Study Protocol

Official Title: Social Media Intervention for Online Victimized Youth (SMILEY)

Clinical Trials.gov ID (NCT number):

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Scientific Background

A1. Online Victimization (OV; i.e., disparaging remarks, images, or behaviors that inflict harm through social media) is common and rates are disproportionately high among Black, Hispanic, and sexual and gender minority (SGM) adolescents. OV is estimated to impact 28% of US youth. Minority youth (including Black, Hispanic and SGM youth) are more likely to experience OV than their non-minority peers, attributable to a range of minority stress factors, including stigma, prejudice, and discrimination. Up to half of Black and Hispanic youth report past-year OV involving discrimination or exclusion based on race. SGM youth report triple the rate of OV than non-SGM youth.

A2. OV is associated with depression and suicidal thoughts and behaviors (STB), and interventions targeting OV can reduce these outcomes. OV has a direct association with depression and suicide risk. Forty percent of youth with OV have considered suicide. Recent meta-analyses showed that OV has a moderate effect on depression, with effect sizes increasing over the past decade, and medium to large pooled effect sizes in relation with STB. Longitudinal studies found OV predicts fluctuations in key risk factors for STB, yet this effect decreases over longer-term periods. This suggests a need to focus on acute experiences of OV, which we define as the past 3 months. A meta-analysis of randomized controlled trials (RCTs) of school-based interventions for youth impacted by traditional and online victimization, showed effectiveness in improving depressive symptoms. While these RCTs did not evaluate STB, intervention components included individual skills training to improve coping and reduce perceived stress: key elements of efficacious suicide prevention interventions. Thus, improving coping among adolescents who have experienced acute OV may decrease risk for worsening depression and STB. The impact is likely to be strongest among minority youth who have higher rates of OV and youth with depression and recent suicidal indicators, who are at higher risk of suicide.

A3. OV uniquely influences depression and STB compared to other forms of victimization. While in-person victimization is linked to depression and STB (and commonly co-occurs with OV), unique elements of online environments, including ubiquity, permanence, and anonymity, may render OV, and its consequences, more pervasive, harsh, and frequent. OV predicts greater exposure to negative online interactions, is associated with fluctuations in depressive symptoms and suicide risk, and contributes to depression and risk for suicidal ideation after controlling for in-person victimization (i.e., physical, verbal, and relational).

A4. Intervening to reduce OV in primary care holds promise to enhance outcomes. Despite recognition that OV is a growing problem linked to mental health, there are few health services for OV. Most are school-based, whereas OV predominantly occurs outside of school, thereby

limiting intervention reach. Pediatric primary care (PPC) is an ideal setting to extend the reach of OV-focused interventions. Screening for depression and STB risk occurs at all PPC well visits, providing the opportunity to identify youth victims of OV and then offer intervention, as aligned with practice guidelines suggesting primary care providers (PCP) intervene to prevent effects of victimization.

A5. Technology-based interventions can expand access to and reach of services. Most technology-based interventions for OV focus on detection and reporting of OV to caregivers, but few offer evidence-based resources to aid youth in coping with OV. Chatbots, a type of technology-based delivery modality that engages in automated conversation, could help improve coping with OV. Mental health chatbots are most acceptable and effective when used for self-management, an appropriate approach for adolescents, given their normative drive for increased autonomy. Chatbots can improve youth mental health self-management and connections to reliable resources for education, introduce coping skills and promote help-seeking within the environment where OV occurs.

A6. Proposed Theoretical Model. Frequency of OV and the resulting perceived stress have been linked to depression and STB .When perceived stress, referring to appraisal of the threat of OV based on one's internal state (e.g., affect, cognitions, arousal), is high in response to OV, youth are more likely to employ maladaptive coping strategies (e.g., self-blame, social withdrawal, considering suicide a viable option) and less likely to use adaptive coping strategies (e.g., seeking support from adults, using technology to block OV). Although positive aspects of social media use can promote resilience, problematic social media use (i.e., use that interferes with daily life) can increase exposure to OV, and potentially perceived OV-related stress. Even low frequencies of OV (i.e., once or twice) can negatively impact adolescents' mental health, and contribute to depressive symptoms and STB. Depressed youth are especially vulnerable to OV exposure, and face unique challenges to stress appraisal and adaptive coping that could exacerbate STB risk. Furthermore, given disproportionate rates of OV, perceived stress is especially prominent in minority youth. As described below, SMILEY targets social media self-efficacy and distress tolerance (mechanisms) with the goal of reducing the frequency of OV and stress associated with OV , and ultimately decreasing depression and STB risk .

