Georgia State University Research Protocol

1. Title

Full Title: Technology-Based Prevention for Adolescents in Primary Care: Pilot Randomized-Controlled Trial

Short Title: Teen Well Check Pilot RCT

Principal Investigator: Amanda K. Gilmore, PhD, School of Public Health, Georgia State University

Sponsor: National Institutes of Health (NIH); National Institute on Drug Abuse (NIDA)

2. External Collaborators: N/A

3. Background & Significance

A. Substance use, sexual assault (SA), and sexual risk behaviors (SRBs) are common among adolescents. Substance use is common among adolescents aged 14-18, with past year substance use being common in 2015[15]: 39.9% used alcohol, 23.7% used cannabis, and 10.5% used other illicit drugs. Substance use and sexual behavior often co-occur, with 22.4% of sexually active adolescents aged 14-18 using substances before their most recent sexual encounter[15]. Substance use before sexual activity impairs sexual decision-making[26]. Impairments in sexual decision-making can lead to a range of problematic behaviors from consensual SRBs to nonconsensual SA. SA and SRBs can result in mental health problems, sexually transmitted infections (STIs), unwanted pregnancies, and legal consequences. Adolescents are disproportionally affected. They are more likely to contract STIs[27], be sexually victimized[18], and experience hardship as a result of unwanted pregnancy[28]. Out of first SA victimization experiences, 42.2% occur before age 18[18] and 50% involve substance use by the perpetrator, victim, or both[32]. Estimated annual costs are $700 billion for substance use[33], $16 billion for the most prevalent STIs[34], $9.4 billion in taxes for teen pregnancy[35], and each rape costs $95,000[36]. Integrated prevention of these three major public health concerns would result in significant cost reductions to our nation. The nation has prioritized reducing SA in colleges[29] and military settings[30]. Improvements in adolescent health, safety, and healthcare costs would likely extend through adulthood and prevention needs to move earlier in the lifespan during the window of adolescents when sexual debut and substance use initiation occurs when rates of SA and SRBs soar.

B. Integrated prevention for substance use, SA, and SRBs is needed. An approach that aims to prevent/reduce substance misuse and use, SA victimization, SA perpetration, and SRBs in an integrated manner is more likely to work than targeting these interrelated problems separately or in partial combinations (i.e., integrated prevention of substance use and SRBs only). The scientific premise for integrating prevention draws from previous work outlining the interrelated nature of these health risk behaviors (e.g., substance use increases risk for SA and SRBs[37-39]; SA results in more SRBs[40-41] and substance use[42] yielding higher risk for sexual re-victimization[41]) combined with the multitude of theories linking substance use and sexual decision making (see Table 1). Integrated prevention of substance use, SA, and SRBs is needed due to the interrelated nature of these health risk behaviors. Integrated prevention approaches are more effective than targeting one health risk behavior by itself[51]. No preventative work has been done to date targeting these four co-occurring risk behaviors among adolescents in an integrated manner. Adolescence is a crucial time to target these specific health risk behaviors because it is when substance use initiation and sexual debut typically occurs and this period can be formative in the development of sex-related cognitions and behavior. If targeted early, it may be possible to prevent sexual behaviors driven by substance use and/or trauma symptoms. An integrated approach would not only be more likely to be effective, it reduces burden to adolescents by providing them with one brief prevention program targeting multiple pertinent concerns.

C. Primary care is an ideal setting to screen and intervene with substance-involved SA and SRBs. The most likely setting for adolescents to seek preventative healthcare is primary care because they are routine visits associated with preventative health in this setting. Recent health reforms have led to increased access to primary care services[20], suggesting that primary care settings will have an even wide reach to adolescents each

year. Health reforms also bring an increased priority for primary care to address a wide variety of issues. The American Academy of Pediatrics recommends that pediatricians complete screening for substance use, brief intervention, and referral to treatment (SBIRT) with all adolescent patients using developmentally appropriate tools[43]. SBIRT is effective and easy to disseminate. However, SBIRT is not universally integrated into primary care despite these recommendations. Further, a major weakness of SBIRT is that substance-involved SA victimization, SA *bystander intervention*, and SRBs are not assessed and integrated prevention programs for these problems are not provided. It is possible that routine assessment of SA and SRBs do not occur in primary care because they are sensitive topics. When assessed in research studies, only 4% of primary care physicians were aware of their adolescent patients' SA histories[44], and when referred for SA-related treatment, 93% of adolescents were interested in referrals and 81% went to their appointment[45]. Further, substance-involved SRBs have not yet been directly prioritized in this setting. It is imperative to provide this integrated SBIRT to adolescents where preventative health screening is routinely conducted.

D. Technology-based brief prevention programs are effective and preferred. Technology-based, brief prevention can be easily personalized, disseminated, and implemented without taking time away from physicians. Technology-based substance use assessments take half the time of provider-led assessments[46] with equal sensitivity/specificity within primary care settings among adolescents[47]. Existing technology-based prevention programs targeting substance-involved SA and SRBs separately[1,31] indicate this prevention delivery mode is feasible and effective. Further, adolescents prefer self-report screening[48].

E. The association between drug use and sexual health is understudied. Considerable research has found that alcohol use is clearly linked to increased risk of SA victimization[39], SA *bystander intervention*[49,50], and certain SRBs[26]. Considerably less attention focuses on the effect of drugs on SA and SRBs among adolescents. The effect of drug use on sexual decision-making is similar to that of alcohol use, with similar underlying mechanisms including cognitive impairments[52], substance use expectancies[53], and social normative beliefs[54]. Further, simultaneous use of alcohol and marijuana or alcohol and prescription drug use can exacerbate consequences associated with alcohol use alone[55]. Prevention programs targeting multiple substances and related SA and SRBs are needed for adolescents.

