Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety (PLANTS): Pilot Cluster-Randomized Controlled Trial

Protocol Number: STUDY21080178

National Clinical Trial (NCT) Identified Number: NCT05897827

Principal Investigator: Robert W.S. Coulter

Sponsor: University of Pittsburgh

Grant Title: Developing and Piloting a School Staff-Based Intervention to Reduce Alcohol and Drug Use Among Sexual Minority Youth

Grant Number: K01AA027564

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2024.04.05

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator:

Signed: Robert W.S. Coulter Date: 2024.04.05

Name: Robert W.S. Coulter

Title: Assistant Professor

Investigator Contact Information

Affiliation: University of Pittsburgh

Address: 6129 Public Health Building, 130 De Soto Street, Pittsburgh, Pennsylvania, USA 15261

Telephone: +1-412-624-0647

Email: *robert.ws.coulter@pitt.edu*

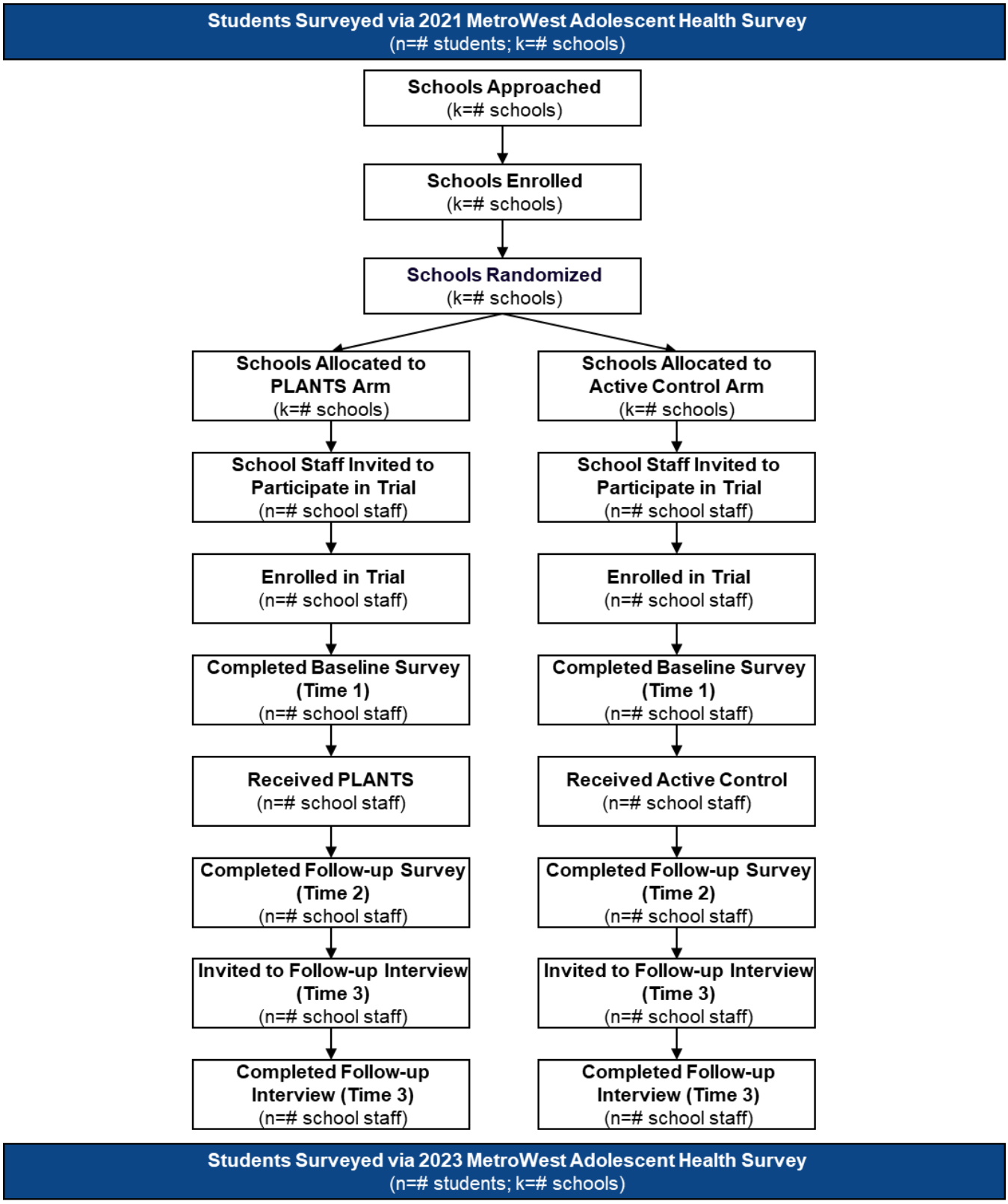
1 PROTOCOL SUMMARY

1.1 Synopsis

Title:	Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety (PLANTS): Pilot Cluster-Randomized Controlled Trial
Grant Number:	K01AA027564
Study Description:	This pilot cluster-randomized controlled trial will evaluate the PLANTS (Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety) course among high school staff. The primary hypotheses are that the PLANTS course will have high acceptability, usability, appropriateness, and feasibility as reported by high school staff.
Objectives:	Primary Objective: -For high school staff, is PLANTS acceptable, usable, appropriate, and feasible? Secondary Objectives: -To what extent was the PLANTS course and trial successfully implemented and safe for high school staff and schools? - Among high school staff participants in the PLANTS arm, do they report pre-post improvements in active-empathic listening, self-efficacy for supporting, affirming, and protecting sexual and gender minority youths, and positive bystander intervention behaviors for bullying? -Among high school staff, is the PLANTS intervention more efficacious in improving their active-empathic listening, self-efficacy for supporting, affirming, and protecting SGMY, and positive bystander intervention behaviors for bullying than an email intervention of publicly available resources?
Endpoints:	Primary Endpoints: Intervention acceptability, usability, appropriateness, and feasibility. Secondary Endpoints: Intervention efficacy for school staff; Success of intervention implementation; Success of trial implementation; Intervention safety.
Study Population:	The primary study population is high school staff, aged 18 years old and over, who work at high schools in the MetroWest Region outside Boston, Massachusetts.
Phase or Stage:	Pilot Phase
Description of Sites Enrolling Participants:	This is a single site study conducted by the University of Pittsburgh.
Description of Study Intervention:	The PLANTS (Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety) intervention course is a community-informed, theory-based intervention for training high school staff to better support, affirm, and protect SGMY. The intervention is web-based, containing self-paced asynchronous modules and synchronous group-based events. The intervention will occur across a period of three months.
Study Duration:	The estimated study duration is 12 months.
Participant Duration:	High school staff will complete all study-related tasks within 9-12 months.

1.2 Schema

Study Flow of Two-Arm Cluster-Randomized Controlled PLANTS Pilot Trial, Nested within the MetroWest Adolescent Health Survey Infrastructure



1.3 Schedule of Activities

	School Screener	Staff Screener (Time 0)	Staff Baseline Survey (Time 1)	PLANTS Program	Control Program	Staff Follow-up Survey (Time 2)	Staff Follow-up Interview (Time 3)
SCHOOL DATA							
Inclusion/exclusion	X						
Public school data	X						
Randomization	X						
STAFF DATA							
Inclusion/exclusion		X					
Informed consent		X					
Demographics			X			X	
Social desirability bias			X			X	
Existing school programs			X			X	
Primary Outcomes							
Intervention Acceptability, Usability, Appropriateness, and Feasibility				X		X	X
Secondary Outcomes							
Implementation Outcomes	X	X	X	X	X	X	X
Adverse Events Reporting			X	X	X	X	X
Active Empathetic Listening			X	X		X	X
Self-efficacy for Working with SGMY			X	X		X	X
Self-efficacy of PLANTS' Change Objectives			X	X		X	X
Bystander Intervention Behaviors for Bullying			X	X		X	X

2 INTRODUCTION

2.1 Study Rationale

Statement of the Problem

Sexual and gender minority youth (SGMY; i.e., adolescents who identify as gay/lesbian or bisexual, who have same-gender sexual behaviors or attractions, who identify as transgender or nonbinary, or whose gender identity do match their sex assigned at birth) are at significantly higher risk than their heterosexual peers for using drugs (tobacco and marijuana) and alcohol.[1-30] Alcohol use is 123-155% higher among sexual minority youth than heterosexual youth and up to 250% higher among gender minority youth than cisgender youth.[2,5-7] SGMY are more likely to drink alcohol at earlier ages.[1-30] For U.S. teens in 9th grade, binge drinking (4+/5+ drinks within 2 hours) was higher among gays/bisexuals vs. heterosexuals (13% vs. 7%) and those with same-gender sexual behaviors vs. heterosexually-behaving youth (28% vs. 16%).[30] These substantial and persistent inequities make SGMY a priority population for interventions that reduce drug and alcohol use; thus, intervention research for SGMY was deemed a priority by national health agencies.[3,31,32] However, there are few efficacious alcohol/drug use interventions for SGMY.[3]