A7. Intervention Components. Given the limited intervention research in this area, we propose rigorous qualitative work in Aims 1 and 2 to inform components of SMILEY. We chose two targets consistent with efficacious interventions for youth suicide risk: 1) individual coping skills training for adolescents and 2) caregiver education. Adolescent coping skills training will focus on improving adolescents' social media self-efficacy,distress tolerance, and social support skills. Social media self-efficacy refers to a person's perceived ability to reach desired outcomes in their social media interactions (i.e., skill in curating a positive and supportive online

environment). Education to promote social media self-efficacy may reduce OV frequency and decrease perceived OV-related stress by increasing adolescents' belief that they have the knowledge and skills to handle difficult situations (e.g., limiting interactions with friends who post hurtful comments) and promote resilience (e.g., increasing interactions with an emotionally supportive friend) in their online interactions. Distress tolerance skills refer to strategies that aid youth in withstanding negative emotional states; such capacity can decrease reactive emotional responses and increase capacity for proactive problem-solving and adaptive coping strategies. Social support skills refer to strategies that reduce youths' hesitancy in seeking support following online victimization experiences. 2) Caregiver education will complement adolescents' skills by equipping caregivers with strategies to support their child in healthier social media use. Caregivers' effective engagement in social media monitoring is protective against OV's negative impacts by offering youth emotional support and problem solving. We target active monitoring strategies that prioritize caregiver-child communication, support adolescents' autonomy, and foster their voluntary disclosure of online interactions, which are more effective than restricting social media use in reducing OV risk behaviors.

A8. Designing with implementation in mind. To maximize intervention effectiveness and uptake, we will design SMILEY in collaboration with end-users and context in mind to ensure that strategies and delivery are acceptable and can be implemented with youth likely to experience OV. We will employ CFIR to guide our initial qualitative inquiry, including perceived intervention barriers and facilitators, as well as post-intervention qualitative interviews We will ensure that SMILEY is perceived as feasible, acceptable, and appropriate by adolescents, caregivers, and providers, and that intervention content and delivery are tailored to victimized adolescents at-risk for STB, including Black and SGM youth; we will also collect preliminary data with Hispanic youth to inform future efforts to intervene with this population. To ensure a culturally informed intervention, we will use the ADAPT-ITT framework, which has been used for cultural adaptation of technology-based interventions. These include assessment and decision-making around adoption or adaptation of intervention content and delivery to meet unique needs of different groups. To ensure future scalability in PPC, we will design SMILEY to be acceptable to PCP without interfering with practice workflow.

C1. Preliminary Data

C1a. Acceptability of Chatbots among Minority Adolescents; Identification of Intervention Components. The investigators completed an ETUDES pilot to develop and test the acceptability and usability of an educational intervention delivered via a social media-based chatbot (REALBot) to optimize social media experience and reduce perceived social isolation among rural-living SGM adolescents. Through qualitative interviews, design sessions, and user testing,

REALBot was acceptable (Acceptability of Intervention Measure, AIM2 mean = 3.9/5) among 20 rural SGM adolescents, with good usability (Chatbot Usability Questionnaire, CUQ mean = 71/100) and satisfaction scores (Client Satisfaction Questionnaire, CSQ mean = 3.7/5). Adolescents identified areas for improvement, including additional content, more intuitive responses, and resources to connect with rural-based, SGM-specific organizations and persons. An investigator is conducting another ETUDES pilot to learn more about adolescents' experience with OV and what would be desired intervention targets. Qualitative interviews with 20 adolescents who experience OV, 10 caregivers, and 11 providers indicate that interventions to increase adolescents' distress tolerance and social media self-efficacy (see A7) and offer resources for caregivers on social media use and OV response are acceptable. These two pilot studies support the use of a chatbot for minority youth with these proposed targets.

C1b. Adolescents and Pediatricians Identify OV as a Problem and View Technology-Based Intervention as Acceptable. We gathered feedback from panels of adolescents (n=12) and PPC providers (n=5). Youth desired for OV to be addressed in PPC and felt a social media-based intervention would be helpful. Providers reported that OV was ubiquitous among youth, but identified barriers (e.g., time constraints) that inhibited their capacity for response. They felt an intervention for OV among youth, with emphasis on minority youth, would extend care they provide, and an automated intervention would be conducive to workflow.

Study Objectives

The objective of this research is to evaluate the feasibility and target engagement of an automated intervention delivered via a social media-based chatbot to reduce: a) online victimization (OV) frequency and perceived stress related to OV and b) depression severity and risk for suicidal thoughts and behaviors. The sample will include adolescents seeking primary care services who report depressive symptoms and online victimization (OV), with special attention to the needs of Black, Hispanic, and sexual and gender minority (SGM) youth.

