



INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST

1. **Date:** 12/1/2022 (Amendment 8)
2. **Study Title:** The Substance Use and Health Risk Intervention (SUHRI) for Justice- Involved Youth – Pilot 2
3. **Principal Investigator (must be a TCU faculty or staff):** Danica Knight, PhD & Jennifer Becan, PhD (MPIs)
4. **College/School:** Institute of Behavioral Research (IBR)
5. **Other Investigators:** List all faculty, staff, and students conducting the study. For those not affiliated with TCU, please provide their names and institution.
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6. **Project Period:** 9/30/2019- 8/31/2023
7. **If you have internal or external funding for this project –**
Funding Agency: NIH **Project #:** 1 R34 DA048065-01 **Date for Funding:** 09/13/2019
8. **If you intend to seek/are seeking internal/external funding for this project –**
Funding Agency: NIDA **Amount Requested From Funding Agency:** \$594,949
Due Date for Funding Proposal: N/A
9. **Purpose:** Appendices to the Protocol Table of Contents
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Summary

The purpose of the Substance Use and Health Risk Intervention (SUHRI) project is to adapt and test an integrated health risk-reduction and motivational enhancement intervention (a cloud-based app) for Juvenile Justice (JJ) youth that will ultimately be (after full testing through a subsequent large-scale RCT) a sustainable intervention implemented within a JJ supervision/case management context to teach and facilitate positive, prosocial, and expected behaviors. The intervention will use interactive graphical approaches to encourage introspection and problem identification, enhance self-regulation, improve analytical problem-solving skills, and promote healthy behaviors in two inter-related target areas: substance use and risky sex practices. App sessions will be self-directed (require minimal instruction/interaction assistance), and also include a service referral piece whereby youth are provided with additional resources for seeking services related to risky health behaviors and substance use.

This research will be carried out in two pilots: (1) Intervention Adaptation and Feasibility and (2) Protocol Feasibility. The specific aims of the project are to (a) examine intervention feasibility and acceptability (Pilot 1), *(b) test the feasibility of the study protocol (adherence, subject retention, instrumentation) with JJ-involved youth (Pilot 2).*

During Pilot 1, intervention content will be adapted from existing evidence-based interventions so that it is developmentally appropriate for the target population and suitable for a web-based format. During Pilot 2, a test of the intervention will yield data on intervention feasibility, acceptability, and impact on youth outcomes. Proximal outcomes include improvements in change mechanisms (e.g., problem recognition, decision making, intention to reduce personal risk) and service initiation (SU or STI-related services). Distal outcomes include reduction in risky behaviors, including substance use (self-report and urinalysis) and sexual health risk (self-reported risky sex practices). Successful completion of the aims will result in an intervention that is appropriate and feasible for use with JJ-involved youth.

Because the project will be carried out in two phases, IRB approval was sought separately for Pilot 1 (Intervention Adaptation and Feasibility; latest continuation approved 9/11/2020) and Pilot 2 (Protocol Feasibility). **This protocol review request is for Pilot 2 only. This protocol will be delivered either in-person at a Tarrant County Juvenile Justice office/public location, or virtually via an online platform such as Zoom.**

10. Background:

Juvenile Justice (JJ)-involved youth are a vulnerable population involved in illegal and maladaptive behaviors—substance use (SU), crime, delinquency, risk-taking behaviors (including risky sex practices)—that present significant challenges to public health and safety. According to the US Census Bureau (US Census Bureau, 2017) there were approximately 17 million youth between 14 and 17 years of age in 2015, with juvenile courts disposing 1.3 million delinquency cases annually (Hockenberry & Puzanchera, 2014; OJJDP, 2015). Adolescent SU, including nonmedical use and abuse of prescription drugs (Palamar et al., 2016; Young et al., 2012), is a concern for its immediate negative consequences, including potential progression to a SU disorder (SUD; Winters & Lee, 2008) and as a risk factor for onset of adult SUDs, including opioid addiction (Englund, Egeland, Oliva & Collins, 2008; Stone, Becker, Huber, & Catalano, 2012; Swift et al., 2008). JJ-

involved youth are 9 times more likely to have SUDs than the US youth population, yet only a third receive treatment annually (Substance Abuse and Mental Health Services Administration, 2013). Furthermore, as they age, JJ-involved youth sustain great risk for sexually transmitted infections (STIs; Romero et al., 2013) and suffer high rates of sexual health-related problems (Golzari, Hunt, & Anoshiravani, 2006). Because they have increased rates of STIs (Aalsma, Tong, Wiehe, & Wanzhu, 2010) and pose a higher transmission risk to others, (Centers for Disease Control and Prevention, 2018) reducing these health risks is of paramount importance. This includes the need to improve communication skills, particularly among youth who often have difficulty communicating assertively when negotiating safe sex (Crosby et al., 2003; Hutchinson & Cooney, 1998; Whitaker, Miller, May, & Levin, 1999). To address these issues effectively, a comprehensive intervention approach is needed that addresses health-related issues as well as crime and delinquency among substance-using youth.

