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Research Article

PrEP Education and Awareness Building through an Intervention for African-Americans Reporting both Condomless Sex and Substance Use During an Emergency Department Visit

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Abstract

Background: Pre-exposure prophylaxis (PrEP) provides women with an effective tool to prevent HIV. Uptake among African American women remains low while new HIV diagnoses continue to rise.

Methods: In a single-armed study, we enrolled African American women (n=14) ages 20-29 years. They acknowledged recent substance use and sex during an emergency department visit. We delivered the 'Increasing PrEP uptake' (iPrEP), an intervention that uses brief messages to raise HIV risk awareness related to substance use and sex, on tablet devices.

Results: Most women completed high school/GED (n=12/14), reported a monthly income below the federal poverty line (n=9/14), were employed (n=9/14), and had a primary partner (n=13/14). Three women reported sex with a recent casual partner. Most women reported substance use within two hours of condomless sex (n=9/14) and willingness to use PrEP (n=9/14).

Conclusion: Our study suggests iPrEP is potentially associated with PrEP willingness among sexually-active African American women who use substances.

Keywords: African American women; HIV; Pre-exposure prophylaxis (PrEP) education; Risk awareness; Substance use

Introduction

There are higher rates of new HIV diagnoses among African American women than among women from other racial and ethnic groups [1,2]. Condomless sex and substance use may compound that population risk [3]. Houston, TX ranks 11th in the nation for HIV incidence rates, of which 36% were women, and 71% of those were African American [4]. Risky sexual behavior in Texas is common: 88% of African American women contract HIV through condomless heterosexual sex [5]. Substance use rates are 13.4% for injection drug use and 32.1% for non-injection drug use [6]. Substance use promotes heightened sexual risk taking, substantiating the public health need of prioritizing HIV prevention interventions for this population.

Truvada, an antiretroviral medication, is FDA approved for use as pre-exposure prophylaxis (PrEP) to prevent HIV transmission to vulnerable HIV negative men and women. PrEP can be a key component of a comprehensive HIV prevention strategy that can be controlled by women. When levels of PrEP adherence are high, oral PrEP demonstrates high efficacy among women; however, women with low PrEP adherence experience low efficacy [7,8]. Yet, PrEP use among African American women remains low [9-12].Through an evaluation of a national pharmacy database that accounts for 39% of all Truvada prescriptions, researchers explored PrEP utilization between 2012 and 2015. Researchers identified nearly 50,000 people who started PrEP and only 21% were women [13]. Further, 74% of PrEP prescriptions were among Whites, 12% Latinos, and 10% African Americans. The majority of PrEP prescriptions were written for non-Hispanic, White patients; far fewer Latinos and African Americans received prescriptions. In addition to continued risk of contracting HIV, low PrEP uptake among women curtails the ability of HIV prevention researchers to quantify efficacy estimates of this approach for addressing HIV as a public health problem for women.

Barriers to PrEP uptake has been explored. An abstract of a cross-sectional study using a convenience sample of ED patients at New York City hospitals demonstrated that Latino patients (17.6%) reported PrEP knowledge more than African Americans (8.8%) and patients who designated their race as 'other' (12.4%) [14]. Cost has been established as a major barrier to PrEP uptake. However, recent changes in guidelines for insurance companies to cover PrEP will potentially overcome this barrier for insured populations. Known behavioral, social, and structural barriers to PrEP uptake that are specific to women have been reported [15]. Evidence from a few studies suggest low perceived risk and concerns about side effects are barriers to

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PrEP uptake. In a qualitative study of PrEP interest in a sample of 114 women, Carley et al. reported an alignment between low self-reported condom use and low perceptions of HIV risk. Specifically, 84.7% of participants who self-reported low condom use perceived themselves at low risk for HIV. In the same study, merely 7.4% of enrolled women maintained interest in PrEP and believed they could adhere to a daily PrEP regimen after learning of the side effects. None of the women enrolled who perceived themselves to be at medium or high risk for HIV upheld an interest in PrEP [16].

