Methodological Considerations for Conducting Research in Correctional Settings: A Field Perspective

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Abstract

This paper outlines the field experiences and challenges encountered while conducting a large-scale research study in community and residential correctional settings with a multi-session, self-administered, tablet-based decision-making app (StaySafe). Study participants completed surveys at baseline, 3-month, and 6-month intervals and were randomly assigned to complete 12 brief StaySafe sessions or receive treatment as usual. Challenges encountered included logistical issues with (1) consenting, (2) data collection, and (3) study attrition. Modifications were designed to address these issues and included developing an alternate consenting approach, using flexible scheduling, and modifying the intervention period with attention to maintaining fidelity to the protocol. Conclusions include recommended strategies for future research planning.

Introduction

Behavioral healthcare standards require evidenced-based interventions, established through rigorous research using randomized clinical trial (RCT) designs. Implementing an RCT design in a real-world setting warrants careful attention to fidelity in all aspects of the intervention protocol while maintaining sufficient flexibility to modify and accommodate when unexpected events are encountered. While these modifications are necessary, they can negatively impact the reliability of the study data linking the mechanisms and procedures being tested (Pankow et al., 2018). Thus, documenting any procedural variation is a critical part of evaluating intervention fidelity and understanding the potential impact (Houchins et al., 2010).

Even the most rigorous study designs used in correctional settings can be vulnerable to a host of factors that challenge protocol fidelity – many of which are especially relevant to working with justice-involved individuals (Houchins et al., 2010; DeMatteo et al., 2011; Jolivette et al., 2013). For example, the transient lifestyle of correctional populations can negatively impact study attrition, resulting in missing data and biased results, and, in turn, issues with obtaining adequate sample size (Jolivette et al., 2013; DeMatteo et al., 2011). Perceived coercion must also be considered in correctional environments and can impact study fidelity by disrupting recruiting efforts and hindering participant engagement (DeMatteo et al., 2011). Additionally, research protocol schedules can be disrupted by facility lockdowns, participant re-incarceration, and supervision requirements (Houchins et al., 2010; DeMatteo et al., 2011). Some challenges are especially relevant to the type of correctional setting in which research is conducted. For example, schedules in residential programs may present fewer opportunities for meeting with participants compared to community corrections schedules that afford people more control of their movement before and after required probation meetings.

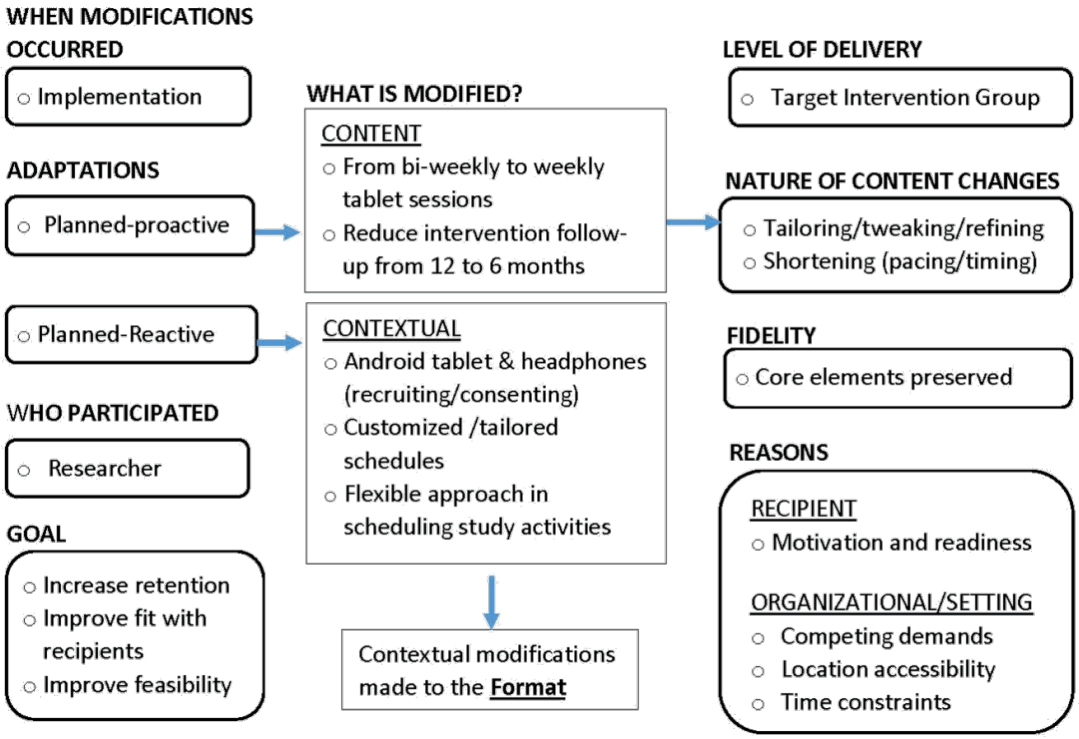
This paper reports on real-world study implementation challenges and adaptive response strategies encountered with the Texas Christian University (TCU) Disease Risk Reduction (DRR2) project – a multi-site RCT testing a software application designed to improve decision-making aimed at reducing health risk behaviors (e.g., drug use and unprotected sex) for individuals on probation. Specifically, field experiences are addressed within three areas: (1) consenting, (2) data collection and

(3) study attrition. In each of these areas, the paper addresses challenges encountered unique to community and residential corrections treatment settings.