The scientific premise of our approach is built around evidence-based practices (EBPs) focused on achieving changes in thinking that lead to changes in emotion and behavior (Gonzales et al., 2004; Magill & Ray, 2009). Two complimentary conceptual models guide the proposed project. The Integrated Judgment and Decision Making (IJDM) model (Dansereau, Knight, & Flynn, 2013) explicates the influence of analytic thinking on promoting self-regulation and behavior change. IJDM is based on theories of dual cognitive processing and applies both experiential and analytic processing systems (Kahneman, 2011; Klaczynski, 2005) to addictive behaviors (Spada, Albery, & Moss, 2015). Judgments and decisions about risk behaviors (such as SU and risky sex practices) are based in the experiential system (i.e., automatic, emotional) and emerge from previous experience and stored episodes.

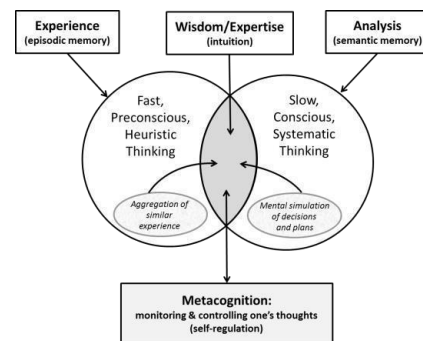


Figure 1. Integrated Judgment & Decision-Making Model
Adapted from Dansereau, Knight, & Flynn, 2013

This system provides instantaneous and preconscious processing (without analysis) about behavioral choices. The analytic system is a more deliberate process (i.e., slower, conscious). IJDM (see Figure 1) posits that metacognitive self-monitoring activities embedded in the analytic system are key to self-regulation and influence how and when the two systems are used. When maladaptive behavior is repeated, decisions can become “automatic,” especially when attentional biases (Cox, Klinger, & Fadardi, 2015). When response inhibition occurs, automated responses have the potential to be overridden (Crone & Dahl, 2012). Based on this model, the key to achieving behavior change is through decision making. Through repetition and practice using problem-solving strategies that engage the analytical thinking system, the decision making processes can be moved into the experiential thinking system, reinforcing procedural memory. Thus, “expertise” or strategies for thinking through complex problems become incorporated into a person’s experiential system memory bank for future use.

Analytically-created schemas (ACS or guide maps for decision making) have been shown to be IJDM vehicles for organizing information and walks users through a series of steps, questions, and exercises that promote analytic thinking. Generating a visual exhibit of options allows for an

objective evaluation of choices when developing plans and making decisions (Dansereau, Knight, & Flynn, 2013). A mapping-based ACS trains individuals to monitor and control their decision making, increases knowledge in a specific topic area (e.g., SU, safe sexual practices, etc.), and improves judgment and behavioral choices (self-regulation). In essence, analytic repetition (analogous to practice in athletic training) is used to develop procedural memory (i.e., skills and tasks that can be stored in long-term memory) that can be accessed rapidly (during efforts to self-regulate behavior) by pattern matching processes, facilitating use by individuals in real-life contexts. The goal is to replace or “override” inaccurate or maladaptive information, expectations, and behavior patterns with accurate health-related information and appropriate attitudes and behavioral choices. While IJDM addresses the decision making process, the Information-Motivation-Behavioral skills (IMB) model (Fisher, 2012; Fisher & Fisher, 1992; Fisher, Fisher, Bryan, & Mishovich, 2002; Fisher, Fisher, & Harman, 2003; Fisher, Williams, Fisher, & Malloy, 1999;;) provides a framework for understanding social and psychological determinants of health behavior. IMB advocates an integrated approach that simultaneously targets exposure to accurate information, increasing motivation to act, and improving requisite behavioral skills (Fisher, Fisher, & Harman, 2003). “Information” includes knowledge about disease prevention and beliefs about health risk behaviors; “motivation” includes problem recognition and attitudes—including associated emotional factors—about social support and personal choices around risk avoidance; “behavior skills” includes the ability (actual or perceived) to successfully engage in healthy behavior.

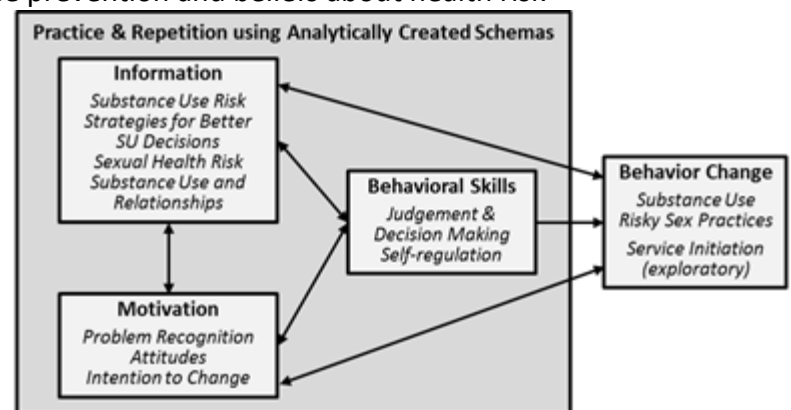


Figure 2. Conceptual Framework for the 8-session Intervention Integrating Judgment and Decision Making with the Information-Motivation-Behavioral Skills Model

