

Protocol for an Adolescent and Young Adult HIV/STI and Substance Use Disorder Digital Health Preventive Intervention

David Cordova, José A Bauermeister, Sydni Warner, Youth Leadership Council, Patricia Wells, Jennifer MacLeod, Torsten B Neilands, Frania Mendoza Lua, Jorge Delva, Kathryn B Fessler, Versell Smith Jr, Sarah Khreizat, Cherrie Boyer

Submitted to: JMIR Research Protocols
on: March 16, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
---------------------------------	----------

Preprint
JMIR Publications

Protocol for an Adolescent and Young Adult HIV/STI and Substance Use Disorder Digital Health Preventive Intervention

David Cordova¹ PhD; José A Bauermeister² MPH, PhD; Sydni Warner³ MSc; Youth Leadership Council⁴; Patricia Wells⁴ MD; Jennifer MacLeod⁵ MSc, CADC; Torsten B Neillands⁶ PhD; Frania Mendoza Lua⁷ MSW; Jorge Delva⁸ PhD, MSW; Kathryn B Fessler⁴ MD, PhD; Versell Smith Jr⁹; Sarah Khreizat¹; Cherrie Boyer⁶ PhD

¹School of Social Work University of Michigan Ann Arbor US

²School of Nursing University of Pennsylvania Philadelphia US

³School of Public Health University of Michigan Ann Arbor US

⁴The Corner Health Center Ypsilanti US

⁵Huron Valley Practice Affiliates Ann Arbor US

⁶School of Medicine University of California San Francisco San Francisco US

⁷Crown Family School of Social Work, Policy, and Practice University of Chicago Chicago US

⁸School of Social Work Boston University Boston US

⁹Chicago House Chicago US

Corresponding Author:

David Cordova PhD
School of Social Work
University of Michigan
1080 S University Ave
Ann Arbor
US

Abstract

Background: HIV/STI remain significant public health concerns in the United States and adolescents are disproportionately affected. Adolescents engage in HIV/STI risk behaviors, including drug use and condomless sex, which increases risk for HIV/STI infection. At-risk adolescents, many of whom are racial minorities, experience HIV/STI disparities. Despite the facts that: (a) At-risk adolescents are disproportionately affected by HIV/STI risk behaviors, and infections, and (b) while CDC recommends routine HIV/STI testing in adolescents, relatively few adolescents report having ever been tested for HIV/STI. With expected increases in health clinic visits as a result of the Affordable Care Act, combined with technological advances, health clinics and mobile-health (mHealth), including apps, provide innovative contexts and tools to engage at-risk adolescents in HIV/STI prevention programs. Yet, a dearth of efficacious mHealth interventions delivered in health clinics to prevent/reduce both condomless sex and drug use and increase HIV/STI testing in at-risk adolescents exists.

Objective: To address this gap in knowledge, we developed a theory-driven, culturally congruent mHealth intervention (hereon referred to as S4E) that has demonstrated feasibility and acceptability in a clinic setting. A next important step is to examine the preliminary efficacy of S4E on adolescent HIV/STI testing and risk behaviors. This goal will be accomplished by two aims: AIM 1 is to develop a cross-platform and universal version of S4E. The cross-platform and universal version of S4E will be compatible with both IOS and Android operating systems, and multiple mobile devices, aimed at providing adolescents with ongoing access to the intervention once they leave the clinic, and AIM 2 is to evaluate the preliminary efficacy of S4E, relative to Usual Care control condition, in preventing/reducing drug use and condomless sex, and increasing HIV/STI testing in a clinic sample of at-risk adolescents aged 14 – 21 living in Southeast Michigan.

Methods: One-hundred adolescents recruited from a youth-centered community health clinic will be randomized via a blocked randomization with random sequence of block sizes to one of two conditions: S4E mHealth intervention or Usual Care. Theory-driven and culturally-congruent, S4E is a mHealth adaptation of the face-to-face Storytelling for Empowerment, which is registered with the Substance Abuse and Mental Health Services Administration National Registry of Evidence Based Programs and Practices.

Results: This paper describes the protocol of the study. The recruitment began May 1, 2018. This study was registered on December 11, 2017, on ClinicalTrials.gov (Registry ID: NCT03368456). All participants have been recruited. Data analysis will

be complete by the end of March 2023, with study findings available by the end of 2023.

Conclusions: This study has the potential to improve public health by preventing HIV/STI and substance use disorders.

(JMIR Preprints 16/03/2023:47216)

DOI: <https://doi.org/10.2196/preprints.47216>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/>

Original Manuscript

Protocol for an Adolescent and Young Adult HIV/STI and Substance Use Disorder Digital Health Preventive Intervention

Abstract

Background: HIV/STI remain significant public health concerns in the United States and adolescents are disproportionately affected. Adolescents engage in HIV/STI risk behaviors, including drug use and condomless sex, which increases risk for HIV/STI infection. At-risk adolescents, many of whom are racial minorities, experience HIV/STI disparities. Despite the facts that: (a) At-risk adolescents are disproportionately affected by HIV/STI risk behaviors, and infections, and (b) while CDC recommends routine HIV/STI testing in adolescents, relatively few adolescents report having ever been tested for HIV/STI. With expected increases in health clinic visits as a result of the Affordable Care Act, combined with technological advances, health clinics and mobile-health (mHealth), including apps, provide innovative contexts and tools to engage at-risk adolescents in HIV/STI prevention programs. Yet, a dearth of efficacious mHealth interventions delivered in health clinics to prevent/reduce both condomless sex and drug use and increase HIV/STI testing in at-risk adolescents exists.

Objective: To address this gap in knowledge, we developed a theory-driven, culturally congruent mHealth intervention (hereon referred to as S4E) that has demonstrated feasibility and acceptability in a clinic setting. A next important step is to examine the preliminary efficacy of S4E on adolescent HIV/STI testing and risk behaviors. This goal will be accomplished by two aims: AIM 1 is to develop a cross-platform and universal version of S4E. The cross-platform and universal version of S4E will be compatible with both IOS and Android operating systems, and multiple mobile devices, aimed at providing adolescents with ongoing access to the intervention once they leave the clinic, and AIM 2 is to evaluate the preliminary efficacy of S4E, relative to Usual Care control condition, in preventing/reducing drug use and condomless sex, and increasing HIV/STI testing in a clinic sample of at-risk adolescents aged 14 – 21 living in Southeast Michigan.

Methods: One-hundred adolescents recruited from a youth-centered community health clinic will be randomized via a blocked randomization with random sequence of block sizes to one of two conditions: S4E mHealth intervention or Usual Care. Theory-driven and culturally-congruent, S4E is a mHealth adaptation of the face-to-face Storytelling for Empowerment, which is registered with the Substance Abuse and Mental Health Services Administration National Registry of Evidence Based Programs and Practices.

Results: This paper describes the protocol of the study. The recruitment began May 1, 2018. This study was registered on December 11, 2017, on ClinicalTrials.gov (Registry ID: NCT03368456). All participants have been recruited. Data analysis will be complete by the end of March 2023, with study findings available by the end of 2023.

Conclusion: This study has the potential to improve public health by preventing HIV/STI and substance use disorders.

Trial Registration: ClinicalTrials.gov NCT03368456

Keywords: youth; mHealth; HIV; STI; illicit drugs; primary care

Introduction

The human immunodeficiency virus/sexually transmitted infections (HIV/STI) and drug abuse remain significant public health priorities in the United States (US) and youth are disproportionately affected. Youth between the ages of 15 - 24 constitute 25% of the sexually experienced population, yet account for 46% and 50% of HIV infections and new STIs, respectively [1-2]. National surveillance data indicate that youth disproportionately engage in HIV/STI risk behaviors, including

condomless sex [3] and licit and illicit drug use [4], which increase their risk for HIV/STI infection. Despite the disproportionately high rates of HIV/STI infection and risk behaviors in youth, fewer than 14% report having ever been tested for HIV [3]. Further, many youth are not routinely screened for asymptomatic STIs as recommended by the Centers for Disease Control and Prevention (CDC) [5]. In Southeast Michigan, the area targeted in this proposed research, HIV/STI are disproportionately high [6-7]. To address these significant public health concerns, we developed an innovative mobile-health (mHealth) intervention—the practice and dissemination of public health through mobile devices—for health clinic settings. Using this AIDS Science Track Award for Research Transition (ASTART) mechanism, we propose to examine the preliminary efficacy of our mHealth intervention.

