



Middle School Parent Module for a Brief Bullying Intervention Program

NCT06002347

March 25, 2021

## **1.1 Study Title**

Middle School Parent Module for a Brief Bullying Intervention Program

## **1.5 ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable.**

NCT06002347

## **2.1 Conditions or Focus of Study**

Bullying, Mental Health, Parent-Based Intervention

## **2.2 Eligibility Criteria**

### **Inclusion Criteria:**

- being a parent of an adolescent enrolled in grades 6, 7, or 8 in a participating middle/junior high school in Idaho.
- speaks and reads English.
- consents to participate.
- 

### **Exclusion Criteria:**

- speaks and reads only a language other than English.
- does not consent for participation.

## **2.3 Age Limits**

21 years old – no age limit

### **2.3.a. Inclusion of Individuals Across the Lifespan**

Parents of any age over 21 will be enrolled. The likelihood that parents are under the age of 21 is very low. There is no restriction on older adults participating in this study. Age will be self-reported by participants.

Children will not be included in this study as the purpose of the study is to conduct a needs assessment and create a Parent Module based on feedback from parents and test the Parent Module's acceptability, feasibility, and short-term outcomes (e.g., changes in parental knowledge, attitudes, behavioral intentions).

## **2.4 Inclusion of Women and Minorities**

There are no criteria for exclusion of any sub-population of participants based on ethnic origin, race, gender, or disability. Women and minorities will be included in this research. N = 40 participants will be recruited from schools in Idaho. According to Idaho Census data for the selected counties, the combined population is 49.4% females. According to demographic data for the selected schools, the combined population is 59.5% White, 38% Hispanic/Latino, 1.0% American Indian, 0.5% Asian, and 1.0% more than one race.

## **2.5 Recruitment and Retention Plan**

### **2.5.1. Recruitment and Screening**

Human Subjects oversight will be conducted by Boise State's IRBs (Boise State IIRB00000924). All recruitment and screening procedures are IRB-approved.

A total of 40 parents will be recruited from three middle/junior high schools located in rural, low-income communities in Idaho. Team members will work with school counselors at the target schools. All parents of students in 6<sup>th</sup>- 8<sup>th</sup> grade meeting inclusion/exclusion criteria will be recruited via e-flyers and email reminders sent by the school and asked to sign up to participate. We will continue recruitment at each school until we reach the target sample. Potential participants will be informed of the study purposes and procedures, given

opportunities to ask questions and have them answered, and provide informed consent according to IRB approved guidelines. All participants will provide consent.

### **2.5.2. Retention and Adherence**

Participants will remain in the study approximately 1.5 hours. Parents will be compensated \$75. For the subgroup of participants who complete focus groups, participants will remain in the study for one week as the focus groups will take place within a week post-training. Parents who participate in the focus groups will be compensated \$50 to encourage retention and incentivize participation.

### **2.7 Study Timeline (PDF)**

<b>Study Timeline</b>	<b>Months</b>			
	<b>1-3</b>	<b>4-6</b>	<b>7-9</b>	<b>10-11.5</b>
Finalize Procedures, Hire and Train Graduate Students	X			
Develop STAC Parent Module, Develop Phase II Participant List		X	X	
Participant Recruitment, Administer Parent Module, Conduct Pre-Post Assessment			X	
Focus Groups, Transcribe/Analyze Data, Quantitative Data Analysis and Report Preparation				X

### **2.8 Enrollment of First Subject**

4/2/2022

### **3.1 Protection of Human Subjects**

#### **3.1.1. RISKS TO HUMAN SUBJECTS**

##### **3.1.1.1. Human Subjects Involvement, Characteristics, and Design:**

The goal of the CTR-IN pilot grant research is to collect pilot data to support an NIMHD STTR/SBIR R41/42 fast-track proposal aimed at developing the STAC-T Parent Module as a companion training to a technology-based bullying bystander intervention for middle school students (STAC-T). The subject population for this study are parents of middle school students.

