

Technology-based Training Tool for an Empirically-Supported Group-Based HIV and STI
Prevention Intervention for Juvenile Offenders

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REVISION HISTORY

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V6	7/10/2024	Updated recruitment (pp.17-18)	
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V8	11/15/2024	Updated data sharing section and indicated analyses will be conducted at an external institution	No
V9	11/18/2024	Response to review of V8	No

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1.0 Study Summary

The current study follows the developmental IRB protocol 2021-1065.

From 2004 to 2016, UIC researchers developed, pilot tested, and conducted a rigorous efficacy trial of Preventing HIV/AIDs among Teens (PHAT) Life, an innovative HIV/STI, substance use, and mental health intervention for justice-involved youth. PHAT Life consists of eight sessions delivered by two facilitators. Topics within the sessions include basic sex education, HIV and STI information, emotional regulation, healthy relationships, and decision-making skills. Study findings revealed less sexual risk taking and substance use at 3-month follow-up, and strong effects for sexual behavior, aggression, and recidivism at 6- and 12-months. Results from the efficacy trial also demonstrated sustained positive outcomes on recidivism at 12-month follow-up.

In its traditional form, training facilitators to provide PHAT Life requires a 2-day in-person group-based meeting and involves didactic material, role plays, practice and feedback. A designated expert trainer travels to participating sites to provide the initial training. Ongoing technical assistance is provided by the expert along with in-person refresher training. These processes presented several challenges to wider dissemination which were confirmed during in-depth interviews with facilitators and administrators.

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The curriculum was described positively by these stakeholders, but the training model was perceived as unsustainable, costly, and impractical.

The next – and perhaps most critical – step in ensuring that this decades-long line of research produces actual, real-world improvements in the lives of justice-involved youth is to identify a facilitator training strategy that is effective, cost-effective, and sustainable for employees who will provide the PHAT Life intervention. Moving evidence-based programs into real-life settings is challenging but essential if their full public health impact is to be realized. To achieve this goal, UIC’s research team began a partnership with Oregon Research Behavioral Intervention Strategies, Inc. (ORBIS), doing business as Influents Inc (hereafter referred to as “Influents”) to adapt the existing facilitator training for a web-based learning management system. Influents is an Oregon C corporation specializing in the invention, development, and commercialization of evidence-based products and services for the health care, social services, and education markets. Influents features a team of nationally recognized research scientists, clinicians, methodologists, data analysts, consultants, certified project managers, audio and video specialists, graphic designers, software architects, and developers.

In 2019, UIC and Influents won a Phase I grant from the NIH’s Small Business Innovation Research agency (SBIR). In the Phase I trial, we refined, enhanced, and completed the technology-based training tool to include (a) an interactive multimedia web browser and mobile application, (b) dynamic multimedia presentations and interactive queries, (c) video examples of mock intervention delivery, (d) audio narration along with scripted language, (e) brief quizzes to ensure comprehension and knowledge acquisition, (f) opportunities to “learn more” by clicking on tabs for supplemental information, (g) targeted referrals to appendix materials, (h) games to promote engagement, and (i) other adaptations based on previous feedback. In the Phase I trial, we created and evaluated prototype interactive web browser and mobile app multimedia training tool. The prototype was then populated with content for the first two PHAT Life group sessions. Eleven para-professionals (e.g., health educators, probation staff, youth care staff) who worked with justice-involved teens completed the training and rated it highly for feasibility and acceptability. Participants also provided feedback on strategies for improvement.

In the spring of 2023, PHAT Life was re-branded as SYNC (Supporting Youth to Navigate Choices). No content or activities were changed – only the name. For the remainder of this document, the term “SYNC” will be used to refer to the program formerly known as PHAT Life.

The current study is a continuation of our previous work from the Phase I IRB protocol 2020-0654. Based on successful results from the Phase I, the UIC/ Influents team applied for and won Phase II funding from the SBIR. The current study consists of the Phase II project and will complete the development and evaluation of a technology-based training tool for SYNC with great potential for sustainability and cost-effectiveness.

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In Phase II, we will test a technology-based training tool that addresses the demand for sustainable interventions. The current study will rely on direct service providers (probation staff, case managers, public health educators, et al.) to complete the technology-based training, including individuals without prior training or advanced education. The current study hypothesizes that technology-based training (a) is likely to be cost-effective by eliminating the cost of in-person training and using remote methods that can deliver training at scale, (b) can be easily accessed and implemented at an individual pace, and (c) strengthens fidelity by leveraging technology to provide consistent training experiences across facilitators over time and place.

UIC's Center for Dissemination and Implementation Science (CDIS) and Influents are the two sites awarded the NIH funding for this project. This study will comply with the NIH Policy on the Use of sIRB for Multi-Site Research. UIC has been selected to serve as the single IRB of record for the research as the human subjects portion of this study will occur at UIC. Both participating sites have agreed to rely on UIC's IRB. Influents' role will be to manage the technology-based training environment, including participant's computer recorded usage data, and facilitate incentive payment. CDIS' role will be to recruit participants, monitor participant's training and study activity, and coordinate study activities that occur outside of the technology-based training environment.