Rationale Underlying the Intervention

One way to reduce alcohol and drug use for SGMY is to foster more supportive and inclusive high school environments by training school staff (e.g., teachers, principals, nurses, counselors) to effectively support and protect SGMY. SGMY who have support from adults at school, greater school connectedness, and lower bullying victimization also have reduced depressive symptoms, suicidality, drug use, and alcohol use.[5,8,9,33-36] Unfortunately, SGMY are more likely than their heterosexual peers to lack supportive adults at school, have lower school connectedness, and to be victims of bullying.[5,6,8,9,37-45] An intervention that trains school staff to better understand and support SGMY and engage in positive bystander behaviors that protect SGMY from bullying victimization may reduce sexual-orientation disparities in drug and alcohol use. An intervention for school staff is further warranted because the presence of gay-straight alliances and SGMY-inclusive school policies fail to eliminate sexual-orientation drug and alcohol disparities.[4,46-48] This is likely due to school staff's lack of knowledge, skills, and self-efficacy about supporting SGMY—and their lack of training on SGMY.[49-51]

Study Intervention: PLANTS Course

The intervention being studied, PLANTS (Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety), is an online-delivered training program, including asynchronous and synchronous activities targeting high school staff. This intervention is informed by the Information-Motivation-Behavior theory to target high school staffs' skills, self-efficacy, knowledge, and outcome expectations. Members of the study population as well as collaborators invested in SGMY well-being provided valuable feedback on PLANTS throughout its development.

Regarding the intervention's targeted behavioral outcomes, upon completion of the PLANTS program, high school staff will: provide interpersonal support and affirmation to SGMY; provide educational resources that are inclusive of SGMY; provide safe spaces for SGMY; promote acceptance of SGMY among cisgender heterosexual youth; prevent and reduce bullying, cyberbullying, and harassment of SGMY; evaluate and advocate for SGMY inclusivity and protections in school policies; and maintain the confidentiality of SGMY. By having high school staff achieve these behavioral outcomes, we hypothesize that SGMY will experience less

risk factors (e.g., bullying victimization) and more protective factors (e.g., school-based adult support), which will in turn reduce SGMY's substance use and mental health problems.

Rationale for the Clinical Trial

The primary aim of this clinical trial is to rigorously test the acceptability, usability, appropriateness, and feasibility of the PLANTS intervention using a 2-armed cluster-randomized controlled trial. We will also examine the efficacy of intervention in improving high school staff outcomes as well as implementation and safety outcomes related to the intervention and trial. Results from this pilot trial will provide necessary information to conduct a fully powered trial of the efficacy of PLANTS for reducing the ultimate health outcome of SGMY alcohol use.

2.2 Background

SGMY health equity intervention research is a priority of many major organizations, including NIH, Healthy People 2030, and the National Academy of Medicine (formerly the Institute of Medicine).[3,31,32,52] To date, little NIH-funded intervention research for sexual minority populations has focused on drug and alcohol use.[53] As shown by the IOM[3] and a systematic review we conducted, there exist few efficacious interventions aimed at reducing drug and alcohol use for SGMY.[54] Our systematic review of the peer-reviewed literature found only one alcohol/drug use intervention for SGMY, which was an individual-level intervention with no improvements in alcohol, tobacco, or marijuana use.[55] Furthermore, the rigor of SGMY-related intervention research can be improved by using validated measures and systematic sampling of SGMY, all of which are addressed in this study.

Despite the lack of SGMY intervention research, a robust body of theoretic and empirical research shows SGMY disparities in alcohol/drug use and mental health are driven by sexuality- and gender-based stigma.[5,6,8,39,56-61] Stigma has the dual effect of reducing stigmatized populations' access to important protective factors (such as adult support) while increasing their experiences of risk factors (such as discrimination).[58,61] Thus, reducing sexuality- and gender-based stigma is an essential component of interventions to effectively reduce SGMY drug and alcohol disparities. However, sexuality- and gender-based stigma reduction is commonly absent in traditional drug/alcohol use programs,[62-64] highlighting the need for new SGMY-specific interventions.

Schools provide an ideal setting for SGMY-specific interventions to reduce drug and alcohol use disparities. High school students spend ~1,195 hours per year in school,[65] providing an ideal place to reach SGMY. SGMY regularly interact with adults, including school teachers, principals, nurses, counselors, and social workers, who are professionally bound by certifying bodies to support the needs of students, including SGMY.[66-70] Nevertheless, implementing interventions in schools is challenging because of schools' limited resources, increasing demands placed on teachers, and difficulty in acquiring school buy-in. These barriers can be overcome by using economical and easily implementable interventions, such as online programs, and developing interventions and implementation strategies in collaboration with school collaborators.

School-based interventions can build upon epidemiologic research identifying factors associated with sexual-orientation disparities in drug and alcohol use. For example, SGMY are more likely than cisgender heterosexuals to experience bullying victimization in school,[5,6,8,9,39-44] which is associated with greater and mental health problems and alcohol/drug use for SGMY.[5,6,8,9,33] Compared with heterosexual youth, SGMY report lower prevalence of adult support at school and reduced school connectedness,[37-39,45] which is associated with better mental health and lower drug and alcohol use.[33-35] Therefore, school-based

interventions aimed at reducing risk factors and increasing protective factors for SGMY will likely reduce their drug and alcohol use disparities.

In particular, training school staff (e.g., teachers, principals, nurses, counselors) to support, affirm, and protect SGMY is hypothesized to reduce bullying victimization, increase school support and connectedness, and mitigate SGMY drug and alcohol use.[51] Unfortunately, school staff often lack the necessary training to effectively support, affirm, and protect SGMY.[49,50] Many school staff have a strong desire to support SGMY.[50] However, they report the primary barrier to supporting SGMY is their lack of training.[50] In 2014, only 13% of teachers across the U.S. received training on SGMY-related issues, and only 29% in Massachsuetts,[49] highlighting the need for SGMY-related professional development training in schools. Offering the free and easily accessible online PLANTS intervention to school staff is hypothesized to be beneficial for school staff and for reducing disparities in drug and alcohol use for SGMY.

2.3 Risk/Benefit Assessment

2.3.1 Known Potential Risks

Immediate potential risks:

- Breach of confidentiality
- Emotional discomfort
- Backlash from people for supporting SGMY

Long-term potential risks:

- Breach of confidentiality
- Emotional discomfort
- Backlash from people for supporting SGMY

2.3.2 Known Potential Benefits

Immediate potential benefits

- Improved interpersonal relationships with SGMY

Long-term potential benefits

- Improved interpersonal relationships with SGMY
- This study is highly significant because we currently have limited promotion and prevention programs for SGMY. Therefore, the benefit of this systematic program evaluation is that the findings may add to the evidence base of violence prevention programs available to help improve health for SGMY.

2.3.3 Assessment of Potential Risks and Benefits

This is a minimal risk study because the risks that could occur from participation in the intervention or trial are unlikely. Furthermore, we have taken several precautions to minimize potential risks.

Breach of Confidentiality: It is possible that breach of confidentiality may occur. However, we have taken the following active steps to minimize the likelihood of breach of confidentiality. First, all surveys are collected electronically via REDCap, a secure web application for building and managing online surveys and databases.

While REDCap can be used to collect virtually any type of data (including 21 CFR Part 11, FISMA, and HIPAA-compliant environments), it is specifically geared to support online data capture for research studies and operations. Second, we ask that you complete the survey in a private place where no one can see your answers. Surveys can be completed on any computer, tablet, or mobile device, allowing you to complete the surveys when they feel most comfortable. Third, only our research team will have access to REDCap. We will never share their individual answers with any other school staff or administrators. Fourth, for interviews, we will use HIPAA-compliant Zoom accounts and ask that interviews be taken in private quiet spaces. Together, these procedures mitigate the risk of breach of confidentiality.

Emotional discomfort: It is possible that some participants may experience emotional discomfort, embarrassment, or distress while answering questions or as a result of intervention/control materials. We take the following precautions to protect subjects. First, you do not have to answer any question that makes you uncomfortable or that you do not understand. Second, participation in this study is completely voluntary. Third, we will not be asking you questions about sensitive traumatic experiences that may have happened to them. Together, these procedures mitigate the risk of emotional discomfort for school staff.

Backlash from people for supporting SGMY: It is possible that some participants may experience backlash, but it is unlikely. We take the following precautions to protect subjects from backlash. First, PLANTS encourages high school staff to consider their sociopolitical environments before implementing strategies to support SGMY. Second, all strategies in PLANTS are suggestions; school staff are not required to implement any strategies they do not want to. Third, all information reported in our study are completely confidential; we never share identifiable information with anyone outside the study team. Fourth, we will only enroll high school staff from schools that agree to participate in the trial, increasing the likelihood that school leadership is in favor of supporting SGMY and minimizing potential backlash.

