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ORIGINAL PAPER

Effectiveness of the SMART Sex Ed program among 13–18 year old English and Spanish speaking adolescent men who have sex with men

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Abstract
Adolescent men who have sex with men (AMSM) have a high HIV incidence and low utilization of testing and prevention services. However, very few HIV prevention programs exist that focus on the unique sexual health needs of AMSM. SMART is a stepped care package of eHealth interventions that comprehensively address the sexual and HIV prevention needs of AMSM. This study examines the impact of the first step of SMART, "SMART Sex Ed," on 13- to 18-year-old AMSM (n = 983) from baseline to three-month follow-up across 18 separate outcomes measuring HIV prevention attitudes, skills, and behaviors. We observed significant change from baseline to three-month post-intervention in nine HIV-related outcomes (e.g., receipt of HIV and STI test, HIV knowledge), as well as largely consistent effects across demographic subgroups (e.g., race, age, rural, low SES). Analyses observed no effects on condom use behaviors. SMART Sex Ed shows promise as an effective sexual health education program for diverse AMSM.

Keywords Adolescent · MSM · HIV prevention · sexual health education · online

Resumen
Los adolescentes hombres que tienen sexo con otros hombres (AHSH) experimentan alta incidencia del VIH y baja utilización de servicios de prueba y prevención. Sin embargo, existen muy pocos programas de prevención del VIH enfocados en las necesidades particulares para la salud sexual de AHSH. SMART es un paquete de intervenciones de cuidado escalonado que usa plataformas electrónicas (eHealth) y que atiende de forma integrada las necesidades de salud sexual y prevención del VIH de AHSH. Este estudio examina el impacto de la primera etapa de SMART, llamada "SMART Sex Ed", entre AHSH (n = 983) entre las edades de 13 a 18 años e integra datos desde el reclutamiento con seguimiento cada 3 meses. Se recopilaron datos de 18 indicadores de actitudes, destrezas y prácticas de prevención del VIH (Ej. Historial de pruebas de VIH o ITS; conocimiento sobre VIH), así como los efectos en diferentes grupos demográficos (Ej. Raza, edad, área rural, y bajo nivel socioeconómico). Los análisis realizados demuestran que las características demográficas no tienen efecto en las prácticas de uso de condón. SMART Sex Ed es una intervención prometedora para educación sexual efectiva para AHSH.

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Introduction

Adolescent (13–18 year old) men who have sex with men (AMSM) have a high HIV incidence and low utilization of HIV testing and prevention services [1–4]. Risk factors that have contributed to this disparity in HIV among AMSM include lack of knowledge about and access to HIV testing and prevention tools (e.g. condoms, pre-exposure prophylaxis [PrEP]) and syndemic risk factors, such as elevated alcohol and illicit drug use before and during sex, mental health problems, and experiences of stigma and discrimination [3, 5–10]. Despite these alarming health disparities, very few HIV prevention programs exist that are tailored to the unique needs of AMSM [11]. While several pilot studies have tested educational and behavioral interventions with AMSM [12–14], there are currently no such interventions listed in the Centers for Disease Control and Prevention (CDC) Compendium of Evidence Based Interventions [15]. Few school-based sexual education programs offer inclusive curricula that address the needs of sexual and gender minority (SGM) adolescents [16, 17]. Further, while parent- and family-based HIV prevention programs are effective and have been implemented with cisgender heterosexual teens, there is a near complete lack of such programs for SGM teens, or AMSM specifically [18]. Due to the lack of sexual health resources for AMSM in more traditional settings, AMSM frequently use the internet to search for sexual health information and do so at higher rates than their heterosexual peers [19, 20], thus necessitating the development of comprehensive, culturally appropriate, AMSM-focused online sexual education and HIV prevention programs.

Meta-analyses and comprehensive reviews have reported significant effects of online programs on reducing HIV risk behaviors and improving utilization of prevention tools [21–23]. With 95% of teens owning a smartphone, online mobile interventions have significant potential for overcoming barriers of reach and access [24]. Moreover, online and mobile programs provide a platform to engage in and access HIV educational materials anonymously, without the potential fear of stigma that may be coupled with seeking in-person methods [25, 26]. SMART was recently developed as a comprehensive online sexual education and HIV prevention program for diverse 13–18 year old AMSM nationwide to address these challenges and improve sexual health [27]. SMART utilizes a stepped-care design [28] to increase the intensity of prevention techniques for those who do not show a response to prior intervention content. The first step of the SMART Program, called SMART Sex Ed, was adapted from an online comprehensive sex education program, called Queer Sex Ed, that engaged 16–20 year old sexual and gender minority adolescents in relationships [29]. Queer Sex Ed used various types of media content, such as storytelling videos, interactive animation, and games to provide information on HIV/STI transmission, sexual health promotion skills, healthy romantic relationships, and self-acceptance and wellbeing. In a pilot study using a single arm pre-test post-test design, Queer Sex Ed demonstrated significant improvements in 15 out of 17 sexual health outcomes at a 2-week post-intervention assessment among 202 SGM youth, including condom use knowledge and attitudes as well as awareness of accessible HIV testing locations.