2.0 Objectives*

- 2.1 This study aims to evaluate a technology-based training tool of the SYNC (Supporting Youth to Navigate Choices) intervention via a 2-arm randomized controlled trial with 130-180 individuals who work with justice-involved youth. All participants will first complete a baseline survey assessing HIV and STI knowledge and confidence delivering sexual health information. Second, all participants will receive the technology-based training tool and half will be randomized to participate in a live consultation session with an expert in SYNC intervention delivery and fellow study participants. Following their completion of training activities, we will evaluate all participants' knowledge of HIV and STIs and confidence delivering sexual health information (SYNC content), satisfaction with the training tool, and fidelity to SYNC. We will also assess key implementation outcomes, including cost, feasibility, adoption, implementation, acceptability, appropriateness, and maintenance.
- 2.2 Analyses will assess for equivalence between the two conditions (technology-based training only vs. technology-based training + live consultation session). Our primary outcome will focus on whether

participants across conditions can perform the SYNC intervention at equivalent levels of fidelity. Similarly, we will examine secondary outcomes including usage, satisfaction, and other implementation science outcomes. We will also evaluate cost, as it is expected that the cost to implement the training tool + live consultation session will cost more than the training tool only.

3.0 Background*

3.1 In 2019, nearly 700,000 youth under age 18 were arrested (Children's Defense Fund, 2021). Justice-involved youth are disproportionately minorities and disproportionately affected by substance abuse (Belenko et al., 2008; Bryan et al., 2007; Chassin, 2008; Dembo et al., 2009; Joesoef et al., 2006; Kahn et al., 2005; Lofy et al., 2006; Malow et al., 2001; Mertz et al., 2002; Robertson et al., 2005; Robertson et al., 2006; Teplin et al., 2003; Teplin et al., 2005; Tolou-Shams et al., 2010; Zhang, 2004), mental illness (Crosby et al., 2004; Grisso, 2008; Teplin et al., 2002; Vermeiren, 2006) and HIV/STI (Belenko et al., 2008; Department of Justice [DOJ], 2006; Goldberg et al., 2009; Romero et al., 2007; Tolou-Shams et al., 2010). Most young offenders are released on community supervision without the same STI, mental health, or substance use screening, diagnosis, and treatment afforded to detained youth, despite similar rates of risk behavior (Belenko et al., 2008; Romero et al., 2007). Justice-involved youth have poor long-term trajectories for mental illness, substance mis-use, HIV risk (Aalsma et al., 2011; Abram et al., 2009; Romero et al., 2007; Schmiede et al., 2009; Tolou-Shams et al., 2010), and multiple domains of life functioning (Abram et al., 2009; Abram et al., 2017).

Evidence-based programs that have the potential to alter justice-involved youths' long-term trajectories are sorely needed (Fagan et al., 2019; Tolou-Shams et al., 2010). Implementation of evidence-based programs in public service systems, including the juvenile justice system, is complex and challenging (Fagan et al., 2019). Hence, uptake of these programs has been disappointing and few evidence-based programs have been sustained over time (Belenko et al., 2008; Fagan et al., 2019; Tolou-Shams et al., 2010). To have a real-world impact on the lives of justice-involved youth, evidence-based programs must be effective, cost-effective, and sustainable (Fagan et al., 2019; Milat et al., 2015). Unfortunately, training to implement evidence-based programs is often costly (e.g., personnel time, effort) posing significant barriers to broad scale-up, dissemination, and implementation (Durlak & DuPre, 2008; Fagan et al., 2019; Korda, 2013).

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As described in section 1.0 of this application, the evidence-base for SYNC established it as an effective intervention for justice-involved youth.

3.2

During Phase I of the SBIR grant, staff members from a public health department were trained to deliver two of the eight SYNC sessions. Phase I participants completed training via a combination of live and technology-based training followed by in-depth interviews to identify implementation barriers and facilitators to additional scale-up in their setting. Feedback from the newly trained staff was positive. Stakeholders and leaders in the field affirmed the need for more cost-effective and sustainable approaches to train individuals in the juvenile justice system to deliver EBP, including SYNC, attesting to the value and benefits of a technology-based training tool as a viable and valuable strategy. Phase I data demonstrated that technology-based training for SYNC showed high acceptability, implementation feasibility, and sustained efficacy.

Further, in 2018, the National Institute of Minority Health and Disparities (NIMHD) released a report of SYNC's efficacy with justice-involved teens. Following the release of this report, the NIMHD received requests from several agencies that expressed interest in adopting SYNC.

3.3

Evidence-based programs (EBPs) are critically needed for justice-involved adolescents to reduce their negative health outcomes (Belenko et al., 2008; Fagan et al., 2019; Robertson et al., 2011), but few exist (Goldberg et al., 2009; Robertson et al., 2011). In fact, 90% of youth service systems do not implement EBPs (Hoagwood & Olin, 2002). Several factors are implicated in the low rates of adoption, implementation, and sustainment of EBPs in youth service settings. Among the determinants of adoption are the characteristics of the EBP (e.g., complexity, efficacy data), factors associated with inner setting (e.g., staff training, setting openness to new interventions, funding and other resources), and implementation processes (e.g., workflow, integration with other programming) (Damanpour, 1991; Durlak & DuPre, 2008; Zielinski et al., 2020). Agency leaders (including those in juvenile justice) have described EBPs as too complex to deliver, not an agency priority, and/or difficult to integrate into existing practices (Fagan et al., 2019; Zielinski et al., 2020). Similarly, the costs and staff time required to train in the EBPs can be prohibitive, especially in settings that face high staff turnover, as is the case in justice settings (Durlak & DuPre, 2008; Fagan et al., 2019; Korda, 2013; Milat et al., 2015; Zielinski et al., 2020). Staff losses require new staff members to

complete the same training, which increases the amount of time and resources required to continue offering a given program (Durlak & DuPre, 2008; Fagan et al., 2019; Korda, 2013). Most EBPs are enhanced by on-going supervision and coaching of staff trained to deliver the program (Durlak & DuPre, 2008; Fagan et al., 2019), but this approach can be resource-intensive (Fagan et al., 2019; Korda, 2013; Milat et al., 2015). Efforts to bring EBPs to scale, therefore, necessitate careful consideration of an EBP's characteristics (e.g., efficacy, complexity), suitability, acceptability, and cost for the justice setting (Korda, 2013).