The efficacy of mHealth [8-10] and brief interventions delivered in health care settings [11-14] aimed at preventing/reducing condomless sex and drug use in youth have been mixed. We believe our intervention, Storytelling 4 Empowerment (S4E), shows promise for several reasons: First, we developed S4E through a community-university collaboration, integrating community-based participatory research principles [15] with the National Institute on Drug Abuse's prevention guidelines [16]. This process transformed the effective Storytelling 4 Empowerment program [17], into a mHealth application (app) [18-22].

S4E is culturally congruent and was adapted in consultation with youth and clinicians from the targeted youth-centered community health clinic. The app is grounded in empowerment [23-24] and ecodevelopmental [22, 25-27] theories. S4E uses innovative storytelling scenarios to address key aspects of our intervention's mechanisms of change: including self-efficacy for condom use and drug use refusal skills (hereon referred to as self-efficacy) and improving clinician-youth communication during the healthcare visit. These elements aim to increase HIV testing and prevent/reduce condomless sex and drug use behaviors among at-risk youth. Our formative research with youth (defined hereon as adolescents and young adults between 14 to 21 years of age) and clinicians demonstrated that youth in the targeted health care clinic: (a) routinely visit the clinic for reproductive and other health care, (b) are at increased risk of HIV/STI, and (c) found S4E to be feasible and acceptable, but also want access to S4E outside of the health clinic to continue participating in intervention activities [18-21,28-30].

Youth-centered community health clinics are an ideal setting for delivering and evaluating the efficacy of a mHealth HIV/STI and drug abuse preventive intervention. Many youth do not seek such service in public health clinics or acquired immunodeficiency virus (AIDS) service organizations [31]. Furthermore, many primary care pediatric practices do not routinely screen youth for HIV/STI or drug use [32]. Thus, a gap in knowledge persists regarding efficacious mHealth interventions that improve HIV/STI testing and prevent/reduce condomless sex and drug use in at-risk youth in health care settings [10,18,33]. Now that S4E has demonstrated feasibility/acceptability, a next important step is to develop a more accessible version of S4E and conduct a Stage I randomized controlled trial (RCT) [34-35] to examine the preliminary efficacy of S4E in at-risk youth.

Aims

The proposed study seeks to accomplish the following two aims:

- **AIM I:** To develop a cross-platform and universal version of S4E. The cross-platform and universal version of S4E will be compatible with both IOS and Android operating systems, and multiple mobile devices, aimed at providing adolescents with ongoing access to the intervention once they leave the clinic.

AIM II: To evaluate the preliminary efficacy of S4E, relative to Usual Care, to improve HIV/STI testing and reduce HIV/STI risk behaviors in a clinic sample (n=100) of at-risk youth ages 14-21 living in Southeast Michigan. We will conduct a Stage I RCT [34-35] to examine the preliminary efficacy of S4E, relative to Usual Care, among a sample of 100 at-risk youth over 6 months. Our primary outcome is adolescent HIV and STI testing. Secondary outcomes include condomless sex and drug use at 3- and 6-months post-baseline. As a secondary exploratory aim, we will examine the extent to which our theoretically guided mechanisms of change (i.e., self-efficacy, clinician-youth communication) lead to increased HIV and STI testing and prevent/reduce HIV/STI risk behaviors.

The proposed study is innovative. It is the first to combine mHealth and storytelling to facilitate clinician-youth communication, deliver prevention services linkage to care, and treatment immediately [27, 36-37]. This research program focuses on increasing HIV and STI testing and reducing key risk behaviors like condomless sex and drug use among at-risk youth. This aligns with the National Institutes of Health (NIH) HIV/AIDS Research Priorities [38]. By doing so, it addresses two critical goals: 1) preventing and reducing new HIV infections, and 2) diminishing HIV-related health disparities. These objectives are among the top four priorities outlined in the United States National HIV/AIDS Strategy [39].

Significance

HIV/STI risk behaviors among youth remain major public health concerns. National surveillance data show that 40.9% of youth report condomless sex at last sexual intercourse [3]. Beyond condomless sex, youth engage in drug use behaviors that increase their risk for HIV/STI. National surveillance data indicate that 66% and 49.1% of youth report lifetime licit and illicit drug use, respectively [4]. Alcohol is the most widely used licit drug, with 37.4% and 66% of youth reporting current and lifetime use, respectively [3-4]. Parallel data from the Monitoring the Future (MTF) study indicate that, from 2008 to 2011, youths' lifetime, annual, and 30-day prevalence of any illicit drug use have increased [4]. Marijuana remains the most widely used illicit drug with 21.2% and 44% of adolescents reporting current and lifetime marijuana use, respectively [4]. Although CDC recommends HIV/STI testing among youth as part of routine care, many are only being tested based on their perceived risk [5]. HIV/STI testing has important prevention implications, including linkage to both care (e.g., preventing transmission of HIV/STI), and important preventive services to remain HIV/STI-free [5].

Racial/ethnic minority youth experience HIV/STI disparities. Youth between the ages of 15 - 24 represent 25% of the sexually experienced population and comprise nearly 46% and 50% of HIV infections and new STIs, respectively [1-2]. In 2014, an estimated 9,731 youth were diagnosed with HIV in the US; 78% of these diagnoses occurred in Black/Latino youth [40]. Although the majority of these infections are among young men who have sex with men [40], African American young women are disproportionately affected by STIs which increases the risk of HIV infection [41]. Given their needs, our sample will consist of a predominantly racial/ethnic minority sample of adolescents 14-21 years old. This age group spans a time of limited HIV testing and increased HIV/STI risk-taking [3-4], and thereby permits us to intervene at a developmental moment of increased risk [42-43].

Youth in the targeted clinic, many of whom are racial/ethnic minorities, are at disproportionate risk of HIV/STI. Our research shows that, relative to the general US adolescent population, youth in the targeted clinic are more likely to report condomless sex at last sexual intercourse (40.9% vs. 57.9%), and lifetime alcohol (66.2% vs. 71.4%) and marijuana (40.7% vs. 46.7%) use, respectively [3, 20].

Given that condomless sex and drug use are risk behaviors for HIV/STI, not surprisingly youth in the targeted clinic experience HIV/STI disparities. In the first quarter of 2016 (Jan-Mar), 52.4% (33 out of 63) of youth who received STI testing services tested positive for an STI, compared to 25% of the sexually active US youth population [2].

Self-efficacy and clinician-youth communication are potential mechanisms by which change can occur. Researchers have identified a number of etiological factors that shape youth HIV/STI testing [44-46] and risk behaviors [47-49], including intrapersonal (e.g., self-efficacy) and ecological (e.g., clinician communication) [42, 50]. At the intrapersonal level, for example, higher levels of refusal skills and knowledge self-efficacy increase HIV/STI testing and prevent HIV risk behaviors in youth [42-45,51-52]. At the ecological level, effective sexual communication can ameliorate HIV/STI testing and risk behaviors. Indeed, higher levels of clinician-patient communication have been shown to yield better health outcomes [53-55]. Drawing from this basic science, the proposed study posits that interventions targeting these potential underlying mechanisms of change (i.e., improving refusal skills, knowledge, and HIV communication, which in turn will improve self-efficacy and clinician-youth communication) may increase HIV/STI testing and prevent/reduce HIV and STI risk behaviors. Furthermore, understanding the role of etiological factors on youth HIV/STI testing and risk behaviors should be viewed through a cultural and developmental lens [26,56-57]. Therefore, integrating cultural and developmental perspective into theoretical frameworks is important to improve HIV/STI testing and reduce risk behaviors [26,56-58].