Overall, this is a minimal risk study: all risks are unlikely to occur, and we provide high school staff with suggestions on how to prevent them from happening when they are within their control. Because we currently have limited scientific evidence about programs that aim to train high school staff to support, affirm, and protect SGMY, the potential benefits of this systematic program implementation far outweigh the minimal risks associated with the study.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To evaluate the acceptability, usability, appropriateness, and feasibility of PLANTS	In the follow-up survey, school staff will complete the following survey measures: - Acceptability of Intervention Measure - System Usability Scale - Intervention Appropriateness Measure - Feasibility of Intervention Measure	We use validated scales that assess high school staff's perceptions of the intervention's tolerability, user friendliness, fit, relevance, and successful execution.
Secondary		
To test the efficacy of PLANTS intervention for improving SGMY behaviors among high school staff	-Active empathic listening -Self-efficacy for supporting, affirming, and protecting SGMY -Self-efficacy of PLANTS change objectives -Positive bystander intervention behaviors	PLANTS is specifically designed to target these behavioral outcomes.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
To assess PLANTS implementation	-PLANTS participation rate -PLANTS completion rate -Participation rate in live Zoom events	These measures assess school staff's implementation and uptake of the PLANTS intervention.
To assess trial implementation	-Participation rate -Attrition rate -Intervention demand	These measures assess the success of the pilot trial in reaching an adequate number of school staff.
To determine the safety of PLANTS	-Parent backlash -Social media backlash -School board backlash -Suspension or removal from employment -Censorship of LGBTQ+ literature/history/stories or removal of books with LGBTQ+ representation from school libraries.	Although we anticipate the incidence of these adverse events to be low, they are the most common and could be most harmful to school staff.

4 STUDY DESIGN

4.1 Overall Design

This is a two-armed cluster-randomized controlled pilot trial of the PLANTS intervention versus an active control group, EMAILS (E-learning to Maximize Academic Inclusion of LGBTQ+ Students). The single study site is the University of Pittsburgh. The primary objective is to assess the acceptability, usability, appropriateness, and feasibility of the PLANTS intervention. We hypothesize that high school staff will rate the PLANTS intervention as having high acceptability, usability, appropriateness, and feasibility in the follow-up survey.

The secondary objectives are to examine the extent to which the PLANTS course and trial successfully implemented and safe for high school staff and schools. We will also evaluate the extent to which, among high school staff participants in the PLANTS arm, they report pre-post improvements in active-empathic listening, self-efficacy for supporting, affirming, and protecting sexual and gender minority youths, and positive bystander intervention behaviors for bullying. We will also assess the extent to which, among high school staff, the PLANTS intervention is more efficacious in improving active-empathic listening, self-efficacy for supporting, affirming, and protecting SGMY, and positive bystander intervention behaviors for bullying than an email intervention of publicly available resources. We hypothesize that participants in PLANTS will report greater active-empathic listening, greater self-efficacy for supporting, affirming, and protecting SGMY, and greater positive bystander intervention behaviors for bullying in follow-up surveys than participants in the active control arm.

We will randomize schools in an equal 1:1 ratio, stratified by large versus small schools, into intervention or active control conditions. We will use block randomization with block sizes of 2, which will be stratified by large schools versus not, where large is ≥1000 students. We use block size of 2 because there are only 4 schools in this pilot trial. Dr. Coulter (PI) will use Stata (ralloc command) to generate the randomization list, which will be entered into REDCap using the randomization module. Because this is a cluster randomized trial, we will randomize schools after they are determined to have met all the eligibility requirements and they officially enroll in the study. Upon school enrollment, a research assistant will be responsible for entering the school into the REDCap database and hitting the "randomize" button. Randomization will occur prior to school staff

screening/enrollment and prior to intervention delivery. We will conceal allocation from schools. This is an unblinded study. This is an educational intervention that cannot be blinded because study participants will be able to tell which condition they are in based on the content they receive. Unblinding could introduce bias, including social desirability bias, attrition bias, bias in intervention participation, and bias in reporting adverse events. Outcomes are assessed via self-reported online surveys, so there is no concern about bias about the blinding for outcome assessors.

PLANTS (Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety) intervention is an online-delivered training program, including asynchronous and synchronous activities. This intervention was informed by the Information-Motivation-Behavior theory to target skills, self-efficacy, knowledge, and outcome expectations. There are approximately 20 asynchronous online modules that cover a variety of topics including lessons on LGBTQ+ terminology, names and pronouns, resources, antibullying, gender neutral bathrooms, student confidentiality, active empathic listening, and school policies. Each module includes recorded presentations, student testimonials, activities, and downloadable resources for future reference. Every month, 7-9 lessons are opened. There are 2-3 synchronous group events delivered via Zoom that are 1.5 hours each.

The active control arm is an email-based intervention, EMAILS (E-learning to Maximize Academic Inclusion of LGBTQ+ Students), in which existing public resources for supporting, affirming, and protecting LGBTQ+ are emailed to participants. All of these resources are also provided to intervention participants. The topics of the email intervention are similar to those of PLANTS.

At the 4 enrolled schools, we will administer online surveys to all staff members (i.e., a census of teachers, administrators, nurses, counselors) via REDCap software. With staff emails provided by administrators, we will send staff a screening survey, consent form, and baseline survey. Subsequently, we will sample a subset of the intervention and control groups for individual interviews to explore implementation outcomes more deeply.

4.2 Scientific Rationale for Study Design

We chose to randomize at the school level as opposed to the individual level for several reasons. We view PLANTS as an intervention that can be implemented within schools as a whole to foster more inclusive, supportive, affirming, and protective environments for SGMY. We also minimize contamination amongst school staff by randomizing at school versus individual levels. By randomizing at the school level, we can estimate the impact that the intervention has had on all youth within a school by leveraging existing surveillance data that assesses censuses of students (such as the MetroWest Adolescent Health Survey). By leveraging existing health surveillance infrastructures, our study will yield large sample sizes and high statistical power for finding health-promoting effects at the individual level.

The comparison group selection was challenging because there is no gold standard for improving school-based environments for SGMY by changing behaviors of high school staff. Nevertheless, we decided to select a practical alternative to the PLANTS intervention; therefore, the active control materials will be freely available online courses that aim to improve SGMY school environments. Note that this is an active control intervention, therefore all participants in this group are expected to receive training in the primary outcomes of the PLANTS interventions. Compared to using a placebo or pure control, our ability to find differences between these the study harms is somewhat hampered. However, we believe using an active control arm is more ethical given the minimal risks of participation in such online trainings plus their potential impact for bolstering environments for SGMY well-being.

4.3 Justification for Intervention

We decided to deliver PLANTS using an online design because this model is more scalable than traditional in-person trainings, thereby reaching more people. We include both synchronous and asynchronous modules, as there is evidence that both is better than asynchronous training only. The length of the intervention evolved throughout the development of the project with feedback from the community. The number of asynchronous elements were identified through our intervention mapping process and by chunking PLANTS' performance objectives into complementary components. The lengths of videos were determined based on expertise provided by teaching and learning experts. Because this is a pilot study including intervention adherence, a participant will have to complete at least one item in the PLANTS intervention to have evaluable data.

4.4 End-of-Study Definition

A participant is considered to have completed the study if they have completed the baseline and follow-up surveys. The post-intervention interview is optional and will be conducted with a sub-sample of the study participants.

The end of the study is defined as completion of the follow-up survey or completion of the staff follow-up interview, as shown in the Schedule of Activities.

5 STUDY POPULATION

5.1 Inclusion Criteria

School Inclusion Criteria:

To be eligible to participate in this study, schools must meet all of the following criteria:

- Participated in the 2021 MetroWest Adolescent Health Survey (MWAHS)
- Plan to participate in the 2023 MWAHS
- Grant us permission to access their MWAHS data
- Willing and able to provide emails addresses for all school staff
- Willing and able to provide us a letter of support denoting their participation in our study

Staff Inclusion Criteria:

To be eligible to participate in this study, staff must meet all of the following criteria:

- Currently employed by an enrolled school in the MetroWest Region of Boston, Massachusetts
- Age 18 years old or older
- Consents to participate

5.2 Exclusion Criteria

School Exclusion Criteria:

N/A

Staff Exclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study:

- Does not interact with high school students at work

5.3 Lifestyle Considerations

N/A

5.4 Screen Failures

Individuals who do not meet the criteria for participation in this trial (screen failure) are unlikely to meet them within the study window and will not be rescreened.

5.5 Strategies for Recruitment and Retention

School Staff

Recruitment. For high schools to be eligible to enroll in our study, school administrators must be willing to provide email addresses for all school staff members so that we can adequately recruit all staff in the high school. At the enrolled high schools, we will administer online surveys via REDCap to all staff members that interact with students (e.g., a census of teachers, administrators, nurses, counselors). We will email participants a screener survey to confirm their eligibility for participation, a consent form, and a baseline survey. We will also place study advertisements in their school mailboxes.

