

Study Title: Efficacy of a Multi-level School Intervention for LGBTQ Youth**Study Procedures****Background**

Sexual and gender minority (SGM; e.g., lesbian, gay, bisexual, transgender, queer) adolescents experience victimization in schools at much higher rates than their peers. Studies, including meta-analyses, have found that gay and lesbian students are 8 to 10 times more likely to be victimized in school than heterosexuals, with rates even higher among transgender youth. Victimization comes from not only other students but also teachers and administrators. This bias-based victimization, part of what is commonly known as minority stress, has been associated with poor behavioral health outcomes for SGM adolescents. This includes disparate rates of depression, anxiety, self-harm, and suicidal ideation and attempt in sexual minority adolescents, with even stronger disparities found among gender minority adolescents. Even compared to similarly victimized non-SGM peers, victimized SGM adolescents report significantly higher rates of suicidality.

Studies also indicate that SGM victimization is more common in schools that lack protective policies and resources such as gender/sexuality alliances (GSAs), SGM-specific antibullying policies, teacher/staff training, and openly supportive allies. When schools lack SGM bullying policies, SGM students are more likely to report suicidality than peers in schools with these policies. We assert that any intervention for SGM youth must simultaneously (a) help SGM youth cope with minority stress and (b) work to reduce the likelihood of future victimization by addressing school-level factors. Thus, it is concerning that a recent review found there are no determinative studies, such as RCTs, of the efficacy of school-based interventions for SGM youth.

Objectives

To fill this gap, we have developed a first-of-its-kind school-based intervention for SGM youth, *Proud & Empowered!* (P&E). The multi-level program was developed over the last 9 years through (a) psychometric, developmental, and acceptability studies funded by the NIH, foundations (Zumberge), and intramural sources; (b) a collaboration with three SGM youth drop-in centers, more than 100 SGM youth, and a dozen academic and clinical experts; and (c) an exploratory study (R21MD013971) to assess the feasibility and preliminary efficacy of the intervention. Given encouraging findings, we now propose to employ a large-scale randomized controlled trial (RCT) with 24 schools in Los Angeles to establish program efficacy. At intervention sites ($n = 12$), after the 10-session small group portion of the intervention with SGM youth is completed, peer allies (who are identified through a popular opinion leader model) are invited to participate in 4-session leadership program focused on changing SGM-related school climate. This is followed by student-led implementation of environmental change strategies at the school level focused on key domains of school climate described by

Thapa et al. (2013): safety, relationships, teaching and learning, and institutional environment. At the SGM student level, analysis will focus on the hypothesized mechanism of change (minority stress) and key behavioral health outcomes (depression, anxiety, PTSD, suicidality, substance use).

Change in school climate will also be assessed qualitatively using content analysis and observational methods in the intervention and post-intervention years. Our specific aims are to: 1) Determine participant-level efficacy of the intervention in an RCT with 24 schools, 2) Determine the schoolwide intervention effects on (a) reporting of minority stress and behavioral health outcomes among all SGM students and (b) perceptions of school climate (norms, attitudes, beliefs, bullying behaviors toward SGM youth, policies) among all students, and 3) Examine factors that may affect intervention success (e.g., fidelity of implementation, barriers or facilitators to implementation, school or student characteristics) to prepare the intervention for future dissemination.

Participants

1. Inclusion Criteria:

a) P&E Intervention Participants will be eligible to participate if they: 1) are students at the selected schools, 2) self-identify as lesbian, gay, bisexual, transgender, or any other non-heterosexual/cisgender identity, 3) speak English, and 4) are able and willing to provide assent/consent.

b) POL Allies/Make Space Participants will be eligible to participate if they: 1) are selected by the student body as a popular opinion leader (i.e. students who others look up to and consider good leaders), 2) are willing to be an ally to the LGBTQ community, and 3) are able and willing to provide assent/consent.