Empowerment and ecodevelopmental theories provide a framework for targeting the theoretical underpinnings of our intervention's mechanisms of change. The empowerment and ecodevelopmental frameworks guide the theoretically driven components of our intervention. The empowerment framework is concerned with linking youths' strengths and proactive behaviors to helping systems [24-25]. Thus, empowerment-informed interventions seek to enhance knowledge of risk factors, refusal communication skills, perceptions of self-efficacy, and engage health care clinicians as resources to accomplish these health goals [24-25]. Equally important is to consider ecological factors. Ecodevelopmental theory [59-60] posits that youth are embedded in integrated ecological systems (micro-, meso-, exo, and macrosystems), including developmental and social interaction, that influence and are influenced by the youth [59-60]. In the proposed research, we focus on the health clinic microsystem and limit the conversation to that high-impact system. Microsystems are defined as systems in which the youth directly participates [59-60]. Researchers have extensively applied ecodevelopmental theory to the family microsystem aimed at improving parent-youth communication [61-63]. With the passing of the Affordable Care Act (ACA), we have an opportunity to apply ecodevelopmental theory to the health clinic microsystem---a system that will only grow larger and increasingly important as a result of the ACA---to understand clinician-youth communication [18-21]. Our formative research supports the use of empowerment and ecodevelopmental theories and provides a robust framework for the proposed research.

Health clinic HIV/STI preventive interventions are needed but limited in availability. A recent review of brief (<60 minutes) health clinic interventions examined 31 trials designed to increase HIV/STI testing and prevent HIV/STI risk behaviors. Of these, only one study focused on HIV/STI risk behavior outcomes through clinician-youth communication. Findings suggest that, relative to Usual Care, an audiotaped risk assessment and education intervention showed an increase in communication with providers on STIs, and condom use [64]. Findings on the efficacy of brief interventions in health care settings on youth licit and illicit drug use have been mixed [11,14,65]. For example, a recent review of brief interventions in health care settings with clinician approaches was conducted, with 10 interventions designed to prevent/reduce youth alcohol use examined. Of these, only three studies were RCT, only one had a primarily racial minority sample, and only one was found to be efficacious in reducing alcohol use [11]. Our community-university approach aims

to overcome limitations of these studies. By engaging community in the development of our mHealth intervention, we believe we will have a greater impact given that community-university approaches increase uptake and optimize outcomes of prevention programs [66]. While federal recommendations highlight the need for clinicians to provide youth HIV/STI and drug use preventive services [67-68], efficacious brief interventions designed to increase HIV/STI testing and prevent/reduce condomless sex and drug use are limited [18,33,64,69,]. Our formative research suggests that youth in the targeted clinic routinely show for health care visits, with over 550 monthly visits from youth 12-21 years of age. This provides us with an exciting opportunity to impact HIV/STI testing and behaviors through an innovative and interactive mHealth app.

mHealth apps provide new opportunities for engaging youth in preventive interventions, but research is limited. Advances in technology and increased availability provide novel opportunities for prevention scientists [70-71]. Although mHealth interventions are efficacious for adolescent health behaviors [71-73], relatively few studies on HIV/STI testing and risk behaviors exist. A recent systematic review of mHealth apps aimed at addressing the HIV continuum of care identified only four published studies and 14 studies underway [10]. Of these, only 7 studies focused on primary prevention of HIV/STI and 6 studies on HIV/STI testing [10]. A limitation to these studies, however, is that they do not target at-risk youth in health care clinics. Our proposed research aims to harness the widespread use of mobile technology [74] and deliver and evaluate a mHealth HIV/STI intervention among at-risk youth, many of whom are racial minorities, in a health care clinic.

Storytelling for Empowerment (SFE) is a foundation to test a new mHealth preventive intervention. Registered with SAMHSA's NREPP, SFE aims to increase self-efficacy and communication about HIV risk behaviors and has been shown to prevent/reduce HIV/STI risk behaviors, and increase (1) HIV/STI and drug use prevention knowledge, (2) HIV/STI communication, and (3) perception of harm and self-efficacy in refusing drugs [17, 75-76]. Adapting SFE into a mHealth version for health care clinics was ideal for several reasons, including SFE has already demonstrated efficacy with other youth populations, and the use of storytelling makes it highly flexible and easily transportable into a brief mHealth modality. Based in empowerment [24-25] and ecodevelopmental [22,26,77] frameworks, the mHealth version of SFE, S4E, consists of 3 modules targeting youth: (a) HIV/STI risk assessment, (b) HIV/STI, and (c) Alcohol/Drugs. The risk assessment assesses youth HIV/STI risk behaviors. Both the HIV/STI and drug modules consist of videos (developed from focus group data on community-specific epidemiology) focused on HIV/STI testing and risk and promotive behaviors, knowledge development, interactive activities, and messaging aimed at increasing clinician-youth communication.

Despite federal guidelines urging clinicians to provide youth HIV and drug use preventative care [67-68], our research [19-20] and that of others [78-80] demonstrates that clinicians' limited HIV/STI communication training, and embarrassment to discuss HIV/STI risk, pose as challenges to engage youth in these conversations. With funding from the NIMH (R25MH067127), we developed a theory-driven and culturally congruent clinician component to overcome these barriers, which provides clinicians with (a) youth risk assessment scores, (b) tailored HIV/STI communication interviewing toolkit (e.g., reflective questioning), and (c) tailored resources to link youth with care. We recognize that youth in health clinics represent one segment of the youth population, but nonetheless an important segment at disproportionate risk of HIV/STI [20,28].

Preliminary Studies

Study 1: Feasibility and Acceptability of S4E

Study Design

Youth were recruited from Southeast Michigan and are primarily African American (67%) and

female (73%); mean age=16.23 (SD=2.09). We used a community-engaged research approach with three phases, including formative focus groups (n=29), app development, and feasibility testing (n=30). We used agile software development [81]. Formative focus group data collection and app development occurred simultaneously.

Results

We developed a theory-driven and culturally congruent mHealth version of Storytelling for Empowerment (Fig. 1). Both qualitative and quantitative data from the Session Evaluation Form [82] ($\bar{x}$ =1.42, SD=.46) and Client Satisfaction Questionnaire [83] ($\bar{x}$ =3.46, SD=.47) indicate S4E is acceptable to youth. Data also show that youth regularly visit the clinic (i.e., 550 visits per month), visit the clinic multiple times ($\bar{x}$ =3 visits), and are at increased risk of HIV/STI risk behaviors. Now that we have demonstrated feasibility, a next important step is to conduct a Stage I preliminary efficacy RCT of S4E on adolescent HIV/STI testing and risk behaviors [18-21].

Study 2: Development of S4E Clinician App [84]

Employing CBPR principles, we collaborated with clinicians from the targeted youth-centered community health clinic in SE Michigan (NIMH #R25MH067127) to inform the development of the clinician components for the S4E app. We used agile software development [81] for the creation of prototype models, obtain rapid feedback from clinicians regarding user interface/experience (UI/UE), and a feedback loop for revisions and to finalize the app. The S4E clinician app provides clinicians with (a) youths' risk assessment scores, (b) tailored HIV/STI communication interviewing toolkit (e.g., reflective questioning, positive reinforcement), and (c) tailored resources to link youth with care. Feasibility/acceptability testing is underway and study findings will be incorporated into this proposed ASTART research.

Methods

Study Design

AIM I is to develop a cross-platform and universal version of S4E. The purpose of developing a cross-platform and universal version of S4E is to create a more accessible app that is compatible with different operating systems (i.e., Android and IOS), and multiple mobile devices, thereby providing youth with ongoing access to the intervention outside of the clinic. Finalizing the universal version of S4E will be streamlined because the app developer, The Annex Group, created S4E for the IOS operating system to use on iPads, which will serve as an existing framework (e.g., code, design database). Similar to the methodology employed in our formative research, as part of the iterative process we will hold weekly meetings with The Annex Group to discuss all aspects of finalizing the app, including framework and UI/UX. At the completion of AIM I, we will have finalized S4E, which will be used for our Stage I preliminary efficacy RCT in AIM II. We will pilot test all study procedures prior to addressing AIM II.

AIM II is to evaluate the preliminary efficacy of S4E to improve HIV/STI testing and reduce HIV/STI risk behaviors in a clinic sample (n=100) of at-risk adolescents ages 14-21 living in Southeast Michigan. To test the preliminary efficacy of S4E, we will conduct a Stage I RCT and use a mixed between/within-subjects design with two levels of intervention (S4E and Usual Care) as the between-subjects factor and 3 repeated measures assessments (Baseline, 3-, and 6-months post-Baseline) as the within-subjects factor.

Participants

A clinic sample of 100 youth and clinicians (n=6) will be recruited from Corner Health Center. In 2015, the clinic reported over 5,600 visits from 12-21 years old; therefore, recruiting 100 youth will

be feasible. With respect to participant race/ethnicity and age, we will recruit a sample that is representative of the clinic population. As in our previous studies, we expect the majority of participants to be racial minority youth and be sexually active (71.4% report past 90-day oral, vaginal, or anal sexual intercourse) [20,28].