Figure 2 illustrates how joint IJDM and IMB models inform strategies and interventions for improving health risk. Through practice applying ACSs to different problem areas, users develop new skills in a logical, step-by-step sequence, increasing use of the analytic system (thinking before taking action). The use of ACSs teaches youth to use effective problem solving approaches, and increase their capacity for metacognition and self-regulation by identifying steps for changing behaviors in future settings. The utility of ACSs for promoting the essential elements of this framework is well supported, and the application of ACSs in clinical practice is incorporated into our proposed study through the use of TCU Mapping Enhanced Counseling (MEC; Dansereau, 2005; Dansereau, Simpson, 2009; National Registry of Evidence-based Programs and Practices, 2008). MEC is a communication and decision- making approach that uses graphic visualization tools to help clients focus on critical issues and behavioral choices, and helps address client problems more clearly than when relying strictly on verbal skills.

It centers on the use of graphical nodes to depict interrelationships among people, events, actions, thoughts and feelings that underlie negative circumstances and the search for solutions. Clients exposed to MEC in SU treatment settings have lower drug use (Czuchry, Dansereau, Dees, & Simpson, 1995; Czuchry, Newbern-McFarland, & Dansereau, 2009; Dansereau, Joe, Dees, & Simpson, 1996; Dansereau, Joe, & Simpson, 1993; Dansereau, Joe, & Simpson, 1995; Dees,

Dansereau, & Simpson, 1997; Joe, Dansereau, Pitre, & Simpson, 1997; Joe, Dansereau, & Simpson, 1994; Knight, Simpson, Dansereau, 1994) and improved knowledge/avoidance of sexual risk (Lehman et al., 2015). Recent studies demonstrate effectiveness of MEC strategies for improving decision making (Knight et al., 2015; Knight et al., 2016), motivation for personal change (Becan et al., 2015; Knight et al., 2018), and treatment (Knight et al., 2016).

The Substance Use and Health Risk Intervention (SUHRI). The SUHRI tablet intervention addresses the interrelated topics of SU and risky sex practices (Baglivio, 2009; Hubbard & Pratt, 2002) identified by JJ staff and youth as being important and needing greater attention.

Research shows that technology-based interventions are associated with reductions in substance use (Champion, Newton, Barrett, & Teesson, 2013; Tait, & Christensen, 2010), and have comparable outcomes to counselor-led interventions, with the added benefits of greater cost-efficiency and treatment access (Bickle, Christensen, & Marsch, 2011; Rooke, 2010).

Technology-based interventions can ensure intervention fidelity, promote greater responsiveness to and enjoyment of program content (Carroll et al., 2008), enable customization and participant choice in activities, and facilitate diffusion and widespread adoption.

SUHRI will include four 60 – 90 minutes sessions proctored by a TCU Research Assistant (RA). Each session will entail interaction with the web-based intervention; and the last 10 minutes will involve interaction with the RA processing session content. RA prompts will include, "Do you have any questions about the material?" "Did anything about the material make you uncomfortable?" This "check in" will enable youth to talk with someone if they have questions/concerns and allow the RA to intervene with an immediate referral to an identified clinician if needed (RAs will receive training in accordance with juvenile justice departmental procedures). Each session includes an introduction to the topic, key facts/strategies for making healthy choices, scenarios and games where youth practice decision making using ACSs, and information about services available to help. Throughout all sessions, ACSs based on a MEC worksheet called WORK-IT are used to provide information, encourage introspection and problem identification, and develop/improve analytical problem-solving skills. Sessions encompass 3 core processes that are recognized components of executive function: goal setting, evaluating options, and implementing the best option. Sessions also will include additional activities to enhance decision-making skills: multiple perspective taking, rating options along several dimensions, and determining implementation intentions.

To ensure fidelity to the study protocol and to avoid any perceived coercion by JJ staff, TCU Institute of Behavioral Research (TCU/IBR) RAs will oversee intervention administration, including voluntary study enrollment and withdrawal if requested. Following our NIDA-funded JJ- TRIALS study protocol, NO participant information (youth participation, youth assessment responses, choices/responses selected during the intervention, completion of sessions) will be shared with JJ staff; only aggregate information will be shared with JJ leadership.

11. Location:

All intervention and assessments sessions will take place either online using a platform such as Zoom, in-person at a Tarrant County Juvenile Services office or another public place, or via a tablet hand-off in an agreed upon public place. All TCU rules and regulations regarding COVID-19

protocols will be followed for in-person interactions including masking, hand- washing/sanitizing, social distancing when able, and sanitizing of all equipment.

12. Subject Population:

Participants will include juvenile justice-involved youth on probation within at least 1 local juvenile probation department (Tarrant County, currently). The Tarrant County Board (TCJS) has granted preliminary approval to submit appropriate requests to TJJD to move forward with planning this study.

We expect to recruit approximately 60 youth who range in age from 14 to 18 years old.

