StaySafe: A self-administered android tablet application for helping individuals on probation make better decisions pertaining to health risk behaviors

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A B S T R A C T

This paper describes the development and protocol for feasibility and efficacy testing of a risk reduction intervention designed to improve behavioral health outcomes among drug offenders on probation under community supervision or in residential substance abuse treatment centers. *StaySafe* is a self-administered tablet-based intervention for teaching better decision-making skills regarding health risk behaviors, especially those involving HIV risks. We are using pre/post, experimental/control group randomized clinical trial (RCT) in both community and residential probation settings with goals to 1) assess the feasibility and acceptance of *StaySafe* by examining participation rates and satisfaction measures, and 2) examine the impact of *StaySafe* on decision-making skills, confidence and motivation to avoid sex and drug risks, willingness to discuss health risks and concerns with helpful others, and engagement in health risk behaviors.

StaySafe consists of 12 brief sessions and utilizes an evidence-based decision-making schema, called WORKIT, which guides participants through steps for identifying the problem and options, evaluating the options and making a decision about which option to carry out. Multiple sessions of *StaySafe* provide a practice effect so that the WORKIT steps become easily accessible to participants when making decisions. Three of the sessions provide participants a choice of activities designed to provide additional information about HIV and reinforce lessons learned during the WORKIT sessions. Preliminary data demonstrate feasibility and high levels of satisfaction with *StaySafe*.

1. Introduction

The Centers for Disease Control (CDC) estimated that approximately 1.2 million people in the US were HIV positive in 2013 and of that group, at least 150,000 did not know their HIV status. HIV/AIDS was the 8th leading cause of death for people aged 25–34 and 9th for the 35–44 age group in 2014 [9]. HIV infection has been disproportionately represented in criminal justice populations with rates as much as 3–5 times as high as the general population in the U.S. [7,38]. However, the vast majority of inmates with HIV contract the virus while in their communities, before they are incarcerated. Drug use among the criminal justice population exacerbates the risk for HIV through sharing needles and association with risky sex behaviors such as unprotected sex and sex with multiple partners [8]. Most inmates eventually will return to their communities, and those who previously engaged in risk behaviors may actively seek and re-engage in high risk drug and sex

behaviors upon their return [4,5,33]. MacGowan et al. [29] found that 13% of newly released inmates engaged in risky sex within one week of release and 36% within 6 months.

The Bureau of Justice Statistics [6] estimates that there are approximately 5 million individuals under community supervision in the U.S. The Center for Substance Abuse Treatment reported that 41% of people on probation had drug or alcohol treatment as a condition of release and 33% had mandatory drug testing [10]. Because of the likelihood of risk behaviors increasing upon return to the community, these data strongly suggest the need for prevention and intervention programs targeting HIV risk reduction in criminal justice populations in the community. However, well established and consistent use of HIV risk reduction programs with continuity of care are often unavailable.

To address this need, the Institute of Behavioral Research (IBR) at Texas Christian University (TCU) developed a risk reduction intervention, *StaySafe,* designed to improve behavioral health outcomes among

drug offenders under community supervision. *StaySafe* is a self-administered tablet-based intervention designed to teach better decision-making skills regarding health risk behaviors. We are using a randomized clinical trial (RCT) to test *StaySafe* in both community and residential probation settings with goals to 1) assess the feasibility and acceptance of *StaySafe* by examining participation rates and satisfaction measures, and 2) examine the impact of *StaySafe* on decision-making skills, confidence and motivation to avoid sex and drug risks, willingness to discuss health risks and concerns with helpful others, and engagement in health risk behaviors compared to participants randomly assigned to a treatment as usual comparison condition.

In this paper, we describe the underlying foundation, development and content in *StaySafe*, the RCT design utilized to test *StaySafe* impact, measures being collected, planned analyses, and we discuss the implications of *StaySafe* in probation settings.

