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Transitioning from Face to Face to the Digital Space: Best Practices and Lessons Learned Leveraging Technology to Conduct HIV-Focused Interventions

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Abstract

Introduction: *Coronavirus disease 2019 (COVID-19) has impacted researchers' ability to continue to deliver HIV prevention and treatment interventions face to face. Although telehealth has been an important strategy to maintain research operations during the current pandemic, participants at increased risk of or living with HIV are often at higher risk of also experiencing poverty, housing instability, and other challenges that may present obstacles to successful remote delivery.*

Methods: *We provide descriptions of remote adaptations to two randomized controlled efficacy trials of behavioral interventions for primary and secondary HIV prevention with descriptive enrollment and retention data.*

Results and Conclusions: *Best practices for implementing telemedicine and e-health procedures are discussed, including procedures for addressing remote participation barriers (economic, health literacy, etc.) and other challenges, such as building rapport and staff support (NCT03092531 and NCT03175159).*

Keywords: *HIV prevention, ART adherence, efficacy trial, remote intervention, telemedicine*

Introduction

On March 7, 2020, the World Health Organization issued social distancing guidance to prevent the spread of coronavirus disease 2019 (COVID-19).[1] The U.S. Centers for Disease Control and Prevention endorsed similar guidelines, resulting in many states ordering individual residents to stay home.[2] As a result, the research landscape was forced to change dramatically and rapidly; although in-person recruitment, enrollment, and other study-related visits and procedures were no longer feasible, ongoing research studies, particularly intervention efficacy trials, had to continue to maintain ethical research standards and ensure scientific validity.

Evidence exists for the use of telemedicine in HIV care, with some populations preferring the use of telephone or secure videoconferencing to traditional office visits.[3–5] Although not as common, with the ubiquitous nature of mobile technologies, public health research has also demonstrated the feasibility of using similar telehealth procedures, including HIV risk-reduction interventions.[6] However, the social distancing requirements due to the current COVID-19 pandemic presented new and unique challenges to research already in process and not designed for remote delivery.

In addition to challenges presented by social distancing, the halting of in-person research also provided an opportunity to reconceptualize how intervention components were delivered to participants, including recruitment, screening, enrollment, implementation, and data and biospecimens collection (e.g., pre-exposure prophylaxis [PrEP] and antiretroviral therapy [ART] adherence measures).

As such, some of the changes from in-person research procedures to remote reflect a shift in the possibilities for research across the HIV prevention and treatment cascade. We present our experiences adapting face-to-face intervention research protocol[7,8] procedures to the digital space (i.e., remote procedures utilizing technology) and descriptive data on research participation in 2020. Finally, we summarize best practices from the perspective of study participants and research staff, highlighting specific challenges we encountered and how we addressed them.

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Methods

PARTICIPANTS AND PROCEDURES

From March 2020 to March 2021, we adapted two studies on the HIV prevention continuum: (1) Positive STEPS, an ART adherence study for adolescents and young adults and (2) Project IMPACT, an HIV prevention study for stimulant using MSM. Although these interventions target different populations and behaviors, they are procedurally similar. To transition to a fully remote research study design, we made the following adaptations, presented here for each stage of research operations.

REGULATORY APPROVAL

Review and approval by institutional review boards of record were necessary for all new and adapted procedures.

SCREENING & ENROLLMENT

All recruitment, screening, and study enrollment procedures transitioned to completely remote. Although online recruitment (e.g., Facebook, Instagram, and GRINDR) had been employed before COVID-19 adaptations, community- and clinic-based recruitment stopped in March 2020.

The requirement that all procedures would be completed remotely precipitated the need for revised eligibility criteria—participants now had to have (1) dependable access to the internet and the ability to download Zoom, (2) privacy to conduct interview sessions, and (3) a reliable mailing address to receive study materials. Participants were also asked to verify identification through picture ID, provide a valid ART prescription, and complete a release of medical information for subsequent HIV confirmation and viral load results collected through medical records. Utilizing REDcap, a web application for building and maintaining surveys and databases, allowed for electronic signature acknowledging informed consent.

INTERVENTION DELIVERY AND BASELINE/FOLLOW-UP ASSESSMENTS

We quickly learned that participants living with HIV were hesitant to risk getting COVID-19 for routine laboratory testing. To avoid missing data for viral load, we implemented at-home dried blood spot testing. Participants collected their blood sample through finger prick and sent it back to the research team for analysis. Along with the dried blood spot kit, participants received study materials by mail before each research assessment and a ClinCard (a gift card for research participants that can be refilled remotely). Counseling sessions and interviewer-administered assessment were conducted using HIPAA-compliant Zoom. For self-reported data collection, screen sharing features were used to provide visual images of scales for assessment items. For self-administered assessments (ACASI), survey links were shared through the live chat function. During ACASI assessments, participants had the option to turn off video and mute microphones or log off and receive the assessment through email to allow for privacy.

BIOSPECIMEN SELF-COLLECTION

Biospecimen data were collected remotely. Before each visit, participants received biospecimen collection and testing kits (e.g., icup instant urinalysis drug testing kit, tenofovir hair concentrations or PrEP adherence collection kit, dried blood spot kit for viral load, HIV rapid test kit, urine tenofovir immunoassay for instantaneous PrEP adherence, drug use detection through saliva screening tests, and rapid urethral gonorrhea/chlamydia/syphilis home test kit) by mail. At the beginning of each remote session, research staff instructed participants on kit use and how to read results.

