AIDS Education and Prevention, 33(6), 465–482, 2021

BARRIERS AND FACILITATORS TO PARTICIPATION IN LONG-ACTING INJECTABLE PREP RESEARCH TRIALS FOR MSM, TRANSGENDER WOMEN, AND GENDER-NONCONFORMING PEOPLE OF COLOR

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We collected 216 responses from sexually active MSM, transgender women, and gender-nonconforming (GNC) people of color through a web-based survey to understand the facilitators and barriers to research participation in a hypothetical LAI PrEP trial. In adjusted models, these items were found to be significantly associated with research participation likelihood: ever participated in HIV research study; comfort with taking daily pill; comfort with providing urine sample; and concerns over potential side effects of shot. Asian participants were more concerned about others knowing they were being recruited than were Black and Latinx respondents $F(2, 216) = 3.98$; $p < .05$. Asian respondents were also less comfortable with being recruited at organizations serving communities of color than Black and Latinx respondents, $F(2, 216) = 5.10$; $p < .05$. Cisgender respondents were more comfortable with being recruited by a friend or colleague than were transgender/GNC respondents, $F(1, 215) = 4.8$; $p < .05$.

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The authors would like to thank the program faculty of the Fordham HIV and Drug Abuse Prevention Research Ethics Training Institute for reviewing various iterations of this article and for providing feedback on the research design and analysis, namely Dr. Kathryn Rose Macapagal at Northwestern University Feinberg School of Medicine and Dr. Jama Shelton at the Silberman School of Social Work at Hunter College, City University of New York.

All eligible participants provided informed consent prior to starting the survey. All collected data was deidentified by the survey platform. The study protocol was approved by the Fordham University Institutional Review Board in December 2019.

The dataset supporting the conclusions of this article is available for review upon request.

The authors declare that they have no competing interests.

The study was supported through a fellowship from the Fordham HIV and Drug Abuse Prevention Research Ethics Training Institute (RETI), funded through the National Institute on Drug Abuse, Grant #R25DA031608.

The first author created the research design, supervised all data collection and completed all data analysis and manuscript writing. The second author helped with data collection, data cleaning, and initial data analysis. The third author helped write the background and discussion sections of the manuscript. The fourth author was the research project mentor, who oversaw the research study design, guided all statistical analyses, and assisted in manuscript writing.

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Keywords: long-acting injectable, PrEP, HIV, prevention, MSM, transgender women, people of color

BACKGROUND

Racial/ethnic minority and sexual/gender minority communities in the United States (U.S.) are at increased HIV risk. Black men who have sex with men (MSM) are nine times as likely as White MSM to be living with HIV and Latino MSM are twice as likely as White MSM to be living with HIV (Centers for Disease Control and Prevention [CDC], 2019). Between 2014 and 2018, the number of Asians receiving an HIV diagnosis who were between the ages of 25 and 34 increased by 10% and HIV incidence among Asians 55 and over increased 43% (CDC, 2020a). In a national survey of over nine million CDC-funded HIV tests, transgender women had the highest confirmed HIV prevalence rate of any gender category (2.7%) and the majority (64.4%) reported that they have never been tested for HIV (Harbata et al., 2015; Pitasi et al., 2017). Black and Latina transgender women are at highest risk among transgender women (CDC, 2018).

Utilization of oral HIV pre-exposure prevention (PrEP) among MSM has increased in the U.S. (Holloway et al., 2020), although financial costs cause barriers to accessing the medication, even for individuals with health insurance (Meyers et al., 2018). Oral PrEP was previously limited to tenofovir disoproxil fumarate/emtricitabine (TDF/FTC, marketed as Truvada) until the FDA approved tenofovir alafenamide (TAF/FTC, marketed as Descovy) in 2019 (Robles et al., 2021). An additional type of on-demand or event-driven PrEP has been shown to be efficacious on a "2–1–1" schedule, meaning that the individual takes two pills 2–24 hours before sex, one pill 24 hours after the first dose, and one pill 24 hours after the second dose (Molina et al., 2015). While generic versions of PrEP are now available, the cost of oral PrEP can still be as high as $1,000 per year (Meyers et al., 2018).