##### **3.1.1.2. Study Procedures:**

Three middle schools in rural, low-income communities in Idaho (N=40) will test the STAC Parent Module to evaluate program acceptability, feasibility, changes in knowledge, confidence, attitudes about bullying, and self-efficacy, and intention to use the parent STAC strategies. Outcomes of knowledge, confidence, attitudes, and self-efficacy will be tested immediately before and after the STAC Parent Module training session.

Program acceptability and intentions to use the strategies will be measures immediately after the STAC Parent Module Training. All parents of students in grades 6, 7, and 8 will be invited to participate. Recruitment will continue until sample size is met. Parents who provide informed consent will be invited to participate in the study during evening hours at a room provided by the school. Parents will be provided a unique study ID number and will complete the baseline assessment. Immediately after completing the baseline assessment (10-15 minutes), parents will participate in the STAC Parent Module training (50 minutes). Participants will then complete an immediate post-training assessment (10-15 minutes). Data collection and training will occur in person although we do have the ability to conduct sessions remotely if needed following similar procedures we have used during COVID-19. Baseline Assessment: Parents will complete a survey assessing knowledge, confidence, attitudes about bullying, self-efficacy, and demographic characteristics. Immediate-Post Assessment: Immediately following the STAC Parent Module training, parents will complete a survey assessing acceptability of the STAC Parent Module, knowledge, confidence, attitudes about bullying, self-efficacy, and intentions to use the STAC parent strategies. Parents will be randomly selected to participate in focus groups which will occur within a week post-training. In three focus groups with parents of middle school students (6-8 per group; N=12-16), participants will be asked to talk about the content of the training, as well as asked about current practices, school needs and interest in the future for a technology-based, bullying parent intervention, and challenges and barriers to use. The focus groups will be led by research staff trained in focus group moderation, encouraging open non-judgmental discussion. Focus groups will be conducted in-person

although we do have the ability to conduct sessions remotely if needed following similar procedures we have used during COVID-19. Focus groups will be audiotaped, transcribed, and analyzed using NVivo. Summary reports will be prepared and reviewed to finalize the content of the STAC Parent Module.

### **3.1.1.3. Study Materials:**

Data from the focus groups and testing of acceptability, feasibility, and short-term outcomes will be collected in the form of handwritten notes, audio recordings, computer files, transcriptions, and questionnaires. Discussions will be recorded, transcribed, and analyzed using NVivo qualitative data analysis software.

Data will be obtained specifically for research purposes and will be kept confidential with access limited to the PI and specific project staff. All data will be kept in locked files.

### **3.1.1.4. Potential Risks:**

There are minimal risks associated with participation in this study. Any potential psychological risks posed by the research are primarily related to the sensitivity of the topic of bullying. Participants may also be hesitant or uncomfortable discussing their opinions regarding the STAC Parent Module. Participants will be allowed to withdraw if they are uncomfortable with providing any of this information. Their responses will in no way be shared with anyone except project staff (i.e., kept confidential). Responses to the questions will be coded to protect confidentiality, and participants may choose not to answer questions. All survey data, notes, and audio recordings will be confidential, accessed only by research staff on this project and stored in locked files. Data converted to computer files will be stored on a secure network server and password protected. Participants will be told that they do not have to answer questions if they are uncomfortable and can terminate the focus group or training session at any time they wish.

Responses to focus group or survey questions would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

## **3.1.2 ADEQUACY OF PROTECTION AGAINST RISKS**

**3.1.2.1. Informed Consent:** Human Subjects oversight will be conducted by the Boise State University IRB (DHHS IRB Reg. No.00000924; FWA No.00000097).

All consenting procedures are IRB-approved. The IRB will review and approve any modification to subject materials (including recruitment emails, letters, consent forms, assent forms, survey instruments) and data management procedures prior to study implementation.