2. Method

2.1. StaySafe description and development

StaySafe includes 12 brief sessions that utilize an evidence-based decision-making schema called WORKIT (see Fig. 1) – a stepwise schema in which participants first identify what the problem is, who will be affected by the decision, and who can help with the decision. Participants then go through specified steps to identify and rate options for the problem, use the ratings to make a choice, think about the steps and actions needed to make the choice happen and then test the results by carrying out plans for making the best choice. An individual who has practiced WORKIT may be more likely to draw upon that schema when faced with a new situation rather than another, poorer strategy from their past experiences. Several studies on adolescents in AOD treatment that used WORKIT showed improved decision making, self-awareness, and problem recognition [3,23,24].
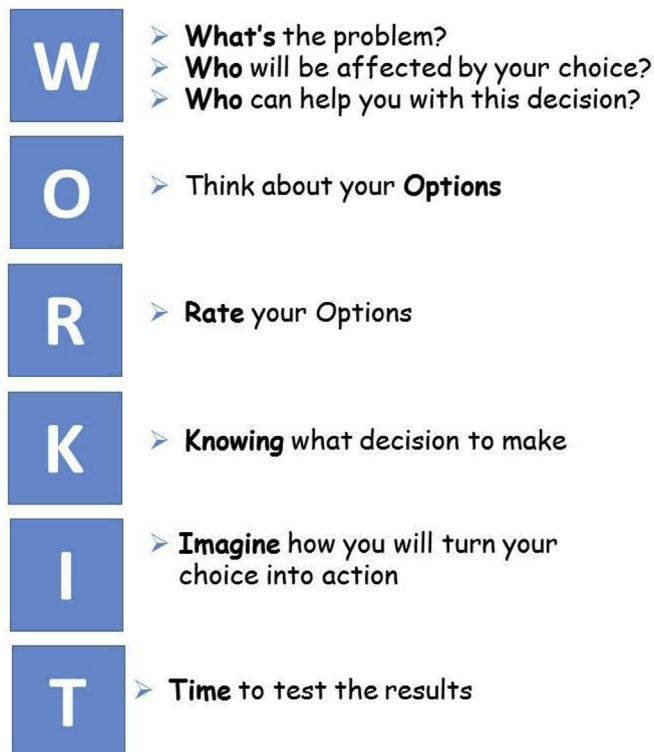

Fig. 1. WORKIT.

StaySafe [25,27] was adapted as a follow-up to a 6-session, group-based curriculum called *WaySafe* that was developed for incarcerated individuals in the last phase of substance abuse treatment [27]. *WaySafe* is a counselor-led, manual-based and highly interactive curriculum designed to help participants identify and plan for risks when they were released back into the community, especially risky sex and drug use behaviors. However, the group-based and highly interactive *WaySafe* sessions can be challenging to implement in community supervision settings. To meet the needs for HIV prevention programming for community supervision settings, we borrowed many of the concepts from *WaySafe* involving making better decisions by identifying and planning for risks to develop *StaySafe* as a self-administered, tablet app that requires minimal staff training or time, resources that are frequently rare in community probation settings.

2.2. Theoretical basis

StaySafe builds on current explanatory approaches in decision making. These approaches use dual processing models that incorporate both experiential and analytic processing systems [18,20]. Judgments and decisions about risks often are based on experiential or episodic memories, are rapid, and stem from automatic reference to previously stored experiences [18,37]. In contrast, decision strategies based on the analytic system need to be reinforced; they are slower and consciously developed. One's ability to master a situation is hypothesized to involve a collection of schematic structures that emerge from repeated analytic practice [13]. Thus, the ability to make more informed decisions regarding health behaviors can be enhanced by developing and repeatedly practicing schematic structures. *StaySafe* is designed to build mastery through repetition by helping participants plan for and make better decisions by practicing a simple approach. Using a sports analogy, athletes train by repeating behaviors until they become automatic. Thought processes can be similarly trained by repeating the process until it is readily invoked when the respondent is faced with a risk or temptation. Making the intervention engaging ameliorates the repetitive nature and helps keep participants on task.

2.3. The StaySafe package

The *StaySafe* intervention consists of 12 brief, 10-min sessions completed by individuals. An introductory session shows how to navigate through the program using the WORKIT schema. There are 8 additional WORKIT sessions and 3 sessions labeled Participant Choice.

Participants begin a WORKIT session by choosing one issue from a list of 11 issues that deal with behaviors, associated with health risk; issues are grouped under People, Places or Things (see Table 1 for list). Participants can repeat an issue used in previous sessions. The idea is not to solve specific problems during the sessions but to learn and internalize the WORKIT decision-making schema using issues that have

Table 1
Problem choices in WORKIT sessions.

Category	Problem Choice
People	1. My partner has HIV—what now?
	2. Telling others about testing positive for HIV
	3. Asking a partner about his or her HIV testing
	4. Hanging out with friends who inject
Places	5. Favorite high-risk places to hang out
	6. Returning to the old neighborhood
	7. Finding medical help for HIV care
Things	8. Practicing safe sex
	9. Getting tested for HIV
	10. Fear of getting HIV testing
	11. Myths about HIV and where to find the facts

been chosen to be relevant for the target population. All material for the rest of the session link to the specific issue chosen for the session. In order to maximize learning of the WORKIT decision-making schema, the participant first observes someone in a brief video making a decision related to the chosen issue (vicarious learning) and rates that decision as good or bad. During some WORKIT steps, the participant is asked to make choices from presented lists (e.g., who might be affected; options for responding to the selected issue). As various choices are selected, boxes appear with supporting facts about that choice. For other WORKIT steps, the participant is asked to think about choices or next steps without making an explicit response; thus, mentally working through the options in choosing the best decision. This approach trains the participant to use imagination to work through problems in preparation to use the WORKIT schema when confronted with issues in the community. Studies have suggested that such mental practice can have beneficial effects on learning compared to simply studying the material [12]. The session ends with a brief quiz game (the maze game) designed to reinforce lessons learned and a seven-item session survey asking about ease of use and whether the program was helpful.