Retention. The follow-up survey will be delivered post-intervention. Several methods used by Dr. Coulter and his mentorship team have proven valuable in retention of participants in longitudinal studies. To keep participants engaged, we will: inform participants at the beginning about the anticipated time burden and associated incentives; provide participants with clear instructions about their tasks; send personalized reminder emails and text messages to participants who have not completed a survey; email participants 1 day in advance of their survey, reminding them to look out for the upcoming survey email and to check spam filters; encourage participants to reach out to us when they have questions or concerns via email, phone, or text; and provide participants with escalating incentives that increase each survey. We will monitor retention on a weekly basis and more frequently if needed to ensure we are maintaining high retention.

Incentives. To incentivize school staff to complete the baseline survey, we will provide $20 gift cards to each participant and will raffle $30 gift cards to 20% of participants who take the baseline survey within each school. To incentivize school staff to complete the follow-up survey, we will provide $30 gift cards to each participant who completes the survey will and raffle $40 gift cards to 20% of participants who take the follow-up survey within each school. For staff who complete the follow-up interview, we will provide $50 incentive as a thank you for their time.

6 STUDY INTERVENTIONS

6.1 Study Intervention Administrations

6.1.1 Study Intervention Descriptions

We have two study conditions, intervention and active control. We describe each condition using the TIDieR Checklist.[71]

PLANTS Course: Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety

This intervention, PLANTS Course, is an online training program for high school staff. The behavioral outcomes of PLANTS are to train high school staff to: provide interpersonal support and affirmation to SGMY; support LGBTQ+ students in meeting their basic needs; provide educational resources that are inclusive of LGBTQ+ students; provide safe spaces for LGBTQ+ students; promote acceptance of LGBTQ+ students among non-LGBTQ+ students; prevent and reduce bullying, cyberbullying, and harassment of LGBTQ+ students; evaluate and advocate for LGBTQ+ inclusivity and protections in school policies; and maintain the confidentiality of LGBTQ+ students. To achieve these outcomes, we harnessed Information-Motivation-Behavior theory to target high school staff's skills, self-efficacy, knowledge, and outcome expectations. PLANTS uses asynchronous and synchronous online activities with 3 primary sections: Trustworthiness, Safety, and Nurturance. Each section includes, as asynchronous activities, recorded presentations, student testimonials, activities, and downloadable resources for future reference. There are required synchronous Live Zoom Events delivered via Zoom that are 1.5 hours each. Live Zoom Events will be moderated by a trained interventionist and will be tailored to the need of participants. Three Live Zoom Event are offered and participants are required to complete all three. Sections are opened once a month for ~3 months. The modules were developed by my research team, including undergraduate students and graduate students with a variety of academic backgrounds, in partnership with high school staff and other professionals specialize in LGBTQ+ youth or education. We use Canvas Learning Management Software to deliver PLANTS. We will monitor intervention compliance and fidelity via module questionnaires, Canvas informatics, event attendance, and follow-up survey questionnaires.

EMAILS: E-learning to Maximize Academic Inclusion of LGBTQ+ Students

The active control, EMAILS, is an email-based intervention in which existing online resources for supporting, affirming, and protecting LGBTQ+ are emailed to participants. These resources are also provided to intervention participants. The topics covered by EMAILS are similar to those of PLANTS, though there are some unique aspects to PLANTS. This intervention is informed by the Information-Motivation-Behavior theory as well. EMAILS includes the following publicly available materials:

- Adagio Health LGBTQ+ Professionalism Training (*https://youtu.be/VX9tDt3gOto*)
- Imi (Audience is LGBTQ+ teens, *https://imi.guide/*)
- The Safe Zone Project (*https://thesafezoneproject.com/*)

These intervention activities include self-paced modules, YouTube videos, and PowerPoints. There is no direct human interaction in this intervention other than email. EMAILS participants are individually emailed using a duration and pace similar to PLANTS (e.g., lasts 3 months). The intervention takes place entirely online. We will not be doing any tailoring of these materials to specific audiences, other than compiling various resources. We will monitor active control compliance and fidelity via email clicks by sending emails with training links from REDCap to participants, and then participants click on the training links in Qualtrics for tracking purposes. We will also use follow-up survey questionnaires to assess use of EMAILS.

6.1.2 Administration and Dosing

PLANTS online modules will be administered online via Canvas. Sections will be opened once per month, and there are a total of 3 sections over 3 months. The synchronous Live Events will be administered via Zoom. There are a total of 3 events. A "Full Dose" of the PLANTS intervention includes completion of all the online modules and 3 Live Zoom Events. The Live Zoom Events are required to be administered by trained interventionists (the PI or Research Assistants). In the Live Zoom Events, participants will interact with each other and a shared interventionist in a virtual environment. Active control materials cannot be tracked as easily

because these online trainings are administered via other agency's websites (not the study team's website). There are no interventionists in the active control arm.

6.2 Fidelity

6.2.1 Interventionist Training and Tracking

The PLANTS Live Zoom Events require effort be made to check that the intervention is appropriately conducted by the interventionists. For each Live Zoom Event, the research assistant(s) will keep detailed notes of the sessions. We will then check these notes against the change methods and learning objectives for each module to ensure fidelity of the intervention. We will also monitor implementation of the PLANTS asynchronous online modules by checking that the release dates are met in the online platform. We use Canvas Learning Management Software to deliver PLANTS. We will monitor intervention compliance and fidelity via module questionnaires, Canvas informatics, event attendance, and follow-up survey questionnaires.

EMAILS has no direct human interaction in this intervention other than email. We will track delivery of EMAILS by checking sent emails against an implementation plan. We will monitor active control compliance and fidelity via email clicks by sending emails with training links from Qualtrics to participants, and then participants click on the training links in Qualtrics for tracking purposes. We will also use follow-up survey questionnaires to assess use of EMAILS.

6.3 Measures to Minimize Bias: Randomization and Blinding

We will randomize schools in an equal 1:1 ratio, stratified by large versus small schools, into intervention or active control conditions. We will use permuted block allocation (with block size=2) to randomize schools to the intervention or active control conditions. We use block size of 2 because there are only 4 schools in this pilot trial. The permuted blocks will be created using the "ralloc" package for Stata. We will use REDCap's Randomization Module. We will randomize schools after they enroll in the study, but before school staff complete baseline surveys. Dr. Coulter will create the randomization files in Stata, and the study coordinator will allocate schools to conditions in REDCap. We will conceal allocation from schools.

This is an unblinded study. This is an educational intervention that cannot be blinded because study participants will be able to tell which condition they are in based on the content they receive. Unblinding could introduce bias, including social desirability bias, attrition bias, bias in intervention participation, and bias in reporting adverse events. Outcomes are assessed via self-reported online surveys, so there is no concern about bias about the blinding for outcome assessors. We do not anticipate planned or unplanned breaking of randomization allocation to participants or schools.

6.4 Study Intervention Adherence

We will make the following efforts to confirm that the subject of the PLANTS intervention is adherent:

- Participants will be required to click "completed" in Canvas modules when they are completed.
- We will ask participants to register for the Live Zoom Events.
- We will track attendance at Live Zoom Events.
- We will contact participants if they have yet to complete the modules or Live Zoom Events.

Canvas module completion and Live Zoom Event attendance will be used to calculate study intervention adherence.

For the active control arm, we will ask participants to self-report completion of the online trainings in questionnaires sent after each email and in the follow-up survey if they completed the trainings.

6.5 Concomitant Therapy

N/A

6.5.1 Rescue Therapy

N/A

7 STUDY INTERVENTION DISCONTINUATION & PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention

N/A

7.2 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue a participant from the study for the following reasons:

- Lost-to-follow up; unable to contact subject
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on the Protocol Deviation Form. Subjects who sign the informed consent form and subsequently withdraw, or are discontinued from the study, will not be replaced.

7.3 Lost to Follow-Up

A participant will be considered lost to follow-up if they fail to complete the follow-up survey and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to complete a study visit:

- Staff will attempt to contact the participant, encourage completion of the study activity, counsel the participant on the importance of maintaining study participation, and ascertain if the participant wishes to continue in the study.
- Before a participant is deemed lost to follow-up, staff will make every effort to regain contact with the participant (where possible, 3 telephone calls, 3 texts, and 3 emails, if necessary). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, the participant will be considered lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 Endpoint and Other Non-Safety Assessments

School Screener

1. Inclusion/exclusion will be assessed over Qualtrics, the phone, Zoom, or in-person by study staff to school administrators. These are the exact questions:
    a. Does your school plan to participate in the 2023 MetroWest Adolescent Health Survey?
    b. Does your school plan to participate in the 2025 MetroWest Adolescent Health Survey?
    c. Does your school grant us permission to access your MWAHS data?
    d. Will your school provide emails addresses for all school staff so we can recruit them to the trial?
    e. Will your school provide our team with a letter of support denoting their participation in our study?
2. Public school data: We will gather all publicly available data from the Massachusetts Department of Elementary and Secondary Education website, including school size.
3. Randomization: Upon enrollment of a school, we will randomize them to either PLANTS or EMAILS based on our stratified blocked randomization.