Project staff will provide participants with IRB-approved consent forms that will describe the purpose of the project, risks and benefits. The consent will occur in person and will be administered by a member of the research team. Project staff will provide participants with copies of their signed IRB-approved consent forms that will describe the purpose of the project, risks and benefits, and selection criteria. Participants will be informed that they have a right to withdraw from the study at any time. No additional data will be collected from participants who decide to withdraw; however, the information collected prior to withdrawal will remain in the study.

Responses to focus group or survey questions will not reasonably place participants at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of subjects. Participants will be informed that they have a right to withdraw from the study at any time and there will be no penalty for non-participation.

All data management, analysis and reporting activities will be conducted by project staff. All notes and printed data collection forms will be stored in locked cabinets; all electronic data files will be stored on secure network servers behind computer firewalls, with routine backup. All identifiers for participants will be stored in secure files and behind computer firewalls. Participant names and study identification numbers will be recorded and stored separately from the research data files. Data forms will be labeled only with participant identification number. Results of analyses will be shared in aggregate form only.

### **3.1.2.2. Protection Against Risk.**

To minimize potential psychological risk, all focus group facilitators will establish ground rules for discussion that includes an open, non-evaluative exchange of comments and ideas. All surveys and data collection forms will be IRB-approved and employed under the supervision of senior project staff. Participants will be told that they do not have to answer any questions which make them uncomfortable and may terminate their participation at any time they wish.

The data collected on this project will be obtained with the survey questions and focus group procedures. Notes, surveys, audio recordings, and data will be accessible only by research personnel. Responses to focus group or survey questions would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Additionally, all data and other information for this study will be maintained confidentially. To protect against risks posed by a potential loss of confidentiality, we will take the following steps. First, participants will be assured that they are free to refrain from answering any questions they do not wish to answer. Second, all data will be identified only by a PIN, which will be randomly generated for study purposes. Third, a master list of names and code numbers will be stored in locked file cabinets under the supervision of the PI and will be available only to research staff on this project. Next, graduate student research assistants will receive training on the importance of confidentiality and all personnel will complete the required NIH training in protection of human research participants and will sign confidentiality statements. Completed questionnaires will be stored in a locked file cabinet under the supervision of the PI. Data will also be retained on computers with restricted and password protected access, without links to the master code list. All data based on this research will be reported in aggregate form. No individual respondents will be identified.

### **3.1.3. Potential Benefits of the Proposed Research to Participants and Others**

Potential benefits for all participants will be the knowledge that one has helped in development of an intervention that teaches parents how to support adolescents who witness bullying, to reduce both bullying and the negative emotional consequences for both targets and bystanders. Also, participants will have the opportunity to make a difference at their school and view themselves as advocates for students in their school community, which can result in positive feelings. Additionally, parents will be compensated \$75 for participation in data collection and the parent training and \$50 for their participation in focus groups.

### **3.1.4. Importance of the Knowledge to be Gained**

The development and implementation of bullying intervention programs for middle school students has the potential for reducing the serious public health problem of bullying and the negative associated consequences. Given the relatively high rates of bullying in middle school and the relationship between bullying and the development of socio-emotional problems, dissemination of efficacious intervention programs has the potential for significant societal benefits. Although current school-wide bullying programs can be effective, both time- and labor-intensive resources required for program implementation pose significant barriers for schools, particularly in low-income and rural communities. Further, few anti-bullying programs provide parents education, and those that do are rarely interactive and do not focus on supporting bystanders. Thus, developing a STAC Parent Module has the potential to enhance the efficacy of the STAC intervention, thereby further reducing bullying and the associated negative consequences for both targets and bystanders.

## **3.3 Data and Safety Monitoring Plan (PDF)**

A data safety and monitoring plan will be implemented for this project, following well-established procedures. We will not set up an independent Data Safety and Monitoring Board because this study is very low risk, does not include use of therapeutics, and psychological risk is not anticipated.

We will maintain strict confidentiality of participants in the project's registration system, provide only ID numbers in data files, and ensure quality control using standard data management routines. We will work to maximize participation to minimize missing data. The project biostatistician will use standard data management procedures. Files connecting data with IDs will be kept confidential.