Participant Choice sessions are interspersed with WORKIT sessions to provide variety and are designed to present supporting information about relevant problems. The participant is given the option to engage in three different activities including 1) watching an informational video from the CDC about HIV/AIDS, 2) viewing a HIV/AIDS facts page which also contains either a brief video interview with someone affected by HIV/AIDS or an informational video about anti-retroviral therapy, or 3) playing the maze game with new sets of questions. Participants may choose to complete one, two or all three activities before completing a satisfaction survey to conclude the session.

2.4. StaySafe production elements

StaySafe content builds on CDC and NIH resources, previous IBR research, and other health-related literature reporting on HIV risk factors and best practices for prevention and treatment of HIV. With this information in hand, the IBR research team created a story board, providing a visual representation of which scripted elements to incorporate in the app. The process was carried out in stages—identifying themes for the issues list, documenting references, scripting dynamic elements, selecting graphics, meeting with programmers on design, editing content to the app specifications—to arrive at the first prototype. Pieces such as voice-over instruction and video production came later in the development process. Content was reviewed throughout development by an experienced drug counselor prior to unveiling with focus groups and theater testing with adult probationers and staff representation from community corrections and behavioral health. The final *StaySafe* app includes 88 HIV-risk and health-related factoids, 77 maze game questions, and 7 original IBR-produced video vignettes.

2.5. StaySafe programming decisions

Three theoretical considerations guided decisions regarding the display of content to maximize what learners took away from each *StaySafe* session [30]. The first was the use of words and pictures with visual and audio connections to represent information. This consideration, supported by dual coding theory [1,2,31], dictated that *StaySafe* programing include dual emphases consisting of both visual and verbal elements. Second, programming and design decisions followed cognitive load theory [1,2,11] because human auditory and visual channels have a limited capacity for processing. It was essential that the *StaySafe* app maximize the text displayed, maintain word contiguity (e.g., adjacent to descriptive graphics), and utilize a brain-friendly content structure in which the information in the intervention was "chunked" (e.g. presented it in shorter parts without losing the whole idea; [36]. This approach presented selected informational words and phrases as audio rather than crowded on-screen text, suggesting

that information overload was minimized for participants [14]. Last, attention to active processing theory [30,39] personalized *StaySafe* information (e.g., "you are about to start … vs. "this program is about …") and importantly guided learners to select, organize, and integrate information.

Programmers consisted of a team of four senior undergraduates enrolled in a capstone course in the university's Computer Science department, guided by their faculty instructor and the *StaySafe* research team. Researchers tasked the students with converting their storyboard designs into an intervention app with the desired functionality. Each screen had challenges to overcome that ranged from having to design custom timing mechanisms, dealing with multiple large graphics on complex layout structures, and building screens with solely dynamic content. Decisions were made regarding what technology platform to use (e.g. tablet or PC, Android, IOS, or Windows), input decisions (e.g., touchscreen, keyboard, or audio input), and considerations for sustainability, e.g., development of a companion program, *KeepSafe*, to readily edit or change dynamic content in *StaySafe* without the need for a programmer.

KeepSafe became a stand-alone curriculum management tool with a simple user interface that allowed the import and export of dynamic content without additional programming [15]. Dynamic content in *StaySafe* includes all text related to problem choices and associated options, facts, and game questions as well as audio, video and pictures. Containing more than 1600 unique text values and inputs, *KeepSafe* gave the option for easy revisions to content and topics, options for up to 30 problem themes, and provided an easy swap-out of voiceover, video, and graphic elements through standardized filename conventions. *KeepSafe* allows the *StaySafe* platform to be easily rescripted for other studies or involving different target populations.

2.6. StaySafe testing

Extensive testing was conducted to ensure the final product would meet the specification requirements using three strategies: (1) black box testing, (2) usability testing, and (3) exploratory testing. Black box testing, sometimes referred to as data-driven or functional testing, focuses on software outputs without regard for code implementation or program structure. It involves taking a predetermined set of inputs and ensuring the software responds in a manner consistent with the specification requirements. In the process of testing *StaySafe*, various sets of inputs containing a large variety of values and combinations of values were created and then systematically entered into the application prototype. Stored session data were later validated against the input sets to verify that software outputs were correct.