Further, adoption of an EBP depends on the ability to train individuals to deliver the program, but staff training in EBP delivery faces a number of challenges. First, most EBPs require a workforce with a pre-determined level of education (e.g., college graduate) or experience (Fagan et al., 2019). Second, training often requires staff attendance for several hours at a time, potentially interfering with the setting's usual programming because staff are engaged in training (Durlak & DuPre, 2008). Lastly, the cost of training in EBP using the typical approach (described above) is potentially prohibitive (Fagan et al., 2019).

The current study's technology-based training tool seeks to address these barriers by producing an efficient, reliable, and acceptable approach to train future SYNC facilitators and to maximize sustainability without diminishing intervention fidelity. The technology-based training tool developed for the current study strives to address two critical implementation barriers shown to impact adoption and sustainment of EBP: (1) staff training and support, and (2) implementation costs.

The training tool will address implementation barriers as follows: (1) Training will be delivered individually at each participant's own pace. Participants can stop and start as needed and refer back to material as desired; (2) Multiple training platforms will be available (computer, android smartphone, apple smartphone) so people can choose the approach that best suits their needs; and (3) A combination of videos, quizzes, and other materials are embedded in the training approach to maximize fidelity to SYNC.

4.0 Study Endpoints*

- 4.1 Primary study endpoint: Fidelity and change over time in STI and HIV knowledge.
- 4.2 Secondary study endpoints: Confidence delivering sexual health information, satisfaction with training, usability, feasibility, adoption, implementation, acceptability, appropriateness, maintenance, utilization, and cost.

5.0 Study Intervention or Observation

5.1

Participants will be randomly assigned to one of two conditions: (1) Training Tool Only vs (2) Training Tool + Live Consultation Session. Thus, all participants will receive the Training Tool. The Training Tool is a technology-based platform designed to train paraprofessional staff to deliver the SYNC intervention. The Training Tool will be a web-app and will include: (a) a self-regulated course to learn facilitation skills and curriculum with dynamic multimedia presentations and interactive queries; (b) electronic system to support and facilitate learning and promote engagement; and (c) online tracking system of participant knowledge acquisition and intervention engagement. The software will use a menu-driven approach and audio narration wherever possible to minimize keyboarding skill and literacy requirements. The training tool is designed such that before the participant can move to the new area of learning, they must complete the previous lesson, including viewing the embedded videos, and obtain a passing quiz score of over 80%. Participants can return to and review previous material in a non-linear format. In each module, participants can “Click here for more information” for more in-depth materials.

In the Training Tool + Live Consultation Session condition, participants will use video-conferencing (UIC zoom) for at least one live consultation session with an expert in SYNC intervention delivery and fellow participants. The SYNC expert is also a study staff member. During the live consultation sessions, the SYNC expert will discuss areas of support and answer participant questions. Attendance will be taken to track participation and content discussed and questions asked will be documented. Participants will also see a static message displayed at the end of each training module. The messages will remind the participant that they can contact the SYNC expert directly with content-related questions and that they need to attend a consultation session. After completing module five, the participant will receive a personalized message from the SYNC trainer.

6.0 Procedures Involved*

6.1

Participants will be recruited from our participating agencies. Once a participant decides to participate, they will indicate their consent via REDCap and complete the baseline assessment. Participants will be randomly assigned to one of two conditions: 1) training tool only or 2) training tool + live consultation session. The randomization ratio will be 1:1 so that there is an equal number of participants in each arm. All participants will complete the training tool. Those in the training tool + live consultation session will have the ability to send

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direct messages to a SYNC expert and will attend at least one live consultation session. All participants will deliver one SYNC session demonstration, via UIC zoom, to determine whether there is equivalence in intervention fidelity across conditions. During the demonstration session, participants will facilitate a SYNC session as if to a group of youth participants. Study staff will play the role of youth. The demonstration session will be video recorded and coded for fidelity to intervention.

6.2

During recruitment, potential participants will receive information on how to enroll in the study. In addition, individuals who express interest in participation will have the opportunity to provide their contact information. See section 13.1 for further detail on recruitment procedures. Following recruitment, study staff will email and/or text message individuals who express interest in participating. The message will include a link to the informed consent in REDCap. Participants will review the informed consent and click “agree” to participate in the study. After indicating consent, REDCap will progress to the baseline survey where they will complete the locator form and the surveys on demographics, HIV and STI knowledge, and confidence in delivering sexual health information. After completing the baseline survey, they will be randomly assigned to one of two conditions: 1) technology-based training tool only or 2) technology-based training tool + live consultation session. All participants will then receive information on how to access the technology-based training tool as well as their personalized login information.

After completing module two, participants in the technology-based training tool + live consultation session arm will have the opportunity to attend at least one consultation session. During the live consultation session, a SYNC expert will discuss areas of support and answer participant questions. Participants will be asked to bring at least two questions about the SYNC program to their live consultation session. Participants in the training tool + live consultation arm will attend at least one live training session during their online training but may choose to attend more than one. Attendance will be taken to track participation and content discussed and questions asked will be documented.