African Americans are two times more likely to consider the emergency departments (ED) as their medical home than Non-Hispanic Whites [17]. Thus, EDs could serve as an access point to increase African American women's awareness and potentially access to PrEP for HIV prevention. Interventions that can both feasibly integrate into the ED patient flow and increase PrEP uptake among substance-using African American women can help protect this vulnerable populations from contracting HIV.

The aim of this article is to investigate whether African American women, who acknowledged both condomless sex and substance use, were willing to take PrEP after receiving the intervention in the ED.

Methods

Research design

We developed a brief, intervention delivered on a tablet device as a prospective, single-arm quantitative pilot study.

Study population

Fourteen African American women between 20 and 29 years of age who reported substance use and condomless sexual activity within the last three months were recruited from the EDs of two teaching hospitals. Any substance use (including the use of alcohol, marijuana, cocaine, amphetamine, methamphetamine, benzodiazepines, barbiturates, and/or PCP)) and at least one sexual encounter in the last three months qualified the participant for eligibility in the study.

Study setting

Recruitment sites included two hospital-based EDs, one privately-funded and the other publicly-funded. Memorial-Hermann – Texas Medical Center, the private hospital's ED, has a patient volume of approximately 72,000 visits each year [18]. Lyndon B. Johnson hospital of the Harris Health System, the public, acute care hospital, has a patient volume exceeding 70,000 visits each year [19,20].

Procedure

The study was approved by the institutional review board at UT Health (HSC-MS-15-0910). Patients seeking treatment in the ED were screened for eligibility through approved access to the patient's medical record and collection of de-identified data for screening purposes. The inclusion criteria that determined eligibility for the study were: 1) African American race, 2) female sex and gender (cisgender), 3) a social history with reported sexual activity and substance use within the last three months, and 4) low acuity (1-3) based on the 5-point emergency severity index [21]. Electronic medical records were screened by trained researchers to identify eligible participants.

Eligible participants were recruited by trained members of the research team from the ED waiting room or from private patient rooms. Patients who were recruited from the ED waiting room were taken to a private designated area prior to initiation of the enrollment process.

Researchers initiated the enrollment period (7 months) with eligible participants in a private area, explaining why they were approached (i.e. meeting the eligibility criteria) for participation and providing a summary of the study's purpose and procedures. The informed consent was discussed and the risks and benefits of study participation were explained. Potential participants were given time to read through the consent form and decide whether or not they wanted to participate. For those who chose not to participate, the researcher inquired about the reason and those reasons were recorded. Those who chose to participate signed the consent form. One copy of the consent form was given to the participant and a second copy was added to the patient's medical record.

Participants were given the tablet device to self-administer the intervention. The intervention instrument included 99-items. At the conclusion of the survey, the participant showed the final screen to the researcher, ensuring that participation was complete. At that time, the researcher provided the participant with a $25 gift card and study participation concluded.

Intervention

The HIV Prevention Trials Network (HPTN 073) study developed a baseline instrument for African American men who have sex with men (MSM) to assess structural and mental health factors predicting PrEP uptake and adherence [22-24]. They used a counseling strategy to promote PrEP use and supported clients through referrals to related services, resulting in a 79% PrEP acceptance rate among enrollees [25]. Based on an adaptation of the HPTN 073 study, a novel intervention, 'Increasing PrEP uptake' (iPrEP), was developed. The adaptation plan for the survey tool focused on the content and format of the HPTN 073 baseline instrument. After adapting the survey tool, it was packaged as an innovative intervention approach with a novel delivery platform using a tablet device. The two aims were: 1) to adapt an intervention that effectively promoted PrEP uptake among MSM for use among African American women and 2) to measure and encourage willingness of African American women seeking healthcare in an ED to use PrEP for HIV prevention.

