

Study Protocol

Official Title: SOVA Ambassadors Community Setting

ClinicalTrials.gov ID (NCT number): NCT06066697

Date of document creation: 8/23/2023

Date of last modification: 9/24/2025

Scientific Background

Despite the significant mental health need in this age group, less than half receive treatment, initial treatment is delayed by 10 years. For anxiety, less than one-fifth use mental health services. Unmet treatment needs are even more concerning for lower-income youth and especially for racial/ethnic minorities who face even higher rates of depression and anxiety with fewer accessing care. These youth are disproportionately affected by adverse childhood experiences, traumatic experiences like discrimination, known predictors of poor adult functioning and contribute to disparities in mental health.

Racial/ethnic minority youth experience multiple barriers to obtaining mental health treatment. A systematic review found the most important barriers for young people overall are a lack of mental health knowledge and negative beliefs about treatment. Negative beliefs in racial/ethnic minority youth are complex, including factors such as wanting to appear tough in front of peers in African American males or not wanting to feel judged among Mexican youth. Youth also may have concerns mental health providers will lack cultural competence. Despite barriers, youth actively talk about experiences with depression and anxiety online and adolescents with unmet mental health needs more frequently use social media (SM) to seek support. While there are some concerns about SM the literature is mixed and moderated sites have been found to be helpful. A moderated SM site for adolescents with depression was highly usable and improved depression scores. Almost all (95%) adolescents have access to a smartphone; this does not vary by race or income. An online environment may be best suited to address health beliefs, as adolescents discuss their depressive symptoms online and use SM for identity exploration and social norms setting. The online environment, especially for racial/ethnic minority youth who are less likely to find help elsewhere, is a point of entry to talk about mental health and find support.

Partnership between SOVA research team and Focus on Renewal (FOR) community agency was formed as part of a CTSI sponsored Community Research Dissemination Challenge called WordOut. FOR provides summer workforce development program in the summer through Learn & Earn to the Sto Rox community where mean household income is \$25,000 and 28% of population is under 18. We administered a mental health curriculum covering various topics to a small group of 5 throughout, and large group of 25 at the end of program. We frequently offered participation in SOVA Peer Ambassador Program. Although youth expressed interest and practiced writing about mental health topics, none engaged in SOVA. FOR Learn & Earn Administrators gave feedback implementation of the program in their setting may improve if the program is introduced to them by other youth and advocates from their community, framed as a career development opportunity and not a mental health program. This informed us that prior to piloting SOVA in a community setting, we needed to take a more calculated approach to understanding what type of implementation strategy may be most effective. We utilized the process of implementation mapping with program administrators of workforce development programs, community leaders, and youth. We gained instrumental feedback from program administrators who facilitate workforce development programs and from our youth research partners. Briefly, the programs envision all yearly 1300 adolescent low-income participants would benefit from the psychoeducational content on the SOVA websites. Instead of the SOVA Peer Ambassador Program serving as a separate worksite to teach an employable skill of writing, the program administrators advised to provide the program as an adjunct activity available to any adolescent. This would also allow the SOVA content and the opportunity to enter the study to be

introduced to youth in multiple programs by our current youth junior researchers during the 6-week summer program, but be available as a longitudinal activity continuing even after the workforce program ends.

Study Objectives

Conduct a 1:1 pilot randomized controlled trial of the SOVA Peer Ambassador Program compared to attention control: brief psychoeducational independent assignments (i.e. reading SOVA articles and responding to open-ended questions without content creation and without peer interaction) (N=40) and evaluate feasibility of implementation strategy. All participants will have access to read content on the SOVA sites, but only Ambassadors will be able to log-in and invited to create content to share with others. We will examine participant adherence to intervention feasibility and acceptability of intervention, attention control, and implementation strategy. We will also assess acceptability of randomization, feasibility of recruitment, quality of training, trainer fidelity. We will generate preliminary data on outcomes, refine proposed study measurements, and assess preliminary effectiveness on resilience.