Also addressed are the adaptive responses by the research team that led to procedural modifications, described within the Framework for Reporting Adaptations and Modifications-Enhanced (FRAME) model (Stirman et al., 2019). Stirman et al. (2019) coded 258 modifications from 32 published articles and organized the FRAME model into eight areas: what was modified; when and how the modification was made; who made the modification, whether the modification was planned or unplanned; the level of intervention delivery modified; whether modification was content or context-level; reasons for the modification; and fidelity to the core elements after the modification (see Figure 1). These eight areas serve to organize the modification process for documenting and interpreting the impact that changes may have on the intervention (Stirman et al., 2019).

Figure 1

FRAME Model and Key DRR2 Modifications



Note: Illustrating modifications to the DRR2 intervention with FRAME categories (Stirman et al., 2019).

StaySafe Intervention

StaySafe consists of 12 brief sessions that use an evidence-based schema called WORKIT (Lehman et al., 2018) to present health topics (e.g., drug abuse and unprotected sex) and skills for identifying risky situations and ways to respond, reflecting the CDC recommendations aimed at reducing health risks. StaySafe sessions provide practice opportunities, thus, increasing the likelihood that the decision-making schema becomes automated for the participant faced with decisions in the real world. All modifications described below were approved by the TCU Institutional Review Board (IRB).

Study Sites

StaySafe was implemented in three large counties at two community correctional facilities and two correctional residential substance abuse treatment facilities. The study design required that individuals have a minimum of six months of probation remaining and have the ability to meet with the researcher once a week in order to complete the StaySafe intervention. Individuals on community supervision also had to have access to a cell phone or email for scheduling StaySafe sessions and data collection meetings. The two-arm study design randomized participants to either the enhanced or control condition. Participants within both conditions completed surveys at baseline, post intervention, and six-month sustainability period. Additionally, the enhanced condition was asked to complete 12 weekly StaySafe sessions – a total of up to fifteen meetings.

Consenting Procedures – Challenges

At the start of the study it became clear that program logistics in one community site with waiting rooms and services delivery on multiple floors posed significant challenges with recruiting and consenting. The original plan to staff each research site with one research assistant (RA) was quickly modified to add a second RA to accommodate the protocol plan for recruiting and consenting in probation waiting rooms to make use of the time that individuals wait to see a counselor or Probation Officer (PO). However, the waiting rooms posed several challenges in some community sites; these included (1) limited privacy due in part to POs, counselors, and other correctional staff calling participants to move to classrooms for group or offices for probation meetings; (2) inadequate time to complete informed consent before and after classes or meetings; and (3) environmental issues such as noise level when waiting rooms filled during peak times, making it difficult to hear the consent presentation or address

questions about the study. Some individuals expressed an interest but declined, preferring not to take a chance on missing the start of a Behavioral Healthcare (BH) group or meeting with their PO, potentially resulting in a probation violation. Public transportation (e.g., bus schedules) also imposed time constraints on individuals to meet with the RA. In community corrections, individuals also have family, employment, and education obligations that competed with interest in the study. In the residential and community sites, the original protocol was to recruit and consent during the first several days after arriving at the facility; however, numerous intake activities contributed to competing priorities for both individuals and staff.

Consenting Procedures – Modifications

A key modification to the consenting procedures used in waiting rooms eliminated paper consents read by the RA in favor of using a tablet computer with headphones, providing individuals with a narrated presentation of the consent document. This modification reduced issues with background noise. With multiple tablets available, one RA could administer consents to several individuals at staggered times, which resulted in improving the number of consents that could be administered by one RA during a single period. Whenever possible, the RA utilized a private room for administering informed consent; but whenever space was not available, the tablet consent could be administered in almost any area of the building without distractions. In the FRAME model, this change is illustrated as a contextual modification, initiated by the research team in reaction to field conditions. The rationale was to improve feasibility of conducting research in probation settings with many different activities and schedules and busy waiting rooms, as well as to improve study procedures to increase recruiting and consenting efforts. The use of a tablet with headphones also improved the privacy afforded to the participant so that other people in the waiting room did not overhear what the participant was listening to. When a participant had privacy, it reduced any potential coercion in the consenting process.