The iPrEP intervention uses informational messages woven into a traditional survey containing questions about sex and substance use. It was delivered in such a way as to indirectly raise awareness among women on how their behaviors, both condomless sex and substance use, could increase their risk for contracting HIV. For example, information was provided in text format about health risks related to condomless sex. After clicking the 'next' button, participants were asked whether or not they agreed with the information presented on the previous screen. In other areas of the intervention, a set of questions were presented as a group. The statement before the set of questions read, 'Please tell us how much you disagree or agree with each of the following statements about HIV.' All statement responses were a 5-point Likert scale (Strongly disagree: Strongly agree) and included a 6th option, 'don't know'. Three of those statements were, 'I am worried about getting infected with HIV', 'My sexual experiences put me at risk for HIV,' and 'I think that I really could get HIV.' These statements helped the participants to apply the information presented

to their own behavior. By doing so, participants were prompted to raise their awareness of their own risk for contracting HIV based on their behaviors.

Questions related to sexual behavior explored quantity of sexual partners, sexual practices, relationship type and length, HIV status of partners, and transactional sex. Questions on substance-using behaviors assessed substance type, frequency of use, and concurrent sex with substance use. We also added standard educational information about PrEP, PrEP protocols, benefits, and side effects. PrEP was defined as 'an HIV medication taken once a day to help prevent HIV infection. By taking it once a day, it can decrease the risk of becoming HIV-infected if exposed.'

Intervention measures

Socio-demographic variables

The study assessed demographics including, age, education, sexual orientation, household income (monthly), and employment status.

Relationship characteristics

Among women with primary partners, we evaluated relationship type and relationship length. Sexual experiences with casual partners were assessed under sexual behaviors.

Sexual behaviors

Sexual behaviors of participants were assessed in four areas: knowledge of partner's HIV status, engagement in transactional sex (engagement in the exchange of sex for resources including money and illicit substances), recent sex with a casual partner, and recent oral sex or tribbing/scissoring (rubbing your vaginas against each other to stimulate the clitoris) with a woman.

Substance-using behaviors

Substance use behaviors were evaluated in three areas: frequency of substance use, concurrent substance use and condomless sex, and concurrent substance use and sex with condoms.

Primary outcome

The primary outcome of the study, willingness to take PrEP, was measured with one question, which read, 'Would you be willing to take PrEP to reduce your own risk of getting HIV?' The 3-item response format allowed participants to answer 'yes', 'no', or 'unsure'.

Screening

A total of 261 potentially eligible women seeking care in either a public or private ED were screened and assessed for eligibility (Figure 1). Reasons for screen failures included: 1) failure to report current substance use, 2) presenting complaint acuity level of four or higher (indicating a serious health condition), 3) classified as ineligible based on race, age or gender, 4) failure to locate eligible participant, and 5) patient discharged between screening and recruitment effort. The reasons for refusal to participate for most eligible women were time constraint.

Statistical analytic methods

Qualtrics XM software was used to administer iPrEP. A frequency analysis using IBM SPSS 21.0 was performed on demographics, relationship characteristics, substance use and sexual behaviors.

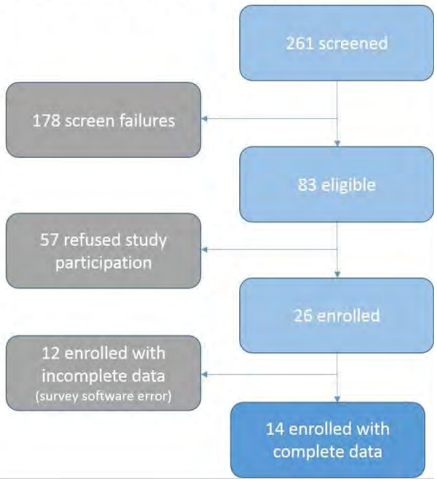

Figure 1: Flow diagram of enrollment cascade.

Results

Twenty-six women were enrolled and included in the study. Fourteen enrolled women completed the survey. The following results are reported for the 14 women. All but two participants (12/14) completed high school, received a GED, or had some college education. Nine women (9/14) were heterosexual and four women (4/14) reported having had sex with both men and women. Nine women (9/14) were employed. One of the employed women (1/14) reported a monthly household income that was below the federal poverty line for one person, as she had a with household income of $1000 per month or less (Table 1).