For MSM and transgender women of color, anticipated stigma and discrimination within health care settings is a significant barrier to oral PrEP uptake and to the receipt of sexual health services (Fisher, Fried, Desmond, et al., 2018; Fisher, Fried, Puri, et al., 2018). For example, although Black and Latinx people account for nearly half (49.6% in 2016) of HIV incidence, 68.7% of oral PrEP users in the same year were White (Kanny et al., 2019). A study examining the experiences of transgender women found that a barrier to consistent usage of oral PrEP was the fear of being viewed as responsible for spreading HIV and being negatively judged by both medical professionals and one's own community (Fisher, Fried, Puri, et al., 2018). Current health care practices offering PrEP guidance are often tailored for gay men and may be unsuitable for transgender women or gender-nonconforming (GNC) people (Sevelius et al., 2016).

Recent research has found that a long-acting injectable form of HIV pre-exposure prophylaxis (LAI PreP; cabotegravir) may be superior to oral PrEP in terms of both effectiveness and adherence (HIV Prevention Trials Network, 2020; Sevelius et al., 2016). Results indicate that participants in the LAI cabotegravir arm (plus placebo daily oral tablets) were significantly less likely to be infected with HIV as compared to those who received daily oral Truvada (plus placebo injections; Marshall et al., 2018). The medication was approved by the FDA earlier this year.

PREP ISSUES FOR COMMUNITIES OF COLOR

Black, Asian, and Latino MSM and transgender women are underrepresented in HIV prevention research and specifically in PrEP research trials (Levy et al., 2014; Rao et al., 2016; Sullivan et al., 2014). Although highly effective, daily oral PrEP is often associated with lack of adherence, especially in socially and economically marginalized communities where risks of stigma and disclosure may be heightened. Data on how MSM and transgender women of color perceive the facilitators and barriers to participating in randomized clinical trials for LAI PrEP will be critical both for obtaining representative research samples and ensuring widespread adoption of this biomedical innovation and potentially other future experimental HIV medications.

Research regarding the likelihood of current oral PrEP users to switch to LAI PrEP has been promising. In one study of 105 respondents who identify as gay or bisexual men currently using oral PrEP and 46.7% of whom identify as people of color, 66.7% reported they would switch to LAI PrEP (Meyers et al., 2018). Given the lower rates of oral PrEP uptake among communities of color, LAI PrEP may be more manageable for MSM and transgender women of color who face obstacles due to medical adherence or stigma (George et al., 2014). Additionally, physicians are less likely to prescribe PrEP to Black MSM as they are perceived to be more likely to not use condoms following initiation (Calabrese et al., 2014). These are judgments that are tied to racial stereotypes viewing Black gay men as promiscuous and hypersexual (Calabrese et al., 2018). These tropes are inaccurate as Black MSM have been found to be more likely or just as likely to use condoms as White MSM (Eaton et al., 2010; Millett et al., 2007; Stokes et al., 1996).

LAI PrEP may therefore assist in alleviating health inequities that exacerbate HIV infection in marginalized groups (Biello et al., 2018). Given the lower rates of oral PrEP uptake among communities of color, LAI PrEP may be more manageable for MSM and transgender women of color who face obstacles due to medical adherence or stigma (Fisher et al., 2017). In a previous study, only about 50% of surveyed gay and bisexual men had ever heard about LAI PrEP; those who had heard about it were fearful of side effects, longevity, and effectiveness of preventing HIV—all factors that can skew the expected uptake of a new medication (John et al., 2018). Engagement of MSM and transgender women of color in HIV research trials is critical to understanding the barriers and facilitators to future LAI PrEP uptake among vulnerable communities.