SMART Sex Ed was adapted from Queer Sex Ed by first conducting an in-depth review of the learning objectives from the original Queer Sex Ed program, updating them to account for changes in sexual education recommendations by the CDC and SIECUS [30, 31], and adapting them for a younger audience who have developmental differences from young adults (e.g., living with parents, navigating school). These new learning objectives addressed four primary content areas: (1) sexual and gender identity; (2) sexual activity, pleasure, and consent; (3) sex education in the real world; and (4) healthy relationships. All content was specifically developed to be "sex positive" (i.e., it aimed to develop positive attitudes toward sexuality), include critical lessons about sex and prevention geared toward sexual minority men (e.g., pre-exposure prophylaxis use, anal sex), and focus on an exclusively SGM audience. Consistent with our learning objective and guidelines set by the CDC and SIECUS [30, 31], the goal of the current study was to assess the impact of the newly-adapted SMART Sex Ed on 18 HIV and sexual health-related variables (e.g., attitudinal, motivational, and behavioral outcomes). We also aimed to explore differences in intervention effects across key groups, including differences in demographics (e.g., race/ethnicity, age) and live experiences (e.g., SES, rural, ever had anal sex prior to enrollment). All subgroup analyses were pre-planned and registered (https://clinicaltrials.gov/ct2/show/NCT03511131) [27].

Method

Participants, Procedures, and Design.

Data were collected between April 2018 and July 2020. The SMART trial employed a sequential multiple assignment randomized trial design [28] to assess the effects of a package of increasingly intensive online HIV prevention programs among racially-diverse AMSM (see protocol paper for more details; [27]). The first intervention in the stepped care sequence was delivered to all participants; "SMART Sex Ed" (the focus of these analyses) is a comprehensive LGBTQ-inclusive sex education program developmentally adapted from the "Queer Sex Ed" intervention [29]. The next step was "SMART Squad," a developmental

adaptation of the "Keep it Up!" intervention [32, 33] that was classified by the CDC as a "best evidence" intervention for HIV risk reduction [15]. The last intervention in the stepped care package was "SMART Sessions," a motivational interviewing protocol based on the CDC-best evidence "Young Men's Health Project" that aims to reduce substance use and sexual risk behaviors [34]. This intervention was adapted developmentally and for delivery via videoconferencing (and phone when necessary).

The SMART Program package of interventions followed the Institute of Medicine's prevention model [35], which suggests increasing intensity of prevention interventions according to risk factors, including low-cost universal interventions (e.g., SMART Sex Ed) that can be delivered to everyone, more intensive interventions selected for those with some increased risk, and finally the most costly and intensive interventions for those with indicators of highest risk/need. All tiers of SMART were informed by the information-motivation-behavioral skills (IMB) model for HIV prevention [36]. SMART Sex Ed focused primarily on conveying information whereas the later interventions in the sequence focused on instilling motivation and behavioral skills. The purpose of the current analyses were to examine the effectiveness of SMART Sex Ed, the first step of the SMART Program. Given that SMART Sex Ed was administered to all participants enrolled in the larger trial, we conducted pre-test post-test analyses of the effectiveness of SMART Sex Ed on various sexual health and HIV-related outcomes at three-months post-intervention (i.e., prior to being randomized for possible "stepping up" to the next intervention based on response).

SMART Sex Ed contained four modules that participants navigated in any order they chose. Media assets included scroll screen (resembling social media feeds), slideshows with narration recorded using near-peer voice actors, videos, games, quizzes, and GIFs. Emojis were liberally used to make topics and lessons more relatable to participants. SMART Sex Ed was delivered in either English or Spanish, depending on participant preference. SMART Sex Ed emphasized sexual health as more than just the absence of disease [37], and included information on healthy romantic relationships, having pleasurable sexual experiences, and acceptance of one's sexual orientation and gender identity. Intervention content also explained HIV/STI transmission and how to acquire and use condoms. Information about PrEP was consistently provided, and after FDA approval for adolescents, content was updated to explain adolescent access. Because cultural factors can lead to differential response to intervention content [38–41], all content was linguistically and culturally adapted for monolingual Spanish speaking AMSM.

Eligibility criteria for SMART were: (1) aged 13–18 years; (2) assigned male at birth; (3) identified as gay, bisexual, queer, pansexual or attracted to cisgender men; (4) reported some sexual experience (i.e., lifetime sexual behavior involving genital contact); (5) being able to speak and read English or Spanish; (6) having consistent Internet access; (7) self-reporting an HIV negative or HIV unknown status; and (8) residing in the United States (U.S.) and territories. Additionally, to be enrolled in the trial, participants were required to complete at least five minutes of SMART Sex Ed once granted access to the program content. Participants were recruited via free and paid social media campaigns on Facebook, Instagram, Snapchat, and Twitter, as well as through a research registry. Advertisements were run in all US states and territories along with focused advertisements in geographic areas with large numbers of racial/ethnic minority residents. Prospective participants clicked on a URL to an online screener. Those who met eligibility criteria were routed to an online consent form, after which they completed four capacity to consent questions that assessed their understanding of the research procedures [42]. A brief videochat was scheduled with research staff to confirm participant eligibility, consent capacity, and complete enrollment. To streamline the enrollment process, starting in March 2020, participants were offered the option to upload a photo ID instead of scheduling a videochat if all capacity to consent questions were answered correctly. Once participants were confirmed eligible they were emailed a URL to the baseline survey, which was hosted on REDCap [43]. Participants completed a post-intervention follow-up survey three months after completing the four modules of SMART Sex Ed. Participants had one month to complete the intervention; those who did not complete all four modules within the month received the follow-up survey three months after the end of their intervention completion window. Participants had 21 days to complete their three-month follow-up survey. Of the 1,306 participants given access to their three-month follow-up survey, 983 (75.3%) completed it in within 21 days and were included in these analyses. Participants were paid $25 for their time spent completing the baseline and three-month follow-up surveys (up to $50 total). All procedures were approved by the institutional review board with waivers of parental permission [42].

