



Middle School Teacher Module for a Brief Bullying Intervention Program

NCT06017752

October 15, 2020

1.1 Study Title

Middle School Teacher Module for a Brief Bullying Intervention Program

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

NCT06017752

2.1 Conditions or Focus of Study

Bullying, Mental Health, Teacher-Based Intervention

2.2 Eligibility Criteria

Inclusion Criteria:

- being a middle school teacher at a participating low-income and/or rural school.
- speaks and reads English.
- consents to participate.
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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

Teachers of any age over 21 will be enrolled. The likelihood that teachers 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 Teacher Module based on feedback from teachers and test the Teacher Module's acceptability, feasibility, and short-term outcomes (e.g., changes in teacher 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 = 20 participants will be recruited from schools in Idaho.

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 20 teachers will be recruited from one middle/junior high schools located in a rural, low-income community in Idaho. A school liaison will work directly with teachers at the target schools. All teachers of grades 6th- 8th meeting inclusion/exclusion criteria will be recruited via an email sent by the school liaison. 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. The Middle School STAC Teacher Module will last approximately 50 minutes and those who consent will be asked to complete questionnaires at baseline and immediately post-training. Teachers will be compensated with a \$50 gift card. 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. Teachers who participate in the focus groups will be compensated \$50 to encourage retention and incentivize participation.

2.7 Study Timeline (PDF)

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

2.8 Enrollment of First Subject

1/1/2022

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 grant research is to collect pilot data to support an NIMHD STTR/SBIR R41/42 fast-track proposal aimed at developing the STAC-T Teacher 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 teachers of middle school students.

3.1.1.2. Study Procedures:

One middle school in a rural, low-income community in Idaho (N=20) will test the STAC Teacher Module to evaluate program acceptability, feasibility, changes in knowledge, confidence, attitudes about bullying, and self-efficacy, and intention to use the teacher STAC strategies. Outcomes of knowledge, confidence, attitudes, and self-efficacy will be tested immediately before and after the STAC Teacher Module training session.

Program acceptability and intentions to use the strategies will be measured immediately after the STAC Teacher Module Training. All teachers of students in grades 6, 7, and 8 will be invited to participate.

Recruitment will continue until sample size is met. Teachers who provide informed consent will be invited to participate in the study during evening hours in an auditorium provided by the school where participants can sit far enough apart from each other so that others cannot see their answers to surveys. Teachers will be provided a unique study ID number and will complete the baseline assessment. Immediately after completing the baseline assessment (10-15 minutes), teachers will participate in the STAC Teacher 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: Teachers will complete a survey assessing knowledge, confidence, attitudes about bullying, self-efficacy, and demographic characteristics. Immediate-Post Assessment: Immediately following the STAC Teacher Module training, teachers will complete a survey assessing acceptability of the STAC Teacher Module, knowledge, confidence, attitudes about bullying, self-efficacy, and intentions to use the STAC teacher strategies. Teachers will be randomly selected to participate in focus groups which will occur within a week post-training. In three focus groups with teachers 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 Teacher 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 Teacher 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 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 training session at any time they wish.

Responses to 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 teachers how to support students 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, teachers will be compensated with a \$50 gift card for participation in data collection and the teacher 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 teacher education, and those that do are rarely interactive and do not focus on supporting bystanders. Thus, developing a STAC Teacher 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. We will use standard data management procedures. Files connecting data with IDs will be kept confidential.

Study progress will be monitored monthly by the PI and Co-PI. All critical events will be reviewed by the Investigators to ensure that our methods have not been intrusive or disruptive. The Co-PI will examine the

quality of data input throughout the data collection period, following standard quality control and assurance procedures. Analyses of the data will be performed by the Co-PI at the conclusion of the baseline data collection period to assess distributional assumptions and the success of randomization.

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 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-Principal Investigator (Co-PI) will ensure that the research project is in compliance with 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.

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.