Staff Screener (Time 0)

1. Inclusion/exclusion will be self-administered via REDCap by high school staff. These are the exact questions:
    a. Which schools do you currently work at? [drop down list of MetroWest Schools + "Somewhere else" + write-in]
    b. How often do you interact with students at your job? [0: Daily; 1: Weekly; 2: Monthly; 3: Yearly; 4: Never]
    c. How old are you? [integer validation]
2. Informed consent: We will provide informed consent materials online via REDCap.

Staff Baseline Survey (Time 1)

These surveys are self-administered online via REDCap by high school staff. The following measures are included in the baseline surveys:

1. **Demographics:** We assess schools staff's role(s) in school,[72] years working as a staff member,[72] age, race/ethnicity,[73] gender identity (including transgender status),[74] sex assigned at birth,[74] sexual identity,[73] past contact with sexual and gender minorities,[75] past encounters working with SGMY,[76] previous professional development related to working with SGMY, highest education level achieved, religious affiliation, and religiosity.[77] We also measure attitudes towards LGBTQ people using the Modified Attitudes Toward Lesbians and Gay Men (Herek & McLemore, 2011; Strong, 2013) Scale. [78-80] This scale has four subscale domains about attitudes towards: gay men (α range = 0.75-0.76)[81]; lesbian women (α range 0.76-0.79); bisexual people; (α range = 0.79-0.81[81]; lesbian women (α range 0.76-0.79)[81]; bisexual people; (α range = 0.79-0.81)[81]; transgender people (α range = 0.79)[81]; and nonbinary people (newly created). Each subscale has three items (e.g., "Having sex with both males and females is just plain wrong"). Response options included a five-point Likert scale ranging from "strongly agree" to "strongly disagree."
2. **Active-empathic listening skills:** We use the valid and reliable Active-Empathic Listening Scale containing 11 items (Bodie, 2011; Gearhart & Bodie, 2011). This scale has three domains: sensing (4 items; e.g., "I listen for more than just the spoken words"); processing (3 items; e.g., "I summarize points of agreement and disagreement when appropriate"); and responding (4 items; e.g., "I assure others that I am listening by using verbal acknowledgements"). Response options included a 7-point Likert scale ranging from "Never or almost never true" to "always or almost always true." We will

calculate the mean score for the total scale. Prior research shows Cronbach's alphas range from 0.88-0.90.[81]

3. **Self-efficacy for working with SGMY:** We assess participants' perceived abilities for working with LGBTQ high school students using 9 items adapted from the Gay Affirmative Practice Scale.[82] Originally for social work practitioners, we adapted this scale by using school-oriented words instead of therapy-oriented words (e.g., "students" instead of "clients"). Example items included "I am able to help LGBTQ students develop positive identities as LGBTQ individuals" and "I am able to challenge misinformation about LGBTQ individuals in the classroom." Response options included a five-point Likert scale ranging from "strongly agree" to "strongly disagree." We will calculate the mean score for the scale. In a prior study, Cronbach's alpha = 0.90.[81]
4. **Bystander intervention behaviors for bullying:** Two multidimensional scales (Teacher Bystander Intervention Model in Traditional Bullying and Cyberbullying[83,84]) measuring 5 subscales of bystander behaviors each: noticing the event (3 items), interpreting event as an emergency (3 items); accepting responsibility to help (3 items); knowing how to help (3 items); and implementing intervention decision (4 items). The psychometric properties of these subscales are good (Cronbach's alphas range=0.57-0.88). We will calculate average subscale scores. We will add items to these scales to specify SGMY-related bullying events using language from GLSEN's National School Climate Survey.[85]
5. **Self-efficacy of PLANTS' change objectives:** Given the limited research contained validated scales of behavior change pertaining to LGBTQ inclusive practices in schools, our team has developed items pertaining directly to the self-efficacy change objectives in PLANTS. Each question will be asked on a scale of 1-5 (1: not at all certain; 2: slightly certain; 3: moderately certain; 4: very certain; 5: extremely certain).
    a. **Provide interpersonal support and affirmation.** How certain are you that you are able to successfully: ask students about their chosen names? Use students' chosen names? Ask students about their pronouns? Use students' pronouns? use "reinforcing language" with students? "affirmations" with students? share about your personal connections to the LGBTQ+ community with your LGBTQ+ students?
    b. **Support LGBTQ+ students in meeting their basic needs.** How certain are you that you are able to successfully: offer safe locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? offer non-stigmatizing locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? Offer nearby locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? refer LGBTQ+ students to LGBTQ affirming outside-school resources?
    c. **Provide educational resources that are inclusive of LGBTQ+ students.** How certain are you that you can successfully: find LGBTQ+ resources? put LGBTQ+ resources where students can easily access them? defend LGBTQ+ inclusive curriculum? integrate LGBTQ+ people, history, or issues into your coursework? Implement LGBTQ+ inclusivity in your curriculum? assess curriculum for LGBTQ+ inclusivity? inform students about LGBTQ+ resources?
    d. **Provide safe spaces for LGBTQ+ students.** How certain are you that you can successfully: wear iconography of LGBTQ+ pride and acceptance? display iconography of LGBTQ+ pride and acceptance for their rooms/offices? display iconography of LGBTQ+ pride and acceptance in common areas? observe LGBTQ+ related holidays and events? Establish a gender-sexuality alliance? Oversee a gender-sexuality alliance? be a Point Person? Provide LGBTQ+ students with a safe space?

e. **Promote acceptance of LGBTQ+ students among non-LGBTQ+ students.** How certain are you that you can successfully: politely correct people who use students' incorrect names? politely correct people who use students' incorrect pronouns? teach students about LGBTQ+ terminology in a positive manner? provide positive verbal reinforcement when non-LGBTQ+ students do something LGBTQ-inclusive?

f. **Prevent and reduce bullying, cyberbullying, and harassment of LGBTQ+ students.** How certain are you that you can successfully: define anti-LGBTQ+ bullying and harassment? implement classroom guidelines and meetings? intervene in anti-LGBTQ+ bullying and harassment? convene an anti-LGBTQ+ bullying task force when necessary? follow-up with victims and bystanders of anti-LGBTQ+ bullying? use non-confrontational ways to engage with perpetrators of anti-LGBTQ+ bullying? enforce clear consequences for people who bully others? explain to students why anti-LGBTQ+ bullying is harmful and wrong? advocate for evidence-based bullying prevention programming?

g. **Evaluate and advocate for LGBTQ+ inclusivity and protections in school policies.** How certain are you that you can successfully: obtain LGBTQ+ students' feedback about the inclusivity and protections for LGBTQ+ students in existing school policies? Amend/dismantle school policies and practices that negatively affect LGBTQ+ students? evaluate how inclusive and protective their school policies are for LGBTQ+ students and staff? share statistics to advocate for LGBTQ+ inclusivity and protections in school policies? share personal stories to advocate for LGBTQ+ inclusivity and protections in school policies? use required methods (e.g., school board propositions) to create/amend school policy? examine how well your school's LGBTQ+ related policies align with local, state, and federal school laws and policies?

h. **Maintain the confidentiality of LGBTQ+ students.** How certain are you that you can successfully: keep students' sexual orientations confidential? keep students' gender identities confidential? make students aware of mandatory reporting guidelines? assess students' safety concerns surrounding disclosure of their LGBTQ+ identity? establish or amend school policies that protect the confidentiality of students' sexual orientations and gender identities?

6. **Social desirability bias:** We will assess school staff's social desirability biases using the short form of the Marlowe-Crowne Social Desirability Scale.[86] The short form of the scale uses 13 self-reported measures of individual characteristics, such as personality and attitudes, to understand the social desirability bias of individuals.[87] The psychometric properties of this scale have shown it to be reliable compared to the Social Desirability Scale developed by Edwards; its use has been studied for both adolescents and adults.[88] We will calculate the social desirability biases of each school staff member based on their responses to the measures during the baseline survey.
7. **Existing school programs:** We will ask each staff member about their school's presence and types of bullying prevention programs, substance use prevention/treatment program, mental health prevention/treatment programs, intervention programs and policies for SGMY.

Staff Follow-up Survey (Time 2)

1. **Demographics:** We will re-ask questions pertaining to demographics that were skipped in the baseline survey.
2. **Intervention acceptability, appropriateness, and feasibility:** Three of the primary outcomes of this study are intervention acceptability (perceptions that the intervention is tolerable); intervention appropriateness (perceived fit and relevance of the intervention); and intervention feasibility (the extent to which the PLANTS intervention is successfully used and executed). These outcomes are measured via three scales with strong psychometric properties: structural, substantive, known-groups, and

discriminant validity; good test-retest reliability (r's=.73-.88); good internal consistency among scientists, providers, parents of trans youth, and SGMY (α's=.84-.94); and 5th grade literacy levels. High school staff participants will complete surveys at the 4-month follow-up online survey. For intervention acceptability, participants will complete a short survey including the Acceptability of Intervention Measure (AIM). AIM has 4 items (e.g., "The PLANTS intervention was appealing to me") using a 5-point Likert-type scale from (1) "Complete disagree" to (5) "Completely agree." We will calculate a mean score for each participant. For intervention appropriateness, participants will complete a valid and reliable measure, the Intervention Appropriateness Measure (IAM). FIM has four items (e.g., "The PLANTS intervention was applicable") and uses a 5-point Likert-type scale, ranging from (1) "Complete disagree" to (5) "Completely agree." We will calculate a mean score for each participant. For intervention feasibility, participants will complete a short valid and reliable measure, the Feasibility of Intervention Measure (FIM). FIM has 4 items (e.g., "The PLANTS intervention was easy to use") and uses a 5-point Likert-type scale, from (1) "Complete disagree" to (5) "Completely agree." We will calculate a mean score for each participant.