Study Design & Methods

This intervention trial will use a randomized trial design where each of the 40 participants is randomly assigned to one of two arms. Adolescents will be randomized at a 1:1 ratio (using randomized block sizes). The arms are SOVA Peer Ambassador Program and attention control: brief psychoeducational independent assignments.

1) conduct a pilot RCT comparing SOVA Peer Ambassador Program to attention control to understand feasibility and acceptability of Ambassador Program and accompanying implementation strategy. Adolescents will be randomized at a 1:1 ratio (using randomized block sizes). The primary endpoint is feasibility of the intervention. Expected Outcomes: We anticipate to learn if the SOVA Peer Ambassador intervention is feasible in a work readiness program setting for low-income adolescents consisting of mostly racial minority youth. We also anticipate to understand feasibility and acceptability of the attention control, implementation strategy, refine proposed study measurements, measure cross-over between groups, and find if there is preliminary effectiveness.

Adolescents who are interested in the study will provide their contact information to the research team and schedule a phone call or video call using Zoom if they prefer. We will also offer a link to appointment times so they can self-schedule this call. During the initial phone call adolescents will undergo screening procedures. Screening will involve inquiring about inclusion/exclusion criteria including asking the PHQ-8 measure and the GAD-7 measure. If inclusion/exclusion criteria is met, the research assistant will proceed to obtaining assent from the adolescent participants. Consent will be obtained from participants between 18 and 21 years. Once written assent/consent is obtained electronically and documented, the adolescent will be sent a baseline survey by text message via REDCap. Preferably, the adolescent will complete the baseline while the research assistant waits. If the adolescent prefers to complete it later, they will schedule a

follow-up call with the research assistant. Enrollment tracking will be conducted by using a RedCAP database which was successfully used by our research team in prior pilot efficacy studies of SOVA. We will use this database to keep track of all episodes of screening, consent, participant payment, and data point completion. Once they complete the baseline survey, then the research assistant will individually randomize them 1:1 (using REDCap) to either the SOVA ambassador arm or the Attention control arm.

If randomized to the SOVA Ambassador arm, the research assistant will provide an onboarding tutorial of the SOVA website contribution expectations. First, users will be asked to provide a username and email they would like to use for the website. The research assistant (RA) will create a login for them for the site. Participants will be asked to not post identifying information on the site and if they do, the site moderator will remove it. By creating a username, they will receive weekly email notifications about new posts. Participants will be notified that the researchers will use the website to track log-in frequency, log-in duration frequency, and website use. Also, any online text will be downloaded and qualitatively analyzed as well - unless the text contains identifying information - in that situation, this content will be permanently deleted. The Ambassador phone call will include information about compensation, blogging expectations, and procedures. There will be disclaimer about safety tips, and reminding participants this website is not an alternative to therapy or other treatment. The RA will share expectations of participating in the SOVA intervention which is to contribute content to the SOVA website at least once a month either by (1) writing a blog article. They can choose what they would like to write about and they will work with a SOVA team member who will edit and provide thoughtful feedback. They will be encouraged to • share personal experiences • share stories • give advice to other members (2) sending information (de-identified photo or video or music) to post. If they choose this option they will be encouraged to submit their own photo, video, or music to the website or they will be encouraged to write a response to a photo, video, or music piece. (3) being interviewed by the RA and then the RA "ghostwriting" an article about the interview which they pre-approve prior to it being posted. • If they choose this option they will get a series of topics and questions to choose from. e.g. people often can disagree – family, friends, partners, co-workers, or random people, offline or online, can you talk about how disagreements in your or others' lives can affect your stress or mental health? If randomized to the Attention Control arm, the research assistant will provide an onboarding tutorial of the expected contributions. This will include going to redcap form where they will receive a link to a SOVA article to read and a question for them to answer about what they read that will be accessible only to the study team. They will be asked to do this a couple times a month and will be reminded about their participation. The articles will be about mental health found on the website sova.pitt.edu. The question asked of the participants in this study arm will be open ended. An example of this will be: The article talked about different types of therapy. What types of therapy do you have experience with? If you do not have experience with the types of therapy which type of therapy do you think is most interesting? Then describe why or why not. Both arm participants will fill out online surveys via REDCap at baseline 6 weeks and 12 weeks. These surveys will take about 30 minutes to complete.