Measures.

All measures were administered at both baseline and three-month follow-up, unless otherwise indicated. English versions of measures were translated into Spanish by bilingual research staff with expertise in sexual health research and translation.

Demographics and Other Group Differences. We examined several factors at baseline in order to both describe the study sample and to examine group differences in

intervention effects. Participant age was calculated from their self-reported birthday, which was confirmed during the videochat or school ID eligibility check described above. Race was self-reported and participants were able to select all racial groups with which they identified from those included in the U.S. census. Hispanic/Latinx ethnicity was assessed with a separate item. Because SMART Sex Ed was offered both in English or Spanish, participants could select which language they felt most comfortable using and were granted access to the program in that language. Socioeconomic status was measured by asking (I don't know/No/Yes), "Do you or anyone in your family receive any form of public assistance such as reduced price meals at school, SNAP, or welfare?" [59]. Rural residence was assessed by categorizing zip codes into Rural-Urban Commuting Area Codes (RUCA) [61]; ZIP codes with 30% or more of their workers going to a Census-defined Urbanized Area were considered urban and all others were considered rural.

We also examined several aspects of sexual experiences for differences in intervention effects, including: (1) any anal sex prior to baseline; (2) CAS in past three months; and (3) receipt of sexual education at school. With regard to sexual activity at baseline, we asked participants whether they had engaged in various behaviors in their lifetime (i.e., kissing, touching someone else's genitals, oral sex, vaginal sex, and anal sex). Participants were considered "sexually active" if they reported ever having had anal sex in their lifetime. Among those who had ever had anal sex, participants reported whether or not they had anal sex without a condom during the three months prior to baseline. Finally, because this was an HIV education program, we asked participants about receipt of HIV and sexual education in school as measured by the Youth Risk Behavior Surveillance Survey item [60]: "Have you ever been taught about AIDS or HIV in school?" Response options were "Yes," "No," or "Not Sure."

Condomless Anal Sex (CAS). We assessed engagement in sexual risk behaviors by creating three variables describing CAS behaviors using the HIV Risk Assessment of Sexual Partnerships (H-RASP) [44]. The H-RASP retrospectively assessed sexual behavior partner-by-partner during the three months prior to baseline and three-month follow-up. First, participants were asked to report the total number of partners with whom participants engaged in CAS during the prior three months. Next, participants were asked to report the total number of condomless anal sex acts they had engaged in with their three most recent partners, split by insertive and receptive acts, during the prior three months. We summed responses across the three most recent partners to create an additional sexual risk behavior variable describing the total number of CAS acts during the prior three months. Prior to analysis, both total CAS acts during the prior three months and total CAS partners during the prior three months were winsorized at three standard deviations to minimize the impact of extreme outliers on the results.

HIV and STI Testing. At baseline, participants reported if they had ever received HIV testing (Yes/No/I don't know) or STI testing (Yes/No/I don't know) in their lifetime by asking: "Have you ever been tested for HIV?" and "In your entire life, have you ever been tested for STIs such as gonorrhea, chlamydia, syphilis, etc.?" At the three-month follow-up, participants were asked if they had been tested for HIV or STIs in the prior three months.

Pre-Exposure Prophylaxis (PrEP) Use. Participants reported at both baseline and three-month follow-up if they were currently taking PrEP (Yes/No). We administered the item, "Are you currently taking any pre-exposure prophylaxis (PrEP) medication such as Truvada or Descovy?"

Condom Use Intentions. We assessed participant intentions to use condoms with future sex partners with an 11-item scale. First, we used four items from the original measure from Kalichman et al. [45, 46]. For example, "How likely is it that you will use a condom every time you have sex?" Participants responded on a four-point Likert scale ranging from "very unlikely" to "very likely." Next, given that the HIV prevention landscape has changed substantially since this measure was originally created, we added seven items assessing intentions to use condoms with varied partner types (e.g., partners living with HIV, boyfriends) and in the context of biomedical prevention use. We utilized the same item structure and response options as the original measure. Example items include, "How likely is it that you will use a condom if a new partner tells you he is HIV negative?"; and "How likely is it that you will use a condom if a new partner tells you he is on PrEP?" We calculated the mean response for each participant across all eleven items. Internal consistency was $\alpha = 0.90$.

Condom Use Self-Efficacy. We assessed participant's perceived self-efficacy to use condoms in varied situations using a five-item scale developed by Kalichman et al. [45, 46]. For example, "How confident are you that you would be able to be sure you and your partner had agreed to safer sex before sex began?" Participants responded on a seven-point Likert scale ranging from "not at all confident" to "extremely confident." We calculated the mean response for each participant across all five items. Internal consistency was $\alpha = 0.87$.

HIV Prevention Self-Efficacy – Safer Sex with Partners. Self-efficacy to engage in safer sex with partners was assessed with six items. First we used five items from the Misovich et al. [47] measure of HIV prevention self-efficacy. Example items were, "How hard would it be for you to consistently use condoms with a partner every time you have a one-night stand or hookup?"; and "How hard would

it be for you to use a condom with a partner after using alcohol or drugs?" Participants responded on a five-point Likert scale ranging from "very hard" to "very easy." We added one additional item, utilizing the same item structure and response options as the original Misovich et al. items to assess self-efficacy related to condom errors: "How hard would it be for you to stop having anal sex if the condom breaks or falls off during sex?" We calculated the mean response for each participant across all six items. Internal consistency was $\alpha = 0.78$.