3. **Intervention usability:** The fourth primary outcome of this study is intervention usability (perception that the intervention can be used effectively, efficiently, and satisfactorily). The 10-item System Usability Scale (SUS) has been shown be valid and reliable measure of program usability.[93] All items use a 5-point Likert-type scale, ranging from (1) "Strongly disagree" to (5) "Strongly agree". We will calculate scores for the total scale (0-100) as recommended.[94]
4. **Active-empathic listening skills:** We use the valid and reliable Active-Empathic Listening Scale containing 11 items (Bodie, 2011; Gearhart & Bodie, 2011). This scale has three domains: sensing (4 items; e.g., "I listen for more than just the spoken words"); processing (3 items; e.g., "I summarize points of agreement and disagreement when appropriate"); and responding (4 items; e.g., "I assure others that I am listening by using verbal acknowledgements"). Response options included a 7-point Likert scale ranging from "Never or almost never true" to "always or almost always true." We will calculate the mean score for the total scale. Prior research shows Cronbach's alphas range from 0.88-0.90. [81]
5. **Self-efficacy for working with SGMY:** We assess participants' perceived abilities for working with LGBTQ high school students using 9 items adapted from the Gay Affirmative Practice Scale.[82] Originally for social work practitioners, we adapted this scale by using school-oriented words instead of therapy-oriented words (e.g., "students" instead of "clients"). Example items included "I am able to help LGBTQ students develop positive identities as LGBTQ individuals" and "I am able to challenge misinformation about LGBTQ individuals in the classroom." Response options included a five-point Likert scale ranging from "strongly agree" to "strongly disagree." We will calculate the mean score for the scale. In a prior study, Cronbach's alpha = 0.90.[81]
6. **Bystander intervention behaviors for bullying:** Two multidimensional scales (Teacher Bystander Intervention Model in Traditional Bullying and Cyberbullying[83,84]) measuring 5 subscales of bystander behaviors: noticing the event (3 items), interpreting event as an emergency (3 items); accepting responsibility to help (3 items); knowing how to help (3 items); and implementing intervention decision (4 items). We will adapt these scales to specify SGMY-related bullying events using language from GLSEN's National School Climate Survey.[85]
7. **Self-efficacy of PLANTS' change objectives:** Given the limited research contained validated scales of behavior change pertaining to LGBTQ inclusive practices in schools, our team has developed items pertaining directly to the self-efficacy change objectives in PLANTS. Each question will be asked on a scale of 1-5 (1: not at all certain; 2: slightly certain; 3: moderately certain; 4: very certain; 5: extremely certain).

a. **Provide interpersonal support and affirmation.** How certain are you that you are able to successfully: ask students about their chosen names? Use students' chosen names? Ask students about their pronouns? Use students' pronouns? use "positive teacher language"? share about your personal connections to the LGBTQ+ community with your LGBTQ+ students?
b. **Support LGBTQ+ students in meeting their basic needs.** How certain are you that you are able to successfully: offer safe locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? offer non-stigmatizing locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? Offer nearby locations where gender diverse youth can use the bathroom (e.g., gender neural bathrooms, staff bathrooms)? refer LGBTQ+ students to LGBTQ affirming outside-school resources?
c. **Provide educational resources that are inclusive of LGBTQ+ students.** How certain are you that you can successfully: find LGBTQ+ resources? put LGBTQ+ resources where students can easily access them? defend LGBTQ+ inclusive curriculum? integrate LGBTQ+ people, history, or issues into your coursework? Implement LGBTQ+ inclusivity in your curriculum? assess curriculum for LGBTQ+ inclusivity? inform students about LGBTQ+ resources?
d. **Provide safe spaces for LGBTQ+ students.** How certain are you that you can successfully: wear iconography of LGBTQ+ pride and acceptance? display iconography of LGBTQ+ pride and acceptance for their rooms/offices? display iconography of LGBTQ+ pride and acceptance in common areas? observe LGBTQ+ related holidays and events? Establish a gender-sexuality alliance? Oversee a gender-sexuality alliance? be a Point Person? Provide LGBTQ+ students with a safe space?
e. **Promote acceptance of LGBTQ+ students among non-LGBTQ+ students.** How certain are you that you can successfully: politely correct people who use students' incorrect names? politely correct people who use students' incorrect pronouns? teach students about LGBTQ+ terminology in a positive manner? provide positive verbal reinforcement when non-LGBTQ+ students do something LGBTQ-inclusive?
f. **Prevent and reduce bullying, cyberbullying, and harassment of LGBTQ+ students.** How certain are you that you can successfully: define anti-LGBTQ+ bullying and harassment? implement classroom guidelines and meetings? intervene in anti-LGBTQ+ bullying and harassment? convene an anti-LGBTQ+ bullying task force when necessary? follow-up with victims and bystanders of anti-LGBTQ+ bullying? use non-confrontational ways to engage with perpetrators of anti-LGBTQ+ bullying? enforce clear consequences for people who bully others? explain to students why anti-LGBTQ+ bullying is harmful and wrong? advocate for evidence-based bullying prevention programming?
g. **Evaluate and advocate for LGBTQ+ inclusivity and protections in school policies.** How certain are you that you can successfully: obtain LGBTQ+ students' feedback about the inclusivity and protections for LGBTQ+ students in existing school policies? Amend/dismantle school policies and practices that negatively affect LGBTQ+ students? evaluate how inclusive and protective their school policies are for LGBTQ+ students and staff? share statistics to advocate for LGBTQ+ inclusivity and protections in school policies? share personal stories to advocate for LGBTQ+ inclusivity and protections in school policies? use required methods (e.g., school board propositions) to create/amend school policy? examine how well your school's LGBTQ+ related policies align with local, state, and federal school laws and policies?
h. **Maintain the confidentiality of LGBTQ+ students.** How certain are you that you can successfully: keep students' sexual orientations confidential? keep students' gender identities

confidential? make students aware of mandatory reporting guidelines? assess students' safety concerns surrounding disclosure of their LGBTQ+ identity? establish or amend school policies that protect the confidentiality of students' sexual orientations and gender identities?

8. **Social desirability bias:** We will re-ask questions pertaining to social desirability bias that were skipped in the baseline survey.

Staff Follow-up Interview (Time 3)

The purpose of this interview is to better understand trial and intervention implementation. Interview domains and questions are guided by the Consolidated Framework for Intervention Research (CFIR). Question domains include:

- **Intervention characteristics:** Relative advantage, adaptability, complexity, design quality and packaging
- **Outer setting:** External policies and incentives
- **Inner setting:** Structural characteristics, networks and communications, culture, implementation climate, tension for change, compatibility, relative priority, goals and feedback, learning climate, readiness for implementation, leadership engagement, available resources
- **Characteristics of individuals:** Knowledge and beliefs about the intervention, self-efficacy, individual stage of change
- **Process:** Opinion leaders, champions

PLANTS Course-embedded Questionnaires

Throughout the PLANTS program we will embed “Confidence Checks” and “Feedback” questions. Results from these items will be descriptively summarized and presented.

8.2 Safety Assessments

In each staff survey, we will assess the following variables. In addition to the questions below, we will also leave open-ended text boxes so people can provide more detail on the incident.

Variables	Description	Levels/range	Justification
Parent backlash	Contact from disgruntled parents/guardians of students because LGBTQ+ inclusivity is in the classroom	Yes/no + Frequency	Parents may not be comfortable with the education their children are receiving and ask questions that educators may not be comfortable or feel safe answering.
Social media backlash	People attack school staff or the school for supporting LGBTQ+ youth	Yes/no + Frequency	This is happening all over the country
School board backlash	School board gets upset or concerned about staff supporting LGBTQ+ youth	Yes/no + Frequency	This is happening all over the country
Suspension or removal from employment	Staff receive negative consequences from employer about supporting LGBTQ+ youth	Yes/no + Frequency	This is happening all over the country

Censorship of LGBTQ+ literature/history/stories or removal of books with LGBTQ+ representation from school libraries.	Promotion and integration of LGBTQ+ issues, history, stories into the school curriculum could lead to attempts to censor that information by parents, school boards, and higher ups in the education system. Oftentimes this has been justified as avoiding “controversial/political topics" in schools. There is the possibility that teachers who teach about “controversial/political” topics could be silenced via threats of losing their jobs.	Yes/no + frequency/quantity	This is happening throughout the country
Emotional discomfort with PLANTS	Staff are uncomfortable with the training program.	Likert 5-point scale + Open-ended	Some topics may provoke discomfort.