Inclusion Criteria

Participants must be (a) female or male youth 14-21 years of age, (b) sexually active, (c) live in Southeast Michigan, and (d) have access to a smartphone or tablet (73% report having access to smartphone [85]). Youth must see an enrolled clinician to participate in the study. Exclusion criteria include (a) report of prior psychiatric hospitalization by adolescent, (b) visible cognitive impairment due to drug use, and (c) adolescent reports (tentative or firm) plans to move out of the Southeast Michigan area during the study.

Recruitment

A multi-pronged recruitment strategy will be implemented: face-to-face interactions, flyer distribution, engagement in the clinic's waiting area, and informing youth with upcoming clinic appointments at the clinic about the study. Potential participants will be informed about the study by research staff, with details about its voluntary nature and the RCT design. Those interested will be sent a study web-based application (app) link, where they can provide digital consent and screen for eligibility. Participants aged 13-17 will be given a waiver of parental permission as per Michigan regulations.

Following consent, participants will undergo baseline assessment and randomization through the study's web-based app. They will then be informed of their group allocation. Research staff will introduce participants to the app and ensure proper navigation. Participants will be incentivized, receiving a total of US \$120; \$30 at baseline, \$40 at the 3-month follow-up, and \$50 at the 6-month follow-up.

Retention

To prevent attrition, we will ask youth to provide the names and contact information of 3 persons who will always know where they can be reached. These names will help maintain contact with the youth in case they move, or their telephone lines become disconnected. Youth may choose to provide the names and contact information of individuals they trust, such as a primary caregiver, relative, or significant adult figure. Youth will be informed that if the research team cannot reach them and needs to contact these individuals, the team will only communicate their intention to get in touch with the youth about a health study. Additionally, a sample of 6 clinicians will be recruited. Similar to our formative research, research staff will provide an overview of the study to all clinicians during a staff meeting and they will be informed that participation is voluntary. To prevent coercion of clinician participation by clinic administration, potential participants will not need to go through, nor inform, clinic administration for participation. An initial list of potential clinician participants will be developed and research staff will follow-up with those clinicians who express interest in the study.

Clinicians

Clinicians will be assigned to either S4E or control condition. In lieu of providing each clinician with an incentive for their participation in the study, the clinic will receive \$2,000 that will benefit the entire clinic. Randomization will occur after baseline assessment. Three of the six clinicians will be assigned to the S4E condition and trained to research criteria. Clinicians will receive a one-hour training, encompassing content delivery, app navigation, risk assessment viewing, note-taking within the app, and effective communication strategies for discussing substance use and sexual behaviors. A

review training will ensure adherence to protocols. All clinicians who express interest in the study and do not report (tentative or firm) plans to move out of the region during the study will be eligible to participate.

Experimental and Control Conditions

Participants were assessed at baseline, randomized to intervention (n=50) or control (n=50) groups using block randomization [86], and then reassessed immediately post-intervention, at 3 months, and at 6 months. Participants in the S4E condition will initially engage with the intervention using iPads available in the waiting area. This includes iPads allocated for this study and an additional 10 from the PI's pilot studies. They will also be instructed on how to download the intervention app onto their personal devices, enabling continued participation in intervention activities after leaving the clinic.

S4E Description

Informed by our formative research, the intervention lasts approximately 60 minutes and was found to be feasible and acceptable to youth. Content includes the theoretically driven components of SFE [17,75-76]: (a) Storytelling scenarios, (b) drug use and HIV/STI knowledge development, (c) interactive activities, (d) increasing self-efficacy to prevent/reduce sexual risk and drug use behaviors, and increase HIV/STI testing, (e) clinician-youth communication, and (f) highlighting prevention principles (Table 1).

Table 1. Experimental condition.

S4E Intervention	Underlying Mechanisms of Change
Adolescent Components Risk Assessment: Youth complete an HIV/STI risk behavior assessment, which include items from the CRAFFT [87] measure, HIV testing, and sexual and drug use behaviors, and provides opportunity/receptivity to being counselled (1 min to complete). HIV/STI Module: Youth are exposed to storytelling scenarios, including community-specific HIV/STI epidemiology (e.g., risk and protective behaviors). Following the videos, youth operate an app aimed at increasing condom use self-efficacy, HIV/STI knowledge development, and interactive activities aimed at engaging youth and testing knowledge. Additionally, youth receive messaging aimed at facilitating clinician-youth communication, and HIV/STI testing (30 min to complete). Alcohol/Drugs Module: Adolescents are exposed to storytelling scenarios, including community-specific Alcohol/Drug epidemiology (e.g., prevalent licit and illicit drugs). Following the videos, adolescents operate an app aimed at increasing drug use refusal self-efficacy, drug use knowledge development, and interactive activities aimed at engaging youth and testing knowledge. Additionally, adolescents receive messaging aimed at facilitating clinician-adolescent communication (30 min to complete). Clinician Components Risk Assessment Scores: Clinicians are provided the youth risk assessment scores, identifying at-risk youth, and provided opportunity to reinforce information provided to youth through the modules (above).	Consistent with empowerment and ecodevelopmental theories, S4E provides opportunity to be counselled, which in turn: • Increases clinician-youth communication • Increases engagement of health care clinicians as collaborators to address HIV/STI and drug use concerns • Increases clinician-youth sexual risk communication • Increases HIV/STI knowledge • Increases condom use • Increases condomless sex refusal skills • Increases clinician-youth drug use communication • Increases drug use knowledge • Increases refusal skills • Clinicians reinforce

Tailored HIV/STI Communication Toolkit: Based on empowerment and ecodevelopmental theories, clinicians are provided a communication toolkit, which includes examples of open-ended reflective questioning, positive reinforcement statements, HIV/STI risk probing, and empowerment messaging. Tailored Resources and Referrals: Clinicians are provided tailored community-identified local resources and referrals, including HIV/STI testing and linkage to care.	prevention strategies and link youth to HIV/STI testing and linkage to care
--	--

Control Condition

Participants in Usual Care (i.e., Control Condition) will not receive the S4E intervention from the study staff. The Clinic's usual care includes a standard risk behaviors intake form, pamphlets highlighting resources, and reproductive and health care services.

Measures

Youth HIV/STI Testing and Risk Behaviors

Post-intervention, we will assess whether youths requested to receive HIV/STI testing at the clinic, and at 3- and 6-months post-baseline (yes/no). Adolescent unsafe sexual behavior will be measured (time points 1-3) using items extracted from Jemmott, Jemmott, and Fong's Sexual Behavior instrument [88]. This gated instrument will assess the adolescent's past 90-day condom use, number of sexual partners, and contraceptive use (non-condom). This measure also assesses the existence of a STI during their lifetime and in the past 90 days.

Licit and illicit drug use behaviors will be assessed (time points 1-3) using items from the MTF [4]. Youth will be asked whether or not they have used licit or illicit drugs in their lifetime and in the past 90 days. Youth who report "Yes" to past 90-day sex will be asked to report frequency of drug use prior to sex. These measures have been used in our formative research [18-21].

Potential Mediators: Clinician-Youth Communication and Self-Efficacy

Completed by both the clinician ($\alpha = .70$) and youth ($\alpha = .69$), clinician-youth communication will be assessed (time points 1-3) using items adapted from the Matched Pair Instrument (19 items; MPI) [89]. MPI assesses process and content of communication, including verbal and action-related behaviors performed by clinicians [89]. Responses range from "1=strongly disagree," to "5=strongly agree," on a five-point Likert scale. A sample statement for clinicians and youths is, "Encouraged the patient/me to express his or her/my thoughts concerning drug use behaviors." Youth's self-efficacy will be assessed (time points 1-3) using two scales, including the Condom Self-Efficacy Scale (19 items, $\alpha = .85$) [90], and Drug Use Resistance Self-Efficacy (24 items, $\alpha = .98$) [91]. Responses range from "1=not sure at all," to "4=definitely sure," on a four-point Likert scale. A sample question for the youth is, "How sure are you that you can refuse if a friend offers you marijuana at a party and you do not want it?" Additionally, youth and clinicians will respond to a demographic survey and asked their date of birth, gender identity, sexual orientation, age, ethnicity/race, income, and education.

