

CONTINUING EDUCATION SESSION

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SESSION	CE HOURS	DATE/TIME	
CE14	1.0	Saturday, November 5th	11:00am-12:00pm
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Charting the Future of Implementation Science for eHealth HIV Prevention among Young Men Who Have Sex with Men with Hybrid Effectiveness-Implementation Trials

AUTHORS

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ABSTRACT

Use of technology-enabled interventions is an increasingly common, if not primary mode of intervention in some areas of sexual health, particularly HIV prevention among young men who have sex with men (YMSM). Given digital programs' increased accessibility and reach due to the ubiquity of internet access in the US, HIV researchers have embraced eHealth's potential for reducing the disparities in HIV incidence that occur at the nexus of sexual orientation, age, and race/ethnicity. A host of eHealth HIV prevention programs have completed or will soon complete efficacy trials, demonstrating promising effects on behavioral and biomedical outcomes. However, despite (and perhaps because of) the rapid advancement in using technology to deliver preventive interventions, little research has studied approaches for implementing eHealth interventions in the real world, thus potentially relegating these promising interventions to sit unused. This symposium will present select findings from 3 effectiveness-implementation hybrid trials of eHealth HIV prevention programs for YMSM. Hybrid trials aim to shorten the lag between traditional effectiveness and implementation research. The first presentation will describe barriers to enrollment of young male couples in comparative effectiveness trials of a dyadic HIV prevention program, highlighting how findings informed the development of a new Hybrid Type 1 trial. The second presentation will describe mixedmethods research with potential implementers and participants of a stepped-care package interventions in a Hybrid Type I trial, highlighting implementation considerations when adapting YMSM interventions for adolescents. The third presentation will describe a Hybrid Type 3 trial comparing two implementation approaches of a self-guided HIV prevention intervention, focusing on pragmatic adaptations to delivery in response to COVID and other implementation challenges. Finally, an international expert in YMSM HIV prevention and eHealth implementation science will collate findings across studies, facilitate discussion of similarities and differences, and suggest areas for future digital sexual health implementation research. Enhancing Reach of 2GETHER: A Relationship Education and HIV Prevention Program for Sexual and Gender Minorities Background: Young men who have sex with men (YMSM) bear a disproportionate burden of the HIV epidemic. A large proportion of new HIV infections occur in the context of serious romantic relationships, particularly among YMSM (up to 79%). Given that romantic relationships provide myriad benefits to individual health and wellbeing, optimizing dyadic functioning among YMSM may be a particularly impactful platform for reducing HIV infections. Method: 2GETHER is a relationship education and HIV



prevention program for young male couples that has been found to reduce biological (i.e., STIs) and behavioral (i.e., condomless sex) indicators of HIV risk in efficacy trials. In preparation for a Hybrid Type I Effectiveness-Implementation trial, we analyzed data from a prior efficacy trial ("2GETHER USA") on participant eligibility, enrollment and engagement in order to enhance reach. 2GETHER USA delivered a 5-session intervention (3 groups sessions + 2 individualized couple sessions) via videoconference to couples across the U.S. Results: 2GETHER USA randomized 200 young male dyads (N=400) to the active or control condition (i.e., couple-based HIV testing) between February 2017 and December 2019. We screened 6392 individuals, of which 11% were eligible (N=672, 336 dyads). With regard to ineligibles, 39.6% were ineligible because their partner never completed eligibility screening, 19.2% were not in a romantic relationship, and 15.9% were not cisgender sexual minority men. Among those who were eligible but did not enroll, 23.9% were lost to follow-up due to difficulties scheduling participants into group-based intervention sessions. Among those randomized, >80% completed all intervention components and >90% completed 12-month follow-up. Conclusions: The substantial drop-off between steps in the eligibility screening process point to opportunities for enhancing reach which we have addressed in the design of our new hybrid trial. First, the shift to an automated, self-paced eHealth program (instead of group-based sessions) will reduce attrition resulting from scheduling issues. Second, a large proportion of individuals were unable or unwilling to engage their partners in the trial, so our hybrid trial will enroll both couples and individuals in relationships. Third, we will enroll single individuals in this preventive relationship education and HIV prevention program to prepare them for future relationships. Finally, we will enroll transgender and non-binary individuals who partner with cisgender sexual minority men who were previously ineligible for the efficacy trial. These program adaptations will reduce attrition and optimize reach of 2GETHER to sexual and gender minorities at high risk for HIV infection. Stakeholders' Perspectives on Implementing an eHealth HIV Prevention Intervention for Adolescent Men Who Have Sex with Men Background: Adolescent men who have sex with men (AMSM) experience tremendous and disproportionate increases in HIV risk as they age but, despite being a priority target for prevention, are often missed by traditional sexual health education. Thus, eHealth is an opportunity to reach AMSM with critical HIV prevention information and skills training. Implementation of eHealth interventions for AMSM may differ from those targeting adults, however, necessitating research to explore how to deliver such programs in the real world. Methods: We conducted mixed-methods implementation research in the context of a national effectiveness-implementation hybrid Type I, sequential multiple-assignment randomized trial of the SMART Program, a stepped-care package of HIV prevention interventions developmentally adapted for AMSM ages 13-18 from three evidencebased interventions. In the trial, SMART participants directly received 1-3 interventions involving either self-paced multimedia content or motivational interviewing with an online coach. To examine different models of future implementation, we conducted interviews with potential implementers of programs for AMSM—HIV service organizations, teachers, and LGBTQ-youth-serving agencies—to identify barriers, facilitators, and potential strategies for delivering SMART. We compared these data to AMSM's ideas for implementation, assessed via post-intervention surveys and purposively sampled exit interviews. Results: We enrolled 1,090 diverse AMSM into SMART. Survey respondents (n=731) rated school credit as the most desired alternative to monetary incentives and school-based implementation as the most preferred delivery setting (followed by direct-to-consumer). AMSM interviews (n=55) corroborated quantitative findings. Potential implementers were excited by SMART as a resource, but each setting had different implementation challenges: For example, HIV service organizations (n=12) had limited experience recruiting adolescents, teachers (n=19) noted extensive policy-level barriers, and LGBTQ agencies (n=4) wanted content relevant to all sexual and gender minority youth. All had limited eHealth experience and capacity to host the technology in house. Conclusions: Despite high acceptability of SMART among AMSM and potential implementers, there is