Specific Aims:

Aim 1 (Pre-Intervention): Apply the Consolidated Framework for Implementation Research (CFIR) to identify perceptions about a chatbot-delivered intervention for OV through qualitative interviews with 40 individuals from 3 groups: adolescents (12-18 years), caregivers, providers (pediatricians, mental health clinicians). To inform intervention development and optimize feasibility, acceptability, and appropriateness, we will inquire about desired intervention targets, content, timing, and barriers and facilitators to implementation among youth, caregivers, and providers.

Aim 2 (Usability): Use ADAPT-ITT to iteratively develop and evaluate the Social Media Intervention for Online Victimized Youth (SMILEY). Informed by Aim 1, we will use rapid iterative design and usability testing through individual interviews with 3 cohorts of 5 victimized adolescents (n=15). We will systematically solicit feedback, evaluate, iterate and re-test SMILEY.

Aim 3 (Randomized Controlled Trial Pilot): Evaluate implementation (primary) outcomes, preliminary effectiveness (secondary outcomes), and equity across these outcomes (n=75; 2:1 randomization). We will compare SMILEY + brief psychoeducation vs. brief psychoeducation. H3a. Feasibility will be high (; completion >50%; attrition <20%, ratings >80%); acceptability (ratings >80%); appropriateness (ratings >80%) H3b. Youth who receive SMILEY will show greater reductions in OV frequency and perceived stress related to OV (. H3c. Improvements in depression severity and risk for STBs will be greater among youth randomized to SMILEY. H3d. Outcomes will be equitable by race and SGM identity. H3e. Exploratory (mechanistic): SMILEY will lead to decreased STBs risk through improved social media self-efficacy, distress tolerance, and social support.

Study Design & Method

Total number of subjects to be enrolled:

200.

Study Design:

Aim 1 will use a qualitative interview design.

Aim 2 will use a rapid iterative design and usability testing design.

Aim 3 will be a randomized clinical trial.

Primary and secondary study endpoints:

Primary Outcomes:

1. Attrition and engagement (rates of initiation, continued usage of intervention/sessions attended)
2. Number of logs
3. Intervention acceptability, usability, feasibility, & appropriateness measured by the FIM, AIM, and IAM
4. Concordance between chatbot questions and teen responses
5. Perceived satisfaction with the chatbot as measured by the Post-Study System Usability Questionnaire
6. Intervention usability as measured by the Chatbot Usability Questionnaire

Secondary Outcomes:

1. Frequency of online victimization measured by Online Victimization Screen and Social Media Use Scale
2. Distress of online victimization measured by Perceived Stress Scale
3. Depression severity measured by PHQ-9M
4. Suicidal ideation and behavior measured by the CSSRS
5. SMILEY intervention mechanism measured by Social Media Self-Efficacy Scale, General Self-Efficacy Scale, Distress Tolerance Scale, and Readiness to Change Rulers

Duration of an individual subject's active participation:
12 months.
Duration anticipated to enroll all subjects:
3 years.
Estimated date of study completion (complete primary analyses):

4/30/2027.

Informed Consent Protocol

How and when consent will take place:

Aims 1 and 2: Consent will take place verbally either in person or over the phone after performing some of the screening procedures but prior to the start of any research activities. Individuals conducting consent discussion will note the date and time verbal informed consent was obtained in study record. Providers will be asked to click next to consent in the survey software when completing the demographics survey.

Aim 3: Consent discussions will take place over the phone and a link with the electronic informed consent will be texted or emailed to the participant to view in advance and during the discussion. Written, electronic informed consent will be obtained due to the nature of the research study intervention in this Aim. Upon family completion of security questions and signature, a copy of the document is saved in the study record. A copy will also be downloaded and sent to participants if they have trouble downloading on their electronic device. Embedded within this consent is the consent for the exit interviews.

All Aims: When needed, the Pitt team will be involved with consent procedures for reliance site participants and will only use the specific reliance site consent documents and scripts in these cases.

Steps of Informed Consent:

Potential subjects will be informed that participation is voluntary, their decision whether to participate will not affect their care or relationship with Pitt/UPMC, and they may withdraw their consent and authorization at any time.

Consent for youth

If a family is approached in person at a healthcare appointment and they cannot make the decision to participate in enough time during their patient visit, the research staff can offer to make an appointment to complete screening and informed consent, as well as randomization and onboarding to the intervention for the RCT phase, at a later time and follow up with primary care provider on results of the intervention visit.

Minors may choose to participate in the interview session only, the design session only, or both. Verbal consents for each option have been developed

Consent for Providers & Caregivers/parents

At time a provider and/or caregiver is approached to participate in the study, they will be given ample time to make a decision to participate in the study. A phone call will be scheduled later to check in if provider or caregiver is interested if they cannot make a decision at first approach

by research staff. Research staff will make clear to providers that the study is voluntary and their participation will have no impact on their relationship with their employer. Research staff will make clear to caregivers that the study is voluntary and will have no impact on their relationship with their child's treatment provider or their own treatment at the institution from which they receive care.