Study progress will be monitored monthly by the PI, Co-I, and Project Biostatistician. All critical events will be reviewed by the Investigators to ensure that our methods have not been intrusive or disruptive. The biostatistician will examine the quality of data input throughout the data collection period, following standard

quality control and assurance procedures (e.g., double entry of hard-copy coded data; detection and estimates of keystroke errors, identification of systematic mistakes in coding or responses; and range checks). Analyses of the Study 2 data will be performed by the Project Biostatistician at the conclusion of the baseline data collection period to assess distributional assumptions and the success of randomization. By having the Project Biostatistician monitor the data, the PI's conflict of interest is reduced.

The Project Biostatistician will attend regular project meetings with the PI and Co-I to routinely report on the quality of the data and other outcomes of this monitoring process. Compliance with data collection protocols will be monitored throughout data collection by the PI and Co-I.

The PI is responsible for reporting all adverse events to the IRB. Only Grade 1 events are expected on this trial. Thus, adverse events will be reported annually, as required by DHHS. This report will be reviewed by the IRB. Any action taken by the IRB or project investigators resulting in a temporary or permanent suspension of the trial will be communicated immediately by the PI to the NIH grant program officer.

#### **3.4 Will a Data and Safety Monitoring Board be appointed for this study?**

Yes  No

#### **3.5 Overall Structure of the Study Team**

The CTR-IN research project will be conducted by a research team at Boise State University (Boise State). Drs. Aida Midgett, Principal Investigator (PI) and Diana Doumas, Co-Investigator (Co-I), are located at Boise State. Drs. Midgett and Doumas will ensure that the research project is in compliance with NIH policies and human subjects requirements and will work to build consensus on administrative and scientific decisions that must be made during planning and execution of the protocol. Drs. Midgett and Doumas will work collaboratively with Boise State business office staff on budgeting and operational issues.

Dr. Midgett (PI) will be responsible for governance of the overall study. The project will be supervised by a Steering Committee comprised of the PI (Dr. Midgett) and Co-Investigator, Dr. Doumas, and Biostatistician, Ms. Bond. Dr. Midgett will chair the Steering Committee which will communicate with the NIH and IRB. Four subcommittees will supervise three important parts of the project. Dr. Midgett will chair the Program Development Subcommittee which will supervise the development of the content of the STAC Parent Module. Drs. Midgett and Doumas will provide expertise in bullying intervention and Dr. Doumas will offer expertise in parent-based interventions. The Recruitment Subcommittee, chaired by Dr. Midgett, will supervise procedures for inviting qualified participants to participate in the project. Dr. Midgett will work closely with Dr. Doumas, on this subcommittee regarding recruitment procedures. The Measurement Subcommittee, chaired by Dr. Doumas, will have oversight of all assessment measures. Dr. Midgett will participate on this subcommittee and provide expertise on bullying intervention. This subcommittee will also develop all protocols for data collection which will be reviewed for statistical appropriateness by Ms. Bond (Project Biostatistician). The Data Subcommittee, co-chaired by Dr. Midgett and Dr. Doumas will plan and conduct all data management and analysis procedures. Dr. Midgett will oversee qualitative data analyses, working closely with Drs. Moody and Peralta, and Ms. Bond will work closely with Dr. Doumas on quantitative data analysis, assisting with interpretation of the statistical analyses and in the preparation of all reports and publications. The PI and Co-I will be a member of all four subcommittees, when not chairing them.

Subcommittees will meet on a weekly, biweekly or monthly basis as needed depending on the project tasks and activities. Ad hoc committee work will be formed to address specialized tasks as necessary. Major decisions concerning the project will be made within the Steering Committee and subcommittees through discussion and consensus (when possible). The ultimate decision-making responsibility will rest with Dr. Midgett. Decisions about the intervention development, recruiting procedures, and data collection, management, and analysis procedures will be made primarily within the subcommittees; subcommittees will report routinely to the Steering Committee, which will review and provide final approval to their procedures.