Usability testing is subjective form of software testing that focuses on user friendliness, functionality, and content delivery. Real time responses to user input, technical aspects of content presentation, and the end user experience are evaluated. The usability testing of the *StaySafe* application included: making sure text content was easily readable and formatted properly, testing the audio levels of multimedia content with headphones that were to be used in the study, ensuring that audio narrations were paced appropriately, and checking that user selections resulted in the presentation of the corresponding content. Exploratory testing has the goal of finding bugs in the software by deliberately trying to cause errors in the program. Testers attempted to enter invalid values, trigger multiple inputs simultaneously, and examined the effects of extreme values on data output.

2.7. Research design

StaySafe is currently implemented in probation facilities in three large counties in a large southern state which include a community supervision office in one county and residential substance abuse treatment centers for probationers in the other two counties. Treatment in the residential centers is typically about 6 months in duration.
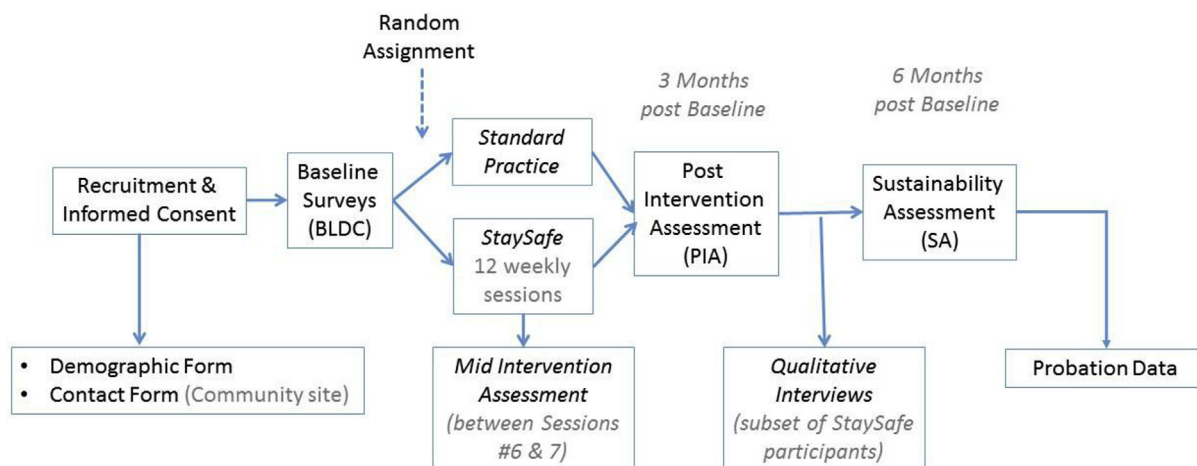
Fig. 2. Research design.

The study design is a randomized two-arm intervention/no intervention design with baseline, post-intervention (at 3 months after baseline) and sustainability (6 months after baseline) surveys (see Fig. 2). The first step involves recruiting participants for the study. In the community supervision location, individuals on probation are recruited using posters on the wall of the waiting room, the study Research Assistant (RA) approaching people waiting for appointments in the waiting room, brief presentations in group sessions, and by word-of-mouth from participants already enrolled in the study. In the residential centers, the RA meets with new intakes to provide information about the study.

Eligibility criteria include (1) a history of substance abuse, (2) at least 6 months of probation supervision remaining, (3) 18 years of age or older, (4) not classified as a sex offender or convicted of a violent crime, (5) absence of a serious mental illness that could prevent participation in the study (6) no pending charges that potentially would result in incarceration during the next 6 months, and (7) a sufficient reading level in English (fifth grade or higher) that will allow completion of the study materials.

Participants are informed that their time in the study will be compensated by payments made directly toward their probation fees. For the residential locations, participants receive $20 for completing each of the three surveys, which take about 30–45 min each. Participants in the community supervision location receive $20 for completing the Baseline Data Collection (BLDC) and $40 for completing the Post-Intervention Assessment (PIA) and $40 for the Sustainability Assessment SA. Payments for the PIA and SA for community participants are higher since they have to make additional appointments and complete the surveys on their own time. Participants in the *StaySafe* arm of the study get $10 for each *StaySafe* session completed, up to $120.

Those who are interested in participating in the study proceed through the informed consent process. The TCU IRB-approved Informed Consent document is read aloud, questions are answered and all who want to join the study are asked to sign the Consent document. Following signing of the Informed Consent, participants are asked to complete a brief demographic form and a contact form (for the community supervision site) to allow research staff to contact them for scheduling purposes. Participants are then scheduled for a baseline survey, generally in the following week.