Inclusion Criteria: Youth ages 14-18 on community supervision are eligible if they have 1 or more indicator(s) of substance use, are English-speaking, and have no indication of current suicide risk or severe cognitive impairment/thought disorders. Youth's parent/legal guardian may be Spanish - speaking. Upon approval of the parental consent document, it will be translated into Spanish and submitted to the IRB for approval.

Exclusion criteria: Youth who are on TJJD (state) supervision rather than county supervision are not eligible to participate. In addition, youth who are currently suicidal, homicidal, or otherwise severely impaired (e.g., active psychotic symptoms) such as severe cognitive impairment or thought disorders are not eligible. Youth younger than 14 and youth 19 or older are likewise not eligible.

13. Recruitment Procedure:

Prior to study start, TCU will meet virtually with TCJS leadership to finalize recruitment, compensation, study implementation, and sharing of youth records. The TCJS Director of Research (DOR) will work directly with TCU and TJJD to ensure that data sharing agreements and procedures for linking study data to youth records are appropriate and secure. For study management purposes providing incentives to families, the DOR will know which youth are participating in the study but will keep this information confidential; supervising officers will not have access to this information. Information shared between the DOR and research team will be retained in and shared via a Box (account owned by TCU) folder with access restricted to the DOR and research team. Prior to participant recruitment, RAs will be trained on the general study protocol (e.g., recruitment, eligibility, consenting), curriculum content (e.g., rationale, content, exercises), delivery strategies, tablet operation, web access (e.g., troubleshooting, technical problem resolution), and how to address sensitive issues. RAs will be trained on identifying symptoms of trauma, handling information disclosed by youth, and will follow specific procedures required by the JJ department for reporting abuse or trauma to health personnel.

We will work with departmental staff to develop recruitment and administration procedures, including identifying the best group(s) from which to recruit participants and troubleshooting options for youth with challenges such as lack of access to Wi-Fi.

As part of supervision orientation procedures, JJ Probation Officers will distribute and/or e-mail flyers (see Appendices 3-4) describing the study to youth under community supervision and their parents/guardians. The flyer will describe the project (purpose, time commitment, compensation, benefits, eligibility criteria), and provide contact information for the research study. They will also give a brief description of the study to the youth and their caregivers, and ask for permission to share the youth and caregiver's contact information with the TCU research team. If they agree, the information will be conveyed using either a spreadsheet or Qualtrics link with the clients PID number, basic demographics, contact information for youth and caregiver, and eligibility criteria. The youth and/or caregiver will contact the study team from TCU if interested or the RA will reach out to families that agree to share their contact information. The RAs will set up an initial virtual or in-person session to evaluate the family's interest, screen for eligibility, and consent/assent. The project ends 8/31/22. All sessions that occur prior to 8/31/22 will be compensated.

14. Consenting Procedure:

The TCU RA will contact the client and family via phone or e-mail to schedule a time for the consent/assent session that is convenient to the family. The RA will reach out to the families via email and text messages

Consent and study sessions will either occur virtually, in-person, or via a tablet hand-off in a public place. A courtesy reminder e-mail and text message providing the information about the session will be sent 3 days prior, 1 day prior and a few hours prior the session with the prepared scripts. The RA will meet individually via a virtual platform or in-person with only those who express interest, screen the youth for eligibility and describe the study.

To obtain youth assent and parental/guardian consent for participation, the RA will use an individualized link to pull up the parental/guardian informed consent document (Appendix 1) in Qualtrics. For those attending the consent/assent conference virtually, the RA will use the share the screen function within Zoom with the family. The RA will explain the study to the family, ensuring they understand the importance of giving informed consent and assent. The RA will answer any questions the youth or parent/guardian has regarding what participation in the study entails. Once the family understands the project and their rights, the youth and/or caregiver will indicate their agreement to participate by making yes/no on the assent and consent documents. The RA will share the consent/assent forms via e-mail with the youth and the guardian for their own records. Youth may provide assent to participate at the start of the first intervention session if they are not available for the initial consent session with the parent/guardian.

Additional Steps for Obtaining Youth Assent: Trained research staff will utilize a two-step assent process to decrease the chances of youth being coerced into participating in the study. The components of the 2-part assent process are: (1) complete disclosure of information and (2) assessment of comprehension.

(1) The complete disclosure of information will include a thorough verbal description of the study using the Youth Assent document (Appendix 2) and a clear statement that electing to participate in the study will **not** affect the youth's treatment by the juvenile justice agency, decisions by the

courts at hearings, or the duration of the youth's supervision; and that in contrast to court-mandated participation in conditions of the youth's probation, this study is completely voluntary. We will also inform the family that while we will not inform their Probation Officers about their participation, we cannot fully guarantee that they will not learn about their participation through internal JJ communication or in the case the youth discloses their participation to their probation officer. (2) To ensure that both caregivers and youth understand the study and all it entails, the RA will assess their comprehension by asking them "what is the purpose of the study", "what are the risks of the study", and "what will happen if you choose not to participate". If the youth and caregiver are unable to answer or they respond incorrectly, the RA will go over the applicable study components again. This will be repeated until the youth and caregiver understand the study and its associated risks.