F. Scientific Premise: As described above, findings from basic research have consistently indicated that substance use, SA, SRBs are related in several ways[37-42]. Previous research has included rigorous experimental studies and prospective examinations. These consistent findings indicate a need for integrated prevention. National studies using rigorous sampling methodologies have yielded high rates of substance use among adolescents[15], high risk of SA[18], high risk of STIs[27] resulting from SRBs, and high rates of sexual activity after substance use[15]. The research base for the need of integrated prevention aimed at reducing substance use, SA, and SRBs for adolescents is strong. However, it has not yet been done. Further, it has not been done in primary care settings, where adolescents regularly seek preventative health care services and services are growing. An alternate consideration could be to implement such prevention in schools. However, given the direct health consequences, it is better served within a healthcare system where health consequences can be easily and efficiently addressed. Further, prevention programs that have targeted multiple health behaviors (i.e., alcohol use and SA or alcohol use and SRBs) tend to do so among adults and prevention is needed earlier in the lifespan. The proposed project draws

from the strengths of previous work and addresses the weaknesses by integrating evidence-based prevention and adapting it to adolescents within primary care settings in a technology-based delivery mode.

4-1. Goals

A. Using technology as a mode of prevention program delivery in primary care. Technology-based brief assessments and prevention programs can revolutionize healthcare by allowing for low-cost, easily accessible, low-burden, effective prevention in healthcare settings without taking away from routine healthcare provided by physicians. It is essential that interventions target multiple health behaviors. This intervention focuses on several high-risk health behaviors among adolescents including substance use, SA, and SRBs, all of which are associated with both physical and mental health problems. This patient-oriented career development award would allow the candidate to pursue this line of research and ultimately develop, test, and disseminate effective technology-based prevention programs related to substance use, SA, and SRBs within primary care settings.

B. Developing an intervention for use by real-world providers. Adolescents prefer to be asked questions regarding substance use using technology-based or pencil paper modalities compared to physician-led assessments[48]. Therefore, the development of a technology-based brief assessment and intervention would be an innovative method to provide services to patients with minimal added burden to providers. Further, this brief assessment and intervention will be informed by both providers and patients in community-based primary care settings, allowing for the specific needs of real-world providers to be addressed in the development of the intervention, thereby increasing the likelihood of dissemination and implementation ease.

C. Informing best practices for implementing assessment and prevention programs targeting SA and SRB in primary care settings. There is limited information in the assessment and prevention of SA and SRB among adolescents in primary care. The proposed research will not only provide feasibility and effect sizes for a future RCT to examine this intervention, it will also result in guidelines to implement substance-involved SA and SRBs within primary care settings guided by patient and provider preferences which could also inform other sensitive topics useful to assess in primary care settings.

4-2. Research Aims

A. Pilot Feasibility Trial

Participants: A total of 250 adolescents aged 14-18 will be recruited for a pilot feasibility trial. Adolescents will be screened using a screening assessment to determine if they are eligible for the study based on inclusion and exclusion criteria described below.

Method: After their Well Check Visit with their pediatrician, adolescents will be recruited virtually or in-person to complete a screening survey about substance use. Participants who are ineligible to complete the study because they did not use substances or have friends that use substances in the past year will receive the recommended reinforcing message for abstaining from substance use such as “You’ve made a smart decision not to use alcohol or drugs” to reinforce choice (adapted from the Alcohol Screening and Brief Intervention for Youth[63]). This “screening out” procedure will allow for adolescent substance non-use to be reinforced in the recommended manner to save time for providers by providing evidence-based care. Eligible participants (and their guardian) will be invited to meet with a research assistant either in person at the clinic, by phone, or in

a video conference meeting to discuss the research and obtain consent. While discussing informed consent, participants and their guardians will be informed of the sensitive nature of the prevention program and that the adolescent will complete the brief survey and then research procedures. Both the adolescent and guardian will be informed that if the adolescent discloses a SA history as a child that has not been previously reported to the appropriate officials (Department of Social Services or Law Enforcement depending on the perpetrator), a report will need to be made prior to the adolescent and guardian leaving the clinic. Both the adolescent and guardian will be informed that if the adolescent discloses imminent risk of suicide and the adolescent is not willing to agree to a safety plan, a mental health professional will need to conduct an exam to determine if hospitalization is needed.

After consenting to the prevention program and completing the baseline survey, the adolescent will be randomized to receive the interactive online prevention program (15 minutes) or no intervention. All participants will then be contacted to complete 1-, 3-, and 6-month follow-up assessments. Participants will receive a $5 gift card for screening for the study, $30 gift card for completing the baseline survey up to the point of randomization (plus $10 for completing the intervention if randomized to that condition), $40 gift card for the 1-month follow-up, $45 gift card for the 3-month, and $50 gift card for the 6-month. Participants may also receive partial payment for the follow-up surveys based on the percentage of the survey they complete. They will also receive a $5 bonus for completing each survey within a week of the date it was sent, and a $10 bonus if they complete all the surveys. Additionally, participants randomized to the intervention group will receive an additional $10.

The research team will observe restrictions imposed by Georgia State University and relevant government or public health authorities in the conduct of research activities.

5. Study Design

A. Organizational

The Principal Investigator of the overall study is Amanda Gilmore and is housed at Georgia State University (GSU). This study is funded by a NIDA career development award to GSU and all funds will go through GSU.