After completing the baseline survey, participants are given an envelope that includes their random assignment to the study arm. Participants who are randomly assigned to the *StaySafe* condition are then scheduled for their first *StaySafe* session generally in the following week. *StaySafe* sessions are scheduled weekly until 12 sessions are completed. Participants randomly assigned to the Standard Practice

(SP) arm are informed that they will be contacted in about 3 months to schedule another survey and then again in 6 months to complete a final survey.

2.8. Data management and scheduling

A Microsoft ACCESS tracking database was developed to help research and field staff manage project goals. The database is available on each RA's laptop and data is uploaded (using a secure server application) to a central database that integrated information from all field sites. RA's use the system to monitor participant appointments for tablet sessions, individual surveys that need to be completed, as well as upload session data files from the tablets, which include the session satisfaction survey. The database also helps manage the receipts and track payments for probation fees that have to be reported back to CSCD in each county. Project management functions include tracking informed consent documents, basic demographics, and study dropout rates which help alert research staff to issues at field sites that need attention or monitoring. It also is used to generate a monthly report which Research staff use to monitor progress at the field sites.

3. Measures

Three main surveys are administered during the study. These include the TCU Baseline Assessment (BLDC), TCU Post Intervention Assessment (PIA) administered about 3 months after the BLDC, and the TCU Sustainability Assessment (SA) administered about 6 months after the BLDC. Participants who stay on schedule with the weekly *StaySafe* sessions, typically complete the 12 sessions before the PIA is administered. However, in order to be compatible with the schedule for SP participants, the PIA is scheduled 3 months after the BLDC regardless of how many *StaySafe* sessions have been completed. Subsequent sessions may be scheduled after the PIA until participants complete all 12 sessions or indicate that they are not interested or able to complete all 12. Further sessions are not scheduled after the SA is administered. In addition to the three main assessments, the brief Mid-Intervention Assessment (MIA) is administered to *StaySafe* participants between sessions 6 and 7 and a qualitative interview is administered to a subsample of *StaySafe* participants within several weeks of completing the PIA.

3.1. Demographics and contact form

A brief demographic form is completed after the Informed Consent and includes date of birth, current age, gender, race/ethnicity, date probation ends and the ID number used by the state's central

Table 2
Baseline, post-intervention assessment, & sustainability assessments.

Proximal Outcomes	
TCU Confidence & Motivation scales	4 scales assessing confidence and motivation around HIV Knowledge Confidence, Avoiding Risky Sex, HIV Services and Testing, and Risk Reduction Skills [26]
How often have you talked about … (PIA & SA only)	12 items on frequency of talking about making better decisions, avoiding HIV risks, or HIV prevention or treatment with probation officers, counselors, trusted friends or advisors, or family members (items developed for current study)
Decision-making	Decision-making from the TCU Treatment Needs and Motivation form and scales assessing Rational and Dependent Decision Making [32]
Health-visits and testing	4 items asking about recent doctor's visits or hospitalizations, and recent testing for HIV, HVB & HVC, and STDs (items developed for current study)
Distal Outcomes	
[a]TCU HIV/Hepatitis Risk Assessment	Items focusing on risks associated with injection drug use and sexual activities as well as scales on Condom Attitudes and AIDS Concerns [34]
Descriptive and Predictive Measures	
[a]TCU Global Risk Assessment (Adult version)	Items on education, employment, family involvement, living arrangements and a broad checklist of background problems [17]
[a]TCU Drug Screen V (Baseline only)	Screens for mild to severe substance use disorder based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Items include assessing problems from substance use, drugs used in last 12 months as well as frequency of use, times in previous treatment, injection drug use, and self-assessment of seriousness of drug problems and importance of getting into drug treatment [21]
[a]TCU Criminal History Risk Assessment (Baseline only)	Items focused on previous arrests, convictions, and incarcerations [16,17]
[a]TCU Treatment Needs and Motivation	Scales on Problem Recognition, Desire for Help, Treatment Needs Index, and Pressures for Treatment [22,35]
[a]TCU Psychological Functioning	Scales representing Depression, Anxiety, Self-esteem, Decision-making, and Expectancy [22]
[a]TCU Social Functioning	Scales representing Hostility, Risk-taking, and Social Support [22]
[a]TCU Health Form (K10 Psych distress)	10 items on symptoms of psychological distress (based on K10; see Ref. [19]

[a] TCU form available at https://ibr.tcu.edu/forms.

correctional agency that is used for requesting archival data. In the community sample, participants are also asked to complete a brief contact form that asks for a phone number or email address and preferred means of communication in order to contact the participants for scheduling appointments, sending appointment reminders and requests for rescheduling when appointments are missed.