In the residential and community settings, recruiting and consenting added to already high stress levels for individuals busy with probation intake activities and requirements. Adjusting study procedures to modify the timing of recruitment from intake to a week after intake when there were fewer competing demands improved the recruiting results without compromising the study follow-up schedule.

Data Collection Procedures – Challenges

In community sites, data collection meetings were scheduled on the same days that individuals reported to probation offices for BH groups and meetings with PO's. Text reminders sent a week before and again two days before the scheduled study activity were aimed at reducing the number of missed meetings; however, consistent communication with participants remained an ongoing challenge, as participant phones were frequently switched off or did not have service and phone numbers changed. Sometimes the participant would provide a number for a family member or friend, but the text reminders did not always reach the participant.

Residential setting procedures, by contrast, did not involve cell phones (not allowed in the residential sites), requiring the RA to coordinate participant availability with staff. Sessions were generally scheduled on the same day of the week at a time when participants were not otherwise occupied with classes or groups. In residential settings, participant movement required a staff escort for study meetings, often impacting the day's data collection schedule. Additionally, participants were housed in different buildings with different schedules for each building. In residential programs, the primary data collection issue was competing priorities with probation obligations; programs are highly structured with little or no free time for residents. Another key issue in community and residential programs was frequent probation schedule changes. This occurred as participants progressed through the program or moved to new classes or activities.

Data Collection Procedures – Modifications

To address the challenge of staying connected with participants, it was determined that the RA would attempt to contact participants in community sites with a minimum of three calls or emails; these efforts were documented for consistency across sites. After three unsuccessful attempts, participants were counted as having dropped out of the study. An important modification made early in the study changed the schedule from bi-weekly to weekly StaySafe sessions; moving from a six-month to a three-month intervention. Correspondingly, this shortened the follow-up data collection (originally scheduled for twelve months from the date of consent) to six months post consent. These pro-active changes (content modifications in the FRAME model) were aimed at maintaining fidelity to study procedures, engaging participants with more frequent sessions across a shorter period of time and to shortening the amount of time

that participants had to commit to the study in an effort to reduce the likelihood of missed data collection due to communication issues.

In residential settings it became necessary to relax scheduling plans in favor of a more flexible approach to meeting participants. This included changing meeting locations, moving from one building to another to meet with participants depending on space availability. Staying flexible in collaboration with program staff streamlined data collection and reduced the burden on participants and staff. Scheduling flexibility in residential settings (contextual modifications in the FRAME model) was reactive and researcher initiated. The goal of the content-related modifications in community settings and contextual modifications in the residential settings was aimed at preserving fidelity to the core elements of the study (i.e., the 12-session treatment dose).

Study Attrition – Challenges

Study attrition took on different forms in the research sites. In community sites, some participants were re-incarcerated due to probation violations or new arrests and information to confirm a participant's status with probation generally was limited for the research team. Changing probation schedules such as moving day classes to evening classes also contributed to study attrition in cases where participants did not have alternate times available to reschedule study activities. Other participants were lost to the study if their probation time was shortened and they no longer attended classes at the study site, or they moved to a different facility to complete probation requirements. Additional factors leading to study attrition, according to participants that did reconnect with the study and from staff feedback, included job and family responsibilities and the challenges with balancing personal, probation and study expectations. Participants faced challenges with completing the number of study activities during the 12-week intervention, especially those in the enhanced condition. Study attrition in the residential settings most commonly was associated with participants violating their probation requirements and returning to jail. In these custodial settings, the research team was made aware of the participant's absence and could track the reason behind it, unlike the community sites. Residential program participants were not withdrawing from the study program so much as absconding from their court-ordered rehabilitation program.

Study Attrition – Modifications

Some types of attrition could not be addressed by modifying the intervention; however, adjustments made over the course of the study helped reduce the drop-out

rate in the community settings. Modifications were for the most part contextual; for example, switching from specific data collection dates to individualized scheduling reduced attrition for those who preferred to come in on a day they did not have classes or meetings at the facility. In addition to reducing drop-outs, the individualized scheduling efforts motivated participants to stay in communication with the RA. A customized schedule also helped account for attrition that resulted from participants' having employment, lack of transportation, or having their class schedules change. The attention to flexibility also required increasing the amount of time that the RA was available in the community sites. Like the tailored scheduling used for data collection meetings to maintain fidelity to the intervention dose, flexible scheduling also helped to keep participants engaged in the study in an effort to reduce the likelihood of attrition.

