Study Protocol

Official Title: SOVA Ambassadors Community Setting

ClinicalTrials.gov ID (NCT number): not assigned

yet STUDY23020021

Protocol Date: 9/27/23

STUDY PROTOCOL:

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 a 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.

The surveys will contain:

At baseline only:
Demographics (age, gender, sexuality, race, ethnicity, education, socioeconomic status)
Adolescent Discrimination Distress Index
Acceptability of implementation strategy (open-ended) at baseline

At baseline, 6 weeks, and 12 weeks:
Rosenberg Self-Esteem Scale
Mental Health Self-Efficacy
Emotional/Information subscale from MOS Social Support Survey
Revised UCLA Loneliness Scale
Perceived Stigma
PHQ-8
GAD-7
Positive Youth Development Short Form

At 12 weeks only:
Acceptability of Intervention Measure at 12 weeks
Acceptability of randomization (open-ended) at 12 weeks

We will also collect data throughout the study on:
- The number of articles written per participant per month in the SOVA arm
- The number of submissions to questions on the REDCap form in the Attention control arm
- Cross over between groups
- Content that is contributed to the website or to the REDCap discussion questions

STATISTICAL ANALYSIS PLAN:

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.

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.