3.2. Baseline, post-intervention and sustainability assessments

The three major assessments have nearly identical content with a few exceptions and are comprised primarily of instruments developed at TCU and available for free download from our website (https://ibr.tcu.edu/forms). Table 2 lists and describes the assessment components, roughly categorized as proximal and distal outcomes, and descriptive and predictive measures.

Proximal measures that are hypothesized to be impacted by *StaySafe* include decision-making measures (decision-making and decision-making style); talking with others about making better decisions, avoiding HIV risks, or HIV prevention or treatment; scales on confidence and motivation around HIV Knowledge (adopted from *WaySafe*), Avoiding Risky Sex, HIV Services, and Risk Reduction; and health visits and HIV/HVB or HVC/STD testing. Distal outcomes include risk behaviors associated with sexual activities.

Descriptive and predictive measures include TCU forms available on our website (ibr.tcu.edu) including the Global Risk Assessment (adult version), the Drug Screen V, Criminal History Risk Assessment, Treatment Needs and Motivation, Psychological Functioning, Social Functioning, and Psychological distress from the Health Form.

3.3. StaySafe data

Data is collected for each completed *Staysafe* session. These data include choices made during the session including the problem choice, who is affected by the problem, who can help with the problem, options chosen for the problem, answers to the 7-item maze game, and responses to the 7-item *StaySafe* session survey. Items for the session survey include feeling comfortable working through the exercises, the session keeping their attention the session helping understand others and myself better, and the session helping work through problems. In addition, timing data on how long the participant spent on each screen

of the session is collected.

3.4. Mid-Intervention Assessment (MIA)

The MIA is administered to *StaySafe* participants on the tablet using Qualtrex Survey Software between the 6th and 7th sessions. This is a brief survey (27 items) that includes the three decision-making scales included in the BLDC, PIA, and SA assessments – Rational and Dependent Decision-making [32] and the Decision-making Scale from the TCU Treatment Needs and Motivation form as well as a scale on tablet usability (adapted from Ref. [28].

3.5. Qualitative interviews

Brief semi-structured interviews are being conducted with a total of 15–20 participants from the three counties in the study. Selected participants are those in the *StaySafe* arm of the study who have completed at least six *StaySafe* sessions and the PIA survey. Interviews are scheduled within several weeks after completion of the PIA and include questions about their experience using the *StaySafe* app, what they have found useful or not useful, and how they have used the information from *StaySafe* in their daily life.

3.6. Probation data

Data is requested from probation records at several different occasions (permission to access data is included in the signed Informed Consent document). When participants are first consented, we request data from probation records including probation end date to verify eligibility and to verify probation ID numbers. After participants have completed the study, we request additional data on disciplinary reports during probation (including absconding, revocations and recidivism).

3.7. Planned analyses

Initial analyses will examine distributions on all study variables and list descriptive statistics. Variable transformations will be conducted as needed to deal with problem distributions (e.g., extreme skewness, outliers greater than 3 standard deviations). We will compare the *StaySafe* and SP groups on baseline variables to determine the

equivalence of the two arms. The groups will be compared on demographic factors, substance use type and severity, background criminality, criminal thinking and the confidence and motivation measures.

The primary data analyses will compare *StaySafe* and SP groups on the outcome measures at three and six months. Analysis of Covariance will be used with treatment arm being the classification variable, the three or six-month outcome measure as the dependent measure, and the baseline assessment of the outcome measure treated as a covariate. The analysis of 6-month outcomes will also include the 3-month measure as a covariate. The main focus of the study plan is to test the major research hypothesis that *StaySafe* participants will have significantly more favorable outcomes than will SP clients. Specifically, compared to the SP group, *StaySafe* participants will (1) report better decision-making skills, (2) be more willing to talk with others (e.g., counselors, probation offices, friends or family) about HIV and other health-related issues, (3) have more knowledge, confidence, and motivation around HIV risk reduction, (4) greater likelihood of HIV/HBV/HCV/STI testing, and (5) fewer/less frequent sex risk behaviors. Because *StaySafe* is targeted at making better decisions regarding risks, we expect effects on other, non-health behaviors. We will examine additional outcomes at 6 and 12 months including UA test results, disciplinary action, probation revocations, and arrests compiled from CSCD data.

We will use an "intent to treat" analysis, with *StaySafe* participants being analyzed together regardless of number of sessions completed. The primary analytical approaches will include ANCOVA and multiple regression (least squares regression for continuous outcomes and logistic regression for binary outcomes). We also will include covariates in models including age, gender, felony or misdemeanor status, drug screen level, and criminal thinking among others. Analyses will be conducted separately for community and residential samples.

Although our primary analyses will use an intent to treat model, we also will examine completion rates of the 12 *StaySafe* sessions. One set of analyses will examine baseline and process measures as predictors of completion rate to identify types of participants who are more likely to be successful at completing sessions and those who are less likely to complete them. Survey questions asking about their experience with *StaySafe* sessions will be important factors to identify barriers to completion. We also will use number of sessions completed as covariates in some outcome analyses and will examine whether there is a threshold of number of sessions that are needed to have significant change.