Middle school students indicate that school bullying occurs most often in the classroom, accounting for 42.3% of all school bullying incidences. However, national data indicate that only approximately half (51.7%) of middle school students report bullying to an adult at school, with report prevalence declining from sixth grade (57.2%) to eighth grade (47%). Although students report bullying to teachers more often than to any other adult at school, reporting behavior is influenced by a student's perception of teachers' responses to bullying. Students are more likely to report when they believe teachers will intervene, effectively handle the situation, and reward students' efforts when they report or intervene in bullying. In addition, students' future reporting behavior is influenced by how teachers respond to students' initial reporting. Students are less likely to report bullying and rates of bullying are higher in the classroom when students perceive that teachers have low self-

efficacy in handling bullying situations. As such, it is important for teachers to demonstrate comfort with and confidence in handling bullying situations. Training teachers to effectively respond to bullying and to encourage and support students who report and intervene in bullying are important components of bullying programs aimed at increasing student bystander intervention.

The overall project goal is to develop the content for a STAC Teacher 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 teacher strategies. The secondary outcomes are related to program acceptability. Teachers will complete baseline and immediate post-intervention assessments.

The proposed project is a first step in developing the STAC-T Teacher 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 Teacher Module for middle schools in rural and low-income communities. The aims of the pilot study are to:

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

(2) Assess the feasibility, acceptability, and immediate outcomes (e.g., knowledge, attitudes, self-efficacy, and behavioral intentions) of the STAC-T Teacher Module. We will conduct a quantitative study with teachers ($N = 20$) from one middle school, assessing program acceptability and post-training outcomes through survey data; a subgroup of teachers ($N = 12-16$) 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; 20 teachers will be recruited from one public middle school located in a rural, low-income community in Idaho. All teachers of students in grades 6th- 8th meeting inclusion/exclusion criteria will be recruited through an email sent by the school liaison and asked to sign up to participate. We will continue recruitment until we reach the target sample. The email will explain the study and include a survey link to sign up for participation, as well as a project phone number and email address. Teachers will be invited to participate in the study in the evening at the school. Teachers who provide consent will be provided a unique study ID number and will complete the baseline assessment. Immediately after completing the baseline assessment, teachers will complete the Teacher Module training. Following the training, teachers will complete the follow-up assessment. Baseline assessments include a survey assessing knowledge, confidence, attitudes, self-efficacy, and demographic characteristics. Immediately following the STAC Teacher training, teachers will complete a survey assessing acceptability of the training, knowledge, confidence, attitudes, self-efficacy, and behavioral intentions to use the STAC teacher 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 Teacher Module

Description: (*up to 1000 characters*)

Teacher-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

Teacher-Advocates Pre- and Post-Scale (TAPPS)

Time Frame

Baseline assessment, immediate post-assessment

Brief Description:

An 11-item questionnaire measuring teacher knowledge of bullying, knowledge of the teacher STAC strategies, and teacher confidence to supporting students 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 measure comfort managing bullying (4 items on a 4-point likert scale), and teachers' self-efficacy in handling bullying situations (2 items on a 4-point likert scale).

Type

Primary

Name

Teacher's Attitudes about Bullying Questionnaire

Time Frame

Baseline assessment, immediate post-assessment

Brief Description:

The subscale to measure confidence in Managing Bullying was used. This included 3 items rated on a 5-point

Likert Scale.

Type

Primary

Name

Intention to Use Teacher STAC Strategies

Time Frame

Immediate post-assessment

Brief Description:

Questions rating teacher intention to use each teacher STAC strategy was measured using four items rated on a 5-point Likert scale. Questions asked teachers the following: How likely are you to support students using these strategies to intervene in bullying in the future? a) Stealing the Show—support students using humor or distraction to get the attention away from the bullying situation, b) Turning it Over—support a student who reported bullying to you or supporting students to report to a principal or SRO, c) Accompanying Others—support students who reach out to the student who was the target of bullying, or d) Coaching Compassion—support students who help the student who bullied develop empathy for the target.

Type

Secondary

Name

Acceptability Survey

Time Frame

Immediate post-assessment

Brief Description:

An 8-item questionnaire measuring acceptability and relevance of the Teacher Module. Items were ranked on a 4-point Likert scale.

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

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 teacher strategies. The secondary outcomes are program acceptability. A total of 20 teachers 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. We propose planning for 20 teachers.

We will evaluate whether the STAC Teacher 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 teacher 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.

Quantitative data from the questionnaires will be analyzed using SPSS (version 28.0; IBM Corp). Before conducting the statistical analyses, the data will be examined for outliers and normality. We will conduct a series of paired-sample t tests to evaluate changes from pretest to posttest measurements. Qualitative summary reports will also be prepared.