Communications among investigators and project staff will be conducted face-to-face, by telephone/video-conferencing, and over the Internet. Project governance will occur through bi-weekly meetings with

investigators and staff to delineate issues, obtain additional information as needed and come to agreement on issues of concern. Meetings will cover all administrative aspects of the project, research planning and scheduling, intervention development, participant recruitment, analytic strategies, publication oversight, and advisory meetings.

Conflict in the team will be handled through frank discussions within the Steering Committee and subcommittees. All sides of an issue or sources of the conflict will be discussed and a final decision will be rendered through group consensus when possible. Conflict arising from differences in interpersonal style will be handled by the PI, respecting the privacy of those involved. If conflict cannot be resolved within the research team, Dr. Jennifer Snow (Dean, College of Education) will meet with both sides in the dispute, and recommend ways to resolve it. If conflict cannot be resolved through Dr. Snow's efforts, representatives of Boise State will serve as a mediation team, meeting with both sides in the dispute and recommending ways to resolve it. If the conflict still cannot be resolved, a mediator from Mountain States Employer Council will be hired to mediate the dispute. This Council provides business advice and services to small businesses. At that point, the research team will agree to make the mediator's decision binding. In the event that the PI cannot carry out her duties, a new PI will be recruited as a replacement, subject to the approval of the Boise State and NIH. Major decisions concerning the project will be conducted through discussion and consensus (when possible). The ultimate decision-making responsibility will rest with Dr. Midgett.

## **4.1 Study Design**

### **4.1.a. Detailed Description**

National statistics indicate bullying peaks in middle school, with approximately 28.0% of middle school students reporting bullying victimization and 33.0% reporting being cyberbullied. Among middle school students, bullying victimization and witnessing bullying as a bystander are associated with a wide range of mental health risks. Rural youth and youth in low-income communities are particularly vulnerable to bullying. Students in rural communities report higher rates of bullying and bullying victimization than those in urban areas and students in low-income households report the highest rates of bullying, physical bullying, bullying-related injury, and cyberbullying across income categories. Although comprehensive, school-wide bullying programs can be effective in reducing bullying, both time- and labor-intensive resources required for program implementation pose significant barriers for schools, particularly in low-income and rural communities. Brief interventions that reduce barriers for implementation to address health disparities are needed to reduce bullying and its negative consequences among students in rural and low-income communities.

To address barriers to program implementation, the PI developed a brief bullying bystander intervention, STAC, using four strategies: Stealing the Show, Turning it Over, Accompanying Others, and Coaching Compassion. Research conducted in rural and low-income communities indicates STAC is effective in reducing bullying perpetration, victimization, and negative mental health consequences for bystanders who witness bullying. Although initially developed as an in-person brief intervention, the research team is currently adapting STAC to a technology-based format (STAC-T) to further reduce implementation barriers for schools in rural and low-income communities. Research indicates there is a need for technology-based bullying bystander interventions at these schools and that schools in these communities have the interest and infrastructure to adopt STAC-T once developed.

Among middle school students, only about half of student report bullying to an adult, fearing adults will minimize or normalize bullying or make the situation worse. When students do report bullying to an adult, they most often report to parents, followed by teachers. Parents, however, are less likely to intervene in school bullying than teachers and when they do intervene, parents may not be effective. In fact, some parents suggest coping strategies that are not only ineffective, but may exacerbate the situation. Further, parents do not have a shared definition of bullying, normalize verbal and relational bullying, feel frustrated and helpless in response to bullying, are often unaware that bullying is occurring, and need information and guidance. However, few bullying interventions include parent education and the resources required for implementation of those that do pose significant barriers for schools. Although research indicates school personnel believe parental involvement in bullying intervention is important, that parents and teachers need to convey unified messages in a comprehensive, coordinated manner, and that parents need information and guidelines about bullying, involving parents in bullying prevention is a challenge for schools, particularly in rural and low-income

communities.