B. Setting and location:

Study procedures will take place at GSU and recruitment will occur at two sites: in the Old Fourth Ward Pediatrics clinic in Atlanta, Georgia and at the Medical College of Georgia-Augusta University Children's Hospital of Georgia in Augusta, Georgia. Adolescents will either complete the consent, baseline survey, and intervention at their primary care clinic or they will complete those study activities online in a private location of their choosing. All participants will complete the follow-up surveys at 1 month, 3 months, and 6 months online in a private location of their choosing. When completing data surveys and/or the intervention remotely, we will ensure that they are in a private space in these ways:
1) displaying a reminder screen at the beginning of all surveys and the intervention that this should be completed in a private location
2) displaying a reminder screen to close the browser at the end
3) language in the consent form for guardians that indicates they do not have access to the adolescent's study information.

C. Community participation (if applicable): N/A

D. Virtual or In-Person Recruitment:
See Figure 1 for a visual diagram of recruitment, informed consent, and data collection methods for this study.

Adolescents aged 14-18 will be recruited to participate in the screening procedures—an online Screening Survey—if they are at a recruitment site for a primary care visit or if they have attended a recruitment site visit in the last month for primary care. We will use in-person recruitment strategies when possible, but we will also use virtual recruitment strategies:

1) Research staff in-person at the recruitment site(s) speak with potential participants and invite them to take the online Screening Survey using a computer in the waiting room.

1a) Researchers will use the "Adolescent Recruitment Script" if only the adolescent is in the waiting room. They will use the "Parent and Teen Recruitment Script" if the adolescent is waiting with their parent.

2) Research staff hang and hand out flyers (see Flyer) with contact information and a QR code in the recruitment site(s) exam and waiting rooms

3) Clinic staff obtain permission from patients for research staff to contact them about the study (see Clinic Staff Recruitment Script and Research Registry Form)

3a) For patients who seem interested in the study but do not have time to consent on the day of their office visit, the clinic staff will ask them to complete a research registry form (see attached) with their contact information.

4) Research staff recruit potential participants virtually using a computer and teleconferencing in the clinic waiting room

4a) For patients and their guardians who are interested in the study and have time to consent on the day of their office visit, clinic staff will alert the research team who is available on the computer via Zoom. The research staff will then use the appropriate recruitment script (adolescent, guardian, or adolescent and guardian) to inform them about the study, screen for eligibility, and consent if appropriate.

5) Research staff recruit by sending messages to potential participants on their online patient portal (see Adolescent Recruitment Script)

Follow-up survey links will be sent via email, text, or social media (ex: Instagram) as preferred by the adolescent participant. The email used for follow-up survey correspondence is attached (see Email Script).

In addition to the survey links, research staff will encourage participation by sending brief, animated videos that relay the information in a more engaging format. These videos will contain information about survey length, study compensation, and what to expect for follow-up surveys.

Inclusion/exclusion criteria will be determined by the screening survey. Inclusion criteria for the pilot feasibility trial:

1) 14-18 years old
2) Attended a primary care visit for a preventative healthcare visit within the past month
3) Endorse self or friend substance use in the past year.

Exclusion criteria for the pilot feasibility trial:

The proposed prevention program will be made in English for the feasibility trial and requires that adolescents appropriately read and understand the program content. Therefore, it would be inappropriate for adolescents who are not able to read English. This is the same rationale for excluding adolescents with an intellectual or cognitive disability. Further, adolescents with intellectual/cognitive disabilities may have unique risk factors concerning sexual consent that will not be addressed in the prevention program. This is not to say that adolescents who do not speak English or who have intellectual disabilities are not at risk for substance use, SA, and SRBs, however, addressing these populations within the proposed research would not possible. The screening questionnaire is written at less than a 6th grade reading level, so we believe people with intellectual/cognitive disability will be able to understand the question.

E. Informed Consent Process:

For adolescents under 18 who are eligible for the intervention, the guardian and adolescent will go through informed consent (guardian) and assent (adolescent under 18) after taking the screening survey (see Parental Consent, 18 Year Old Consent, and Assent Forms). While discussing informed consent, participants and their guardian will be informed of the sensitive nature of the prevention program and that the adolescent will complete the prevention program online. Both the adolescent and guardian will be informed that if the adolescent discloses a SA history, a trained research staff will contact them to report the SA to the appropriate location (Department of Social Services or Law Enforcement depending on the perpetrator) and to provide any needed referrals for treatment. After guardian consents and adolescent assents to the prevention program, the adolescent will complete the study procedures in private. Although guardians will be informed that they might be contacted to help remind their child to complete the surveys. This will be discussed with the guardian during the consent process.

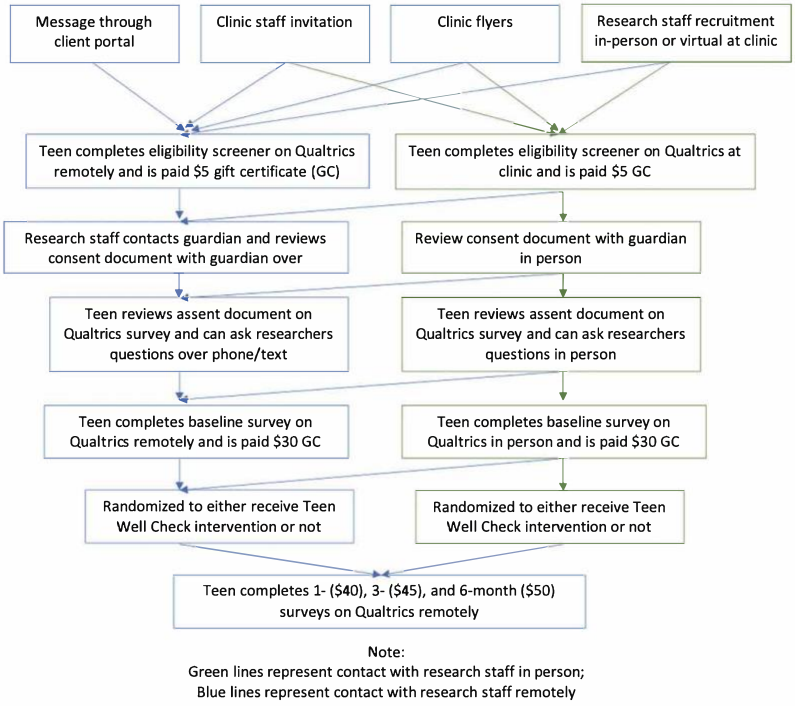
For adolescents 18 years of age who are eligible for the intervention, they will go through informed consent after taking the screening survey (see 18 Year Old Consent Form). While discussing informed consent, participants will be informed of the sensitive nature of the prevention program and that they will complete the prevention program online. The adolescent will be informed that if they disclose a SA history, a trained research staff will contact them to report the SA to the appropriate location (Department of Social Services or Law Enforcement depending on the perpetrator) and to provide any needed referrals for treatment.