Relationship characteristics, sex and substance use behaviors are shown in table 2. All but one of the women (13/14) had a primary partner and ten participants (10/14) reported that their relationship had lasted more than eight months. Only one woman (1/14) reported that her partner was HIV positive, while twelve others (12/14) believed their partner to be negative. Only one woman (1/14) reported engaging in transactional sex. One women (1/14) reported oral sex or tribbing/scissoring with a woman in last 3 months. Three women (3/14) reported recent sex with casual partners. Substance use within the last three months ranged from one time to daily. However, over half of women (9/14) enrolled reported substance use within two hours before or after engaging in condomless sex. A similar number of women (8/14) reported substance use within two hours of engaging in sex with condoms.

After receiving the educational messages that were embedded in the survey, participants were asked whether they would be willing to take PrEP. Nine women (9/14) said yes, one (1/14) said no, and four (4/14) were unsure.

Discussion

Brief education-based interventions can feasibly be delivered on a tablet device during an ED visit. This intervention strategy can serve as an information source about PrEP while inspiring PrEP uptake among African American women, a population at significant risk for HIV. African Americans are more likely to use the ED to meet

their primary care needs than other racial/ethnic groups [18]. ED clinicians commonly treat individuals with sexually transmitted infections [26-29]. The ED is an appropriate clinical environment to engage an at-risk population and broaden the prevention scope to include brief primary prevention strategies.

Socio-demographic variables	Subcategories	N	%
Age	20	3	21.4
	23	3	21.4
	24	2	14.3
	26	1	7.1
	27	4	28.6
	29	1	7.1
Education	Some high school education	2	14.3
	High school education or GED	6	42.9
	Some College	5	35.7
	Graduate education	1	7.1
Sexual orientation*			
	Heterosexual	9	64.3
	Bisexual	2	14.3
	Woman who has sex with women and men	2	14.3
	Missing	1	7.1
Household Income (monthly)			
	Less than $500	5	35.7
	Between $501 and $1,000	4	28.6
	Between $1,001 and $1,500	2	14.3
	Between $1,501 and $2,000	2	14.3
	$2,001 or more	1	7.1
	Employed	9	64.3
	Unemployed	5	35.7
If unemployed, reason for unemployment			
	Stay at home Mom	2	40
	Cannot find a job	2	40
	Don't know	1	20

Table 1: Socio-Demographics of the study sample (N=14).

Legend: * - refers to a missing variable. 1 subject did not report sexual orientation. Percentages may not add up to 100 due to rounding.

In order to achieve maximum benefit from an effective HIV prevention strategy for African American women, PrEP should be included. Previous studies have aimed to better understand PrEP awareness among PrEP-eligible women. Findings demonstrated low levels of PrEP awareness and high levels of interest in PrEP [9,11,30]. Those studies used focus groups and traditional qualitative methods that were absent of intervention elements. For the first time, to our knowledge, enrolled women engaged in an intervention designed to enhance their willingness to adopt PrEP for HIV prevention. Willingness to use PrEP could translate to higher uptake rates among people who need it most.

Sexual networks of African American women in the South are often racially homogeneous. African American sexual networks also have a higher prevalence of HIV and STIs when compared to other races and ethnicities [31,32]. Most women enrolled reported concurrent HIV risk behaviors. Some enrolled women engaged in substance use with sex (both with condoms and without).