Intervention Dosage for Both Clinicians and Youth (Not Given to Participants)

S4E includes a login procedure. In addition to the login procedure serving as a mechanism by which to ensure the secure access and confidentiality of participants, the login procedure will facilitate the

close monitoring of participants' dosage. The login procedure will be used to record whom (i.e., participant), when (i.e., day/time), how long (e.g., dosage), and for what purpose (e.g., module). We will assess participants' satisfaction with S4E across platforms (e.g., mobile phone), and use of intervention once they leave the clinic. Higher frequencies of access and longer durations of app use will indicate higher levels of dosage and engagement with the intervention.

Statistical Analysis

Given sample size and Stage I RCT pilot nature of our study, we will not conduct a formal test of efficacy. Researchers affirm [92] that effect size estimates obtained using Stage I RCT data may not be reliable given their large variability. Therefore, our primary purpose is to estimate the critical parameters [92] required to inform the potential effects of S4E in a Stage II RCT. As part of the preliminary efficacy process, we expect that following intervention exposure, relative to Usual Care participants, S4E participants will have:

H1: Increased odds of repeat HIV/STI testing post intervention

H2: Decreased odds of past 90-day condomless sex at 3- and 6-months post-baseline

H3: Decreased odds of past 90-day licit and illicit drug use at 3- and 6-months post-baseline.

As a secondary exploratory aim to examine potential mechanisms of change (Figure 2), we also anticipate that S4E participants, compared to Usual Care participants, will report: (1) higher mean levels of clinician-youth communication, and (2) drug use and HIV/STI self-efficacy.

To test differences between conditions post-randomization, we will plot means and proportions by condition over time for descriptive analysis of overall patterns of change across time in the outcomes for the S4E and Usual Care conditions. We will use linear mixed models (LMM) for continuous outcomes (e.g., clinician-adolescent communication scale scores measured to address exploratory aim) and generalized linear mixed models (GLMM) for discrete data (e.g., HIV/STI testing measured to address H1) to evaluate the proposed preliminary hypotheses. GLMMs fitted to discrete outcomes (e.g., H2: condomless sex) will employ a binomial distribution with a logit link; GLMMs fitted to count outcomes will use the best-fitting distribution from the Poisson family (e.g., zero-inflated Poisson) with the log link function [93]. We will assess whether clustering effects associated with clinic physicians must be accounted for in these analyses. All mixed models will be estimated via maximum likelihood estimation and will be fitted to ensure that all requisite information is available in the survey and data to perform the types of analyses typically undertaken in a Stage II RCT. Similarly, although the modest sample size precludes investigating mediation and moderation formally, we will employ the same LMM and GLMM approaches described above to examine potential mediators (i.e., clinician-adolescent communication, self-efficacy) and moderators (e.g., gender, race) of the S4E intervention.

Power Analyses

Due to the modest sample size, significance testing will be de-emphasized. The purpose of the Stage I RCT is to determine preliminary efficacy rather than to conduct formal hypothesis tests; nevertheless, we conducted power analyses using nQuery Advisor Version 7.0 [94] to estimate the magnitude of effect we could observe given our pilot sample size. With 50 cases per group, we would have 80% power to detect an odds ratio of 3.7 in receiving HIV testing immediately post intervention between the two conditions. This would be considered a large effect size [95]. Using GLMM models to compare the two groups in terms of trends in the probability of binary outcomes over 6 months (e.g., condomless sex), we performed a custom simulation study to estimate the size of the interaction between group x time that we could detect with 80% power when fitting our models (and assuming a within-subject correlation of 0.1 in the binary measures). We would be able to detect percentages in the intervention group of 70% at 3 months and 25% at 6 months as representing a significantly different reduction in the percentage with this outcome over time (i.e., a

significant group x time interaction) with approximately 80% power, which would again be considered a large effect.

Results

This study has been designed to develop an mHealth intervention program (S4E) and evaluate its preliminary efficacy to improve HIV/STI testing and reduce HIV/STI risk behaviors among youth populations. Study findings will contribute to reduce HIV/STI infections and risk behaviors among youth.

Principal investigator (DC) received approval from the University of Michigan Institutional Review Board (IRB) to begin research in February 2017 and was awarded funding from the National Institute on Drug Abuse on February 01, 2017. The development of the intervention has been completed, and recruitment for the preliminary efficacy trial began in May 2018. We completed the trial in August 2020. We recruited 100 participants, data analysis are underway, and the results are expected to be published in 2023.

Discussion

The overarching goal of this program of research is to move a program of intervention research from efficacy to scale, and to examine the extent to which these modules are generalizable to similar youth populations. If found to have preliminary efficacy, a next step in this program of research is to conduct a Stage II RCT to examine the effects of S4E on youth HIV/STI testing and risk behaviors. We are aware that there may be the potential for contamination by conditions. Although it might not be possible for youth to see the same clinician at 3- and 6-months post-baseline, we have the Corner Health's support that youth will only see clinicians in the condition to which they are assigned (i.e., S4E or Usual Care). The proposed age range (14-21) may seem wide; however, this is an age group at increased risk for HIV/STI [1-2]. Further, this age range was established in consultation with the Corner who, in considering both the strengths and limitations, preferred a universal app that was relevant to the clinic population. Our two-arm, baseline, 3-, 6-months post-baseline design was chosen given the scope of the R03 ASTART mechanism.

Our protocol explores the behavioral change practice methods (i.e., proposed mechanisms underlying the observed changes), namely clinician-youth communication and self-efficacy. The use of storytelling scenarios, created by youth through a community-engaged research method grounded in community-based participatory research principles, could offer an innovative strategy for future studies. This approach highlights the importance of the relationship between clinicians and youth, as well as the role of self-efficacy.

Our protocol may benefit society by providing compelling evidence for the preliminary efficacy of a mHealth intervention in promoting HIV and STI testing and reducing sexual and substance use risks among adolescents and young adults. The promising intervention, combined with the proposed recruitment and retention strategies, may provide evidence for larger-scale trials. Given the pressing demand for efficacious interventions in this domain, this protocol may have a significant societal impact. Further, this proposed research aligns well with the broader goals of the NIH HIV/AIDS Research Priorities [38], the National HIV/AIDS Strategy [4], and the recommendations issued by the U.S. Preventive Services Task Force to reduce youth's HIV and drug use risks by linking them to screening and care services in community health clinic settings [67-68].

Acknowledgements

Financial support for the conduct of this research was provided by the National Institute of Mental

Health Grant# R25 MH067127, National Institute on Minority Health and Health Disparities Loan Repayment Program Grant# L60 MD006269, Office of Vice President for Research at the University of Michigan and Vivian A. and James L. Curtis School of Social Work Research and Training Center grant# 23665. These sponsors had no role in the study design, collection, analysis, or interpretation of the data or in the writing of this report or the decision to submit this article for publication.

Conflicts of Interest

None declared.

