Sustainable HIV Risk Reduction Strategies for Probationers (DRR2)

NCT #02777086

April 8, 2020

We developed a multi-session, brief tablet app, *StaySafe*, designed to improve decision making around health risk behaviors for people under community supervision who had substance use disorders. As part of a randomized clinical trial testing post-treatment outcomes hypothesized to be associated with *StaySafe* administration, this study examines improvements in decision-making skills associated with reductions in health risk behaviors, especially those involving HIV and Hepatitis B or C (for more detail on *StaySafe* development and the research protocol, refer to Lehman et al., 2018).

## 1.1 Decision-making and Analytically-created Schemas

StaySafe is based on cognitive processing models derived from Analytically-Created Schemas (ACS) and TCU Mapping Enhanced Counseling (MEC; Dansereau, 2005; Dansereau & Simpson, 2009) that include experiential and analytic systems (Kahneman, 2011; Klacynski, 2005). Experiential systems reference previous experiences (Kahneman, 2011; Weber & Johnson, 2009) believed to be used in making decisions about risk behaviors because they are rapid and refer to familiar behaviors, even those with negative outcomes. Analytic systems are typically slower because they often require conscious referencing and reinforcement. Schemas using the analytic system are created through repetition and practice.

The ACS approach can be a vehicle for organizing information through a series of steps and exercises that develop analytic thinking. Exhibiting options visually when developing plans and making decisions can contribute to an objective evaluation of available choices (Dansereau et al., 2013). This can help individuals monitor and control decision making (metacognition), increase knowledge in specific areas (e.g., substance use, treatment initiation, etc.), and improve judgment and behavioral choices (self-regulation). Analytic repetition (similar to practice in athletic training) can develop procedural memory (i.e., skills and tasks that can be stored in long-term memory) that can be accessed rapidly. This process, developed by repetition, can then be used in real-life contexts rather than the more labor-intensive analytic processing. The goal of the *StaySafe* intervention is to replace or "override" inaccurate or maladaptive

information, expectations, and behavior patterns with accurate health-related information and appropriate attitudes and behavioral choices.

### 1.2 WaySafe

The ACS-based tablet app that is used in this study grew out of an NIH-funded disease risk reduction study of *WaySafe*, a group-based curriculum that used an ACS approach to help people in prison-based substance use treatment make better decisions around health risk behaviors when they return to the community. The highly interactive curriculum relies on MEC to prepare individuals for the transition back to the community by demonstrating interrelationships among constructs including problem recognition, commitment to change, and strategies for avoiding behavioral health risks; key information for developing plans to address risky situations. Research has shown that, when compared to standard practice (SP), participants randomly assigned to *WaySafe* groups had greater improvements on knowledge and confidence measures related to HIV information and testing, avoiding risky sex and substance use, and risk reduction skills (Joe et al., 2019, Lehman et al., 2015, Lehman et al., 2019).

# 1.3 WORKIT

WORKIT, a major component of *StaySafe*, is a specific ACS schema that teaches a simplified structure for analyzing problems, weighing and rating options to make a decision, and then planning how to carry out that decision -- **What** is the problem; **Who** is affected by the problem; **Who** can help with the problem; **Options** for dealing with the problem; **Rating** the options; **Knowing** what to do based on the ratings; **Imagining** steps to carry out the decision; and then **Testing** those steps. Several studies using WORKIT have shown improved decision making, self-awareness, and problem recognition (Becan et al., 2015; Knight et al., 2015, 2016).

# 1.4 StaySafe

StaySafe was developed as a self-administered Android app for people participating in treatment while under community supervision, targeting decision-making skills to reduce health risk behaviors. Based on WaySafe, StaySafe uses the WORKIT ACS with accompanying health

information facts to train users in making more systematic and informed decisions (Lehman et al., 2018). The intervention includes 12 weekly sessions for participants to learn the WORKIT ACS through systematic repetition.

## 1.5 Research goals

A randomized clinical trial was conducted to address three primary research goals around the *StaySafe* app: 1) examination of the participation rates of *StaySafe* sessions, 2) test of the effect of *StaySafe* on knowledge, confidence and motivation around health risk behaviors and better decision-making skills, and 3) assessment of the relationship between greater *StaySafe* participation and greater pre-post change from baseline to follow-up time points.