The overall CTR-IN pilot project goal is to develop the content for a STAC Parent Module. The project will be completed in 11.5 months and will consist of two stages: (1) content development and (2) testing of program acceptability, feasibility, and short-term outcomes. The primary outcomes are increases in knowledge and confidence, changes in bullying attitudes, increases in self-efficacy to manage bullying, and intentions to use the parent strategies. The secondary outcomes are related to program acceptability. Parents will complete baseline and immediate post-intervention assessments.

The proposed project is a first step in developing the STAC-T Parent Module. This project will provide the pilot data needed to support a NIMHD STTR/SBIR R41/42 fast-track proposal aimed at developing the STAC-T Parent Module for middle schools in rural and low-income communities. The aims of the pilot study are to:

**(1) Develop the content for the Parent Module.** Our previous research with school personnel and the bullying literature will guide the creation of the Parent Module content.

**(2) Assess the feasibility, acceptability, and immediate outcomes (e.g., knowledge, attitudes, self-efficacy, and behavioral intentions) of the STAC-T Parent Module.** We will conduct a mixed-methods study with parents ( $N = 40$ ) from two middle schools, assessing program acceptability and post-training outcomes through survey data; a subgroup of parents ( $N = 12-16$ ) will participate in focus groups, providing feedback about content, feasibility, and acceptability of the Parent Module for schools in rural, low-income communities.

A mixed-methods approach will be utilized; 40 parents will be recruited from three public middle school located in rural, low-income communities in Idaho. All parents of students in 6<sup>th</sup>- 8<sup>th</sup> grade meeting inclusion/exclusion criteria will be recruited through e-flyers and email reminders sent by the school and asked to sign up to participate. We will continue recruitment at each school until we reach the target sample. The e-flyer will explain the study and include a survey link to sign up for participation, as well as a project phone number and email address. Parents will be invited to participate in the study in the evening at the school. Parents who provide consent will be provided a unique study ID number and will complete the baseline assessment. Immediately after completing the baseline assessment, parents will complete the Parent Module training. Following the training, parents will complete the follow-up assessment. Baseline assessments include a survey assessing knowledge, confidence, attitudes, self-efficacy, and demographic characteristics. Immediately following the STAC Parent training, parents will complete a survey assessing acceptability of the training, knowledge, confidence, attitudes, self-efficacy, and behavioral intentions to use the STAC parent strategies.

Study consents and assessments will be collected via paper-pencil format. All data will be input into SPSS; data will be de-identified and stored in Boise State's secured database. Boise State's protocols for quality assurance (valid ranges; internal consistency checks, etc.) will ensure high quality data.

#### **4.1.b. Primary Purpose**

Prevention

#### **4.1.c. Interventions**

Type:

Behavioral

Name: *(up to 200 characters)*

STAC-T Parent Module

Description: *(up to 1000 characters)*

Parent-based bullying intervention

#### **4.1.d. Study Phase**

## Phase 1

Is this an NIH-defined Phase III clinical trial?

Device and behavioral intervention studies may select "Yes" here even if the answer above is "Other".

Yes  No

### 4.1.e. Intervention Model

Single Group

### 4.1.f. Masking

If yes:

Choose an item.

### 4.1.g. Allocation

N/A

## 4.2 Outcome Measures

### Type

Primary

### Name

Parent-Advocates Pre- and Post-Scale (PAPPS)

### Time Frame

Baseline assessment, immediate post-assessment

### Brief Description:

An 11-item questionnaire measuring parent knowledge of bullying, knowledge of the parent STAC strategies, and parent confidence to supporting their adolescent to intervene in bullying situations.

### Type

Primary

### Name

National Education Association Bullying Survey

### Time Frame

Baseline assessment, immediate post-assessment

### Brief Description:

This questionnaire has items that measures comfort managing bullying (4 items on a 4-point likert scale), confidence about managing bullying behavior (3 items on a 5-point likert scale), and role in managing bullying behavior (4 items on a 4-point likert scale). The questionnaire also has items related to experiences with bullying.