Due to using Qualtrics to obtain informed consent, a waiver of signed informed consent request was approved by the IRB in the initial project submission (see Appendix 8). It was stamped & approved by the IRB on 1/13/21 and uploaded into Cayuse for AM2 to bring files up to date.

15. Study Procedures:

Procedures

The project ends on 8/31/23 and no sessions will occur past this date. Youth and Caregivers will be informed during consent and assent (verbally and written), that the project ends on 8/31/23. Project referrals will cease on 05/31/2023 to allow clients an opportunity to participate in all study activities prior to project end.

If consent is completed first, the RA will schedule the first session with the youth and perform the assent process at the start of the session and assessment after. The RA will provide the youth with up to 3 reminder e-mails and text message before the session to ensure the youth has log-in information if required, or address of the agreed location to meet. They will also be reminded of the day and time of meeting. See appendices 3 for email and text scripts.

Following assent and assessment the youth will receive a tablet to use during the study. The RA will walk through a tutorial with youth to ensure they learn how to use the tablet. The youth will then have the first intervention session with the RA. The RA will complete administrative procedures to ensure the youth is presented with the correct modules for the session, and the youth will complete the session independently with the RA available to answer questions. Once the youth completes the session, they will complete an end of session evaluation (using Qualtrics), and the RA will transition the youth out of the session and schedule the next session or the follow-up assessment (following the 4th session of the intervention).

The first intervention session will occur approximately a week after the consent/assent meeting, and each session will occur a week to several weeks apart (spanning across approximately 1 month).

Following the last session, the youth will be scheduled to complete a 1-month assessment either in-person or online with the RA. The youth will receive 2 reminder e-mails and text messages leading up to the assessment appointment. The youth will also complete a 3- month post- intervention assessment proctored virtually or in-person by the RA. The youth will also receive 3 reminder e-mails and text messages leading up to the final assessment. Reminder e-mails will come from the e-mail address SUHRIProject@tcu.edu with the subject line "SUHRI Reminder" directly to the youth's personal e-mail address to reduce the chance that another individual will see the e-mails. No reference to a research project will be made in the text.

Each follow-up assessment will last approximately 60 minutes, with intervention sessions lasting approximately 60 – 90 minutes each.

To request corroborating data from the local JJ department as well as the Texas Department of Juvenile Justice (TJJD), the research team will request that the TCJS research director provide the TJJD-based identification number (PID) for consenting participants as well as demographic, substance screening and assessment, and relevant service attendance information. These data will be shared via a spreadsheet available to the director of research and the research team via Box.com— a secure file-sharing platform. The research team will provide the PID numbers along with headquarters county ID to the TJJD data team via spreadsheet in a Box folder in return for state-level data specific to the youth's substance use screening and assessments as well as offense, background, and service-seeking data. The TJJD research proposal submitted in September 2020 can be found in Appendix 9. be found in Appendix 9.

Intervention

The youth will receive 4 sessions of the interactive, cloud-based intervention administered via a tablet we give them. Each session of the intervention will focus on one of topics associated with drug use and risky sex practices. The final session will include an integrated module ensuring that youth process through a scenario that examines how drug use and risky sex behaviors are related. The youth will complete the final WORK-IT scenario within the app with processing questions (see Appendix 5.7) to work through this integrated scenario and also a quiz-like activity on Kahoot to learn more about local resources for substance use and sexual health.

Each session includes two modules including a WORK-IT module where youth will work through a scenario they select using the WORK-IT framework. The other module includes two interactive games; the Escaping the Downward Spiral (EDS) game and Jeopardy style trivia. In the EDS game, youth will play a game that focuses on decision-making in scenarios involving substance use and sex, while in the Jeopardy style game, they will learn about facts around substance use and risky sexual decision-making. Participants may receive a small token (e.g., fidget spinner or equivalent toy of size/cost) if they answer a certain number of questions correctly in the trivia game at the end of the intervention sessions. If the last session is virtual, RAs will offer to mail the token to participants and request their mailing address to do so. The tokens will be mailed with a "congratulations" leaflet (Appendix 12) that congratulates the participant on winning the trivia and requests them to be on the lookout for a follow-up survey (the assessment session). Intervention sessions will last approximately 60 - 90 minutes. The youth will complete these independently on a tablet/computer but the RA will be available in-person or via virtual platform to proctor participation. Modules also include the provision of additional information and service information related to substance use and risky sex practices.

Assessment

Participants will be asked to complete a battery of assessments at baseline, 1-month post-baseline, and 3 months post baseline. The assessment/measures package has been approved in several submissions across the initial study submission, AM 1, AM 2, AM 4, and AM6. Participants will also be asked to complete post-session feedback for each intervention session (approved on AM 2 & AM4).

Compensation / Community Service Hours

Compensation will be provided to the youth either in form as a gift card or community service

credits for each intervention session. Youth will get to decide at each session if they want to receive a gift card or community service credit. They can receive \$20 or 3 community service credits for each intervention session. They will also receive \$20 for each follow-up assessment session. Youth will also be reminded at each session that the project activities will end on August and they will be compensated for the activities completed before then.