2. Exclusion Criteria: not meeting the inclusion criteria above

3. Special Population:

a) Minors: a waiver of parental permission for youth participation has been granted as there is concern that an IRB requirement of parental permission will put some sexual minority youth at risk regarding disclosure of their sexual orientation to their parents. This may then place these youth at risk for parental harassment, abuse, or expulsion from the parental home.

b) Pregnant Women: There is no risk to pregnant individuals due to participation. Therefore, we will allow those who are pregnant to participate in the study.

4. Limitations:

a) Although our feasibility trial had one school with 17 youth participating in the Proud groups, we found that this group was too large to manage effectively, and so we will limit the individual-level intervention group size to 12.

b) Given that this is a Los Angeles-based study with a limited budget and that the majority of schools in the Greater Los Angeles Area are English speaking, we will be restricting enrollment those who speak English.

Recruitment

LGBTQ Cohort: Students will be asked in the schoolwide Popular Opinion Leader (POL) survey (administered at the start of the school year) if they would be interested in hearing more about an intervention to improve the mental health of LGBTQ+ youth. Students who endorse interest will receive a short description of the study and if interested, can add their names to the subject pool. Youth will be told that if selected to participate in the program they will be contacted by Study Coordinator (Senese). In week three of the school year, we will randomly select 12 names at each school from the LGBTQ+ youth identified via these recruitment methods to be invited to participate in the LGBTQ+ youth cohort portion of the study.

POL Allies: To identify POL allies, we adapt methods used successfully in school-based anti-smoking campaigns. That is, the school wide surveys will also ask students to list the names of five students in their school who they “respect,” “look up to” and “consider good leaders”. The top twenty nominated students (POLs) will be contacted by Study Coordinator and screened for interest in participating in the school climate portion of the program. Other than the biostatistician, PI and Study Coordinator, no one will know the identity of these twenty individuals. This screening will assess for the student’s willingness to operate as an effective LGBTQ ally (e.g., willingness to provide visible support for SGM students), and students who are not interested, for any reason (related to topic or otherwise), will not be asked to participate. After screening each POL for interest in participation, Study Coordinator will then randomly select ten of the students identified to participate in the school-wide intervention portion of the study.

Methods

Proud & Empowered! Intervention: The proposed study is intended to rigorously test the efficacy of Proud & Empowered! (P&E) program in a large-scale RCT with 24 high schools across the Greater Los Angeles Area. Schools will be randomly assigned to an intervention or control condition. LGBTQ participants in the intervention schools will participate in P&E, whereas those attending control schools will complete only study survey measures during the study on the same timeline (all three time points) as the intervention schools.

LGBTQ Youth Procedures: For LGBTQ P&E participants, **measures (information on measures can be found in the *Instrumentation* section below) will be obtained at three time points: the beginning of the P&E intervention (September), after the intervention period (November), and at the conclusion of the school year (May).** LGBTQ+ youth participants will create a Unique ID that study team will use to link measures taken over time. Detailed information on

recruitment of LGBTQ youth participants can be found in the *Recruitment* section above. Names of LGBTQ youth participants who opt-in to participation will be shared with a school counselor. School counselor will ensure there is a time and space available for each student to meet for a 45-minute intervention session once per week for 10 weeks. The study activities will occur at the school during school hours and the school counselor will ensure students can discreetly participate in the intervention sessions by either 1) grouping participating youth into the same homeroom/advisory period where the intervention will administered by Study Facilitator/Study Coordinator, or 2) providing students with a counseling slip, allowing them to miss a class to participate in the intervention session. Schools will choose what works best for them. If option 2 is selected, intervention sessions will be staggered and run during a different class period each week so that participating youth do not miss the same class every week. USC study staff (Senese, Rhoades) will present adolescents with information sheets/assent, or informed consent from those aged 18 or older, and obtain verbal assent/consent in order to keep as little identifying information about LGBTQ+ participants as possible. Next, each LGBTQ participant will create a unique identification code that will be used in the participant's survey entries to link successive data points. Surveys will be self-administered on tablets, laptops, or cell phones. The data manager (Lopez) and study facilitator at the study site will track participant names and unique identifiers to keep track of the number of sessions attended by students (dosage). School staff will not have access to participant data from surveys. Youth who turn 18 during the study will complete an informed consent.