Participants in the technology-based training tool + live consultation session arm will receive view static messages at the end of each module. The static messages will remind participants (a) that they can directly contact a SYNC expert any time they would like and (b) to attend live consultation sessions with a SYNC expert. After completing module five, participants will also receive a personalized direct message from a SYNC trainer.

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Participants who are randomly assigned to the training tool only arm will receive a REDCap survey containing a 15-minute video that provides information on an unrelated topic (e.g., disability rights). This placebo task will balance time and activity requirements for both arms. Participants in the training tool only arm will receive the link to this video after completing module two (the same point at which participants in the consultation arm will begin receiving information to attend a live consultation session).

After completing the technology-based training tool, participants will receive the post-training REDCap survey, which will include measures of HIV and STI knowledge, confidence in delivering sexual health education, technology-based training tool satisfaction, usability, feasibility, adoption, implementation, acceptability, appropriateness, and maintenance.

After completing all training activities and post-training surveys, each participant will deliver one SYNC demonstration session via zoom. All participants will demonstrate the same session (session 4). The demonstration sessions will be video recorded so that study staff can code for fidelity.

Throughout study activities, study staff will monitor progress. UIC study team will contact participants to facilitate study completion as needed. It is expected participants will complete training activities within approximately 4 weeks. This will be clearly stated in the consent document and communicated by study staff.

If a participant begins the technology-based training tool and completes the first five modules, but ultimately does not complete the entire course, then the participant will still be eligible to participate in the demonstration session. Participants who complete at least the first two modules, but ultimately do not complete the entire course, are eligible to receive the post-training survey.

6.3

Measures will be administered to participants at three time points: T1 (baseline), T2 (post-training), and T3 (after demonstration session). T1 will be administered after consent and before randomization. T2 will be completed after the participant completes the technology-based training tool or (for participants who do not complete the course) one-three months after training began. T3 will be completed after the participant completes the demonstration session.

The following data will be collected:

Measure or Construct	Time	Definition	Method to Obtain
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Locator Form	T1	Contact information	REDCap survey
Demographics	T1	Age, gender, race, ethnicity, education, experience working with youth, number of years at the facility, and job roles	REDCap survey
HIV Knowledge	T1, T2	Current knowledge of HIV	REDCap survey
STI Knowledge	T1, T2	Current knowledge of STIs	REDCap survey
Sex Education Confidence	T1, T2	Confidence in providing sex education	REDCap survey
Technology-based Training Setting	T2	Platform used and where completed training	REDCap survey
Satisfaction	T2	Satisfaction with the technology-based training tool and live consultation session (if applicable)	REDCap survey
Delivery Support	T2	Follow-up or booster session and training frequency	REDCap survey
Usability	T2	Usefulness of videos, printed manual (if applicable), live consultation sessions, messages to/from SYNC expert	REDCap survey
Technology-based Training Length	T2	Perception of length of time to complete training	REDCap survey
Feasibility	T2	Perception of whether participant has sufficient resources to complete technology-based training	REDCap survey
Additional Training and Improvements	T2	Additional training wanted and open-ended question about	REDCap survey

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		any improvements to be made	
Adoption	T2	Support for adopting the intervention at the setting	REDCap survey
Implementation	T2	Support for implementing the intervention at the setting	REDCap survey
Appropriateness	T2	Beliefs about whether the intervention is appropriate	REDCap survey
Maintenance	T2	Support for maintaining the intervention	REDCap survey
Acceptability	T3	Acceptability of intervention based on participant's evaluation of demonstration session	REDCap survey
Utilization	In real time as participant completes technology-based training tool	Computer-recorded usage data: # modules completed or logged into, time of day at log on, length of time on website/app, number of times logged on, length of time spent in information, support, video, and assessment areas of the training website/app, external resources accessed, quiz scores, homework modules completed, and how training tool was accessed (app or website).	Embedded within the technology-based training tool
Fidelity	T2	Staff coded adherence and competence in delivering an intervention session	Pencil and paper observer measure
Cost	NA	Relative costs of the SYNC technology-based training tool	Logged participant time to complete

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		delivered with vs. without live training session	training, time to complete live consultation session, average salary by job title at each participating agency, constructed variable to measure the cost of each participant's time in the training, constructed variable to measure the total cost to participating agency in terms of staff time. Logged time of SYNC experts to prepare for and complete consultation sessions, and to respond to messages from participants.
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6.4

No long-term follow-up will occur once all research related procedures are completed.

6.5

See attached documents:

Eligibility Screening and Contact Request

Snowball Sampling Text

Informed Consent

Locator Form

Pre- and Post- Measures

Fidelity (Observer Evaluation)

7.0 Data Collection and Retention*

7.1

Data will not be banked for future use in another study or project.

7.2

See sections 6.3 and 17.2 for a list of data to be stored.

7.3

At UIC, if researchers from other institutions (outside of UIC and Influents) request study data for secondary analysis, then the following procedures will be followed. Individuals will complete and submit the “CDIS Research Concept Form,” indicating the research question, background justification, and variables requested. PIs Kendall and Smith, and CoI Emerson will review the application. If the application is approved, a data use agreement will be executed, and appropriate steps taken to ensure their activities are following IRB requirements (e.g., determination of engagement, reliance agreement). Once these requirements are in place, data will be sent to the individual using a secure server (e.g., Box).