no clear path to implementation. Multiple potential delivery settings exist, each with unique barriers and facilitators. Future research can develop strategies needed to implement SMART in these settings and/or blend approaches that can work across contexts. Solving Implementation Challenges During a Type III Hybrid Trial of the Keep It Up Digital HIV Prevention Program Background: eHealth HIV prevention interventions have been tested in research trials, but we know little about their real-world implementation. Keep It Up (KIU) is a CDC-endorsed online HIV prevention program for young men who have sex with men (YMSM) consisting of a 6-episode webseries with interactive activities. We are testing KIU in a hybrid type III effectiveness-implementation RCT, which focuses primarily on studying intervention implementation and secondarily on intervention effectiveness. This trial compares a community-based organization (CBO) delivery model, where CBOs offer access to KIU to YMSM who test HIV-negative, with direct-to-consumer (DTC) delivery, where YMSM self-register for KIU online and complete at-home HIV testing. We describe our adaptations to DTC delivery in response to the challenges of real-world implementation amidst the COVID-19 pandemic. Methods: Trial recruitment began in October 2019. DTC KIU was initially delivered in 22 counties, with an enrollment goal of N=2200. Centralized staff recruited YMSM through online ads, packaged and shipped HIV/STI test kits to them, and granted them access to the KIU webseries after an HIV-negative self-test. Research surveys were administered at baseline and 3-, 6-, and 12-months post-intervention. Participants were offered chances to win gift cards and sexual health products for completing KIU. Results: By March 2020, we had enrolled only 20 participants after screening >1000 individuals, and our offices also closed due to COVID-19. We paused shipping HIV/STI tests and partnered sexual behavior decreased due to social distancing, both of which impacted our outcome data. Competing priorities during the pandemic, civil unrest, the long follow-up period, and lack of guaranteed incentives were barriers to participation. We consulted with NIH, implementation scientists, and youth advisors to discuss changes to KIU delivery. To mitigate COVID-19 risks, we temporarily arranged third-party HIV/STI test shipping and front-door Fed-Ex pickups of test samples; eventually we resumed in-house test shipments at reduced frequency. To increase enrollment, we guaranteed financial incentives. Ultimately, more significant changes were implemented (e.g., increasing incentives; relaxing inclusion criteria; abbreviating follow-up period), after which we saw a rapid increase in participants (N=1147) and improved retention (83%). Conclusions: Although we designed DTC KIU delivery with real-world constraints in mind, when we encountered these conditions in the trial, it was clear that nimble adaptations were needed to ensure we reached and engaged our end-users. Interventionists who implement digital interventions originally designed in research contexts should be prepared to make agile changes to ensure implementation success, while also striving to maintain intervention fidelity.

LEARNING OBJECTIVES

To identify the three types of effectiveness-implementation hybrid trials.

To explain at least two potential benefits of eHealth sexual health interventions to address health disparities through increased access and reach.

To describe at least two real-world implementation challenges of eHealth sexual health interventions.