16. Potential Risks and Precautions to Reduce Risk:

Risks are minimal and include potential risks to breach of confidentiality. No physical risks are involved in participation. Minimal risk of emotional discomfort may exist.

Because youth will be asked about substance use and risky sex behaviors, minimal risk of emotional discomfort may exist. Exposure to some content within the intervention could trigger memories of events if the individual has experienced something similar. TCU RAs will be trained on identifying symptoms of trauma, handling information disclosed by the youth or caregiver, and will follow specific procedures required by each department for reporting abuse or trauma to health personnel. Steps will be taken to minimize risks introduced by meeting virtually (e.g., using meeting specific links, HIPAA-comparable security settings for virtual meeting platforms, and passwords to join, and emphasizing the need for maintaining confidentiality). Any reports or papers produced with data, will maintain respondent confidentiality; no identifiable individual responses will be disclosed.

SUHRI DATA AND SAFETY MONITORING PLAN

Our Data and Safety Monitoring Plan (DSMP) will be consistent with plans and procedures we have used in our other federally-funded research projects. These include installation of an 800 (toll free) number in the US for research sites to use for reporting adverse events (AEs) to the PI, Co-Is, and research team. The PI will serve as liaison with our university IRB and will monitor and report problems and AEs as directed. Specific plans and reporting formats will be developed and reviewed and approved by the IRB prior to the onset of any research involving the proposed pilot studies. Reporting forms will be developed and participating staff will be trained to identify and report problems and AEs. The agenda for the weekly data management team meetings also will include problem and adverse events reports, and all reports will be immediately forwarded to the PI. The PI will assume overall responsibility for assuring the safety of study participants and will assure that the TCU IRB is informed of all safety issues.

Definitions of Adverse and Serious Adverse Events

The proposed studies will follow established procedures based on our previous NIDA studies outlining Common Adverse Events (AEs) and Serious Adverse Events (SAEs) for substance abuse research. Adverse events are defined as any event or outcome that has resulted in harm to the participant, has affected the participant detrimentally, has worsened as a result of participation in the study, or has resulted in increased risk to the participant or others whether or not the risk actually results in harm.

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Specific Adverse Events (as observed or reported by participants or staff) include:

- Violation of confidentiality (e.g., release of participant data to a non-authorized 3rd party)
- Institutionalization in residential treatment or substance use rehabilitation
- Probation revocation, re-arrest, reincarceration (e.g., jail, prison, juvenile detention)

Specific Serious Adverse Events (as reported by the partner JJ agency or youth participants) include:

- Drug overdose
- Death
- Serious injury
- Life-threatening experience
- Suicide attempt
- Hospitalization
- Impairment due to a persistent or significant disability or capacity

Unexpected events are defined as any event or outcome that was not described as a risk of participation in the research or, even though described as a risk, which has occurred with unexpected severity or frequency. These SAEs will be monitored in interim analyses and will be systematically assessed as part of the post-intervention assessment. Although the enrolled participants are not considered to be at elevated risk for suicide (due to exclusion criteria), our collaborating JJ agency screens, identifies, and monitors mental health and suicide risk on an on-going basis and adheres to all local, state and federal policies regarding required reporting and intervention procedures. Specifically, all departments within the state of Texas are required to administer the Massachusetts Youth Screening Instrument Version 2 (MAYSI-2) within 2 weeks of referral to the department. Individuals with a “caution” score are identified and immediately referred to a Psychiatrist for a full evaluation. If a child is in a detention center, they are placed under “constant watch” for observation. If not in a detention center (i.e., living at home in the community), they are triaged into a crisis intervention program operated by clinicians and supervised by a Psychiatrist. This information (suicide risk, referral to psychiatrist, program participation) is logged in the electronic record system. The same procedure is employed if a suicide risk is identified at any point during involvement with JJ.

Within 24 hours prior to the first session, the TCU research assistant (RA) will confirm with the TCJS Director of Research (DOR) that the youth has met eligibility requirements (one or more indicator of substance use; on community supervision; no indication of suicide risk or thought disorder). Biweekly, RAs will provide a list of active participants to the DOR, who will identify any youth with a newly identified risk for suicide or thought disorder. Study staff also will monitor and report disclosures of suicidal ideation during study meetings as required by law and in accordance with TCJS departmental procedures.

Plan for Monitoring Adverse Consequences

Training of staff will include information on the definitions of SAEs and AEs and reporting procedures. SAEs will be identified by a **proactive system of “incident” reports filed in relation to providing interventions or participating in the research procedures**. These events will be reviewed by the PI and graded for their severity and attribution to the intervention, and ALL events will be reported in writing to the local IRB within 3 business days. Also, in accordance with local reporting requirements, all AEs occurring during the course of the study will be collected, documented, and reported by the investigators to the IRB at the time of their annual continuing reviews. The PI will prepare a summary report of all Adverse Events to be submitted to the IRB. The analysis of all adverse events accumulated-to-date will include a listing of all AEs.