In addition, for rapid tests, research staff asked participants to hold completed test kits to the screen or text a picture to verify results. For HIV testing, research staff walked each participant through HIV testing procedures, including a hypothetical reactive test result; this discussion included helping to make a plan for support and connection to care. In addition, a study counselor was always on call. All biospecimen collection kits requiring laboratory analysis were sent out with prepaid/preaddressed envelopes to ease participant burden.

MEASURES

Participant accrual was measured by number of individuals screened, consented, enrolled, and randomized, and is presented as percentages of target enrollment for each study from March 2020 to March 2021. Retention was measured by number of participants completing of follow-up visits for the same time period.

Results

From March 2020 to March 2021, 20% of Positive STEPS participants enrolled in the study, representing 33.3% of target enrollment for that time period, with 82% retention. Project impact enrolled 28% of participants in the study period, representing 25% of target enrollment for that time period, with 80% retention.

Discussion

This brief communication reviews the continuation of research during a year of the COVID-19 pandemic. Working within institutional social distancing constraints, we were

able to continue recruiting and enrolling participants to two HIV prevention and care efficacy trials. Although we did not hit accrual targets set before May 2020, we retained participants at higher rates than anticipated.

One of the major advantages of moving the research to fully remote is that we are no longer restrained geographically. Although we had previously enrolled individuals who lived in or around the cities where our study sites were housed, implementation of remote procedures allowed us to dramatically broaden our catchment area, in some cases even nationally. In addition, this allowed for diversification of the participant population, particularly related to rural versus urban. As such, we are reaching a more diverse population than before March 2020 and feel that we can stay on track with study timelines.

To prepare participants for remote visits, research staff built a supportive environment by ramping up communication with participants before each visit. This rapport building had downstream advantages, including creating a safer space for discussing sensitive topics or handling a reactive HIV test. In fact, in exit interviews, participants reported that remote participation was a positive experience. Participants also described advantages, such as convenience (e.g., visits could be scheduled around other commitments) and reduction in structural barriers to participation (travel, upfront costs, childcare, etc.). As a result, retention rates for intervention sessions and assessments have been higher in our remote configuration than for in-person visits.

Although conducting HIV prevention and adherence interventions remotely can provide innovative methods for intervention delivery and widen catchment areas for research participation, it can limit participation for those with limited technological literacy or access to technology (e.g., stable WiFi and smartphones, tablets, or computers), further deepening disparities in access to research and care.[9] Furthermore, the need to have their own private space to receive remote counseling presented additional challenges for participants without stable housing. Mailing study materials presented challenges for individuals who had unstable housing (e.g., no address) or lived in shared housing (e.g., lack of privacy).

Although a few participants conducted remote visits from less than ideal spaces (e.g., park benches), we have been able to successfully leverage community partnerships with organizations that remained open for services, including shelters, substance use treatment centers, and harm reduction agencies. Participants were able to retrieve study materials, and access the internet and private space at these organizations to participate in the research studies. We also created "remote" workstations at our on-campus research laboratories where participants could conduct the study in a private room, remaining distant from research staff in another area of the building.

Remote procedures also presented new challenges related to health literacy. For example, biospecimens that were previously collected by research assistants or study nurses were now self-collected. The biospecimen collection can be complex, including finger pricks and dried blood spots, hair sampling, and rectal swabs. To support participants, we developed and provided pictorial and video instructions for home biospecimen collection.

Research staff members were trained in best practices in health communication, including agenda setting to let participants know everything that will be covered in the visit, using plain language to describe procedures, using teach-back methods (i.e., asking participants to explain procedures in their own words), and taking breaks to avoid information overload and burn out.[10] Although this may have placed a larger burden on the research staff, these additional challenges often resulted in enhanced communication with participants in the remote configuration compared with the in-person visits.

Although staff reported positive experiences with remote study implementation, conducting study visits, particularly behavioral intervention sessions, from a home office can present challenges for staff as well. Staff also had to have a quiet and confidential space to conduct visits, as well as stable internet connections. Moreover, conducting visits from home sometimes blurred the boundary between work and personal life.

Many participants in our studies experience daily hardships and turn to research study staff for support, which can exacerbate this issue. Increased opportunities for debriefing helped combat staff emotional fatigue. Taking time in research operations meetings to connect with staff and give peer support or strategies to deal with additional stress can help increase morale. Without the ability to meet with staff and debrief after study visits, we have implemented monthly supervision for staff support with the study therapist or senior study staff.

This brief communication aims to characterize metrics of study accrual and retention during a year that limited face-to-face enrollment and research operations due to pandemic precautions. As such, there are limitations to this study. First, we cannot compare 2020 metrics with 2019 metrics as research was in different phases. Second, we are not testing statistical associations between leveraging technology and accrual or retentions. Future research on HIV behavioral studies should aim to compare the efficacy between the same intervention utilizing remote versus in-person strategies.

Conclusions

Moving from in-person study procedures to completely remote behavioral intervention efficacy trials can be done successfully using technology, creativity, and flexibility. Communication before the remote study visit is increased because of additional steps, which provides an additional opportunity for rapport building. Communication training, role-playing sensitive scenarios, and consistent debriefing with staff are key given the additional complexity presented by remote visits. To ensure participation is equitable, partnership with community organizations can reduce exclusion related to resources.

Authors' Contributions

J.O. and W.L. informed the section on procedures and adaptations. L.B.K.-F., K.B.B., and M.J.M. drafted and edited the text in each section. All authors discussed the results and contributed to the final article.

Disclosure Statement

No competing financial interests exist.

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