Procedures are the same for UIC collaborators except a data use agreement will not be executed and the individuals will be added to the research protocol as personnel.

8.0 Sharing of Results with Subjects*

- 8.1 Aggregated study results will be shared with our Community Advisory Board and will be reported in peer-reviewed manuscripts.

9.0 Study Timelines*

9.1

The approximate time to complete the consent and baseline survey is 20 minutes. The estimated time to complete the technology-based training is approximately 12 hours. The approximate time to complete the post-training survey is 30 minutes. For participants who are randomly assigned to the live consultation session arm, the live

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sessions are expected to last no more than 1 hour. For participants who are randomly assigned to the training tool only arm, the video will last approximately 15 minutes. The estimated time to complete the demonstration session is approximately 2 hours.

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It is expected that all participants will be enrolled by the end of 2024.

10.0 Subject Population*

10.1 Eligible subjects will be 18 years and older, speak and understand English, and currently work at an agency that serves justice-involved youth. Participants will include a diverse sample of 130-180 paraprofessionals (e.g., probation staff, caseworkers, public health educators, et al.) working at agencies serving justice-involved youth. Individuals in the population who previously have completed or attended training for PHAT Life will not be eligible.

10.2 We will be recruiting participants who currently work at agencies serving justice-involved youth and who are in positions at those agencies where they provide services to justice-involved youth.

10.3 This project will not include any vulnerable populations (i.e., adults unable to consent, individuals who are not yet adults, or prisoners). Pregnant women will not be excluded from the research, but no data will be collected related to their condition of being pregnant.

11.0 Vulnerable Populations*

11.1

This research does not involve vulnerable populations.

12.0 Number of Subjects

12.1 We aim to recruit 130 participants to complete all study activities. Power analyses were performed using G*Power Version 3.1.9.6. The primary parameter of interest for these analyses is the observed effect size for planned comparisons of the two groups (treatment group) in a TOST (two one-sided T-test) approach. Data will be analyzed utilizing an intent to treat approach, so power was based on complete sample analyses. The proposed design retains power $>.80$ to detect effects as small as Cohen's $d = .50$. (a medium effect), our metric of equivalence. Using this guideline, 130 will be a sufficient sample size to detect the smallest effect size of interest. Due to the possibility of participants dropping out of the study or failing to complete study activities within the required time frame, we

anticipate recruiting 180 participants to obtain 130 subjects with complete data.

13.0 Recruitment Methods

13.1

We will recruit participants from agencies which directly serve justice-involved youth, or which serve youth including justice-involved youth. Multiple methods will be used for recruitment. Materials will include flyers, email communications, and recruitment scripts for presentations. Materials will provide summaries of the study, eligibility requirements, and/or space for potential participants to enter their names and contact information. Study staff will collect flyers with participants' contact information. Separate flyers will be posted in relevant spaces (such as break rooms) with researcher contact information. Similar recruitment strategies have been used in other successful studies where SYNC facilitators were recruited.

CDIS study staff members will present the project at agency staff meetings and at recruitment-specific events (in-person or via video-conference). At in-person meetings or events, potential participants will indicate interest in hearing more about the study by using the 'recruit screener flyer'. Study staff will collect and secure all flyers, even forms where agency staff indicate no interest, to minimize privacy concerns. Video-conference recruitment will be similar. At zoom/virtual recruitment events that are hosted by CDIS study staff, the following tools will be used to protect potential participants' privacy. First, chat functions will be pre-set so that participants can only send messages to CDIS study staff. Second, CDIS study staff members will use poll functions to ask questions about attendees' interest in participating in the study and contact information. These two tools will ensure that responses can only be viewed by CDIS study staff, rather than by all attendees. At zoom/virtual recruitment events that are not hosted by CDIS study staff members (such as those hosted by a participating agency), CDIS study staff will not ask attendees to indicate their interest or for their contact information. Rather, CDIS study staff will provide their own contact information and ask attendees to contact them. When feasible, CDIS study staff members will display the recruitment flyer (for example, when they are able to share screen).

In addition, agency staff members may provide study staff members with names, e-mail addresses, and phone numbers of colleagues that they believe are eligible for the study. This may include an agency contact who provides study staff members with an agency roster of individuals who work directly with youth or by snowball sampling. In the case of snowball sampling, we will ask individuals who are eligible if they know of any colleagues who they believe we should

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talk to. If so, the individual will provide the name, email address, and phone number of that colleague. Agency staff members who refer potential participants will not be informed if their referrals participate in the study. Referred individuals will not be informed of who suggested them as potential participants.

If an individual is suggested for study participation, study staff members will contact the individual using email and/or text message to ask if the individual is interested in participating in the study (see attached document). Study staff members will not contact suggested participants via phone calls.

Once an individual directly indicates interest in participation, study staff members will contact the individual by email, phone, text, and/or instant messenger (e.g., Facebook messenger; LinkedIn, Slack). Study staff will verify eligibility, fully explain the study, and ask for their consent to participate. Participants will indicate their consent via REDCap prior to the baseline survey.

For individuals who express interest and provide contact information, but ultimately do not enroll in the study, their contact information will be discarded after the enrollment period ends. This same time frame will be followed for individuals who are recommended for the study, but who do not enroll.

Study staff members who are responsible for recruitment activities will receive necessary training in research ethics and data protection (as will all study staff members). Study staff members will not use their personal cell phones or personal email for recruitment activities or when interacting with participants. Rather, CDIS will purchase a study-specific phone for recruitment activities.