If possible, the consent procedures will happen in-person at the doctor's office immediately after the teen's clinic visit. Otherwise, consent will happen virtually either through video conferencing (e.g., WebEx or Zoom) on the computer located at the clinic

or by phone after the patient has left the clinic. If consent occurs via video (e.g., Zoom or Webex) or by phone, the teen and their guardian will be directed to open the study website on an internet browser, where there will be online consent and assent forms. The research team will obtain an e-signature for consent through the online form. No teen under 18 will be allowed to participate in the study without their parent's consent.

All participants will receive referral information pertinent to treatment of substance use disorders, mental health and physical problems subsequent to SA victimization, treatment for SA perpetration, and STI testing recommendations.

Figure 1. Virtual and In-Person Recruitment, Consent, and Data Collection Procedures for Teen Well Check



F. Virtual or In-Person Field Methods:

If eligible and consented/assented for research, adolescents will complete a Baseline Survey and (if randomized to experimental condition) the intervention in privacy. Throughout the online intervention, the adolescent will have access to a research assistant (virtually by phone/text or in-person) to answer any questions that arise.

Participants complete the prevention program, which includes intervention content provided online regarding substance use, sexual assault, and sexual risk behaviors. All informed consent, baseline assessment, and the intervention (if randomized to the program) procedures will take approximately 1 hour to complete. Adolescents will be paid $5 for screening for the study whether they are eligible or not. If they are eligible, adolescents will receive a $30 Walmart e-gift card for participating in the baseline portion of the study (plus $10 for completing the intervention if randomized to that condition). They will complete online follow-up surveys (see "1 Month Follow-up Survey," "3-Month Follow up Survey," and "6-Month Follow up Survey") one-, three-, and six-months after participating in the baseline procedures. They will be paid a $40 Walmart e-gift card for the one-month follow-up survey, a $45 Walmart e-gift card for the three-month follow-up survey, and a $50 Walmart e-gift card for the six-month follow-up survey. Participants may also receive partial payment for the follow-up surveys based on the percentage of the survey they complete. All of the follow-up surveys will take approximately 30 minutes to complete.

6. Potential Risks/Discomforts

The two potential risks to participants that may be associated with involvement in the study include: 1) potential threats to confidentiality, particularly with regard to reporting sexual assault and reporting of imminent suicide risk without agreeing to a safety plan; and 2) potential embarrassment or distress from responding to questions or engaging in the prevention program targeting sensitive topics including substance use, sexual assault, and sexual risk behaviors. These risks are discussed in greater detail below. In addition, although not a risk specifically linked with participating in the study, the vulnerability of adolescents who have experienced sexual assault necessitate consideration of procedures in the cases of psychiatric emergencies (e.g., suicidal attempts). These considerations are noted here and in the following Protection Against Risk section.

First, regarding potential threats to confidentiality, there may be emotional and/or legal consequences if personal information obtained during the assessment is released to outside parties. That is, mandatory reporting laws necessitate that new disclosures (i.e., previously unreported) of qualifying incidents of child abuse (including SA of someone under the age of 18 years old), be reported to the Department of Social Services/DSS (when perpetrator of abuse is in a caretaking position) or the local law enforcement agency (when perpetrator of abuse is in a non-caretaking position). Reports to such agencies may result in DSS involvement with the family, removal of family members or child from the home, or criminal charges/arrests. With regard to likelihood of this threat to confidentiality in relation to child abuse reporting, sexual assault history will be initially assessed through the assessment during the feasibility trial prior to beginning the prevention program. Participants will be informed of these risks of mandatory reporting laws prior to completing the assessments. A research assistant and licensed psychologist (e.g., P.I. Amanda Gilmore) will be immediately informed if an adolescent discloses a sexual assault victimization.

Further, if an adolescent indicates that they have suicidal ideation within the survey, this will prompt a full suicide risk assessment (see Safety Plan) to be completed by the research personnel supervised by a licensed mental health professional. If there is acute risk of suicide, the guardian will be informed. The safety plan—detailing what to do and whom to speak with if ideation should occur—will be discussed with all adolescents who screen positive for suicidality, including specifics on how to access 24-hour care for

suicidality via dialing 9-1-1 and/or going to the closest emergency department when a mental health professional is not available.

If there is any disclosure requiring reporting, the research personnel (supervised by a licensed mental health professional) will contact both the adolescent and guardian (if under 18, or adolescent alone if 18) to discuss mandated reporting and to provide any needed referrals for treatment. A report will be made to the appropriate location (DSS or law enforcement agency) by the researcher under the supervision of a licensed mental health professional.