HIV Prevention Self-Efficacy – Individual Prevention Behaviors. Using the same response scale as the original Misovich et al. items (described above) [47], we created three items to assess self-efficacy related to participants' perceived ability to obtain and utilize HIV prevention services. These items were: "How hard would it be for you to get an HIV test?"; "How hard would it be for you to get a rectal STI test?"; and "How hard would it be for you to talk to a doctor about post-exposure prophylaxis or PEP (a medication that can help reduce your chances of getting HIV) if you suspected you may have been exposed to HIV?". We calculated the mean response for each participant across the three items. Internal consistency was $\alpha = 0.86$.

HIV Knowledge. Participants' knowledge of HIV transmission and prevention was assessed with an 11-item measure. First, we used seven items based on recommendations from Janulis et al. [48], who created a brief HIV knowledge measure using Item Response Theory based on data from six studies of MSM. Second, we added four items to capture more nuanced knowledge specific to biomedical prevention, CDC prevention guidelines, and sexual positioning that are highly relevant to AMSM but were not captured in the initial seven items. Additional items included: "It is impossible to get HIV from an HIV-positive partner who has an undetectable viral load"; "Taking pre-exposure prophylaxis (a pill, also known as PrEP or Truvada or Descovy) regularly can reduce the risk of contracting HIV from an HIV-positive sex partner"; "Current guidelines say that guys who have sex with other guys should get tested for HIV at least every six months"; and "There is a medication you can take after being exposed to HIV that reduces your risk of contracting HIV". Participants respond either "True," "False," or "I Don't Know." Correct responses were recoded as "1" while incorrect and uncertain responses were coded as "0". A composite score was created from the percentage of items a participant answered correctly.

Perceived Vulnerability to HIV. Participants' perceived vulnerability to HIV was assessed with two investigator-created items ("How likely do you think it is you will get HIV if you have sex without a condom or PrEP?" and "How likely do you think it is that you will become HIV-positive at some point in your lifetime?"). Participants responded on a five-point Likert scale ranging from "very unlikely" to "very likely". Responses were summed to create a composite score.

Attitudes towards HIV Prevention. Based on a measure originally created by Misovich et al. [47], we administered an eight-item measure to assess participants perceived importance of engaging in various HIV-related preventive behaviors in different situations. We adapted the items to reflect more current HIV preventive practices (e.g., biomedical prevention). We also changed the response scale to more directly reflect attitudinal beliefs; the previous scale rated statements from "good" to "bad," which tended to result in ceiling effects because statements were very often rated as "good." Our adapted response scale asked participants to assess various statements on a five-point Likert scale ranging from "very unimportant" to "very important". Example items included: "Talking to a partner about pre-exposure prophylaxis (a pill, also known as PrEP or Truvada or Descovy) would be…"; "Talking about safer sex with a partner before having anal sex with them would be…"; and "Always using condoms with a partner would be…". Participant responses were summed to create a composite score. Internal consistency was $\alpha = 0.85$.

Health Protective Communication. This five-item measure assesses safer sex communication between participants and their partners. We adapted four items from the original measure by Catania et al. [49] to assess these behaviors during the three-month timeframe before study assessments. An example item is, "In the last 3 months, did you ask a sexual partner to use a condom?" We added one investigator-created item assessing communication about one's HIV status with partners, "In the last 3 months, did you tell a sexual partner your HIV status?" Participants answer "Yes" [1] or "No" (0) and responses were summed to create a count of communication behaviors.

Perceived PrEP Candidacy. We created an item to assess whether participants perceived that they were good candidates for PrEP, "Do you think PrEP is right for you?" Participants responded on a five-point Likert scale ranging from "No, PrEP is definitely not right for me" to "Yes, PrEP is definitely right for me."

Perceived Access to HIV Prevention. We created two items to assess participants' perceptions about their ability to obtain HIV prevention services where they live. Items were: "How confident are you that you could get tested for HIV where you live?" and "How confident are you that you could get pre-exposure prophylaxis (PrEP) where you live?" These items were measured on a four-point Likert scale ranging from "not at all confident" to "very confident."

Condom Use Errors and Failures. We used a 12-item adapted version [50, 51] of a measure originally created by Crosby et al. [52] to assess both condom use failures

(three items) and condom use errors (nine items), among those participants who reported using condoms during the three months prior to baseline or three-month follow-up. Responses were measured on a five-point Likert scale ranging from "always" to "never." An example condom use error item was: "When you used condoms during the last 3 months, how often was space left at the end of the condom when putting it on?" and an example condom use failure item was: "When you used condoms during the last 3 months, how often did it break during sex?" (all condom use failure items were reverse scored). In the present analyses, we created binary variables for each item in which "always" (or for reverse scored items, "never") responses were coded as "0" and referred to the absence of failures or errors, and all other options were recoded as "1" to refer to the presence of failures or errors. The recoded items were then summed to create condom use error and condom use failure composite scores, as has previously be reported in the literature [50, 51].