13.2

We will recruit participants from agencies which directly serve justice-involved youth or which serve youth and have justice-involved clients. Evening Reporting Centers (ERCs) are community-based alternatives to juvenile detention. The program is administered by local non-profit organizations and overseen by Cook County's juvenile justice system. Organizations that administer Evening Reporting Centers will be included in recruiting activities. These organizations include Treatment Alternatives for Safer Communities (TASC), Aunt Martha's, Lawrence Hall, and Youth Outreach Services (YOS). In addition, the Juvenile Justice Collaborative is an umbrella group that coordinates communication and activities across agencies that provide services to justice-involved youth. The Juvenile Justice Collaborative will also serve as a partner to provide information about the current study by sending flyers to their email list serve, including SYNC information at Collaborative meetings, and linking SYNC study staff members to their contacts. Individuals

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that work at agencies that are part of the JJC will be included in recruitment activities and eligible to participate.

In addition, Lurie Children's Hospital's Adolescent Medicine Department has two sex education teams that partner with multiple agencies that serve justice-involved youth. Staff members from these two teams will also receive recruitment materials and be eligible to participate. See LOS submitted with this modification.

Finally, many individuals who are connected to UIC serve justice-involved youth through partnerships with community-based organizations. Therefore, UIC listservs will be used to post recruitment materials and individuals who respond to recruitment messages will be screened for eligibility. If eligible, they will receive information to enroll in study.

We will post recruitment materials to additional listservs that are likely to include potential participants. Similarly, we will post recruitment flyers at physical locations that potential participants may frequent.

13.3

Participants will be identified when they respond to recruitment materials and/or when they agree to be contacted by study staff members. In addition, participants may be identified when agency contacts provide study staff with lists of agency staff members who appear to be eligible and/or when potential participants identify co-workers who they believe to be eligible.

13.4

Flyers and recruitment material have been developed (see attached). Attached documents include:

SYNC one-pager

SYNC recruitment flyer

SYNC recruitment flyer with eligibility screen (updated 7 10 2024)

SYNC recruitment email text for UIC listserv and other listservs (5 17 2024)

SYNC snowball sample text

13.5

For participants who complete all study activities, incentives will be paid on the following schedule. Participants will receive \$250 across five data collection milestones (\$25 after completing the baseline survey and the first two modules of technology-based training, \$25 after completing live consultation session/placebo video, \$50 after completing the technology-based training, \$50 after completing the

post-training survey, and \$100 after completing the demonstration session). Participants will receive compensation in the form of checks or money orders. For participants who do not complete all study activities, the incentive payment schedule will vary. For example, if a participant completes the baseline survey and the first two modules of the technology-based training tool, but stops activity after module three, then that participant will receive the first payment of \$25. If that same participant responds to requests to complete the post-training survey, then they will receive a payment of \$50 for completing the post-training survey.

UIC study staff will track participant activity and payment eligibility via an excel spreadsheet. UIC study staff will send the spreadsheet to Influents and Influents will send payments to participants.

It is possible that a specific agency's staff members will be prohibited from accepting incentives, based on the agency's funding structure or contract requirements. In addition, each agency will determine, for all staff who participate in the study, whether staff members will be able to participate while at work or whether they are expected to participate on their own time. During recruitment, we will know in advance which agencies allow participation during work hours and inform potential participants of this.

14.0 Withdrawal of Subjects*

14.1

There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

14.2

If a participant requests to withdraw from study activities, then they will not be contacted to schedule any remaining activities (such as live consultation sessions or demonstration sessions). Their study ID will be retained, data collected prior to withdrawal will be retained unless the participant requests data to be removed from the study records, and subsequent data will indicate that the participant has withdrawn.

15.0 Risks to Subjects*

15.1

The potential benefits of this project greatly outweigh the risks. With respect to risks, almost all the activities conducted in this study are typical of either educational or program evaluation assessments or involve services with evidence of their positive effects. Two areas of risk exist: 1) Survey items, quizzes, and training materials address

topics that some of the participants might find sensitive (i.e., sexually transmitted infections; condom use). We will minimize risk by using widely accepted and validated survey items. The survey items are brief and focus on specific knowledge, attitudes, preferences, beliefs, and satisfaction. With the training materials, we will minimize risk by ensuring participants know they can stop the training if they are uncomfortable. The materials were used in the SBIR Phase I without reported concerns. 2) A second risk is that though the most rigorous steps to protect confidentiality will be implemented, there is always a risk that confidentiality could be compromised. We describe our steps to minimize loss of confidentiality in sections 15.2, 17, and 18 of this protocol.

15.2

To lessen the risk of feeling uncomfortable with the material, participants can exit the study at any time they choose. In terms of risk for compromise of confidentiality, see section 17 for data protection protocols.

15.3 N/A

15.4 N/A

15.5 N/A

16.0 Potential Benefits to Subjects*

16.1

The proposed research will test the ability of a technology-based training tool to teach participants to deliver an evidence-based intervention, SYNC. The technology-based training tool will include interactive web browser and mobile app multimedia content to enable participants to deliver SYNC to youth. The long-term goal of the program is to teach individuals to deliver a high-impact HIV/STI prevention program and remove barriers to SYNC adoption, implementation, and sustainability. Ultimately, the goal is to improve the negative health outcomes of justice-involved youth. Hence, the potential benefits of this study outweigh the minimal risks and are sufficiently advantageous to justify the study.