Discussion

Correctional settings present challenges for conducting research, particularly for a large-scale, multiple site project with unique characteristics—logistical, procedural, or both. Careful attention with intervention development is aimed, in part, at anticipating such differences and other events that may challenge the fidelity of the research, as well as identifying strategies to address issues. Given the complex nature of field research, experiences can often become the basis for a lessons-learned narrative. The characteristics of the StaySafe study sites and the unanticipated events encountered required a degree of modification to the study procedures, while weighing the need for flexibility with procedural fidelity, as changes to an intervention can affect the reliability and validity of the results. When these modifications are reported within the context of the FRAME Model, the reasons for the adjustments and several aspects that are relevant to understanding the nature and scope of the changes become clearer. This organizing system can help researchers understand the impact that modifications have on intervention implementation, as well as provide a logical framework for documenting changes and identifying any corresponding potential threats to fidelity.

Documenting approaches vary and may present different advantages for research teams. Methods such as field notes and checklists are useful tools that capture unwanted variations and possible procedural drift – issues that can be addressed during the study. For example, Kubiak et al. (2014) reported that interviewing researchers revealed several barriers such as lack of time, changes in meeting location, and prison events (i.e., mobilization and drug testing); barriers that could be reviewed

and modified during the project. Not to be overlooked is the importance of documenting and evaluating those modifications that require additional review and approval by an Institutional Review Board (IRB) prior to implementation. Additionally, translating intervention modifications into a frequently asked questions (FAQ) feature benefits research teams with standardized responses to study questions that will improve adherence to the study protocol.

Table 1

Summarizing DRR 2 Challenges and Modifications

Area	Original Strategy	Challenge	Modifications
Informed Consent	One Research Assistant (RA) per study site	Building logistics - multiple floors and multiple waiting rooms	Added second RA
	Recruit/consent in waiting rooms	Waiting rooms too noisy; privacy issues	Worked with site staff to arrange private room
	Administer informed consent in groups	Competing schedules made groups difficult to arrange	Consent provided in audio format on tablet with head phones
	Recruit and consent at start of probation intake	Demands of starting probation competed with interest in study	Pushed recruit/consent to a week after intake
Data Collection	Support phone contact with text messages	Service disconnection, lost phones, changed phone numbers	Established minimum of three contact attempts using phone and email
	Individualized scheduling for bi-weekly StaySafe sessions	Program scheduling changed frequently resulting in missed sessions	Moved to weekly StaySafe sessions; follow-up at six instead of twelve months
	Residential: Meet with individuals during free periods	Structured residential program with limited free time	RA's increased their availability and flexibility
Attrition	NA	Community: Competing priorities (jobs, family, education) contributing to attrition	Flexible data collection scheduling; extended RA time on-site to increase participant access

A summary of the original StaySafe protocol strategies, challenges encountered, and the context and content modifications (see Table 1, above) informed the following recommendations. Addressing challenges with data collection and study retention could include developing interventions for a smart phone or web-based application as an alternative to table-based technology; thus, enabling participants to utilize their own technology in keeping up with the schedule of study activities, since most individuals

have mobile phones (or a study-issued phone can be provided). Social media is another tool that could be beneficial in connecting the researcher to the study participant for scheduling meetings. Social networking technologies such as wall posts, chatting, sending messages, and uploading videos could be integrated into research to enhance participant retention (Young et al., 2007). Combining social networking platforms with traditional retention methods such as phone/email potentially provides the researcher with a wider range of communication tools. According to Mychasiuk and Benzies (2012), use of social media (Facebook) increased participant retention by 16% in a difficult to trace population.

Another recommendation aimed at intervention development involves creating an advisory group with researchers, correctional staff, and representation from the target study population. An advisory group can facilitate input in the research process by offering constructive feedback on data collection methods and helping to develop effective recruitment and retention strategies (Isler et al., 2015). In addition, strategies like conducting a walk-through, as outlined in McCarty et al. (2007), or experiencing the treatment process as a client would inform the research team about many challenges prior to rolling out the study. In fact, conducting multiple walk-throughs on different days and at different times would have provided evidence of the extent of variation in the four StaySafe study sites, particularly regarding logistical differences that made it difficult to reach participants.

Implications for Behavioral Health

This account and the recommendations for multi-site research planning are aimed at advancing methodology for conducting research in justice settings. The pre-planning stages of a study provide opportunities to anticipate changes and design adaptations; yet, even with such efforts, new challenges may arise during the implementation phase. Modifications that occur as a result of unanticipated challenges should be documented to determine their impact on overall outcomes as part of evaluating and reporting the efficacy of an intervention as well as monitoring fidelity to the study protocol. Reviewing modifications may also provide important information about the sustainability of the intervention beyond the study timeline. For example, the StaySafe app was conceptualized for use in community corrections waiting rooms; however, given the numerous distractions in that setting, waiting rooms may not be optimal for interventions that require more than a few minutes of time to complete.

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