Statistical Analysis

We tested the effects of SMART Sex Ed by examining change from pre-test to three-month post-intervention in 18 outcomes, as well as differences in change across 25 subgroups (i.e., demographic, life experiences). All subgroup analyses were pre-specified in the trial protocol (https://clinicaltrials.gov/ct2/show/NCT03511131), and the ability to conduct subgroup analyses was a key goal of the larger SMART Program from which these data are drawn. For each outcome (except lifetime STI and HIV testing), and within each subgroup, we tested the null hypothesis of no change in pre- and post-intervention mean against a two-sided alternative using a *t*-test. For lifetime STI testing and lifetime HIV testing, because the proportion can only increase over time, we tested the null hypothesis that the pre-test post-test difference in lifetime testing rate was no larger than would be expected under standard care. To estimate the increase in testing rates per year, we used the difference in baseline measurements across age groups. For example, to estimate the null increase for subjects at age 13 at enrollment we took the difference between the baseline testing rates of subjects at age 14 at enrollment and subjects at age 13 at enrollment and then prorated this difference to the follow-up period of three months. To estimate the null increase for subjects at age 14 at enrollment, we took the difference between baseline rates among those at age 14 and those at age 15 and so on. Subjects at age 18 were tested against a baseline change of 2.5%. Because we tested a large number of hypotheses (18 outcomes x 25 subgroups = 450), adjustment for multiple testing was necessary. We controlled the false discovery rate (FDR) to be no more than 0.10 using the Benjamini-Yekutieli procedure [53]. Missing data were handled using multiple imputation by chained equations (MICE) [54], and we did not observe systematic differences between participants who did and did not complete three-month follow-up with regard to demographic factors, including race/ethnicity, age, socioeconomic status, or rurality.

Results

See Table 1 for a full demographic breakdown of the study sample. The mean age of the sample was 17.1 *(SD* = 1.3). With regard to race/ethnicity, participants could select more than one group, so categories are not mutually exclusive; only 36.1% of the sample identified as exclusively non-Hispanic White. People who selected "Other" for their race wrote in responses; the vast majority of these write-in responses were individuals of Hispanic/Latinx decent who wrote in a specific country of origin (e.g., Mexican) and these individuals were re-coded as both Other race and Hispanic/Latinx to match their identities. With regard to sexual orientation, the majority identified as gay (67.4%), followed by bisexual (24.4%), pansexual (3.6%), unsure/questioning (2.4%), queer (1.5%), lesbian (0.2%) and not listed (0.4%). In terms of participants' primary language, 3.8% were monolingual Spanish speakers. Participants resided in 49 states, the District of Columbia, and Puerto Rico, and 16.1% of participants lived in a rural area as defined by RUCA 61. With regard to sexual experience at baseline, 67.5% reported ever having had anal sex. A majority (69.6%) reported never having received an HIV test in their lifetime.

Results of the pre- to post-intervention tests for each of the 18 outcomes for the sample as a whole, along with their associated *p*-values, are displayed in Table 2. For the sample as a whole, we observed significant change from baseline to three-month post-intervention in many behavioral and attitudinal variables. Regarding behavioral outcomes, we observed a significant increase in the likelihood of having had a lifetime HIV test and the likelihood of having had a lifetime STI test three months after completing SMART Sex Ed. We also found a significant increase in the likelihood of being a current PrEP user at three-months post-intervention, and a significant decrease in condom use errors. Consistent with the goals of SMART Sex Ed, we observed a significant increase in HIV knowledge from baseline to three-months post-intervention. We also observed significant improvement in several attitudinal variables, including HIV prevention self-efficacy, perceived PrEP candidacy, confidence in getting PrEP, and confidence in getting an HIV test.

Next, we tested *a priori* specified group differences across all 18 study outcomes. Of the 450 null hypotheses tested,

Table 1 Demographic Description of Participants who Completed SMART Sex Ed and 3-month Follow-Up (analytic N = 983)

	N	%
Age at Baseline, years (*M* = 17.1; *SD* = 1.3)		
13	9	0.9
14	56	5.7
15	150	15.3
16	206	21.0
17	239	24.3
18	323	32.9
Race/ethnicity[a]		
Black	207	21.1
Hispanic/Latino/a/x	345	35.1
White	629	64.0
Asian	107	10.9
American Indian or Alaskan Native	64	6.5
Native Hawaiian or Other Pacific Islander	28	2.8
Other	104	10.6
Language		
English	946	96.2
Spanish	37	3.8
Rurality		
Urban	825	83.9
Rural	158	16.1
Anal sex history		
Lifetime, but not in the last 3 months	221	22.5
In the last 3 months	442	45.0
Never	320	32.6
HIV testing		
Lifetime, but not in the last 3 months	103	10.5
In the last 3 months	196	19.9
Never	684	69.6
Sexual orientation		
Gay	663	67.4
Bisexual	240	24.4
Pansexual	35	3.6
Unsure/Questioning	24	2.4
Queer	15	1.5
Lesbian	2	0.2
Not listed	4	0.4

Note: M = mean; *SD* = standard deviation

[a]Participants could endorse multiple race/ethnicities so categories are not mutually exclusive

Table 2 Change in HIV-Related Outcomes among SMART Sex Ed Participants at 3-Month Follow-Up