Eligibility Criteria

List the inclusion criteria:

Adolescents Ages 14 to 21 Can read and understand English Has completed 6th grade Scores at least 5 or greater on the PHQ-8 (depression) and/or 5 or greater on GAD-7 (anxiety) consistent with at least mild symptoms

List the exclusion criteria:

Adolescent no access to internet Has an intellectual or physical ability which prohibits reading text on the internet (can participate if able to use with assistance, e.g. can use text to speech) No active email account (can participate if plans to create one)

Statistical Considerations

Methods for sample size: Feasibility of the intervention will be established if an average of 2.3 articles are written per individual over the 12 weeks. This is because anticipating a SD of 0.5, that would give us a confidence interval width of 0.59 with a sample of $N = 20$. If results are very skewed, we will log transform any outliers. We have designated this sample size due to budgetary and programmatic constraints. Programs typically have 20 adolescents enrolled, so as we anticipate involving 2 programs, 40 total could be enrolled (20 in the intervention, 20 in the control).

Feasibility of the intervention will be established if an average of 2.3 articles are written per individual over the 12 weeks. This is because anticipating a SD of 0.5, that would give us a confidence interval width of 0.59 with a sample of $N = 20$. If results are very skewed, we will log transform any outliers. We have designated this sample size due to budgetary and programmatic constraints.

Data analysis: Our main goal is to understand feasibility of the pilot trial. Engagement with the SOVA Peer Ambassador intervention will be the main outcome and will be determined by the average number of articles written per participant at 12 weeks. We will use summary statistics (frequencies and percentages for categorical variables; means (standard deviations); and medians (ranges) for continuous measures) to describe measures. We will follow all recommendations from the pilot CONSORT statement. We will record number, percentage survey items missing and will summarize. We will capture proximal and main outcomes listed in Table 1 by study arm and assess change (from baseline to 6-week, and baseline to 12-week) using a linear mixed model for continuous outcomes. We will use a linear mixed model to estimate initial associations between treatment arm and resilience outcomes. The statistician conducting analyses will be blinded to randomized arm. Sample size: Feasibility of the intervention will be established if an average of 2.3 articles are written per individual over the 12 weeks. This is because anticipating a SD of 0.5, that would give us a confidence interval width of 0.59 with a sample of $N = 20$. If results are very skewed, we will log transform any outliers. We have designated this sample size due to budgetary and programmatic constraints. Expected Outcomes: We anticipate to learn if the SOVA Peer Ambassador intervention is feasible in a work readiness program setting for low-income adolescents consisting of mostly racial minority youth. We also anticipate to understand feasibility and acceptability of the attention control, implementation strategy, refine proposed

study measurements, measure cross-over between groups, and find if there is preliminary effectiveness.

Engagement with the SOVA Peer Ambassador intervention will be the main outcome and will be determined by the average number of articles written per participant at 12 weeks. We will use summary statistics (frequencies and percentages for categorical variables; means (standard deviations); and medians (ranges) for continuous measures) to describe measures. We will follow all recommendations from the pilot CONSORT statement. We will record number, percentage survey items missing and will summarize. We will capture proximal and main outcomes listed in Table 1 by study arm and assess change (from baseline to 6-week, and baseline to 12-week) using a linear mixed model for continuous outcomes. We will use a linear mixed model to estimate initial associations between treatment arm and resilience outcomes. The statistician conducting analyses will be blinded to randomized arm.