#### 2. Methods

# 2.1 StaySafe intervention

StaySafe includes 12 brief (10 minutes) self-administered sessions on a tablet; one session per week. Nine of the sessions involve the WORKIT ACS and three Participant Choice sessions include several information-based activities around HIV and health risks.

The first *StaySafe* session presents the participant with an overview of how to navigate through the *StaySafe* app, followed by a demonstration of a WORKIT exercise. Those sessions featuring WORKIT start with choosing from a list of 11 problem themes related to (1) people (e.g., "Asking a partner about his or her HIV testing"), (2) places ("Favorite high-risk places to hang out") or (3) things ("Practicing safe sex"). Topics were designed to be relevant for people under community supervision with substance use disorders, incorporating feedback from probation officers, substance use treatment counselors, and recommendations from the Center for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) on reducing health risks.

After choosing a topic (**What** is the problem?), the participant views a vignette showing actors working through a risky situation (vicarious learning), prior to proceeding through the rest of the WORKIT steps. Some of the WORKIT steps involve selecting from a list of possible

responses to questions such as "Who is affected by the decision?" or "Who can help with the problem?" For the WORKIT step, "Options for dealing with the problem," participants select from a series of four options that are related to the chosen topic. For example, two of the options for the problem theme, "It's hard to ask a partner about his or her HIV testing," are "Don't ask, but always use condoms," and "Have unprotected sex just this one time." Supporting health facts for each option "pop up" on the screen, thus providing educational information embedded within the decision-making schema. Mental practice such as this is deemed to help prepare the participant for using the WORKIT schema in the "real world" and therefore an effective way to learn (Cooper et al., 2001). The goal is not to have the participant solve specific problems during sessions, but through repeated practice using relevant examples across multiple *StaySafe* sessions, to internalize the schema. A final activity in the WORKIT sessions is a "maze" game in which an animated character moves around a maze as participants responded to quiz questions designed to reinforce information from the session.

Participant choice sessions are interspersed among the WORKIT sessions in order to provide more in-depth information about HIV and health risks and to vary the tablet presentations. Three different activities were offered including (1) a CDC video giving information about HIV/AIDS, (2) an information page about HIV/AIDS with a brief discussion about HIV medication therapy or someone affected by HIV/AIDS talking about their experience, and (3) the maze game with additional question content. Participants chose one or more of the activities.

# 2.2 Procedures

The study took place at five community supervision and corrections department (CSCD) facilities in three large counties in Texas; these included two CSCD community-based locations and three residential facilities. In the community-based facilities, recruiting materials included flyers, posters, and brief presentations at the beginning or end of orientation or group sessions; additionally, the research team spoke with individuals in CSCD waiting rooms about the study

opportunity. All recruiting was conducted by TCU researchers. At the CSCD residential facilities, researchers provided a brief overview of the study to groups of new client admissions within a week of their arrival into the substance use treatment program. Those interested in participating completed TCU IRB-approved informed consent and brief demographic forms. Participants completed baseline surveys the following week according to individual community supervision schedules. Community-based site participants also provided contact information for receiving meeting reminders about study data collection appointments. Participants were randomized into study conditions (i.e., *StaySafe* and SP arms) following completion of the baseline survey packet. The project utilized a permuted block randomization approach, with block size varying randomly between 2, 4 or 6.

- 2.2.1 Data Collection. Sources of data used for the project included surveys and tablet data. Participants in both conditions completed surveys, and those in the StaySafe condition also contributed tablet data. In community facilities, researchers coordinated survey administration and tablet sessions with participants on the same day as their required community supervision activities (e.g., treatment groups and meetings with counselor or probation officer [PO)]. A subset of individuals in the StaySafe arm who had completed at least six tablet sessions were also invited to interview with a senior member of the research team about the StaySafe experience. Qualitative results are reported in Pankow et al. (2019). For those in the community locations, participants were handed a scheduling card with the date/time of the next study activity and a contact number for the researcher in case of scheduling conflicts. In residential facilities, scheduling was coordinated with program staff who provided the researcher with a list of available time slots when participants were free to complete study activities.
- 2.2.2 StaySafe sessions. The 12-session StaySafe intervention was designed to be administered one session per week for 12-weeks post consent. In cases where a participant missed a week, two sessions were administered in a single week. Sessions were completed on a hand-held Android tablet, and participants were provided with headphones to listen as a

narrator relayed the content of each tablet screen. Researchers utilized a tracking system (developed for the study) to coordinate data collection and manage the history of completed activities. Participant survey and tablet session data were linked by a study identification number; no identifiable information was recorded on the data sources.