16.2

There is no direct benefit to participation.

17.0 Data Management* and Confidentiality

17.1

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Primary Outcome: Fidelity. Metrics of fidelity include (a) coder-rated checklist activities in demonstration session; and (b) coder ratings of session quality. Checklist data regarding demonstration session activity completion (adherence) will be divided by the number of activities in that session to produce a proportion of session activities completed for coder-rated checklists. These will be evaluated for equivalence using the TOST approach described above. Similarly, evaluative ratings of the demonstration session (competence) will be averaged across features to produce an average fidelity quality rating.

Secondary Outcome: Usage, Satisfaction, Attrition, and Barriers. A critical element of consumer satisfaction is represented by dosage estimates. Thus, within this framework, we will descriptively report the percentage/number of participants that completed each module. All completion variables represent a facet of attrition that is meaningful for viewing satisfaction and acceptability relative to different components of the technology-based training tool. We will view satisfaction relative to the percentage of participants who report favorable ratings on each item of satisfaction, pairing these ratings with intervention effect and attrition results. Specifically, we will assess barriers to user engagement and see what changes are required to increase engagement.

If the results of our primary and secondary evaluations show equivalent (a) fidelity and (b) satisfaction and engagement across conditions, we expect that the more cost-effective technology-based training tool only implementation strategy (without live training session) can be leveraged to increase the likelihood for widespread dissemination of the evidence-based SYNC program.

Power analyses were performed using G*Power Version 3.1.9.6. The primary parameter of interest for these analyses is the observed effect size for planned comparisons of the two groups (treatment group) in a TOST (two one-sided T-test) approach. Data will be analyzed utilizing an intent to treat approach, so power was based on complete sample analyses. The proposed design retains power $>.80$ to detect effects as small as Cohen's $d = .50$. (a medium effect), our metric of equivalence. Using this guideline, 130 will be a sufficient sample size to detect the smallest effect size of interest.

17.2

The table below summarizes types of data, who will have access to the data, and how the data will be secured during storage and use.

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Data Type	Who Has Access	How Data is Secured – CDIS	How Data is Secured - Influents
REDCap Survey responses (identifiable and coded)	CDIS study staff	- In REDCap - Password protected folder on a secure server maintained by UIC's Department of Medicine (DOM) - Coded data may be used and stored in UIC Box	N/A
Participant activity tracking (identifiable)	CDIS study staff	Password protected folder on a secure server maintained by UIC's DOM	N/A
Incentive payment tracking (identifiable)	CDIS study staff and Influents administrative staff	- Password protected folder on a secure server maintained by UIC's DOM - Shared with Influents via SharePoint on a weekly basis	Identifying information used to process and send payments will be stored in password protected documents that are stored on protected servers.
UIC Zoom Video- conferencing recordings of demonstration sessions (identifiable)	CDIS study staff	Recordings will be downloaded and deleted from Zoom and secured in a password protected folder on a secure server maintained by UIC's DOM	N/A
Paper & pencil measures or hard	CDIS and Influents study staff	Locked cabinet in locked office	Locked cabinet in locked office

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documents containing participant data or notes from study activities (identifiable and coded)			
Other electronic spreadsheets or datasets (identifiable or coded)	CDIS study staff and Influents study staff	- Password protected folder on a secure server maintained by UIC's DOM - Coded data may be used and stored in UIC Box	Password protected file servers with limited staff access
Technology-based training tool data for account creation (first name, last name, email address, research ID, phone number)	CDIS and Influents study staff	Data will be stored within the training website. Limited number of study staff members have log-in credentials as administrators with the ability to view study participant's PII. Details about website security in next column.	The training website uses VeriSign SSL and will be established within the Influents network with firewall to maintain security. The website will be accessible via the Internet with username and password protection.
Technology-based training tool data for course completion/progress (identifiable)	CDIS and Influents study staff	Data will be stored within the training website. Limited number of study staff members have log-in credentials as administrators with the ability to view individual participant	The training website uses VeriSign SSL and will be established within the Influents network

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		progress. Details about website security in next column.	with firewall to maintain security. The website will be accessible via the Internet with username and password protection.
Exported reports of technology-based training tool data for course completion progress	CDIS and Influents study staff	- Password protected folder on a secure server maintained by UIC's DOM - Coded data may be used and stored in UIC Box	Password protected file servers with limited staff access

At UIC, access to data will be limited to individuals on the study protocol. At Influents, access is limited to individuals who work on the study. All study staff members at UIC and Influents will complete a confidentiality agreement and will be trained on the importance of participant privacy and confidentiality.

A certificate of confidentiality was automatically obtained through NIH.

At UIC, links to identifiers and study IDs (master lists) will be used and stored in RedCap, password protected folder on a secure server maintained by UIC's DOM, and within the technology-based training website.

Secure servers (SharePoint) will be used to transmit data between Influents and UIC study staff members.

At Influents, data (including identifiable, coded, and master list data) will be secured using the following protections: (1) All user accounts are under strict password control including routine scrutiny of passwords by password "cracking" programs; (2) All remote access is strictly monitored and requires monthly changes of passwords; (3) Root access is strictly controlled and allowed only by select members of the computer staff and limited to on-site access only; (4) All programs providing port based access are the latest and most secure available; tftp is not allowed; (5) All file system mounts are strictly controlled by the Unix based "netgroup" system; (6) SetUID shell scripts and User .rhost files are not allowed; (7) Direct access to most

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devises is via root only; modems and terminal servers are password protected at the port level; (8) Software is downloaded in source form and compiled on site. Illegal or suspicious software is immediately removed from the system; (9) A routing “firewall” is in place limiting offsite access to a set of secure services on, in most cases, a single host. IP spoofing is prevented by the “firewall.” Influents Innovation’s upstream IP provider (RainNet) also does IP spoof guarding on routes to us. WWW/CGI executables are run in the safest way on the single WWW server that is visible to the outside world. All personnel who have access to subject information are trained in confidentiality procedures and have completed an extensive online human subjects training before they have any contact with participants or data files.