Study Outcome	Range of Possible Scores	Pre-Test Mean (SD)	Post-Test Mean (SD)	*p*-value
CAS Acts in Prior 3 Months	0 - ∞*	1.57 (4.45)	1.64 (4.73)	0.68
CAS Partners in Prior 3 Months	0 - ∞*	0.50 (1.02)	0.52 (1.07)	0.54
Lifetime HIV Test	0–1	0.30 (0.46)	0.40 (0.49)	< 0.001
Lifetime STI Test	0–1	0.28 (0.45)	0.36 (0.48)	< 0.001
Currently on PrEP	0–1	0.02 (0.15)	0.05 (0.22)	< 0.001
Health Protective Communication Scale	0–5	2.71 (1.59)	2.77 (1.62)	0.48
Condom Use Intentions	1–4	3.00 (0.63)	3.02 (0.64)	0.34
Condom Use Self-Efficacy	1–7	5.29 (1.34)	5.33 (1.40)	0.30
HIV Knowledge	0–100	68.06 (19.85)	80.47 (15.46)	< 0.001
Perceived Vulnerability to HIV	2–10	5.73 (1.64)	5.82 (1.69)	0.09
Attitudes Towards HIV Prevention	8–40	35.18 (4.54)	35.10 (4.83)	0.59
Individual HIV Prevention Self-Efficacy	1–5	2.79 (1.02)	2.97 (1.11)	< 0.001
Safe Sex with Partner Self-Efficacy	1–5	3.75 (0.73)	3.75 (0.79)	0.84
Perceived PrEP Candidacy	1–5	3.42 (0.88)	3.61 (1.06)	< 0.001
Confidence to get an HIV Test	1–4	2.88 (0.99)	2.96 (1.02)	< 0.01
Confidence to get PrEP	1–4	2.46 (1.02)	2.68 (1.05)	< 0.001
Condom Use Errors	0–9	4.04 (1.90)	3.70 (2.28)	< 0.05
Condom Use Failures	0–3	0.73 (0.90)	0.70 (0.99)	0.70

Note: CAS = condomless anal sex; ∞ = infinity

*Data was winsorized at three standard deviations to reduce the effect of outliers

119 were rejected using the Benjamini-Yekutieli procedure, and therefore represent statistically significant baseline to three-month post-intervention change. Figure 1 shows the *t*-statistics for each test coded so that positive values indicate improvement from pre- to post-treatment, with each of the statistically significant effects outlined in red. The figure shows consistent improvement across subgroups and outcomes, with a positive effect in 78.4% of outcome-subgroup combinations. The outcome was significantly worse in only two of the 450 (0.44%) outcome-subgroup combinations. More specifically, participants who (at baseline) reported no lifetime history of anal sex had significantly more CAS acts and CAS partners at the three-month follow-up.

Recognizing that some outcome-subgroup combinations resulted in small cell sizes and were therefore likely underpowered, we also examined for potential differential impacts of the intervention across the following factors as a whole: race, age (after adjusting for sexual activity at baseline), language (Spanish versus English), and population density (urban versus rural). For each of the 18 outcomes, we thus tested the global null of no effect of the factor using an ANOVA. Using Holm's step-down procedure for type I error control at level 0.05, we found no significant association of race or urban/rural with changes in any of the 18 outcomes. We observed no significant association of age with 16 of the outcomes (after adjusting for baseline sexual activity). Subjects aged 14 had a larger increase in