Abbreviations

HIV: human immunodeficiency virus

JMIR: Journal of Medical Internet Research

RCT: randomized controlled trial

S4E: Storytelling 4 Empowerment

STI: sexually transmitted infection

References

1. HIV surveillance report, 2014. Centers for Disease Control and Prevention; 2015. URL: <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2014-vol-26.pdf> [accessed 2015-03-12]
2. Sexually transmitted disease surveillance 2014. Centers for Disease Control and Prevention: U.S. Department of Health and Human Services; 2015. URL: <https://www.cdc.gov/std/stats/archive/surv-2014-print.PDF>
3. Youth behavior surveillance-United States, 2013. Centers for Disease Control and Prevention: U.S. Department of Health and Human Services; 2014. URL: <http://www.cdc.gov/mmwr/pdf/ss/ss6304.pdf> [accessed 2014-11-17]
4. Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. Monitoring the future national results on adolescent drug use: overview of key findings, 2011. Institute for Social Research, The University of Michigan; 2012. URL: <https://files.eric.ed.gov/fulltext/ED529133.pdf>
5. Vital signs: HIV infection, testing, and risk behaviors among youths — United States. Centers for Disease Control and Prevention; 2012. URL: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6147a5.htm> [accessed 2015-03-12]
6. Biannual HIV surveillance report Washtenaw County. Michigan Department Community Health; 2013. URL: <http://www.michigan.gov/hivstd> [accessed 2022-01-13]
7. Youth behavior surveillance-United States Detroit, MI 2014 and United States 2013 results. Centers for Disease Control and Prevention; 2014. URL: <https://nccd.cdc.gov/youthonline/App/Default.aspx> [accessed 2014-11-17]
8. Marsch LA, Carroll KM, Kiluk BD. Technology-based interventions for the treatment and recovery management of substance use disorders: a JSAT special issue. J Subst Abuse Treat 2014;46(1):1-4. doi:[10.1016/j.jsat.2013.08.010](https://doi.org/10.1016/j.jsat.2013.08.010)
9. Villarruel AM, Loveland-Cherry CJ, Ronis DL. Testing the efficacy of a computer-based parent-adolescent sexual communication intervention for Latino parents. Family Relations 2010;59(5):533-543. doi:[10.1111/j.1741-3729.2010.00621.x](https://doi.org/10.1111/j.1741-3729.2010.00621.x).
10. Muessig KE, Nekkanti M, Bauermeister J, Bull S, Hightow-Weidman LB. A systematic review of recent smartphone, internet and web 2.0 interventions to address the HIV continuum of care. Curr HIV/AIDS Rep 2015;12(1):173-190. doi:[10.1007/s11904-014-0239-3](https://doi.org/10.1007/s11904-014-0239-3)
11. Boekeloo B, Griffin M. Review of clinical trials testing the effectiveness of physician approaches to improving alcohol education and counseling in adolescent outpatients. CPR 2007;3(1):93-101. doi:[10.2174/157339607779941679](https://doi.org/10.2174/157339607779941679)
12. Hosek SG, Lemons D, Harper GW, Telander K. Evaluating the acceptability and feasibility of project accept: an intervention for youth newly diagnosed with HIV. AIDS Educ Prev 2011;23:128-144. doi:[10.1521/aeap.2011.23.2.128](https://doi.org/10.1521/aeap.2011.23.2.128)
13. Mason M, Pate P, Drapkin M, Sozinho K. Motivational interviewing integrated with social network counseling for female adolescents: a randomized pilot study in urban primary care. J Subst Abuse Treat 2011;41:148-155. doi:[10.1016/j.jsat.2011.02.009](https://doi.org/10.1016/j.jsat.2011.02.009)
14. Haller DM, Meynard A, Lefebvre D, Ukoumunne OC, Narring F, Broers B. Effectiveness of training family physicians to deliver a brief intervention to address excessive substance use among young patients: a cluster randomized controlled trial. CMAJ 2014;186(8):263-272. doi:[10.1503/cmaj.131301](https://doi.org/10.1503/cmaj.131301)
15. Israel B, Eng E, Schulz a MYJ, Parker E. Introduction to methods for CBPR for health. In: *Methods in community-based participatory research for health*. San Francisco: Jossey-Bass; 2005. p. 1-36. ISBN: 9781118021866
16. Principles of drug addiction treatment: a research-based guide. US Department of Health and Human Services; 2012. URL: <https://nida.nih.gov/sites/default/files/675-principles-of-drug-addiction-treatment-a-research-based-guide-third-edition.pdf>

17. Nelson A, Cordova D, Walters AS, Szecsy E. Storytelling for empowerment for Latino teens: increasing HIV prevention knowledge and attitudes. *J Adolesc Res* 2016;31(2):202-231. doi:[10.1177/0743558415588350](https://doi.org/10.1177/0743558415588350)
18. Cordova D, Bauermeister J, Delva J, Alers-Rojas F, Waller N, Youth Leadership Council. A community-engaged approach to developing a primary care substance abuse prevention and sexual health promotion app. Poster presented at: Society for Prevention Research; 2014; Washington, D.C.
19. Cordova D, Bauermeister JA, Fessler K, et al. A community-engaged approach to developing an mHealth HIV/STI and drug abuse preventive intervention for primary care: a qualitative study. *JMIR Mhealth Uhealth* 2015;3(4):106. doi:[10.2196/mhealth.4620](https://doi.org/10.2196/mhealth.4620)
20. Cordova D, Alers-Rojas F, Lua FM, et al. The usability and acceptability of an adolescent mHealth HIV/STI and drug abuse preventive intervention in primary care. *Behav Med* 2018;44(1):36-47. doi:[10.1080/08964289.2016.1189396](https://doi.org/10.1080/08964289.2016.1189396)
21. Cordova D, Bauermeister J, Delva J, Alers-Rojas F, Waller N, Youth Leadership Council. Developing an m-Health primary care HIV/STI preventive intervention for urban adolescents: methodological considerations in the context of policy and technological advances. Poster presented at: National Conference of the Society for Prevention Research; 2015; Washington, D.C.
22. Coatsworth JD, Pantin H, Szapocznik J. Familias Unidas: A family-centered ecodevelopmental intervention to reduce risk for problem behavior among Hispanic adolescents. *Clin Child Fam Psychol Rev* 2002;5(2):113-132. doi:[10.1023/A:1015420503275](https://doi.org/10.1023/A:1015420503275)
23. Perkins DD, Zimmerman MA. Empowerment theory, research, and application. *Am J Community Psychol* 1995;23(5):569-579. doi:[10.1007/BF02506982](https://doi.org/10.1007/BF02506982)
24. Zimmerman MA, Israel BA, Schulz A, Checkoway B. Further explorations in empowerment theory: an empirical analysis of psychological empowerment. *Am J Community Psychol* 1992;20(6):707-727. doi:[10.1007/BF01312604](https://doi.org/10.1007/BF01312604)
25. Szapocznik J, Coatsworth JD. An ecodevelopmental framework for organizing the influences on drug abuse: a developmental model of risk and protection. In: Glantz MD, Hartel CR, eds. *Drug abuse: origins & interventions*. American Psychological Association; 1999:331-366. doi:[10.1037/10341-014](https://doi.org/10.1037/10341-014)
26. Cordova D, Ciofu A, Park K, Parra-Cardona JR, Holtrop K, Cervantes R. The role of intrapersonal and ecodevelopmental factors in the lives of Latino alternative high school youth. *J Ethn Cult Divers Soc Work* 2014;23(2):148-167. doi:[10.1080/15313204.2013.809510](https://doi.org/10.1080/15313204.2013.809510)
27. Tebb KP, Sedlander E, Bausch S, Brindis CD. Opportunities and challenges for adolescent health under the Affordable Care Act. *Matern Child Health J* 2015;19(10):2089-2093. doi:[10.1007/s10995-015-1737-7](https://doi.org/10.1007/s10995-015-1737-7)
28. Cordova D, Alers-Rojas F, Mendoza-Lua F, et al. The usability and acceptability of an adolescent mHealth HIV/STI and drug abuse preventive intervention in primary care. Poster presented at: National Conference of the Society for Prevention Research; 2016; San Francisco, CA.
29. Cordova D, Munoz-Velazquez J, Mendoza Lua F, et al. Pilot study of a multilevel mobile health app for substance use, sexual risk behaviors, and testing for sexually transmitted infections and HIV among youth: randomized controlled trial. *JMIR Mhealth Uhealth* 2020;8(3):e16251. doi:[10.2196/16251](https://doi.org/10.2196/16251)
30. Cordova D, Mendoza Lua F, Muñoz-Velázquez J, et al. A multilevel mHealth drug abuse and STI/HIV preventive intervention for clinic settings in the United States: a feasibility and acceptability study. *PLoS ONE* 2019;14(8):e0221508. doi:[10.1371/journal.pone.0221508](https://doi.org/10.1371/journal.pone.0221508)
31. Peralta L, Deeds BG, Hipszer S, Ghalib K. Barriers and facilitators to adolescent HIV testing. *AIDS Patient Care STDs* 2007;21(6):400-408. doi:[10.1089/apc.2006.0112](https://doi.org/10.1089/apc.2006.0112)
32. Goyal MK, Witt R, Hayes KL, Zaoutis TE, Gerber JS. Clinician adherence to recommendations

