrollment. Study staff will facilitate consent meetings with Spanish proficient parents via phone. Study staff will call language services to speak with an interpreter and once the connection with the interpreter is established, study staff will proceed with reviewing the intervention consent form with the Spanish proficient parent. Informed consent will be documented by research staff at the

conclusion of the consent meeting. Families will be sent a copy of the consent form via email or by mail**.** Consent will be documented using the verbal consent signature blocks.

8.6.5 Teachers providing data about eligible and enrolled students

Teachers will be provided with a public survey link from REDCap to review the IRB approved information sheet. After reviewing the information sheet they will be prompted to enter their email address to receive a copy of the consent form and the following statement will be included in REDCap, "By clicking "next" you agree to participate in Project CARE". Participation will be documented electronically via survey completion. If teachers want to discuss or have questions about the information sheet, study staff will be available to speak via phone or WebEx. A copy of the information sheet will be provided to the teachers.

8.7 Payment to Subjects/Families

Study interventions will be provided at no cost to families. Parents will receive $20 for completing screening and baseline measures and $20 for completing outcome measures. Teachers will receive $20 for completing screening and baseline measures and $20 for completing outcome measures at post. Children will receive small gifts (e.g., pencils, notebooks, small toys) as reinforcement for participating and reaching certain goals in-group sessions. Behavioral health staff will receive between $200 to $250 depending on condition for conducting targeted screenings with students, for participating in remote trainings, implementing EBPs, and participating in a qualitative interview. School administrators will receive $30 for the completion of the qualitative interview.

9 PUBLICATION

The data generated in this grant project will be presented at national professional conferences and published in peer review publications. All final peer-reviewed manuscripts originating from this project will be submitted to the digital archive PubMed Central. No individually identifiable protected health information will be published.

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