10-week P&E Intervention Procedures: A PDF of the intervention program can be found in "supporting documents" at the end of this application (Section 40.1). The 10-week protocol includes an introductory and data collection session, then sessions on Stress and Coping, Disclosure, Families, Peers and Friendship, School-related Stress, Spirituality/Religion, Social Justice, Health and Wellness, and a final Celebration and data collection session. Each session runs about 45 minutes and will be Facilitated by a MSW-level USC study staff. No data other than session attendance (dosage) and the confidential surveys will be collected during the intervention.

School Policy Scan

Content analysis. Schools will provide the research team with access to current copies of the student handbook and internal policy documents that relate to LGBTQ students (including non-discrimination, curricular inclusion, name and pronoun policies, student data privacy protocols, gender-neutral facilities, bullying interventions, and suicide prevention policies). Schools will also provide the research team with recent copies of history, social science, and health education curriculum. The research team will conduct qualitative content analysis of provided materials, the result of which will compose part of a pre-Making Space intervention "policy scan" of the school. This process will be conducted in the year that the school participates and will be repeated in the same schools in the year following participation to allow for assessment of changes in policy over the intervention year.

Observational site visits. Two members of the research team (Rhoades, O'Brien) will conduct an on-site visit of the school during the intervention year and in the following year. To prepare for

observational site visits, schools will be asked to provide a campus map, a list of student groups, and the meeting room for any LGBTQ-focused student group (such as Gender and Sexuality Alliances). During observational site visits, the research team members will walk around the school campus and take notes and photographs of campus facilities, such as classrooms and gender-specific facilities like restrooms and locker rooms. Notes and photographs will focus on the availability, accessibility, acceptability, and quality (AAAQ) of LGBTQ-specific or -relevant campus facilities, such as the classroom where an LGBTQ student group meets or the relative accessibility of gender-neutral restrooms vs gender-segregated restrooms. Photographs will only be used as reference material to compare change from year to year and will not include any images of students, school staff, or school names or branding (i.e. the school mascot in the background). Photographs will be labeled in records using the date and time of the site visit, such that schools will not be associated with photographs by name.

Make Space Intervention Procedures: A brief survey at the beginning of the year will be used to identify popular opinion leader (POL) allies who will participate in the school climate advocacy portion of the intervention. To identify POL allies, school surveys will ask students to list the names of five students in their school whom they respect, look up to, and consider good leaders. All surveys will be anonymous, so we will have no information about nominated students beyond their names and there will be no way to link nominated students to other identifying information, nor to the person(s) who nominated them. Other than the biostatistician, PI, and Study Coordinator, no one will know the identity of the nominated individuals. The top 20 nominated POLs will be contacted by the Study Coordinator and screened for interest in participating in the school climate portion of the program. This screening will assess each student's willingness to operate as an effective LGBTQ ally (e.g., willingness to provide visible support for LGBTQ students), and students who are not interested, for any reason (related to topic or otherwise) will not be asked to participate. Study Coordinator will then randomly choose 10 of the identified students who expressed interest in participation. Students who report interest and are chosen for participation will provide assent (or consent if they are 18+), similar to the process described for LGBTQ youth.

The Make Space intervention is a student leadership and advocacy intervention training program. The training will be facilitated by MSW-level USC staff and is completed over four, 45-minute sessions, similar to how the P&E intervention sessions will be run. The Make Space intervention includes modules on: Team Building, Exploring LGBTQ+ Issues, Capacity Building, and Youth Activism. LGBTQ youth who are part of the P&E intervention will take part in this training, as will those youth identified through the POL process. After the training, ongoing intervention planning and organizing sessions will be facilitated by MSW-level USC study staff focused on planning the school climate project chosen during the Make Space training. To support youth in identifying a school climate project for their school, USC study staff will provide participating youth with their schools' results of the policy scan. Youth will work with the USC study staff as frequently as is needed to implement the chosen activities. Similar to the P&E Intervention implementation plan, study activities will occur at the school during school hours and the school counselor will ensure students can discreetly participate in the intervention sessions by either 1) grouping participating youth into the same