Our proposed methodology was developed in order to balance the safety of human subjects with the ability to acquire accurate data. We have used similar procedures in both local and national studies. We ultimately chose a tablet-based intervention because individuals are more likely to disclose information about sensitive topics like sexual assault, alcohol use, and sexual risk behaviors in self-report measures than when asked by a person. Therefore, including the tablet-based intervention rather than an in-person intervention will increase the likelihood of disclosures. However, this is balanced with the human subjects concern and ethical concern of mandatory reporting laws. It is essential to ensure that children are safe from child abuse, and sexual assault is a form of sexual abuse. We have included mandatory reporting within these procedures to ensure that participants within this study are protected from future harm. However, it is notable that in the National Survey on Adolescents, which several of the mentors on the current project oversaw the Child in Danger protocol, out of the approximately 3600 youth confidentiality was broken in less than 5 cases total. Previous and current studies conducted by the research team have revealed that adolescents do in fact still disclose sexual assaults even with being informed that it is mandatory that we report the incident. However, it is possible that some adolescents will not disclose sexual assault if they are informed in will be reported to the authorities if disclosed. Because of this, we ensured that all participants will receive the same information and resources despite their reported histories to ensure that they receive the best care possible. It is a potential limitation that the sexual assault victimization experiences will likely be under representative of the actual rates in the population being observed.

Similarly, if an adolescent is threatening to hurt her/himself or someone else, confidentiality may have to be broken to make a report to the guardian and/or necessary authorities. Given that suicidality is common among child sexual abuse victims, while not a direct risk of the study, it is an important issue to assess and monitor closely with participants. Procedures for assessing and addressing suicide attempts are addressed in the following Protection Against Risk section.

The second potential risk of the proposed study is the possibility that some participants might experience distress when asked questions pertaining to sexual assault and sexual risk behaviors. Many people assume that asking such questions produces substantial distress, particularly in research settings. However, our prior clinical research experience, as well as the empirical literature, suggests that this risk is minimal, and that individuals with traumatic event histories actually report obtaining positive benefits from their participation in studies using assessment instruments similar to the ones proposed. Procedures to protect against this risk are described in more detail below. Nonetheless, protocols are in place in the unlikely event that participants become significantly distressed during the assessment or prevention program process (see Protection Against Risk below).

With regard to potential alternative treatments, no “standard of care” exists for the integrated prevention of substance use, SA, and SRBs among adolescents within primary care settings. Provision of parallel or sequential treatments for each presenting problem could be considered. However, depending on the pre- treatment symptom presentation of the youth, this would potentially require that control participants and their families attend numerous treatment programs (e.g., a research-based outpatient treatment for substance use, psychoeducation for healthy dating and sexual decision making), placing significant burden on these families. Nonetheless, when the study is being described to potential participants, it will be made very clear that the adolescents and caregivers have the right to choose not to participate in the study and to be provided with appropriate referrals if they so prefer.

All participants will receive a Resource Sheet with information about referrals for additional support. This will be provided at the end of Teen Well Check program and at the end of each survey.

Protection Against Risks:
To protect against violations of confidentiality: (a) a federal certificate of confidentiality has been automatically granted because it is study funded by NIDA to render the data immune from subpoena (due to the sensitivity of some of the data that we are collecting - e.g., self-reports of drug use and SA - and the potential legal jeopardy faced by some of the participants); while aware of the ambiguities about the reach of the certificates, we are convinced that they are the best protection available for confidentiality of research data; (b) all staff will sign confidentiality agreements, and our training sessions will emphasize the critical importance of confidentiality; (c) all hard copies of data will be kept and locked within the research office; (d) the computer containing the data will be password-protected as a security precaution to eliminate unauthorized access; (e) all digital data including survey responses will be stored on the encrypted GSU Enterprise Dropbox account that requires dual-identity log-in and is only available to members of this study team.

Regarding the risks of breaking confidentiality due to mandated reporting laws: a) adolescents and guardians (if under the age of 18) will be informed of the risks during the consent process, and continually reminded of the risks throughout the study (e.g., at each assessment time-point); and b) when a question arises about whether a situation falls under a mandated reporting law, the research personnel and/or a licensed psychologist will be alerted immediately by text message and email. The PI will make all final decisions about whether a mandated report must be made on behalf of a study participant. If a mandated report is required, guardians and/or adolescents will be encouraged to make the report themselves (e.g., from the office within the primary care clinic), such that confidentiality is not broken by the project staff. If the guardian or adolescent refuses to make the report, then the research personnel will be required to make the report. This leads to very limited instances where confidentiality is actually broken by staff. The proposed mentorship team has extensive experience in dealing with these issues with trauma- exposed child populations.

Ongoing monitoring of SA victimization will be conducted throughout the duration of the study using self-report measures. As described above, any youth or caregiver reports of harm to the child will be made to the local division of the Department of Social Services and/or law enforcement agency, when necessary. In the event that there is evidence (by

child/guardian report or physical evidence) that the child would be in danger of physical harm upon returning to the home, the appropriate law enforcement agency will be called and the child will not be permitted to leave with the guardian (i.e., if the abuser lives in the home).

Dr. Gilmore is well-versed in mandating reporting and will be available on an as needed on-call basis during the duration of the study to pediatricians who may have any questions regarding study policies. Mandatory reporting within the study, combined with discussion of other sensitive topics including substance use may bring up questions from pediatricians regarding best practices concerning adolescent substance use, SA, and SRBs. Therefore, Dr. Gilmore will be available on call.