Incident Reporting and Procedures

Any SAE, whether or not related to study intervention, will be reported to the PI within 24 hours of detection. Within 3 business days, the PI will submit a completed SAE report to the IRB. Written reports of adverse experiences will follow statutory regulations.

In the event that a subject either withdraws from the study or the investigators decide to discontinue a subject due to an SAE, the subject will be monitored by PI via ongoing status assessment until (1) a resolution is reached (e.g., the problem requiring hospitalization has resolved or stabilized with no further changes expected); (2) the SAE is determined to be clearly unrelated to the study intervention; or (3) the SAE results in death. Outcome of SAEs will be reported to the IRB in quarterly reports. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIDA.

The DSM report, to be submitted with the annual progress report, will include information organized into the following sections: study description, sociodemographic characteristics of the accumulated participants at baseline (pre-intervention assessment), data on the status of study participants, quality assurance issues, regulatory issues, data on AEs and SAEs, and efficacy.

Approach for Reviewing Problems

Each AE will be classified by the PIs as serious or non-serious and appropriate reporting procedures will be followed as stated above. The PIs will classify each SAE according to the following attribution of risk categories:

Definite: SAE is clearly related to the intervention
Probable: SAE is likely related to the intervention Possible:
SAE may be related to the intervention Unlikely: SAE is
doubtfully related to the intervention Unrelated: SAE is
clearly not related to the intervention

Participants' descriptions of adverse events (incident reports) will be grouped in a reasonable way, counted, and compared by study groups. A designation of "more-common" will be given to events occurring at an incidence of at least 5% in participants assigned to an intervention group, and for which the incidence is at least twice that observed in a comparison group. Staff will be trained to carefully observe participants' reactions to the study protocol and to take appropriate action including support, discontinuance, or referral to additional counseling services, if necessary. Based on previous experience and the current use of these TCU materials with other IRB research projects we have found that such occurrences are rare.

Reporting Timeline

SAEs will be reported to the PI within 24 hours of detection. Within 3 business days, the PI will send a full report on the SAE, including the action taken with regard to continued study participation to the IRB. Non-serious AEs or adverse effects that lead to subject removal from the protocol will be reported to the IRB within 7 business days. The PI will maintain a record of the SAEs, which can be provided to the IRB electronically. The outcome of SAEs also will be reported to NIDA in annual reports. A summary of the SAEs and AEs that occurred during the previous year will be included in the annual progress report to NIDA.

17. Potential Benefits:

Youth participation may result in introspection and problem identification, and promote and improve analytical problem-solving skills and healthy behaviors. From a larger perspective, participation may help to improve the quality of care for JJ- involved youth experiencing drug- related problems, and this may benefit not only the individual by reducing his/her pain and suffering but also by lessening the burden placed on their family and society at large. Formal adaptations of these materials for JJ youth will provide information on the potential usefulness of a highly active and engaging intervention for changing attitudes and intentions with regard to drug- related problems and health risk. We will also gain valuable information about the use of computerized technologies for delivering the intervention. The minimal and potential risks appear reasonable in relation to the anticipated benefits.

18. Compensation:

Compensation will be provided to the youth either in form as a gift or community service credit for each intervention session. Youth will get to decide at the beginning of each session. They can receive \$20 or 3 community service credits for each intervention session. They will also receive \$20 for each follow-up assessment session.

Although we do not consider the token/toy given for participating in the trivia game as compensation, it is worth noting that participants will receive a small token/toy such as a fidget spinner or equivalent in size/cost for participating in the trivia game and getting a certain number of questions correct.

Youth will also be reminded at each session that the project activities will end on August 31st, 2023 and they will be compensated for the activities completed before then.

19. Procedures to Maintain Confidentiality:

Procedures for protection of participant confidentiality will be followed (i.e., Human Subject Certification of all research staff, all data coded with an ID number, identifying information and research data stored in different places under lock and key, electronic data on a secure server without names).



The research design requires that client subjects be linked across assessment completion and to agency records. All participants will be assigned an arbitrary research ID that will be used to link all of their data. Data forms will only be identified with the research ID, personally identifying information will not appear on data forms. The PI will keep a link file linking names and research IDs on a secure server that does not contain other data. The assessments are intended to be administered online using Qualtrics. The RA will prepare the online assessment, which the participant will access by using a personalized link that is connected with their unique participant ID.

In order to personalize the virtual intervention and app experience, at the beginning of the first session, the RA will log the youth into the system using the client research id, the client will be asked to create their own unique user name, called a “FROG NAME.” Similar to the games on social media that provide users with a formula for creating fantasy names (see image to right), the youth will be presented with a formula to create their Horned FrogName.

For example:

First letter of your first name: R=Tangerine Month you were born: April=Canvas Favorite color: Black=17 Your FROG NAME is: TangerineCanvas17

On subsequent intervention sessions, the youth, once logged in by the RA, will be greeted with their unique frog name (e.g., “Hello TangerineCanvas17!”) while completing the virtual intervention session.