Study team members will have contact staff and will be able to report adverse events in the appropriate case report form. In the post-trial interviews, we will interview a subset of participants who reported experiencing adverse events. We will ask questions about the AE during interviews, which will help support knowledge of the study intervention effects. We will follow-up with individuals if the event is severe (see the MOP).

8.3 Adverse Events and Serious Adverse Events

8.3.1 Definition of Adverse Events

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

8.3.2 Definition of Serious Adverse Events

An adverse event is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.3.3 Classification of an Adverse Event

8.3.3.1 Severity of Event

Dr. Coulter will classify the severity of an adverse event which is a qualitative assessment of the degree of intensity, and will be classified as follows:

- Mild: Does not impact (in any way) the participant’s functioning or well-being at work.

- Moderate: Impacts the participant's functioning or well-being at work but is not life-threatening, incapacitating, or job-loss threatening.
- Severe: Severely affects well-being at work; employment termination; lawsuit; fatal, life threatening, permanently disabling; severely incapacitating and/or prolongs inpatient hospitalization.

8.3.3.2 Relationship to Study Intervention

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained investigator based on temporal relationship and their scientific judgment. The degree of certainty about causality will be graded using the categories below.

- Related – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- Not Related – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

8.3.3.3 Expectedness

Dr. Coulter will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 Time Period and Frequency for Event Assessment and Follow-Up

An unsolicited AE would occur without any prompting or in response to a general question such as "Have you noticed anything different since you started the study?" A solicited AE is one that is specifically solicited such as "Have you experienced any problems at work since starting this study intervention?"

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel via surveys, Live Zoom events, interviews, or contact with a study participant or upon review by a study monitor. We will solicit information about AEs directly in surveys and interviews.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, the PI assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a report), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any adverse event that is present at the time that the participant is screened will be considered as baseline and not reported as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The PI will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

8.3.5 Adverse Event Reporting

Any adverse events will be reported to the Office of Human Research Subjects Protection in accordance with the policy described in Chapter 3, Section 3.3 of the University of Pittsburgh's IRB Reference Manual. All adverse events will be reported to Funding IC at the National Institute of Health.

8.3.6 Serious Adverse Event Reporting

If any serious adverse event occurs (death, life threatening, new serious, or permanent disability), it will be reported within 48 hours to the IRB. Specific information that will be recorded on the study protocol's adverse event form will include details of the adverse event, treatment required for the event, the participant's condition after the event, an estimate of the extent of injury, and ways to prevent similar events from occurring in the future. SAEs and unanticipated events which are considered "at least possibly related" during the treatment and follow-up phases must be reported to the local IRB and to the NIAAA project officer within 48 hours of knowledge of the SAE. All other SAEs and unanticipated events must be reported within the time period mandated by the local IRB.

8.3.7 Reporting Events to Participants

N/A

8.3.8 Events of Special Interest

N/A

8.3.9 Reporting of Pregnancy

N/A

8.4 Unanticipated Problems

8.4.1 Definition of Unanticipated Problems

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 Unanticipated Problems Reporting

The Principal Investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and to the funding agency within 48 hours of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and to the funding agency within 10 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 14 days of the IRB's receipt of the report of the problem from the investigator.

8.4.3 Reporting Unanticipated Problems to Participants

N/A

9 STATISTICAL CONSIDERATIONS

9.1 Statistical Hypotheses

Below we describe our formal statistical analysis plan. At ClinicalTrials.gov, this plan will be posted publicly and registered before the study begins. We also plan to publish a protocol paper.

Primary Endpoint Hypothesis:

We hypothesize that high school staff will rate the PLANTS intervention as having high acceptability, usability, appropriateness, and feasibility in the follow-up survey. We based our benchmarks of success (which are means >3.75 out of 5 for FIM, AIM, IAM and > 70 out of 100 for SUS) on prior research.[95-103]

Secondary Endpoint Hypotheses:

Regarding trial implementation and PLANTS safety, we hypothesize: school staff will have high participation rates in the study (≥50% consent); school staff will have a low attrition rate for the follow-up survey (≤25% drop-out); high school staff in the PLANTS arm will have high intervention demand (≥75% adhere to the intervention protocol); and high school staff in the PLANTS arm will have low adverse event prevalence (≤20% of PLANTS participants will report adverse events).

We hypothesize that participants in PLANTS will report greater active-empathic listening, greater self-efficacy for supporting, affirming, and protecting SGMY, and greater positive bystander intervention behaviors for bullying in follow-up surveys than participants in the active control arm.

9.2 Sample Size Determination

Primary Endpoints

To adequately evaluate the primary endpoints, we need precise estimates of acceptability, appropriateness, and feasibility. We calculated our sample size based on our primary outcomes, a 5% error rate, and best practices for feasibility studies.[104-111] The median number of teachers at each MetroWest Region high school is n=86. With 4 schools in our sample, we anticipate inviting a total ≥344 school staff to participate in the pilot study. Assuming 50% agree to participate, 50% of participants are in the PLANTS study arm, and 75% of PLANTS participants complete the follow-up survey (reduced n=65), we can estimate 95% CI widths ≤0.33 for AIM, IAM, and (based on the largest upper CI limit of the AIM, IAM, and FIM standard deviations[89,112]) and ≤10.1 for SUS.[113,114] Such precision levels are sufficient.

Secondary Endpoints

We anticipate inviting at least 344 school staff to participate in the pilot study, and assuming 5% type I error rate, we will be able to estimate a 95% confidence interval width of no more than 0.11 for the participation rate. Assuming a participation rate of 50% (n=172), we will be able to estimate a 95% confidence interval width of no more than 0.15 for the attrition rate. Assuming half of the consenting participants are in the intervention arm (n=86), we will be able to estimate 95% confidence interval widths of no more than 0.21 for the proportion of school staff who adhere to the PLANTS intervention and for the proportion of school staff who report adverse events.

Qualitative Endpoints

For qualitative interviews, we aim to interview people with a diversity of intervention fidelity, acceptability, usability, feasibility, and appropriateness. This is an exploratory interview study in nature, so idea generation and exploration are the goals (not thematic saturation). We aim to interview PLANTS (n=20-30) and EMAILS (n=10-20) participants, and these sample sizes will provide us with ample information about the CFIR domains.

9.3 Populations for Analyses

We will analyze data from the following populations:

- PLANTS Primary Endpoint Population: This includes all participants who were in the PLANTS study arm and have AIM, IAM, or FIM data as reported in the follow-up survey.
- Intention-to-Treat (ITT) Analysis Population: This includes all staff participants who enroll in the study.
- Per-Protocol Analysis Population: This includes all staff participants who enroll in the study.
- PLANTS Condition Population: Staff participants in the PLANTS arm.
- EMAILS Condition Population: Staff participants in the PLANTS arm.
- Qualitative Interview Population: Staff who participate in interviews.

9.4 Statistical Analyses

9.4.1 General Approach

With the ITT Analysis Population, we will calculate baseline descriptive statistics by study arm using means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. We will test for differences in potential confounders between intervention and control arms using baseline staff- and school-level data with Rao-Scott chi-square tests for categorical variables and linear mixed models (with a random effect for school) for continuous variables (models adjusting for the clustering of staff within schools). Secondary analyses will adjust for imbalances between arms. For previously validated scales, we will report

internal consistency via Cronbach's alpha for continuous scales. For newly created items, we will conduct exploratory factor analyses to examine the dimensions of our outcomes as well as internal consistency using baseline surveys. We will use the most recent version of Stata. All tests are two-tailed and α=0.05. Given the small sample size and pilot nature of these analyses, we will not perform any corrections for multiple tests.

Regarding qualitative analyses, we will transcribe, de-identify, and quality check all data.[115-118] We will perform qualitative analyses in Dedoose.[119] We will use CFIR as a guiding framework. Two qualitative coders will independently read interviews and compare coding until they agree they are on the same page. Once the coders, we will create a final codebook with definitions, rules, and examples for each code.[117,118] Two coders will then recode all data using the final codes. We will calculate inter-rater reliability (i.e., Kappa statistic) to examine code application between coders.[120] Coders will discuss any discrepancies until they reach agreement; Dr. Coulter will resolve disagreements.[117,118] We will use either a qualitative descriptive coding approach[121] (wherein we describe and count the number of code applications) or axial coding[122] (wherein we combine inductive codes into broader categories to define emerging patterns or themes). We will identify and interpret patterns in the data using a thematic analytic approach.[123]

9.4.2 Analysis of the Primary Endpoints

To answer our primary research question, we use best practices for pilot/feasibility studies.[104-111] Thus, we will analyze our primary outcomes using descriptive statistics.[104-111] We will not correct for multiple tests.[104-111] AIM, IAM, and FIM are calculated as an average of their 4 respective items in the follow-up survey. We will calculate SUS as recommended. Among people in the PLANTS primary endpoint population, we will calculate means and 95% CIs for participants' responses to the FIM, AIM, IAM, and SUS.[89] Our benchmarks of success are means > 3.75 out of 5 for AIM, IAM, FIM and scores > 75 out of 100 for SUS.