- for screening of adolescents for sexual activity and sexually transmitted infection/human immunodeficiency virus. *J Pediatr* 2014;165(2):343-347. doi:[10.1016/j.jpeds.2014.04.009](https://doi.org/10.1016/j.jpeds.2014.04.009)
33. Kumar D, Arya M. mHealth is an innovative approach to address health literacy and improve patient-physician communication – an HIV testing exemplar. *JournalMTM* 2015;4(1):25-30. doi:[10.7309/jmtm.4.1.6](https://doi.org/10.7309/jmtm.4.1.6)
34. Rounsaville BJ, Carroll KM, Onken LS. A stage model of behavioral therapies research: getting started and moving on from stage I. *Clin Psychol: Sci Pract* 2001;8(2):133-142. doi:[10.1093/clipsy.8.2.133](https://doi.org/10.1093/clipsy.8.2.133)
35. Gad SC, ed. *Clinical trials handbook*. Wiley; 2009. ISBN:9780471213888
36. Hofer AN, Abraham JM, Moscovice I. Expansion of coverage under the Patient Protection and Affordable Care Act and primary care utilization: expanded coverage under PPACA and primary care use. *Milbank Q* 2011;89(1):69-89. doi:[10.1111/j.1468-0009.2011.00620.x](https://doi.org/10.1111/j.1468-0009.2011.00620.x)
37. Swendeman D, Rotheram-Borus MJ. Innovation in sexually transmitted disease and HIV prevention: internet and mobile phone delivery vehicles for global diffusion. *Curr Opin Psychiatry* 2010;23(2):139-144. doi:[10.1097/YCO.0b013e328336656a](https://doi.org/10.1097/YCO.0b013e328336656a).
38. Eisinger R. NIH HIV/AIDS research priorities and guidelines for determining AIDS funding; 2015. URL: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>
39. National HIV/AIDS strategy for the United States. The White House Office National AIDS Policy; 2015. URL: <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf>
40. HIV among youth. HIV in the United States by age. Centers for Disease Control and Prevention. URL: <https://www.cdc.gov/hiv/group/age/index.html>
41. Reported STDs in the United States: 2013 national data for chlamydia, gonorrhea, and syphilis. Center for Disease Control and Prevention; 2014. URL: <https://stacks.cdc.gov/view/cdc/26427> [accessed 2022-12-13]
42. Prado GJ, Schwartz SJ, Maldonado-Molina M, et al. Ecodevelopmental × intrapersonal risk: substance use and sexual behavior in Hispanic adolescents. *Health Educ Behav* 2009;36(1):45-61. doi:[10.1177/1090198107311278](https://doi.org/10.1177/1090198107311278)
43. Cordova D, Huang S, Arzon M, Freitas D, Malcolm S, Prado G. The role of attitudes, family, peer and school on alcohol use, rule breaking and aggressive behavior in Hispanic delinquent adolescents. *Open Fam Stud* 2011;4:38-45.
44. Balaji AB, Eaton DK, Voetsch AC, Wiegand RE, Miller KS, Doshi SR. Association between HIV-related risk behaviors and HIV testing among high school students in the United States, 2009. *Arch Pediatr Adolesc Med* 2012;166(4):331-336. doi:[10.1001/archpediatrics.2011.1131](https://doi.org/10.1001/archpediatrics.2011.1131)
45. Decker MR, Rodney R, Chung SE, Jennings JM, Ellen JM, Sherman SG. HIV testing among youth in a high-risk city: prevalence, predictors, and gender differences. *AIDS Care* 2014;27(5):555-560. doi:[10.1080/09540121.2014.986048](https://doi.org/10.1080/09540121.2014.986048)
46. Uppal A, Chou KJ. Screening adolescents for sexually transmitted infections in the pediatric emergency department. *Pediatr Emerg Care* 2015;31(1):20-24. doi:[10.1097/PEC.0000000000000322](https://doi.org/10.1097/PEC.0000000000000322)
47. Prado G. Effects of a family intervention in reducing HIV risk behaviors among high-risk Hispanic adolescents: a randomized controlled trial. *Arch Pediatr Adolesc Med* 2012;166(2):127. doi:[10.1001/archpediatrics.2011.189](https://doi.org/10.1001/archpediatrics.2011.189)
48. Reid RJ, Garcia-Reid P, Forenza B, Eckert C, Carrier M, Drag S. Let our voices be heard: urban minority adolescents share their perspectives regarding substance abuse and HIV/AIDS prevention messages. *Am J Health Promot* 2014;29(2):107-114. doi:[10.4278/ajhp.130117-QUAL-34](https://doi.org/10.4278/ajhp.130117-QUAL-34)
49. Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: implications for substance abuse prevention. *Psychol Bull* 1992;112(1):64-105. doi:[10.1037/0033-2909.112.1.64](https://doi.org/10.1037/0033-2909.112.1.64)

50. DiClemente RJ, Salazar LF, Crosby RA, Rosenthal SL. Prevention and control of sexually transmitted infections among adolescents: the importance of a socio-ecological perspective—a commentary. *Public Health* 2005;119(9):825-836. doi:[10.1016/j.puhe.2004.10.015](https://doi.org/10.1016/j.puhe.2004.10.015)
51. Mahat G, Scoloveno MA, Scoloveno R. HIV/AIDS knowledge, self-efficacy for limiting sexual risk behavior and parental monitoring. *J Pediatr Nurs* 2016;31(1):e63-e69. doi:[10.1016/j.pedn.2015.06.015](https://doi.org/10.1016/j.pedn.2015.06.015)
52. Cordova D, Lua FM, Ovadje L, et al. Adolescent experiences of clinician–patient HIV/STI communication in primary care. *Health Commun* 2018;33(9):1177-1183. doi:[10.1080/10410236.2017.1339379](https://doi.org/10.1080/10410236.2017.1339379)
53. Stewart MA. Effective physician-patient communication and health outcomes: a review. *CMAJ* 1995;152(9):1423-1433. PMID:[7728691](https://pubmed.ncbi.nlm.nih.gov/7728691/)
54. Coelho KR, Galan C. Physician cross-cultural nonverbal communication skills, patient satisfaction and health outcomes in the physician-patient relationship. *Int J Family Med* 2012;2012:1-5. doi:[10.1155/2012/376907](https://doi.org/10.1155/2012/376907)
55. Zolnieriek KBH, Dimatteo MR. Physician communication and patient adherence to treatment: a meta-analysis. *Medical Care* 2009;47(8):826-834. doi:[10.1097/MLR.0b013e31819a5acc](https://doi.org/10.1097/MLR.0b013e31819a5acc)
56. Nelson A. Multicultural model of HIV prevention for youth. *Int J Learn* 2004;11:1555-1564.
57. Szapocznik J, Prado G, Burlew AK, Williams RA, Santisteban DA. Drug abuse in African American and Hispanic adolescents: culture, development, and behavior. *Annu Rev Clin Psychol* 2007;3:77-105. doi:[10.1146/annurev.clinpsy.3.022806.091408](https://doi.org/10.1146/annurev.clinpsy.3.022806.091408)
58. Cordova D, Estrada Y, Malcolm S, et al. Prevention science: an epidemiological approach. In: Sloboda Z, Petras H, eds. *Defining prevention science*. Springer US; 2014:1-23. doi:[10.1007/978-1-4899-7424-2_1](https://doi.org/10.1007/978-1-4899-7424-2_1)
59. Ortega J, Huang S, Prado G. Applying ecodevelopmental theory and the theory of reasoned action to understand HIV risk behaviors among Hispanic adolescents. *Hisp Health Care Int* 2012 Jan 3;10(1):42-52. doi:10.1891/1540-4153.10.1.42
60. Prado G, Huang S, Maldonado-Molina M, et al. An empirical test of ecodevelopmental theory in predicting HIV risk behaviors among Hispanic youth. *Health Educ Behav* 2010;37(1):97-114. doi:[10.1177/1090198109349218](https://doi.org/10.1177/1090198109349218)
61. Perrino T, González-Soldevilla A, Pantin H, Szapocznik J. The role of families in adolescent HIV prevention: a review. *Clin Child Fam Psychol Rev* 2000;3(2):81-96. doi:[10.1023/A:1009571518900](https://doi.org/10.1023/A:1009571518900)
62. Pantin H, Schwartz SJ, Sullivan S, Coatsworth JD, Szapocznik J. Preventing substance abuse in Hispanic immigrant adolescents: an ecodevelopmental, parent-centered approach. *Hisp J Behav Sci* 2003;25(4):469-500. doi:[10.1177/0739986303259355](https://doi.org/10.1177/0739986303259355)
63. Prado G, Pantin H, Schwartz SJ, Lupei NS, Szapocznik J. Predictors of engagement and retention into a parent-centered, ecodevelopmental HIV preventive intervention for Hispanic adolescents and their families. *J Pediatr Psychol* 2006;31:874-890. doi:[10.1093/jpepsy/jsj046](https://doi.org/10.1093/jpepsy/jsj046)
64. Cooper B, Toskin I, Kulier R, Allen T, Hawkes S. Brief sexuality communication-a behavioural intervention to advance sexually transmitted infection/HIV prevention: a systematic review. *BJOG: Int J Obstet Gy* 2014;121:92-103. doi:[10.1111/1471-0528.12877](https://doi.org/10.1111/1471-0528.12877)
65. Sterling S, Kline-Simon AH, Satre DD, et al. Implementation of screening, brief intervention, and referral to treatment for adolescents in pediatric primary care. *JAMA Pediatr* 2015;169(11):1531-1545. doi:[10.1001/jamapediatrics.2015.3145](https://doi.org/10.1001/jamapediatrics.2015.3145)
66. Naik AD, Lawrence B, Kiefer L, et al. Building a primary care/research partnership: lessons learned from a telehealth intervention for diabetes and depression. *Family Practice* 2015;32(2):216-223. doi:[10.1093/fampra/cmu084](https://doi.org/10.1093/fampra/cmu084)
67. The guide to clinical preventive services, 2014: recommendations of the U.S. Preventive Services Task Force. U.S. Preventive Services Task Force: Agency for Healthcare Research and Quality; 2014. URL: <https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/clinicians->