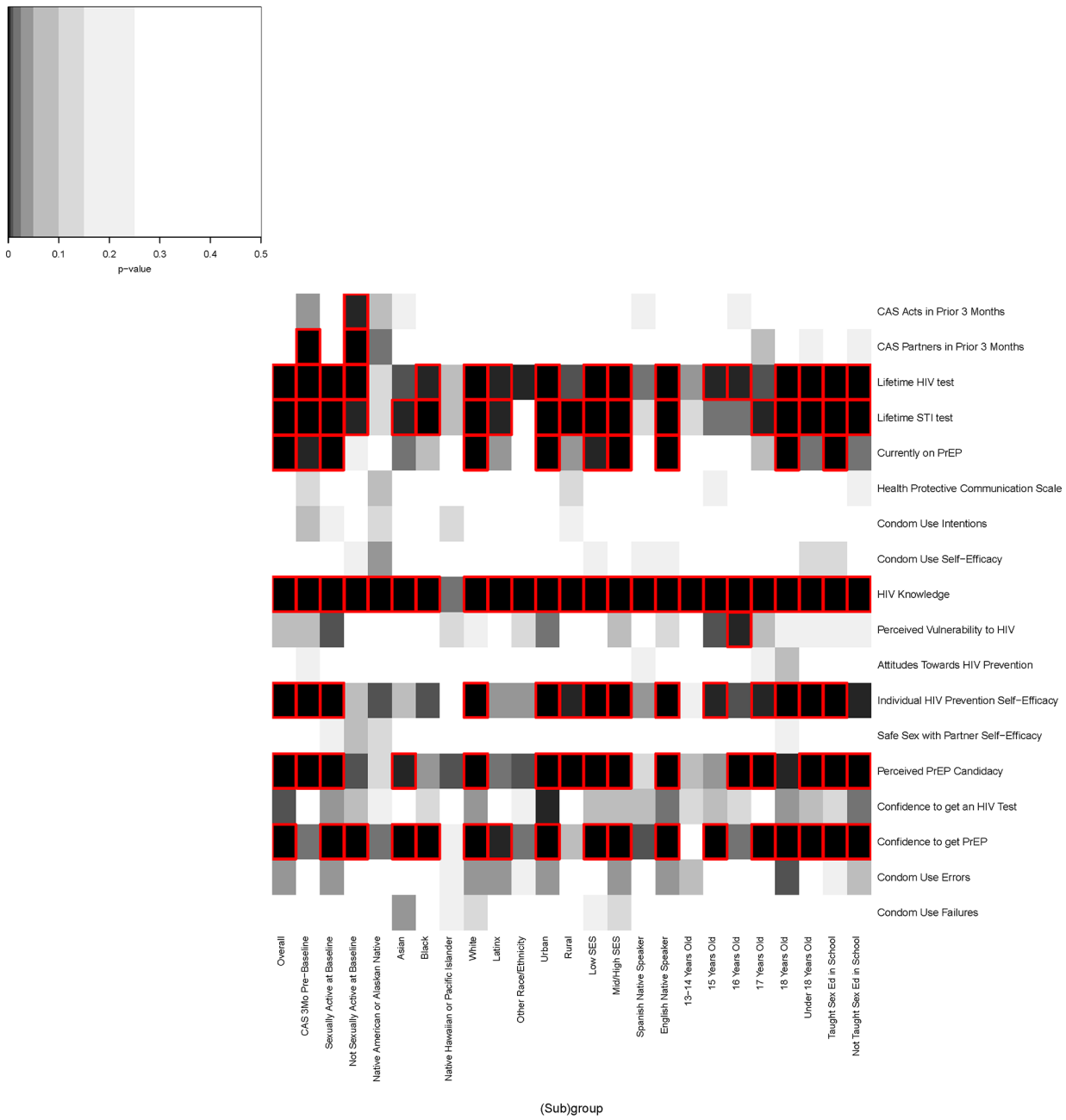

Fig. 1 Change in HIV-Related Outcomes from Baseline to 3-Month Follow-Up among Demographic Subgroups. (*Note.* Each cell in the figure represent an individual *t*-test examining change in the study outcome in a specific demographic subgroup. Cells outlined in red represent statistically significant effects.)

HIV knowledge compared with older subjects. Subjects aged 14 and 15 had smaller changes in perceived HIV vulnerability compared with older subjects. Finally, we found no difference between Spanish and English versions of the interventions in 17 outcomes, but we found that change in HIV self-efficacy was smaller among those receiving the Spanish intervention.

Discussion

SMART Sex Ed showed promise as a successful intervention for AMSM across several key sexual health informational and behavioral metrics. HIV testing, STI testing, HIV knowledge, and confidence to get on PrEP improved across virtually all subgroups. Additionally, improvements across most groups were found for starting PrEP, perceived

PrEP candidacy, and HIV prevention self-efficacy. Across all tests conducted, and regardless of statistical significance, about 80% of metrics showed positive relational movement towards better sexual health outcomes. These findings suggest SMART Sex Ed to be an effective comprehensive sex educational program for AMSM; and given its specific tailoring for AMSM, one that might compensate for critical HIV prevention lessons for this population that are often omitted from traditional high school sexual health curricula (e.g., PrEP information, site-specific/rectal STI testing).

SMART Sex Ed provided AMSM with information and learning tools that supersede those taught or used in traditional settings. For this reason, it is not surprising that lifetime HIV and STI testing saw a significant increase from baseline to three-month follow-up (i.e., over and above natural increases given age and maturation). Participants were explained their rights, under the laws of their own specific state or territory, to independently access testing without the need for parental permission. The intervention explained the sexual HIV transmission risk behaviors that should be followed by testing. Encouraging the use of up-to-date HIV and STI testing locators, usable within the intervention, facilitated testing by providing a local clinic that could offer the relevant services. Moreover, AMSM participants could email themselves the testing site information (e.g., location address, hours, services offered, languages spoken, etc.) while using the locator to save for future use. It is likely because of these sorts of lessons about HIV and STI testing (and supported by identification of local resources) that the sample responded with increased testing.

Our sample also reported marked increases in perceived candidacy for PrEP (i.e., belief that PrEP is "right for me"), confidence to start using PrEP, and actual use of PrEP. PrEP is virtually non-existent in the curricula currently taught across the U.S. [55]. It is only recently (as of 2021) that states (e.g., Michigan) are even broaching requiring PrEP education to be taught during comprehensive HIV education in schools [56], and such legislation is heatedly debated within state politics. This leaves the onus on teens to become aware of PrEP through social media, advertisements, parents, friends, and providers—each of which have their own barriers for being a viable source of information. We prioritized education about PrEP within SMART Sex Ed, even before it was FDA-approved for teens above 35 kg (which occurred in 2018 during the course of this trial). We provided comprehensive information on PrEP, the PrEP options available (i.e., Truvada or Descovy), what might qualify a teenager to take PrEP, and how to obtain it through a provider. When PrEP became FDA approved for use by teens we updated intervention content to reflect this change.

In addition to these behavioral outcomes, SMART Sex Ed also increased several motivational and attitudinal measures of HIV prevention. First, we observed improvements in prevention self-efficacy across the participants, specifically with respect to being able to ask providers for key screening and prevention tools (e.g., asking for PrEP, an HIV test, and a rectal STI screening). Adolescents often do not know what to ask for regarding their sexual health, and more importantly, the confidence to ask or demand from providers the screenings and preventions tools they need [57, 58]. These tend to develop over time and into adulthood, but given that many AMSM are at elevated risk for HIV acquisition, receipt of such skills during the teen years is paramount. To help build these skills, SMART Sex Ed specifically addressed AMSM sexual health rights by state, outlined what precisely they are entitled to ask from providers, and what preventive healthcare services they need based on their level of sexual activity. Additionally, the intervention provided a sexual behavior risk calculator, which illustrated for AMSM the degree of risk associated with various sexual behaviors (e.g., anal sex, oral sex), with specific types of partners (e.g., HIV-positive, unknown status), and in the context of prevention use (e.g., PrEP, viral suppression, condoms). This risk calculation tool allowed AMSM to make key cognitive connections between current risk and future prevention techniques they could adopt (e.g., PrEP) in order to lower their risk. It is our hope that by seeing increases in self-efficacy, long-term confidence to engage in effective HIV prevention will turn into actualized condom use, testing, and PrEP acquisition.