homeroom/advisory period where the intervention will administered by Study Facilitator/Study Coordinator, or 2) providing students with a counseling slip, allowing them to miss a class to participate in the intervention session. Schools will choose what works best for them. If option 2 is selected, intervention sessions will be staggered and run during a different class period each week so that participating youth do not miss the same class every week. No data will be collected as part of our study during this portion of the intervention. Rather, change in school climate will be measured using the California Healthy Kids Survey (CHKS) that is already conducted at schools throughout the state. We will request CHKS data from WestEd. All data we receive will be anonymous third-party data and will be analyzed independently from all other study data.

Instrumentation

All measures are valid and reliable psychometric tests. As this is a quantitative study, all measures are closed-ended and survey-based. Information on each specific measure is as follows:

Sexual Minority Adolescent Stress Inventory: 54-item survey across 10 domains of minority stress. Assesses experiences of minority stress among adolescents. Each statement reflects past-30-day thoughts, feelings, and situations a person may have experienced.

Beck Anxiety Inventory: 21-item self-report assessment of anxiety symptoms.

PTSD Checklist for DSM-5 (PCL-5): 20-item self-report assessment of post-traumatic stress disorder (PTSD) symptoms which addresses all 20 DSM-5 symptoms of PTSD.

Beck Depression Inventory: 21-item self-report assessment of depression symptoms and severity of depression.

Adapted CSSRS Suicide Questions (Columbia Suicide Severity Rating Scale): Six items assessing current suicidality that were adapted from the longer, treatment-based Columbia Suicide Severity Rating Scale

Youth Risk Behavior Survey Substance Use Questions: Measures individual's usage of various substances in their lifetime and within the past 30 days as well as the ways in which individuals have used marijuana, tobacco, or nicotine in the past 30 days.

Coping Strategies Inventory: 16-item assessment measuring specific coping strategies people use in response to stressful events with each item assessing components of Problem Solving, Cognitive Restructuring, Social Support, Expressed Emotions, Problem Avoidance, Wishful Thinking, and Social Withdrawal.

California Healthy Kids Survey General Bullying and Gender Identity/Sexual Orientation-Based Harassment Module: Assesses students' perceptions of harassment experiences on school campus among the general student population in addition to bullying and harassment experiences on school campus specific of students who identify as, or are perceived to be, lesbian, gay, bisexual, transgender, questioning, or gender nonconforming.

Data Analysis

A series of analyses will be conducted to thoroughly investigate the program effects and its fidelity on outcomes of interest. First, a cluster-randomized repeated measures ANOVA will be used to examine the intervention effects on minority stress, behavioral health outcomes, and coping skills among the cohort of SGM adolescents who participate in the small group intervention and their control-school counterparts. Second, the school-wide intervention effects of reporting minority stress and behavioral health outcomes among all SGM students across all schools and school climate outcomes among all students across all schools will utilize multilevel regression analyses with mediation and/or moderation, to understand how participant-level and school-level characteristics influence these outcomes. Third, qualitative content and observational analysis by study staff will be used to conduct a baseline policy scan in the intervention year, inform Make Space participant activities, and evaluate change in policies over the course of the year.

Data Protection

All survey data will be coded using a unique code selected by each participant. Coded data will be held separately from all identifying data, such as recruitment information. Assent/consent will be obtained verbally in order to keep as little identifying information about LGBTQ+ participants and allies as possible. All contact information used for recruitment be destroyed at the conclusion of the study. Downloaded data will be stored on dual-authentication and password-protected computers. Only the PI and authorized study staff will have access to survey data. California Healthy Kids Survey data will anonymous third-party data shared by WestEd., and will be analyzed and held separately from all other study data.

Dissemination of Findings

The proposed study plans to consistently disseminate findings from study data and – if warranted – to provide broad access to the final intervention program. The dissemination plan aims to inform research on minority health, risk and protective factors among SGM youth. Research findings will also be disseminated through peer-reviewed journals, national conferences, and relevant compendiums of intervention research if possible (e.g., Cochrane).

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