#### 2.3 Data collection and measures

Paper and pencil surveys were administered at baseline prior to random assignment and again three months after baseline. Outcome measures included the TCU Confidence & Motivation scales, and three decision-making scales – Rational decision-making, Dependent decision-making, and the TCU Decision-making scale. The surveys also included demographic and background measures from the TCU A-RSK form (IBR, 2008). Variables included age, gender, race/ethnicity, education, marital status, and in the last six months before entering their current program – employment, public assistance, arrested, on parole or probation, in jail or prison, and treatment in an emergency room, for mental health, alcohol use, and illegal substance use.

2.3.1 TCU Knowledge, Confidence, and Motivation scales (KCM). Four scales included HIV Knowledge Confidence, Avoiding Risky Sex, HIV Services & Testing, and Risk Reduction Skills. Each of the scales, except for HIV Services & Testing, included items that assessed how knowledgeable (K) the participant felt about the topic, how confident (C) they were about their knowledge, and how motivated (M) they were to act on the knowledge. HIV Services & Testing only included knowledge and motivation items (Lehman et al., 2015). The knowledge, confidence, and motivation components for each scale were included in an overall score as well as examined as separate subscales.

The TCU *HIV Knowledge Confidence* scale has 13 items (alpha = .93) and sample items include "You know enough to teach others what they should do if they think they have been exposed to HIV" (K), "You feel very confident that you could be a role model for others in helping reduce HIV risks" (C), and "You are totally committed to helping your friends and/or

family avoid HIV/AIDS" (M). Coefficient alpha reliabilities for the three subscales ranged from .75 to .88. The TCU Avoiding Risky Sex scale has 13 items (alpha = .93 and ranged from .81 to .84 for the three subscales) and includes items such as "During the past month, you have learned about what situations might lead you to make a poor decision about risky sex" (K), "During the past month, your confidence in managing emotions in sexual situations in the real world has increased" (C), and "During the past month, you have become more motivated to protect your sexual partner from HIV risk in the real world" (M). The TCU HIV Services & Testing scale consists of 7 items (alpha = .81 for the full scale, .62 and to .79 for the knowledge and motivation subscales respectively). Sample items include "During the past month, you have become more knowledgeable about how to get HIV services in the real world" (K) and "You will get tested for HIV if you think that you might have been exposed" (M). The TCU Risk Reduction Skills scale is comprised of 14 items (alpha = .91 and ranged from .65 to .82 for the three subscales) and includes items such as "During the past month, you have a better understanding of how your shoulds and wants can conflict in the real world" (K), "During the past month, you have become more confident in balancing your shoulds and wants in the real world" (C), and "During the past month, your motivation to avoid personal HIV risks in the real world has increased" (M).

All items for the TCU Confidence & Motivation scales use a 5-point Likert-type response scale ranging from 1=Disagree Strongly to 5=Agree Strongly. Items worded in the opposite direction from the scale construct were reflected by subtracting the score from 6. Scale scores were then computed by calculating the average score for items within the scale then multiplying the average score by 10 to obtain a range from 10 to 50. Scores above 30 indicated at least some agreement with the scale construct and scores below 30 indicated at least some disagreement.

# 2.4 Analytical approach

Three primary sets of analyses were conducted. In the first set, characteristics of the research sample are reported and *StaySafe* participation in terms of number of sessions completed by the *StaySafe* group are calculated. A second set of analyses compared the *StaySafe* and SP groups on baseline and post-intervention measures using SAS Proc GLM. Analyses were conducted separately for the community and residential samples. The *StaySafe* and SP groups were first compared on demographic and background variables, and baseline measures of the outcome variables to check for group equivalence. The *StaySafe* and SP groups were then compared on outcome variables from the post-intervention surveys using the appropriate baseline measure as a covariate. Effect sizes (Cohen's d) were computed for each outcome measure by taking the difference between least square means of the *StaySafe* and SP groups and dividing by the standard deviation of the SP group (Cohen, 1988).