9.4.3 Analysis of the Secondary Endpoints

Hypothesis: School staff will have high participation rates in the study (≥50% consent).

The Participation Rate equals the number of school staff who consent to participate divided by the total number of school staff who are invited. We will calculate an overall participation rate with a 95% confidence interval.

Hypothesis: School staff will have a low attrition rate for the follow-up survey (≤25% drop-out).

The Attrition Rate equals the number of school staff who failed to complete the follow-up survey divided by the total number of school staff who were consented. We will calculate an overall rate with a 95% confidence interval.

Hypothesis: High school staff in the PLANTS arm will have high intervention demand (≥75% of enrolled participants will adhere to the PLANTS intervention).

Intervention Demand will be a variable ranging from 0-100%. Investigators assess PLANTS adherence, which is a composite variable ranging from 0% to 100%, comprised of 55% for module completion (based on the number of completed items divided by the total number of items offered) and 45% for Live Zoom Event attendance (where each event is 15%). These proportions are based on approximate time allocations.

Adherence is reflected by a score of 100%. We will calculate an overall adherence rate among PLANTS participants with a 95% confidence interval.

Hypothesis: High school staff participants in the PLANTS arm will report pre-post improvements in active-empathic listening, self-efficacy for supporting, affirming, and protecting sexual and gender minority youths, and positive bystander intervention behaviors for bullying.

To examine the pre-post changes in high school staff outcomes, investigators will first use descriptive statistics, such as means and percentages at each timepoint within arms. To test for within-arm statistical significance, investigators will use linear mixed models for continuous outcomes and generalized linear mixed models for binary outcomes, which account for within-school and within-person clustering using random effects. Investigators will estimate the intraclass correlations for within-school and within-person effects. These models will adjust for school size (*a priori* design variable).

Hypothesis: Participants in PLANTS will report greater active-empathic listening, greater self-efficacy for supporting, affirming, and protecting SGMY, and greater positive bystander intervention behaviors for bullying in follow-up surveys than participants in the active control arm.

We will use linear mixed models for continuous outcomes and generalized linear mixed models for binary outcomes—which account for within-school and within-person clustering effects (using random effects). We will estimate the intraclass correlations for within-school and within-person effects. Regression models will include a fixed term for school size (a priori design variable), intervention group (intervention or control), time (baseline or follow-up), and the interaction of intervention group × time (our variable of interest). The test of intervention effects on secondary outcomes will be primarily based on intent-to-treat estimates. We will estimate per-protocol effects in secondary models. If there are differences in potential confounders by intervention group, we will adjust for them in secondary multivariable analyses.

Additional Analyses

Participant bias assessment will compare staff participants' demographics (at baseline) to publicly available school-level data. We will report significant differences as potential validity threats.

Attrition bias assessment will compare staff respondents who completed follow-up surveys versus those who did not by baseline demographics and outcomes.

9.4.4 Safety Analyses

Hypothesis: High school staff in the PLANTS arm will have low adverse event prevalence (≤20% of PLANTS participants will report adverse events).

We will estimate the prevalence of adverse events by calculating the percentage and 95% confidence interval of school staff that reported adverse events experienced any time after PLANTS deployment and use.

Additional Analyses

We will report overall frequency (adding together all the adverse events reported) of adverse events by study arm, followed by the frequency of all types of adverse events by study arm. We will also report the total number of adverse events by severity and average duration, overall and by arm. We will also examine the frequency and percentage of school staff reporting adverse events (which will be counted once only for a given participant). We will also calculate adverse events by school level. We will report study arm-specific percentages of schools that had staff who reported any adverse event and by each type of adverse event.

9.4.5 Baseline Descriptive Statistics

Study arms will be compared on baseline characteristics (e.g., demographics) using descriptive statistics. We will test for differences in potential confounders between intervention and control arms using baseline staff- and school-level data with Rao-Scott chi-square tests for categorical variables and linear mixed models (with a random effect for school) for continuous variables (models adjusting for the clustering of staff within schools).

9.4.6 Planned Interim Analyses

N/A

9.4.7 Sub-Group Analyses

Primary endpoints will be analyzed based on gender, sexual identity, race/ethnicity, intrinsic religiosity, religious attendance, religious activity, and role in school. Average score differences will be estimated using mixed models with demographic characteristics as predictors and the primary endpoints as outcomes, adjusting for school clustering.

Secondary endpoints of PLANTS efficacy will be analyzed based on gender, sexual identity, race/ethnicity, intrinsic religiosity, religious attendance, religious activity, and role in school (i.e., effect modifiers). Multivariable models will contain the 3-way interaction term, all 2-way interaction terms, main effects of time, study arm, the potential effect modifier, and any variables that meaningfully differ between study arms at baseline. We will conduct both intent-to-treat and per-protocol analyses. A significant 3-way interaction suggests the presence of intervention effect heterogeneity. Following the approach of Kraemer[124,125] to focus on effect size derivation, we will use Stata's postestimation "margins" command to probe the 3-way interaction terms to provide simpler meaningful results.

9.4.8 Tabulation of Individual Participant Data

Individual participant data will be examined and presented in ways that fully protect participants' privacy and anonymity.SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.5 Regulatory, Ethical, and Study Oversight Considerations

9.5.1 Informed Consent Process

9.5.1.1 Consent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention. The following consent materials are submitted with this protocol:

- Screener Consent
- Informed Consent for Trial Participation
- Interview Consent

9.5.1.2 Consent Procedures and Documentation

Informed consent will be self-administered in REDCap using the e-Consent module. Informed consent is only offered in English because school staff are required to read English.

9.5.2 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants and funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to the study's schedule of activities.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies.

9.5.3 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor, and the sponsor and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator. The study site will permit access to such records.

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored in Pitt's OneDrive. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by sites and their research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived via University of Pittsburgh regulations and policies.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies: It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific

study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality: To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in *45 CFR Part 75.303(a)* and *NIHGPS Chapter 8.3*, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

9.5.4 Future Use of Stored Data

Data collected for this study will be analyzed and stored at the University of Pittsburgh. After the study is completed, the de-identified, archived data will be stored at the University of Pittsburgh, for use by other researchers including those outside of the study via request.

9.5.5 Key Roles and Study Governance

Principal Investigator
Robert W.S. Coulter, PhD, MPH, Assistant Professor
University of Pittsburgh
130 DeSoto Street, Pittsburgh, PA 15261
1-412-624-0647
Robert.ws.coulter@pitt.edu

The Executive Committee consists of Dr. Robert Coulter (PI), Dr. Elizabeth Miller (Co-Investigator, pediatrician scientist) and Dr. Kaleab Abebe (Co-Investigator, biostatistician).

9.5.6 Safety Oversight

There are low risks associated with participation in the proposed study. We include an Internal Safety Executive Committee. Safety oversight will be under the direction of the Safety Executive Committee composed of individuals with the appropriate expertise, including LGBTQ+ health, biostatistics, and pediatrics.

This group will meet monthly and confer on an as-needed basis when adverse or difficult events occur (within 48 hours).

9.5.7 Clinical Monitoring

N/A

9.5.8 Quality Assurance and Quality Control

Our team will perform internal quality management of study conduct, data collection, documentation, and completion. We will follow a common quality management plan. Quality control (QC) procedures will be implemented as follows:

Informed consent: Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data: Data will be initially captured in REDCap.

Intervention Fidelity: Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations: The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

9.5.9 Data Handling and Record Keeping

9.5.9.1 Data Collection and Management Responsibilities

Data collection will be the responsibility of the trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All data will be completed in REDCap in a neat, legible manner to ensure accurate interpretation of data. Clinical data (including adverse events) will be entered into REDCap, a 21 CFR Part 11-compliant data capture system provided by the University of Pittsburgh. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate.

9.5.9.2 Study Records Retention

Study documents will be retained for a minimum of 2 years after the last approval of a marketing application in an International Council on Harmonisation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

9.5.10 Protocol Deviations

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly. Some expected deviations, such as loss-to-follow-up or intervention nonadherence, will not be reported.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.
- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 3 working days of identification of the protocol deviation, or within 3 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, reported to NIAAA Program Official. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

9.5.11 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers by contacting the PI. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

9.5.12 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with NIAAA has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

9.6 Additional Considerations

9.7 Abbreviations and Special Terms

AE	Adverse Event
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
CRF	Case Report Form
DHHS	Department of Health and Human Services
EMAILS	E-learning to Maximize Academic Inclusion of LGBTQ+ Students
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ITT	Intention-To-Treat
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer, and More
MOP	Manual of Procedures
NCT	National Clinical Trial
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
PLANTS	Providing LGBTQ+ Adolescents with Nurturance, Trustworthiness, and Safety
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SGMY	Sexual and gender minority youth
TIDieR	Template for intervention description and replication
UP	Unanticipated Problem
US	United States

9.8 Protocol Amendment History

N/A

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