While the significant pre-test post-test changes observed in this study suggest positive effects of SMART Sex Ed on many sexual health outcomes among the AMSM participants, changes in condomless anal sex rates, condom use intentions, condom use self-efficacy, and health protective communication did not change. This was consistent with our hypothesis that, as an information-based intervention that did not contextualize behavioral skills through scenario-based lessons (e.g., how to talk to a partner about condoms) or address motivational factors, we would see effects on knowledge and clinical encounters, but not sexual HIV transmission risk behaviors and dyadic skills. Other interventions in the SMART package that focus on HIV prevention motivations and contextualized behavioral skills (i.e., SMART Squad and SMART Sessions) are hypothesized to induce changes in HIV risk and preventive behaviors across different kinds of partnerships.

The SMART Program randomized controlled trial employed rigorous optimization methodologies to prevent threats to generalizability, reliability, validity, and other biases. However, all trials have limitations. Our study enrolled a diverse sample of AMSM to better test for racial and ethnic differences in intervention effects. While we had excellent enrollment from Black, Latinx, Asian, and White

adolescents, we fell short regarding our recruitment goals for Native American/Alaskan Native, Native Hawaiian and Other Pacific Islander AMSM. Yet, even with these smaller populations, our study remains one of the largest powered samples exploring these rarely reached groups. Another sampling limitation was our reach to sexually active participants aged 13. In the analyses, we were forced to collapse those aged 13 and 14 together into one group. It is notable that during our trial screening process, we identified hundreds of AMSM aged 13; however, virtually all of them had failed to reach the sexual activity inclusion criteria we had mandated for the study. While the generalizability may be limited for those aged 13, we did collect a larger sample of AMSM aged 14. Despite this challenge this is one of the largest samples of such young MSM ever collected. We also emphasize that across these subgroups we found almost no evidence of differential intervention effects, suggesting that SMART is relevant and effective across racial, ethnic, and developmental groups.

There were also statistical limitations given the number of participant subgroups we were comparing on the myriad sexual health variables we identified for our study outcomes. To test the entirety of the intervention across multiple *a priori* specified outcomes and subgroups, we employed 450 tests. Although we used appropriate, conservative statistical corrections while producing this quantity of results, conducting such a density of statistics may still invite a Type I error into the findings. An additional statistical limitation is the lack of multivariable testing that might have better elucidated or disentangled some of our key findings. For example, the oldest participants (those aged 18) were, by nature of maturation, more likely to have engaged in anal sex relative to those aged 13 and 14. Some independent variables may share overlapping variance that more selective and nuanced testing could identify. However, given we had such a preponderance of testing to identify the overarching effects of the intervention, we did not also add multivariable analyses into this report of primary outcomes.

Conclusion

SMART Sex Ed provides an engaging and effective alternative to traditional sexual education for a population that is at high risk for HIV and poorly served by existing sexual health education programs. SMART Sex Ed has an informational curriculum suitable to all AMSM, regardless of whether they have engaged in oral or anal sexual behaviors, and represents a high standard for sexual education for queer, gay, bisexual, pansexual, or questioning adolescents. Its accessibility through traditional internet-ready devices makes it uniquely suited to address the anonymity and privacy needs of AMSM to learn about their sexuality outside of the usual sexual health classroom. Its ability to educate adolescents on health topic areas usually unaddressed by their teachers (e.g., PrEP, rectal STI testing, same-sex sexual preparations, lubrication) could provide the next generation of adolescents a levelled playing field with their heterosexual counterparts regarding sexual health prevention access and use. Given the results observed in this study, we assert that providing AMSM a comprehensive and culturally relevant online HIV prevention program at this critical stage of their sexual development can positively shape their emerging sexual patterns and behaviors and can be impactful in reducing HIV risk and improving utilization of HIV testing and prevention services. The intervention appears to be equally effective across key demographic subgroups, which is an important consideration for equity and implementation. To learn more about SMART and its content visit: https://esmart.northwestern.edu/.

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Availability of data and material (data transparency) Data used for these analyses are available upon request and approval by the corresponding author.

Code availability (software application or custom code) Custom coded web application developed by internal Research Application Design and Development (RADD) team at the Institute for Sexual and Gender Minority Health and Wellbeing (ISGMH).

Declarations

Conflicts of interest/Competing interests (include appropriate disclosures) No conflicts of interest to declare.

Ethics approval (include appropriate approvals or waivers) All partici-

pants provided informed consent for their involvement in the project. A waiver of parental permission was awarded by the IRB.

Consent to participate (include appropriate consent statements) Prospective, eligible participants were routed to an online consent form and capacity-to-consent assessment. In order to complete enrollment, a video chat with staff confirmed eligibility and consent. Waivers of parental permission were approved by the IRB.

Consent for publication Not applicable.

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