To minimize distress or discomfort associated with participation in the study (from either assessment or the prevention program): (a) research staff will be carefully chosen and highly trained by the P.I.; (b) participants will be informed that they can discontinue participation at any time; and (c) if other problems arise, the research personnel or a licensed psychologist will contact the family to address and resolve these issues. To ensure this is possible, the research personnel and/or a licensed psychologist will be available during recruitment procedures at all times virtually.

For participants enrolled in the study, in any circumstances where a research assistant or a licensed psychologist is concerned regarding suicidal ideation or attempt, the P.I. will be contacted immediately. All research staff will have a cell phone number where the P.I. will be available 24 hours 7 days a week. In rare instances where she cannot be reached, a licensed psychologist will serve as a back-up. Dr. Gilmore will ensure research assistants are well-trained in assessing distress and suicidality (intent, plan, etc) using a Safety Plan that includes the Linehan risk assessment and management protocol (LRAMP) (see “TWC Suicide Safety Plan Revised 041321”). In circumstances where adolescents in either condition express suicidal ideation and are sincerely willing to contract for safety (i.e., will agree to keep her/himself safe), the guardian will not be informed. The safety plan—detailing what to do and whom to speak with if ideation should occur—will be discussed with all participating adolescents who screen positive for suicidality, including specifics on how to access 24-hour care for suicidality via dialing 9- 1-1 and/or going to the closest emergency department (research staff will help families determine this location) when a licensed psychologist and/or supervisor is not available. Thus, a 24-hour safety plan is in place, including access to medical care 24 hours per day. Further, any participant in which it is deemed that medication is warranted will be referred to a hospital or community-based psychiatrist for such services and monitoring. Suicidal risk factors - including suicidal ideation, intent, plan, and means - will continue to be assessed on an ongoing basis throughout the adolescents’ participation in the study via the baseline and follow-up surveys.

If a participant is deemed at risk for suicide and the adolescent will not contract for safety, or has made any indication of acute suicidal risk, the guardian will be informed immediately and the adolescent will be assessed by local emergency department for possible inpatient hospitalization.

In all surveys, if a teen reports a sexual assault or suicidal ideation while completing the online survey, a notification will be made to Dr. Gilmore automatically. No matter the teen's responses, all teens will receive information for the suicide hotline and information about how to report a sexual assault if they have experienced one as a child. However,

to ensure the safety of the child, a member of the research team supervised by a mental health professional will contact the participant within 24 hours to follow-up

Finally, all participating families enrolled in the study will be given Dr. Gilmore's contact information on the consent/assent forms.

All participant data will be collected via Qualtrics, which meets GSU standards for encryption. GSU has extensive experience safeguarding the security and integrity of sensitive materials, including protected health information and sensitive financial information. Respondent confidentiality will be masked in all data files by the use of project identification numbers rather than personal information. All other electronic records, including digital recordings of sessions, are de-identified in collection and will be maintained in password-protected locations on the secure server. All paper records will be de-identified and maintained in a locked file cabinet on a secure floor. The only document linking participants with identification numbers will be retained in a password-protected encrypted file on the secure server. That linking document will be destroyed at the end of the study. Data presented at professional meetings or published in journals or books will not allow identification of individual participants. These procedures are expected to minimize any potential adverse effects from participating in this study.

7. Benefits

Potential benefits to participants who receive the prevention program are substantial, including decreased likelihood of substance misuse, sexual assault victimization, sexual assault perpetration, and engagement in sexual risk behaviors, thereby decreasing the risk of subsequent development of substance use disorders and sexual revictimization, though these cannot be guaranteed. In addition, the successful demonstration of feasibility for a clinically useful and cost-effective technology-based approach to improve the efficiency, effectiveness, and reach of prevention programs to primary care would be of significant benefit to society. Further, this technology could be adapted to other populations if effective.

8. Compensation

Participants in the pilot feasibility trial will receive:

- A $5 Walmart e-gift card for completing the screening survey even if they are not eligible or do not finish the study.
- A $30 Walmart e-gift card for completing the baseline survey
- A $10 Walmart e-gift card for completing the online prevention program (if randomized to the intervention)
- A $40 Walmart e-gift card for completing the 1-month follow-up
- A $45 Walmart e-gift card for completing the 3-month follow-up
- A $50 Walmart e-gift card for completing the 6-month follow-up
- In addition, participants who complete each survey within a week of the date they were sent the survey will receive an additional $5 per survey.
- Participants will also receive a $10 bonus for completing **all** surveys
- Participants may also receive partial payment for the follow-up surveys based on the percentage of the survey they complete.

9. Data Analysis: Data Management & Monitoring

To address electronic data security, Qualtrics at GSU will be used for data collection. Questionnaire data will be collected via software that meets GSU standards for encryption. GSU has extensive experience safeguarding the security and integrity of sensitive materials, including protected health information and sensitive financial information. Respondent confidentiality will be masked in all data files by the use of project identification numbers rather than personal information. All other electronic records, including digital recordings of sessions, are de-identified in collection and will be maintained in password-protected locations on the secure server. All paper records will be de-identified and maintained in a locked file cabinet on a secure floor. The only document linking participants with identification numbers will be retained in an encrypted file on the secure server with access limited to Dr. Gilmore and the research personnel. This linking document will be destroyed at the end of the study. Data presented at professional meetings or published in journals or books will not allow identification of individual participants. These procedures are expected to minimize any potential adverse effects from participating in this study. All final data will be stored on GSU secure servers, on GSU password-protected computers.