4. Preliminary results

4.1. Design and procedure modifications

StaySafe was initially implemented in community corrections settings in two large counties in a large southern state and was designed to be completed over a 6-month period. However, experience in the field led to several modifications to our research design.

The first modification was to adjust the scheduling of *StaySafe* sessions. We initially scheduled the 12 *StaySafe* sessions over a 6-month period with the first several sessions front-loaded (scheduled weekly) so that participants could more quickly learn the WORKT schema. Subsequent sessions were then scheduled every two weeks so that they would all be completed within six months. This schedule was modified to a weekly schedule for several reasons. We found that scheduling weekly was easier for participants to remember as they frequently came in for meetings on a regular weekly schedule. In addition, with the 6-month *StaySafe* schedule and subsequent 6-month and 12-month surveys, attrition in the study was larger because of more chance for participant schedules to change so they were no longer available, absconding from probation, or transferring to different probation offices. The original requirement of 12 months of probation remaining to complete all study activities also made recruiting more difficult as many potential recruits either did not have enough probation time left to complete the study or were as willing to commit to a study for a full

year. In addition, once the residential treatment facilities were added, the typical stay at those sites is about 6 months.

Even with the shortened timeline for participation, there were additional challenges working in community corrections. A common issue is maintaining communication with participants for scheduling and follow-up for missed appointments. Contact phone numbers that participants provided at the beginning of the study are frequently disconnected, or belong to another party who does not forward messages. Based on our study protocol guidelines, we limited follow-up attempts to no more than three contacts for scheduling or rescheduling missed appointments and if there was no response, the participant was dropped from the study. We did not attempt to update contact information through the community corrections department, as part of the study confidentiality – limiting information-sharing about study participation between researchers and probation staff. However, in the absence of constraints due to research-driven data collection and confidentiality, many of these scheduling concerns may not apply to the real world application of *StaySafe* in community corrections.

Participants in community settings also have other life commitments that make continued participation over multiple sessions challenging. They often have to depend on friends or family for transportation and thus may have to go directly from their appointments at the probation office without being able to take time to complete surveys or *StaySafe* sessions. When some participants obtain employment, their schedule might change to classes outside the research hours or the additional income might make them less invested in the study process.

A second major modification of the design was to expand from community corrections settings to residential treatment settings for people on probation. A major objective was to test the feasibility and efficacy of *StaySafe* in a residential treatment settings to see if participants would willingly use their limited free time to complete *StaySafe* sessions. Implementation in residential treatment settings also circumvented many of the communication issues inherent in community corrections settings. Thus recruiting and scheduling is simplified in the residential treatment settings, but because participants are not "in the community," some outcome measures such as sex risk behaviors and getting tested for HIV/HVC/STDs are not relevant during the time at the facility.

4.2. Uptake and satisfaction

To date, we have consented 460 participants across the three counties, with 229 in the community corrections sample and 231 from the residential facilities. A total of 155 participants have completed baseline surveys in the community sample (68% of those consented) with 79 randomly assigned to the *StaySafe* group and 76 to the SP group. Of these, 54% are male, 39% are 18–29 years of age, 34% are in the 30–39 age range, and 28% are 40 years or older (range from 21 to 65). Almost one half of the sample are White (48%) and 40% are African American; about 27% of participants identify themselves as Hispanic.

In the residential sample, 203 have completed baseline surveys (88% of those consented), with 104 of those randomly assigned to the *StaySafe* group and 99 assigned to the SP group. Of these, 58% are male, 42% are 18–29 years of age, 31% are in the 30–39 age range, and 27% are 40 years or older (range from 18 to 59). More than half of are White (59%) and 31% are African American; about 35% of participants identify themselves as Hispanic. There were no significant differences between the *StaySafe* and SP arms in the distribution of genders, age, or race/ethnicity in the community or residential samples. Table 3 shows the distributions of demographics for *StaySafe* and SP participants within the two samples.

Almost all of the participants in the *StaySafe* arm who completed a baseline survey have completed at least one *StaySafe* session. In the community sample, 66% of participants who completed a *StaySafe* session have completed at least 6 sessions and 27% have completed all

Table 3
Demographic distributions for community and residential samples.