Dr. Nyssa Snow-Hill and students under her supervision will analyze data. Dr. Snow-Hill is faculty at DePaul University, she’s also a faculty affiliate at the Center for Dissemination and Implementation Science. A data use agreement will be executed to share limited data with DePaul. DePaul collaborators will not receive funding.

Data to be shared with DePaul collaborators include the following:

- Dates participants completed study activities, dates and number of times participants were contacted to complete study activities
- REDCap survey responses (e.g., demographics, HIV and STI knowledge, sex education confidence ratings, responses about the platform used and where they completed the training, satisfaction with the training tool, whether participants felt they needed more training support, usability of the training tool, perceptions of the length of time it took to complete the training, feasibility, adoption, implementation, appropriateness, maintenance, and acceptability of the training tool, additional training desired and open-ended questions about any improvements that need to be made).
- Demonstration session fidelity (adherence and competence in delivering the session activities) coding spreadsheets
- Training tool utilization (e.g., number of modules completed or logged into, what modules were completed or logged into, time of day training was completed, length of time using training tool, including time spent on information, support, video, and assessment areas of the training, external resources accessed, number of times logged on, quiz scores, homework modules completed, how training tool was accessed).
- Notes taken during consultation sessions

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- Cost estimations (e.g., time it took to prepare for and complete consultation sessions, and to respond to messages from participants, estimated salary by job titles of each participating agency)

Data will be shared with DePaul collaborators using Box Health and the UIC data manager will ensure that datasets do not include direct identifiers listed in Attachment 2 of the data use agreement.

17.3

This study will use REDCap for data collection and storage, including the use of REDCap's tools for data management, validation during data entry, and data storage. In addition, the project director will perform quality control reviews of data entered by study staff, fidelity coders, and data manager.

17.4

See sections 6.3 and 6.5 for what information will be included in the data. Section 17.2 describes how data will be secured, stored, and defines who has access to the data. UIC study coordinator and data manager will be responsible for receipt and transmission of data. Identifying data will be destroyed after data analysis is complete. De-identified datasets will be maintained from that point on. All videos will be deleted within five years of the end of data collection unless written permission is provided for further specified retention.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1

Throughout the study, there is a small risk that co-workers or supervisors will somehow find out who is participating. Risks to privacy will be reduced in the following ways. First, participating agencies (recruitment sites) will not have access to the names of participating employees. Second, the informed consent document reviews confidentiality and privacy of participation.

A potential risk to privacy may occur during the live consultation sessions if participants know each other. During live consultation sessions, participants will be reminded of the confidentiality of study participation.

18.2

Participants might find the surveys, quizzes, and training materials uncomfortable. The materials address topics that are sensitive (i.e., sexually transmitted infections; condom use). We will minimize risk

by using widely accepted and validated survey items. The survey items are brief and focus on specific knowledge, attitudes, preferences, beliefs, and satisfaction. With the training materials, we will minimize risk by ensuring participants know they can stop the training if they are uncomfortable. The materials were used in the SBIR Phase I without reported concerns.

18.2

The only sources of information that the research team will access are those that have been specified in this IRB protocol. Only those team members working directly on this project will have access to study data unless as specified in section 7.3.

19.0 Economic Burden to Subjects

19.1

The technology-based learning course will occur online via a secure website or app. Participants can view the materials at home or at work using a desktop computer, tablet, or smartphone. If participants complete the course via the app on a personal device, they may incur data charges. Participants in the live consultation session arm will complete the sessions via zoom. If they do so via the app on a personal device, they may incur data charges. Participants will complete demonstration sessions via zoom. If they do so via the app on a personal device, they may incur data charges.

20.0 Consent Process

20.1

Study staff from UIC will speak directly with all paraprofessionals interested in participating in this study. They will explain the study, screen for eligibility, and answer any questions that potential participants may have. Once an individual agrees to participate in the study, UIC study staff will send the individual the consent form and baseline measures via REDCap. Participants will indicate their consent via REDCap prior to completing the baseline measures. The consent page will include the study's purpose, anticipated participant numbers, length of study participation, activities involved in participation, possible benefits and risk of participation, privacy and confidentiality protection measures, stopping participation after enrollment, study incentives, and contact details of a study staff member if the participant has study-specific questions. The consent page will emphasize that all study activities are voluntary, that the

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participant can withdraw at any time, and that the participant can decide not to answer any questions they do not want to answer.

Non-English Speaking Subjects

Individuals who are non-English speaking will be excluded from this study. Currently, the technology-based training tool is only available in English.

21.0 Setting

21.1

- We will recruit from agencies which directly serve justice-involved youth or which serve youth, included justice-involved youth.
- Participants will complete the REDCap surveys, technology-based training, live consultation session or placebo video, and the demonstration session at a location of their choosing. Consent will be completed via REDCap. Data collection will occur within REDCap, within the technology-based training tool, and via video-recorded zoom sessions.

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