Providers interacting with software survey can choose to not complete any or all portions of the survey by exiting the survey.

Ensuring Ongoing Consent:
During each follow up phone call, the assessor will ask the family if they are still interested in participating in the questions before collecting data. No participants from Aims 1 or 2 will be reconsented to participate in Aim 3.

Ensuring understanding of consent:
The research staff is trained to ascertain if the participant understands the consent and research activities. The research staff will answer any questions and explain informed consent concepts.

Research assessors are trained to ascertain if a participant is adequately understanding what is being said during the informed consent discussion and the research questions. Assessors will describe the study in wording to reflect appropriate literacy level of a teen and parent. Assessors will ask if the family has questions throughout the process and provide responses to questions as they arise.

Who will obtain consent:
The research involves minimal risk thus research staff and co-investigators trained in the process of informed consent will obtain informed consent for study participation and document that they certify they gave informed consent. Due to the nature of research activities an investigator will not practicably be available to participate in the consenting process of each subject. The study aims to enroll from at least 16 practices that conduct daily patient visits across the state. An investigator will be made available to those subjects who wish to speak to them.

Consent process for child participants:
For children under 18, the research staff will inquire if a parent is biological or adoptive and it will be documented. Adults without this status must present paperwork to the research staff

who will filter it to the IRB and legal counsel for review and verify if an adult is legally able to consent for the child. Participants will not be enrolled if unable to confirm legal guardianship.

The youth must assent and the parent provides their consent. The research staff will ask the youth if they understand what is involved in the research and if they are willing to participate. During Aims 1 and 2, the research staff will document the response of each the parent and child during this process and any questions that came up in the study database. During Aim 3, the child will provide written assent on electronic document.

If a child participant turns 18 while enrolled in the research:
If a child turns 18 years old, the research staff will use the addendum consent language to obtain consent of the individual as an adult for continued participation.

Eligibility Criteria

Inclusion Criteria:

Pre-Intervention Phase (Aim 1)

1. Adolescents age 12-18 in the ETUDES Center Pediatric Primary Care Study
2. Patients must screen positive for depression, PHQ-9-M score ≥ 11, and online victimization (OV). A positive screen will be OV that occurred "a few times" for at least one type of OV or "once" for at least two (see uploaded OV screen).
3. Caregivers of adolescents enrolled in the ETUDES Center Pediatric Primary Care Study
4. Providers, including pediatricians and mental health clinicians, in Center-affiliated practices

Usability Phase (Aim 2)

1. Adolescent users age 12-18 in the ETUDES Center Pediatric Primary Care Study
2. Patients must screen positive for depression, PHQ-9-M score ≥ 11, and online victimization (OV). A positive screen will be OV that occurred "a few times" for at least one type of OV or "once" for at least two (see uploaded OV screen).

Randomized Pilot Phase (Aim 3)

1. Adolescents age 12-18 in the ETUDES Center Pediatric Primary Care Study
2. Patients must screen positive for depression, PHQ-9-M score ≥ 11, and online victimization (OV). A positive screen will be OV that occurred "a few times" for at least one type of OV or "once" for at least two (see uploaded OV screen). Adolescents who do not have a Messenger account will be asked to download the app and create a Facebook account during intervention onboarding. If caregivers do not want their adolescents to have a Facebook account, then they can delete the Facebook account but still have access to Messenger. Note: For the qualitative aim, youth of interested caregiver participant does not have to participate for caregiver to be eligible. Caregivers can also opt out but can give youth permission to participate. Youth can also participate in both Aims 1 & 2.

Exclusion Criteria

Youth exclusion criteria-Aims 1-3

1. Conditions that might impair their ability to effectively deploy ETUDES interventions, including, bipolar disorder, current manic or psychotic episode, presence of a life-threatening medical condition requiring immediate treatment, intellectual or developmental disability precluding comprehension of study procedure

2. Referring providers will be advised that adolescents must be capable of safely participating, specifically that they do not need urgent medical or psychiatric treatment.

Caregiver Exclusion Criteria-Aims 1-3

1. Caregivers must be at least 18 years old
2. Caregivers will be excluded if they are not biological/adoptive parent or court appointed guardian who can present paperwork that they are able to consent for research for the youth involved in the study.

Provider Exclusion Criteria-Aims 1-3

1. Providers will be at least 18 years old
2. Providers who are not part of an affiliated ETUDES Center recruitment practice will be excluded