	Community			Residential		
	StaySafe N = 79	SP N = 76	Total N = 155	StaySafe N = 104	SP N = 99	Total N = 203
Gender						
% Male	50.6	57.9	54.2	52.9	62.6	57.6
% Female	49.4	42.1	45.8	47.1	37.4	42.4
Age						
% 18-29	33.8	44.0	38.9	39.0	44.3	41.6
% 30-39	35.1	32.0	33.6	31.0	30.9	31.0
% 40-65	31.1	24.0	27.5	30.0	27.7	27.4
Race						
% Black	40.3	40.5	40.4	33.7	28.3	31.0
% White	44.2	52.7	48.3	52.9	65.7	59.1
% More than one	13.0	2.7	8.0	12.5	5.1	8.9
% Other	2.6	4.1	3.3	1.0	1.0	1.0
% Hispanic	27.9	26.3	27.1	32.7	37.4	35.0

12 sessions. In the residential sample, 78% of participants who completed a *StaySafe* session have completed at least 6 sessions and 48% have completed all 12 sessions. The average number of sessions completed is 7.1 for the community sample and 8.6 for the residential sample with many participants still actively completing more sessions.

Ratings of satisfaction from each *StaySafe* session indicates that participants rate *StaySafe* sessions as helpful and enjoyable. Satisfaction scores averaged 4.0 or higher on a five point disagree-agree Likert scale (scores above 3.0 indicated at least some agreement with the item on average and higher scores reflected stronger agreement) for all items for Session 1 except for "helping understand other people better" which had a mean of 3.8. Mean satisfaction scores for all items were greater than 4.0 for Session 6 and for the first PC session, indicating that evaluation scores remain high as the study progresses.

5. Discussion

StaySafe is an easy-to-use, self-administered tablet-based app designed to help people on probation make better decisions around health risk behaviors, especially those around HIV risk. *StaySafe* is based on a theoretical model of decision-making involving experiential and analytical systems and uses an evidence-based decision-making schema called WORKIT. We have developed the *StaySafe* package to incorporate multiple ways of learning – vicarious, active, and virtual learning modes, and incorporated cognitive load and visual processing theory elements into the design of *StaySafe* screen to maximize efficiency. In addition, *StaySafe* content was developed based on our previous research experience developing interventions, clinical experience, NIH and CDC materials, and input from probation officers and counselors as well as probation clients.

A rigorous RCT design has been implemented to test our main goals of examining the uptake and acceptance of *StaySafe* as an easy-to-use tool for justice-involved individuals and to determine its effect on improving confidence, and motivation to avoid HIV risk behaviors, improve decision-making approaches, reduce risk behaviors, and increase HIV testing.

This protocol has important implications for probation departments who often do not have integrated and consistent HIV programming in spite of the high levels of risk among people on probation, especially those with substance abuse problems. If the *StaySafe* platform is shown to be acceptable to individuals on probation, and preliminary evidence reported above shows promise, and outcome data collected through this protocol show *StaySafe* effective for increasing confidence and motivation and reducing risk behaviors, then probation departments have a useful, inexpensive and easy to use tool for addressing much-needed

HIV programming. Budgets are tight and probation officers and other staff are busy and are not likely to implement tools that require significant training, implementation, or administrative time. *StaySafe* provides a platform that requires minimal training by staff, is self-administered by participants and thus requires minimal time by staff to administer, and the brief sessions can easily be conducted during down time when those on probation are waiting for appointments or group sessions.

In addition to the low-cost aspects of *StaySafe* (the program will be made available at no cost) and staff time, the *KeepSafe* curriculum management tool allows content to easily be revised or updated without the need for programmers and thus can be adapted to meet changing needs of probation departments or treatment programs, or new content can developed to address other areas of concern such as relapse, recovery, or recidivism. Indeed, we are currently pilot testing content using the *StaySafe* platform that addresses women's reproductive health needs.

5.1. Limitations

Several limitations of this protocol should be noted. The recruiting approach relies on voluntary participation and is not designed to be representative of the target population of people on probation who have had substance abuse treatment. Instead, we are using an RCT to create equivalent treatment/control groups to examine effectiveness and then will use participant characteristics as predictors or moderators to examine how these characteristics impact those outcomes. A second limitation is that many of the outcomes rely on self report and thus are subject to the potential recall or bias errors inherent in self-report measures. A third limitation is that the study is being conducted in three large counties in a large southern state and results could differ in other locations.

5.2. Conclusions

There is a strong need for accessible HIV programming for people on probation. The *StaySafe* tablet-based app described above, based on decision-making theory, utilizing an evidence-based decision-making schema, and utilizing learning and cognitive principles to maximize its effectiveness, has potential to help meet that need. Preliminary evidence to date indicates that study participants are highly satisfied with *StaySafe*, find it easy to use, and are willing to come back and complete multiple sessions. A carefully designed RCT is underway to provide data on effectiveness for improving decision-making skills, increasing knowledge, confidence, and motivation for avoiding HIV risks, and reducing risk behaviors.

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