10. Plans for Analysis, Statistical and/or Otherwise

Feasibility will be determined based on recruitment, retention, execution of study protocols, and satisfaction of adolescents and providers. Feasibility is the primary goal of this aim. Recruitment will be considered successful if 250 adolescents are screened and 70 meet criteria for the study. Study retention will be considered successful if 80% of participants are retained for 1-, 3-, and 6-month follow-up assessments. Satisfaction will be considered adequate if participants report at least average satisfaction with the prevention program. Feasibility will be used to inform a larger randomized clinical trial. Preliminary effects: Preliminary effects will be examined as a secondary goal to determine preliminary evidence of effects on substance use, SA victimization, SA perpetration, and SRBs. The small sample size prevents any conclusions regarding prevention program efficacy to be determined, however, ANOVAs (gender X treatment

condition) will be conducted to determine if there are any preliminary effects on substance use, SA victimization, SA perpetration, and SRBs. Given that the primary aim is to determine feasibility and not to determine effects on outcomes, this will be preliminarily examined.

11. Training of Study Team

All study staff will be approved by all involved IRBs and will receive extensive training from the grant PI (Dr. Gilmore) on study procedures and risk protocols. Specifically, study staff will receive training on suicide risk assessment and suicide risk management as well as on assessing for child safety in relation to sexual assault histories. All investigators and study staff will complete the required CITI training and study staff with direct contact with participants will have weekly supervision meetings as well as 24-7 access to Dr. Gilmore, a licensed clinical psychologist, for any study-related concerns.

12. Plans for Monitoring the Study for Safety

Dr. Gilmore will be responsible for monitoring the safety and efficacy of this trial, executing the NIDA- approved Data and Safety Monitoring (DSM) plan, and complying with the reporting requirements. Dr. Gilmore will provide a summary of the DSM report to NIDA on an annual basis as part of the progress report. The DSM report will include the participants' socio-demographic characteristics, expected versus actual recruitment rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, and any actions or changes with respect to the protocol. The DSM report to NIDA will also include, when available, the results of any data analyses.

A. Participant Safety

Diligent safety monitoring will be conducted by the candidate throughout this study in compliance with the following required elements of the GSU IRB and continuing review process:

1. tracking of subject accrual (enrollment, drop-outs, demographics)
2. timely and appropriate reporting of informed consent process deficiencies, protocol deviations, privacy breaches, conflicts of interest, and/or changes in personnel
3. ongoing monitoring and appropriate reporting of adverse event activity: a. Internal: i) frequency of unexpected, related or possibly related, and serious or more prevalent than expected adverse events; ii) frequency of internal deaths occurring during the study or within 30 days of study termination, even if expected or unrelated b. External: frequency of unexpected, related or possibly related, and serious adverse events
4. interim assessment of risk/benefit relationship in reference to adverse event occurrences, preliminary observations, and emerging information
5. timely and appropriate IRB submission of safety-related documents such as audit reports, sponsor progress reports, and other materials or communications that might impact the safe conduct of this study
6. active cooperation with the IRB and other applicable entities in the event of a random or for-cause internal or external audit

Participant Safety Relevant to Specific Application. Regarding the risk of harm to self or others, the nature of the population (adolescents at risk for using substances, SA, and SRBs) entail that specific adverse events, such as suicidal and homicidal ideation and

attempts, are possible given the high-risk nature of the population under study. Regardless, both expected adverse events and unexpected adverse events will be monitored and addressed continuously throughout the course of the project. Risk of harm to self and others will be directly assessed through self-report questionnaires. Participants in the study who indicate any risk of harm will immediately be assessed and referred for treatment, if needed. Dr. Gilmore and her mentorship team have extensive training in crisis management. Dr. Gilmore was directly clinically trained by Dr. Marsha Linehan, the developer of Dialectical Behavior Therapy which is effective at reducing suicidal behavior. Therefore, she is well versed and very experienced in the assessment and management of acutely suicidal individuals. Both expected and unanticipated adverse events will also be continuously monitored by the candidate and mentorship team. All study staff will be closely supervised by the candidate, who will hold weekly meetings with the staff to address clinical barriers, prevention program and enrollment progress, and safety issues throughout the feasibility trial. Dr. Gilmore will also be available 24/7 to study staff by phone if any additional support is needed. Participant safety is assessed routinely as part of the research context through assessments given at each time point to evaluate substance use, SA, SRBs, and risk of harm.

For participants enrolled in the study, in any circumstances where the study staff is concerned regarding suicidal or homicidal ideation or attempt, or SA perpetration against a minor, s/he will immediately contact Dr. Gilmore, who is a licensed psychologist in South Carolina (License No. PSY.1417). Dr. Gilmore will assess safety and provide instructions to the study staff to address any risks. Dr. Gilmore will ensure that the study staff are well-trained in assessing distress and suicidality (ideation, intent, plan, etc). In circumstances where participants express suicidal ideation and are sincerely willing to contract for safety (i.e., will agree to keep her/himself safe), a plan will be made and carefully monitored. If a participant is deemed at-risk for suicide and will not contract for safety or has made a suicidal behavior or attempt, the participant will be assessed by a local emergency department for possible inpatient hospitalization. Dr. Gilmore or trained research staff will also ensure that participants who present with risk for suicidal or homicidal ideation are well educated on how to access 24-hour emergency care (through 9-1-1 or going to the local Emergency Department). Dr. Gilmore will be on-call for study therapists, 24 hours per day, 7 days per week.

B. Procedures for Monitoring Safety of Data

Regarding data management and storage, all data will be collected using computerized self-report questionnaires. Only participants' study identification codes will be inputted computer-based databases. The codes that link the name of the participant and the study ID will be kept confidential by Dr. Gilmore in a secured cabinet. The data will be imported directly into a password-protected SPSS data file stored on the GSU server. The server is protected by the GSU network, and a secured log-in is required from all users. All research personnel collecting and manipulating data will have completed a Human Subjects Research Training and will meet weekly with Dr. Gilmore or a postdoctoral fellow in the lab to ensure strict compliance with the DSM plan. Only study personnel (candidate, research staff, and mentorship team) will have access to data. No data will be released to other agencies unless participants consent to release.