### Type

Primary

### Name

Parent Self-Efficacy Scale

### Time Frame

Baseline assessment, immediate post-assessment

### Brief Description:

The Parent Self-Efficacy Scale measures parent self-efficacy . A 6-item scale measures parent self-efficacy in

helping adolescents respond to bullying behavior. Items are rated on a 4-point Likert Scale. A 6-item scale measures parent communication self-efficacy in talking to adolescents about bullying. Items are rated on a 5-point Likert Scale.

**Type**

Primary

**Name**

Attitudes about Bullying Questionnaire

**Time Frame**

Baseline assessment, immediate post-assessment

**Brief Description:**

The 10-item Attitudes about Bullying Questionnaire measures parent attitudes about bullying. Items are rated on a 5-point Likert Scale.

**Type**

Primary

**Name**

Student Social Behavior Questionnaire

**Time Frame**

Baseline assessment, immediate post-assessment

**Brief Description:**

The 13-item Student Social Behavior Questionnaire measures parent attitudes about bullying. Items are rated on a 5-point Likert Scale.

**Type**

Primary

**Name**

Intention to Use Parent STAC Strategies

**Time Frame**

Immediate post-assessment

**Brief Description:**

Questions rating the parent intention use of each parent STAC strategy using a single item rated on a 5-point Likert scale: How likely are you to use these strategies to support your adolescent to intervene in bullying in the past month? (a) Stealing the Show; (b) Turning it Over; (c) Accompanying Others; and (d) Coaching Compassion.

**Type**

Secondary

**Name**

Acceptability Survey

**Time Frame**

Immediate post-assessment

**Brief Description:**

An 8-item questionnaire measuring user-friendliness, utility, and relevance of the Parent Module

**Type**

Secondary

**Name**

Qualitative questions

**Time Frame**

Immediate post-assessment

**Brief Description:**

Brief open-end questions that ask how helpful the program was, how the liked program was, and whether the user has any suggested changes to the program.

### 4.3 Statistical Analysis Plan

Analyses will be conducted on data collected. While unlikely, data may not be missing at random (NMAR). Ms. Bond, Project Biostatistician, will assign all lost responses to extreme category and perform multiple imputation procedures that can handle various amounts of missing data and use covariates and propensity scores.

The primary outcomes are detecting positive changes in knowledge acquisition and confidence, attitudes about bullying, self-efficacy regarding bullying, and intention to use of the STAC parent strategies. The secondary outcomes are program acceptability. A total of 20 parents within one school provides at least 80% power to detect a difference in baseline and immediate follow-up corresponding to a medium effect size (e.g., Cohen's  $d = .5$ ) with a 5% type I error probability. For this power analysis, pilot data from a sample of teachers were analyzed using measures similar to those proposed in this study. We will use three schools to ensure ecological validity and estimate the random effect for school for powering our future proposals involving multiple schools. We propose planning for 40 parents.

Descriptive statistics will be used to initially characterize the outcomes. We will use linear or generalized linear mixed model framework, with random effects of repeated observations on parents and parents nested within school.

We will evaluate whether the STAC Parent Module increases knowledge and confidence, changes attitudes about bullying, and increases self-efficacy from baseline to immediate follow-up, as well as intention to use the STAC parent strategies at the immediate follow-up. We will also evaluate acceptability at the immediate follow-up. Means, SDs, and percentages will be used to describe the primary and secondary outcomes. To identify changes in outcomes, we will evaluate each outcome using analysis of variance in a linear or generalized linear mixed model framework, with random effects of repeated observations on parents and parents nested in school. We will address the appropriateness of the model for non-normal outcomes and apply the appropriate distribution as necessary, and we will assess models for the necessity of all random effects using Akaike information criterion (AIC<sub>C</sub>). As the proposed project is intended to test feasibility and short-term outcomes to provide data for a larger multi-site study, we do not propose testing of moderators. However, we will examine demographic variables as a fixed effect whenever possible. Because our focus is on reception and usability, we will not perform a counterfactual analysis, but will have preliminary data to power for this in future proposals. Qualitative summary reports will also be prepared.