Variables	Response Options	N	%
Relationship type			
Primary partner	Yes	13	92.9
	No	1	7.1
Length of relationship			
	Less than 1 month	1	7.1
	1-4 months	2	14.3
	5-7 months	1	7.1
	8 months or more	10	71
Sexual behaviors			
HIV status of primary partner			
	HIV negative	12	85.7
	HIV positive	1	7.1
	Unsure or don't know	1	7.1
Transactional sex			
(Gave/received goods for sex)			
	Yes	1	7.1
	No	13	92.9
Sex with casual partner in last 3 months			
	Yes	3	21.4
	No	11	78.6
Oral sex or tribbing/scissoring with a woman in last 3 months			
	Yes	1	7.1
	No	13	92.9
Substance use behaviors			
Frequency of substance use in the last 3 months			
	Once	1	7.1
	A few days a month (1-2 days/month)	3	21.4
	Several days a month (3-4 days/month)	3	21.4
	A few days a week (1-2 days a week)	1	7.1
	Several days a week (3-4 days a week)	3	21.4
	Daily	3	21.4
Substance use within 2 hours before or during condomless sex			
	Yes	9	64.3
	No	5	35.7
Substance use within 2 hours before or during sex with condoms			
	Yes	8	57.1
	No	1	7.1
	Missing	5	35.7

Table 2: Summary of participant responses on relationships, sex and substance use.

Despite high vulnerability to HIV to African American women in the South, primarily due to condomless heterosexual sex, PrEP uptake among women remains low [33]. Disparate rates demonstrate potential benefit of PrEP to 500,000 African Americans versus filled prescriptions of only 7,000 between 2015 and 2016 [34]. Increased PrEP uptake among African American women could provide a complementary HIV preventive strategy when condoms fail or are not used [35,36]. Sexually-active African American women who engage in substance use require HIV prevention strategies to overcome vulnerabilities driven by race, gender, sexual network, and sexual behaviors [2,37]. A prospective assessment of 300 people (57% were African

American) attending an HIV clinic in Houston, Texas revealed that only 27% of attendees always used condoms, although 67% perceived personal HIV risk [37]. These findings substantiate challenges in navigating condom use to African American women locally.

Limitations

A primary limitation of the study is the small sample size. Of the 26 women enrolled, twelve surveys were not usable due to a software error. Due to the sample size, findings cannot be generalized to other groups of African American women who report substance use and sexual activity. In addition, the presence of a single-arm study design limits hypothesis testing. This pilot study should be expanded as a two-armed study using a randomized clinical trial (RCT) method comparing iPrEP to usual care with a larger sample size and at other emergency departments. This was a sample of African American women in which the majority of them reported having sex while under the influence of substances; thus, findings should not be generalized to all African American women. The response format for sexual orientation did not allow participants to select more than one option. This may have obscured distinctions between sexual orientation and sexual practice. Lastly, the population is not representative of the general population in the Houston area; however, they may offer insights about those who seek care in EDs. Participants had varying levels of education and access to health care.

Conclusion

The 'Increasing PrEP uptake' (iPrEP) intervention was demonstrated to be feasible, associated with willingness to use PrEP using a single-armed approach, and is ready to be tested in a RCT. This pilot study led to a funded randomized controlled trial (RCT) that is actively enrolling participants to assess whether iPrEP is more effective at increasing willingness to take PrEP than usual care among a broader demographic of African American women ages 18-55 years during an ED visit for a non-emergent condition. The RCT will also evaluate whether iPrEP intervention plus a PrEP referral increases visit attendance at the PrEP clinic and promotes PrEP uptake within six months. Findings will further determine feasibility, acceptability and efficacy of iPrEP as well as determine effect size estimates for a future, large-scale efficacy trial. Public health benefit to communities at risk for HIV may be realized via innovative intervention and referral mechanisms that increase currently low rates of PrEP uptake among at-risk minority populations.

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Conflict of Interest

Dr. Mandy Hill received an investigator sponsored research award from Gilead Sciences, Inc. after the research presented in this paper was conducted in 2019. This industry sponsors manufactures Truvada, the drug used as pre-exposure prophylaxis. Dr. Mandy Hill declares no additional conflicts. Dr. Charlene Flash has no conflicts of interest. Dr. Angela Heads has no conflicts of interest. Dr. Marylou Cardenas-Turanzas has no conflicts of interest. Dr. Richard Grimes has no conflicts of interest.

Research Involving Human Participants and/or Animals

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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