Adverse Events

The candidate, with consultation from the mentoring team—which includes a licensed clinical psychologist (Gilmore)—will be responsible for monitoring data and participant safety. Adverse events will be one of the standard agenda items during weekly research meetings. Any adverse event that occurs will be reported by Dr. Gilmore to the GSU IRB, as well as NIDA. In keeping with the IRB requirements, events that are not considered severe are reported to the IRB in writing no later than 10 working days after the Investigator learns of the event, whereas those that are severe will be reported immediately and no longer than 48 hours after learning of the event. If instances arise where the severity of the event is questionable to the candidate, the IRB official assigned to the protocol will be contacted for guidance. In addition to reporting the adverse event to the IRB, those events that involve maltreatment of a child or risk of harm will be reported to appropriate child protection and law enforcement agencies. All reported events and any action taken by the IRB will be reported to the NIH.

Adverse Identification, Detection, Grading, Attribution, and Reporting

1. **Identification.** Potential risks identified for participants will be listed in the IRB-approved informed consent document. Additional unknown risks might occur and, if so, will be identified through diligent investigator monitoring throughout the conduct of this study.
2. **Detection.** During the informed consent process, participants will be advised of the potential risks of participation as identified in the IRB-approved informed consent document. Participants will be advised during the informed consent process that they should promptly inform the investigators of any concerns regarding adverse events related to participation in the study. Participants will be advised to notify Dr. Gilmore of any suspected adverse events in a timely fashion. Safety parameters will be followed by the candidate as outlined above.
3. **Grading**. Adverse events will be assessed and graded as follows:
    1. Expected/Anticipated Adverse Event: Identified in nature, severity, or frequency in the current protocol, informed consent, investigator brochure, or with other current risk information.
    2. Unexpected/Unanticipated Adverse Event: Not identified in nature, severity, or frequency in the current protocol, informed consent, investigator brochure, or with other current risk information.
    3. More Prevalent: Occurs more frequently than anticipated or at a higher prevalence than expected.
4. **Attribution.** Adverse events will be attributed to study participation according to these parameters:
    1. Unrelated: There is not a reasonable possibility that the adverse event may have been caused by participation in the study.
    2. Possibly Related: The adverse event may have been caused by participation in the study; however, there is insufficient information to determine the likelihood of this possibility.
    3. Related: There is a reasonable possibility that the adverse event may have been caused by participation in the study.
    4. Seriousness: Results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, or any other event that may jeopardize the participant’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
5. **Reporting.** Adverse events experienced by participants will be reported using the GSU IRB's password protected on-line adverse event reporting system, as follows:

IRB Reporting Requirements for Adverse Events

Internal Adverse Events. An internal adverse event is reportable if the occurrence meets all three of these conditions: 1) is unexpected, 2) is related or possibly related to participation in the research, and 3) is serious or places participants or others at greater risk of physical/psychological harm than was previously known or recognized. Internal adverse events are not reportable under these conditions: 1) expected and not more prevalent than expected, whether related or unrelated, and 2) unexpected and unrelated, regardless of seriousness, aside from death.

Internal Deaths. All internal deaths occurring during the conduct of the study or 30 days post-termination from protocol are required to be reported as adverse events even if they are expected or unrelated.

IRB Reporting Schedule for Adverse Events

For any unexpected and related or possibly related, serious or more prevalent event occurring during a research study, a report must be made through GSU's online reporting system as soon as possible but no later than 10 working days after the investigator first learns of the event. All other (expected adverse events) are reported as aggregate data at the time of IRB continuing review.

Report of Changes or Amendments to the Protocol

The annual DSM report will describe any minor actions or changes with respect to the protocol. In the unlikely event that major changes are required, Dr. Gilmore will discuss the needed changes with the NIDA Program Official first, reach a consensus agreement on the changes with the Program Official, and then provide a written description of the changes to NIDA.

A Data Safety and Monitoring Board (DSMB) will be led by Dr. Kathleen Baggett, the Director of the Mark Chaffin Center for Health Development at GSU. Dr. Baggett will serve as the Security Officer and will convene the DSMB quarterly to review and ensure the on-going safety of the participants. With the help of Dr. Baggett, Dr. Gilmore will appoint other members of the DSMB who are not involved on the project prior to beginning the randomized pilot trial.

13. Confidentiality

Regarding data management and storage, all data will be collected using computerized self-report questionnaires. Only participants' study identification codes will be inputted computer-based databases. The codes that link the name of the participant and the study ID will be kept confidential in a secured cabinet or in a password-protected file on the encrypted GSU Enterprise Dropbox account, and then destroyed at the end of the study. The data will be imported directly into a password-protected SPSS data file stored on the GSU server. The server is protected by the GSU network, and a secured log-in is required from all users. In addition to these precautions, all personnel will have earned at least a bachelor's degree and have experience in conducting research. All research personnel collecting and manipulating data will have completed a Human Subjects Research Training and will meet weekly with the candidate to ensure strict compliance with the DSM plan. Only study personnel (Dr. Gilmore, research staff, and mentorship team) will have access to data. No data will be released to other agencies unless participants consent to release. Audio recordings of therapy and data collection sessions will be used solely for research purposes.

Audio files will be stored on an encrypted hard drive at the research office, digital recordings will only be identified by numeric codes, and recordings will be destroyed at the end of the study. Only the candidate, project staff, and mentorship team will hear the content of the audio recordings.

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