TCU computers are secured by redundant firewall and password access (to both the network domain and email user accounts). Procedures for confidentiality will include de-identified data to assure confidentiality. The general policy adopted by the present investigators is based on those used successfully for many years in other similar projects. Research files at the TCU Institute of Behavioral Research (IBR) do not include the names of the subjects involved in studies. In accordance with standard procedures used by the IBR, the confidentiality and privacy of client information will be protected by well-planned and comprehensive procedures. Only unique code numbers assigned by program staff during

the project will identify all research records. The data files that are created and retained for research will remain anonymous and are entered into computer research files for analysis with only the code numbers as identification. Reports issued will never include subject-level information that could be linked to any individual, and all published data and reports will be based on aggregate information. Participants will be informed that they can choose not to answer uncomfortable questions in order to minimize potential discomfort when responding to survey questions or intervention material. Furthermore, information provided as part of the study will not be shared with participating probation department, including any reported drug use.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use information that may identify a person in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as, but not limited to child abuse and neglect, or harm to self or others.

Data shared with the research team by TCJS and TJJD will be transmitted via Box.com through a secure file-sharing folder that only the appropriate parties have access to. PID and headquarter county numbers will be shared with TJJD to identify the data needed. Files connecting youth to their PID will be kept secure on TCU- owned shares accessible by the PI. Once data are shared, they are stored on TCU- owned shares that are protected by firewalls and passwords. Any additional security measures requested by the department or TJJD, such as scrambling PID numbers upon receipt of the data will be outlined in subsequent data sharing agreements and followed.

20. Data Analyses:

Implementation feasibility measures will be recorded, summarized, and reviewed monthly by the PI and team in order to inform real-time protocol adjustments (e.g., changes in recruiting practices if target numbers are not reached). Once the targeted youth recruitment goal has been achieved, psychometric properties of baseline measures will be conducted (means, SD, coefficient alpha, exploratory/confirmatory factor analysis). Because the design calls for repeated measures at baseline, month 1, and month 3, measures will not be revised between administration points.

However, psychometrics (conducted on data from all time points) will be used to inform modifications prior to a full-scale R01 RCT and reliability of scales for use in exploratory analyses of intervention efficacy.

Baseline characteristics will be included as covariates in analyses. The distal outcome will be the percent of study subjects who use drugs (self-report, corroborated with positive urine test) at follow-up (1- and 3-months). All study participants (regardless of study retention) will be included in analyses (i.e., an intent-to-treat approach; ITT). Baseline variables that directly relate to our aims (e.g., drug use, risky sex practices) will be evaluated for use as covariates. Abstinence at each

follow-up time point will be compared using chi square test. Our proximal outcomes will include putative measures (e.g., problem recognition, decision making, intention to reduce personal risk) and receipt of SU services (dichotomous measure from youth records). Because proportions of females and their SU rates are generally lower among JJ youth compared to males,⁶ and males/females may respond differently to MEC interventions,¹⁶ we will explore sex (as a biological variable) differences in SU, risky sex practices, and exploratory outcomes using univariate analyses (e.g., chi square, t-tests, ANOVA). We will also explore potential racial/ethnic disparities in order to more fully inform whether cultural modifications are needed for a subsequent application. A log rank test will be used to assess intervention dropout. Participants who withdraw consent or are lost to follow up will be missing on outcome measures. To address this, stochastic multiple-imputation will be attempted, which will provide maximum likelihood estimates, account for uncertainty in missing values, and provide unbiased estimates of the treatment effect if data are missing at random. Effect sizes will be used to calculate sample sizes needed for the larger R01. Calculations will include samples needed to assess intervention feasibility across sex and race/ethnicity subgroups.

21. Check List for the Items That Need to be Submitted:

- | | |
|---|--------------------------|
| a. Protocol | <input type="checkbox"/> |
| b. Consent document | <input type="checkbox"/> |
| c. HIPAA form if applicable | <input type="checkbox"/> |
| d. Protecting Human Research Participants Training certificate
for each investigator | <input type="checkbox"/> |
| e. Recruitment flyers, letters, ads, etc. | <input type="checkbox"/> |
| f. Questionnaires or other documents utilized in screening and
data collection | <input type="checkbox"/> |

Principal Investigator Assurance

22. By signing below, I certify to the following:

- The project described herein will be conducted in accordance with applicable TCU policies and procedures, as determined by the IRB of record. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Protection (“OHRP”) regulations at 45 CFR 46 and all other applicable federal and state laws and regulations (collectively “Applicable Law”)
- I have a working knowledge of Applicable Law
- All personnel who work with human participants under this protocol have received, or will receive, appropriate training in protocol procedures and protection of human subjects prior to working with humans.
- All experiments involving human participants will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.

- Procedures on experimental subjects described in this IRB protocol accurately reflect those described in the funding applications and awards, if externally supported.
- I and all personnel have read and will comply with any pertinent safety information, IRB requirements, and security procedures.
- I will maintain records of all human participants and the procedures carried out throughout the entire term of my project.
- As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care, treatment, and protection of the human participants.



Jennifer Becan

Signature of Principal Investigator

12/1/22

Date

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