- [providers/guidelines-recommendations/guide/cpsguide.pdf](#)
68. Recommendations for primary care practice. U.S. Preventive Services Task Force; 2015. URL: <http://www.uspreventiveservicestaskforce.org/Page/Name/recommendations>
 69. Levine D, McCright J, Dobkin L, Woodruff AJ, Klausner JD. SEXINFO: A sexual health text messaging service for San Francisco youth. *Am J Public Health* 2008;98(3):393-395. doi:[10.2105/AJPH.2007.110767](https://doi.org/10.2105/AJPH.2007.110767)
 70. CDC's vision for public health surveillance in the 21st century. Centers for Disease Control and Prevention; 2012. URL: <https://www.cdc.gov/mmwr/pdf/other/su6103.pdf>
 71. Lightfoot M. HIV prevention for adolescents: where do we go from here? *Am Psychol* 2012;67:661-671. doi:[10.1037/a0029831](https://doi.org/10.1037/a0029831)
 72. Allison S, Bauermeister JA, Bull S, et al. The intersection of youth, technology, and new media with sexual health: moving the research agenda forward. *J Adolesc Health* 2012;51(3):207-212. Doi:[10.1016/j.jadohealth.2012.06.012](https://doi.org/10.1016/j.jadohealth.2012.06.012)
 73. Civljak M, Car J, Hartmann-Boyce J, Stead LF, Sheikh A. Internet-based interventions for smoking cessation. *Cochrane Database Sys Rev* 2013;10(17):1-75. doi:[10.1002/14651858.CD007078](https://doi.org/10.1002/14651858.CD007078)
 74. Smith A. U.S. smartphone use in 2015. Pew Research Center; 2015 Apr. URL: <http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/>
 75. Nelson A, Arthur B. Storytelling for empowerment: decreasing at-risk youth's alcohol and marijuana use. *J Prim Prev* 2003;24(2):169-180.
 76. Nelson A. Final report submitted to the Virginia G. Piper Charitable Trust. The WHEEL Council; 2006.
 77. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med* 2009;36(5):452-457. doi:[10.1016/j.amepre.2009.02.002](https://doi.org/10.1016/j.amepre.2009.02.002)
 78. Sterling S, Kline-Simon AH, Wibbelsman C, Wong A, Weisner C. Screening for adolescent alcohol and drug use in pediatric health-care settings: predictors and implications for practice and policy. *Addict Sci Clin Pract* 2012;7(1):13. doi:[10.1186/1940-0640-7-13](https://doi.org/10.1186/1940-0640-7-13)
 79. Schuster MA. Communication between adolescents and physicians about sexual behavior and risk prevention. *Arch Pediatr Adolesc Med* 1996;150(9):906. doi:[10.1001/archpedi.1996.02170340020004](https://doi.org/10.1001/archpedi.1996.02170340020004)
 80. Epstein RM, Morse DS, Frankel RM, Freary L, Anderson K, Beckman HB. Awkward moments in patient-physician communication about HIV risk. *Ann Intern Med* 1998;128(6):435-442. doi:[10.7326/0003-4819-128-6-199803150-00003](https://doi.org/10.7326/0003-4819-128-6-199803150-00003)
 81. Dybå T, Dingsøyr T. Empirical studies of agile software development: a systematic review. *Inf Softw Technol* 2008;50(9-10):833-859. doi:[10.1016/j.infsof.2008.01.006](https://doi.org/10.1016/j.infsof.2008.01.006)
 82. Harper GW, Contreras R, Bangi A, Pedraza A, Suarez-Balcazar Y. Collaborative process evaluation: enhancing community relevance and cultural appropriateness in HIV prevention. *J Prev Interv Community* 2003;26(2):53-69. doi:[10.1300/J005v26n02_05](https://doi.org/10.1300/J005v26n02_05)
 83. Attkisson CC, Greenfield TK. The UCSF Client Satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In Maruish M, ed. *The use of psychological testing for treatment planning and outcomes assessment: Instruments for adults*. Vol 3. Mahwah, NJ: Lawrence Erlbaum Associates Publishers; 1999. p. 1333-1346. doi: [10.4324/9781410610614](https://doi.org/10.4324/9781410610614)
 84. Cordova D, Guzman K, Martin C, et al. A community engaged approach to working toward the implementation of mental health best practices in a primary care setting. Poster presented at: 7th annual conference on The Science of Dissemination and Implementation; December 2015; Bethesda, MD.
 85. Lenhart A. Teen, social media and technology overview 2015. Pew Research Center; April 2015. URL: <https://www.pewresearch.org/internet/2015/04/09/teens-social-media-technology-2015/>
 86. Efird J. Blocked randomization with randomly selected block sizes. *IJERPH* 2011;8:15-20. doi:[10.3390/ijerph8010015](https://doi.org/10.3390/ijerph8010015)

87. Knight JR, Sherritt L, Shrier LA, Harris SK, Chang G. Validity of the CRAFFT substance abuse screening test among adolescent clinic patients. *Arch Pediatr Adolesc Med* 2002;156:607-614. doi:[10.1001/archpedi.156.6.607](https://doi.org/10.1001/archpedi.156.6.607)
88. Jemmott JB III, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for African American Adolescents: a randomized controlled trial. *JAMA* 1998;279(19):1529. doi:[10.1001/jama.279.19.1529](https://doi.org/10.1001/jama.279.19.1529)
89. Campbell C, Lockyer J, Laidlaw T, MacLeod H. Assessment of a matched-pair instrument to examine doctor-patient communication skills in practising doctors. *Med Educ* 2007;41(2):123-129. doi:[10.1111/j.1365-2929.2006.02657.x](https://doi.org/10.1111/j.1365-2929.2006.02657.x)
90. Hanna KM, Tompkins ES. An adolescent and young adult condom perception scale. *West J Nurs Res* 1999;21(5):621-634. doi:[10.1177/01939459922044081](https://doi.org/10.1177/01939459922044081)
91. Carpenter CM, Howard D. Development of a drug use resistance self-efficacy (DURSE) scale. *Am J Health Behav* 2009;33(2):147-157. doi:[10.5993/ajhb.33.2.4](https://doi.org/10.5993/ajhb.33.2.4)
92. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry* 2006;63(5):484-489. doi:[10.1001/archpsyc.63.5.484](https://doi.org/10.1001/archpsyc.63.5.484).
93. Breslow NE, Clayton DG. Approximate inference in generalized linear mixed models. *J Am Stat Assoc* 1993;88(421):9-25. doi:[10.2307/2290687](https://doi.org/10.2307/2290687).
94. Elashoff JD. nQuery Advisor Version 7.0 User's Guide. "Statsols" (Statistical Solutions Ltd); 2007.
95. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. New York: Routledge; 1988. doi:[10.4324/9780203771587](https://doi.org/10.4324/9780203771587)