The reasons why MSM and transgender women of color decide whether or not to participate in an injectable PrEP randomized control trial remain largely unknown. Given the unique social and cultural contexts for HIV infection and PrEP usage among communities of color, factors associated with PrEP research participation are likely to differ for MSM and transgender women of color. Previous research has documented that barriers to oral PrEP adherence for young MSM and transgender women of color include stigma, health system inaccessibility, side effects, competing stressors, and low HIV risk perception whereas facilitators included social support, health system accessibility, reminders/routines, high HIV risk perception, and personal agency (Wood et al., 2019). Only very limited research has focused on the unique social circumstances faced by MSM and transgender women who are Asian American.

Our study sought to address these gaps in the extant research by surveying MSM and transgender women of color on their attitudes regarding participation in a hypothetical LAI PrEP research trial in the U.S. The research questions we sought

to answer were: (1) Which barriers and facilitators to LAI PrEP are associated with research trial participation for MSM and transgender women of color? And (2) What racial/ethnic differences exist in these barriers and facilitators to LAI PrEP research participation? In the current context of the COVID-19 pandemic, understanding facilitators and barriers to PrEP research participation may also help ensure greater understanding for research involvement in HIV prevention trials for communities of color.

METHODS

PARTICIPANTS AND PROCEDURES

As part of a larger, anonymous, online national survey, data was collected over a 3-month period between December 2019 and February 2020. Recruitment and data collection were implemented through Qualtrics XM, an aggregator of survey panel websites. Qualtrics sent emails and posted ads to individuals who had previously signed up to respond to surveys. Interested participants first completed a 10-item eligibility screener. Eligibility criteria included: (1) assigned male sex at birth; (2) had sex with a cisgender man in the past year; (3) resides in the U.S.; (4) over the age of 18; (5) self-reported HIV-negative serostatus; and (6) self-identified as Asian, Black/African American, or Latinx/Hispanic. The screener also collected information on gender identity. To ensure adequate representation of race/ethnicity, we conducted stratified sampling to obtain roughly equal numbers of responses from people who identified as Asian, Black, and Latinx with about 70 participants from each of these three racial/ethnic groups. Given that the focus of the study was differences across these three racial/ethnic groups, 7 individuals who were biracial, multiracial, Native Alaskan/American Indian, or Native Hawaiian/Pacific Islander were excluded from the sample. Average survey completion time was approximately 20 minutes.

We implemented various techniques to validate responses. The issue of confirming the identity of respondents is common in technology-based (i.e., internet and cell phone) studies. However, we note that respondents can also lie about their identity in mail surveys and telephone surveys where their age, sex, and other demographic features are not usually discernable. We utilized methodologies or participant verification that are drawn from technology-based methods and have been widely replicated in the collection of validated data. Our multi-pronged strategy to reduce the likelihood of respondent deception is consistent with best practices in social science research.

The eligibility screener was formatted in such a way as to disguise qualifying criteria so that those interested would not immediately know the "right" answers. A Qualtrics system feature excluded participants who did not meet eligibility criteria and prevented their IP address from re-entering the screener. This may also help prevent bots from repeatedly taking the survey multiple times. Manual data validation protocols were established to exclude fraudulent or repeat participants; consistency between age and date of birth; inconsistency between reported city in which the survey was taken and zip code; and responses with identical IP addresses. Qualtrics also includes a speed check to exclude participants who respond in less than half the time of the median survey response. For this study 2,193 individuals completed the eligibility screener, 381 (17.4%) met eligibility criteria, and 216 (9.8%) completed the survey and passed the speed check.

Research Compensation and Ethical Review. Participants received an incentive, ranging in value from $12 to $20 in points on the Qualtrics survey platform. The range of incentives depended on the particular Qualtrics panel from which participants were recruited based on prior agreements between panel members and Qualtrics for survey completion. A higher incentive was provided to participants on panels that were more difficult to recruit. This amount could be exchanged for a gift card of their choice within 7 days following survey completion. Participants could elect to not answer questions that made them feel uncomfortable, without penalty. Participants could also end their participation in the study at any time by closing the survey window. However, participants who started and did not complete the survey did not receive the incentive.

MATERIALS AND SURVEY ITEMS

Eligible participants were immediately routed to a site providing informed consent information. Those who checked a response button indicating agreement to participate were routed to the online study. Here they were provided with a brief review of the purpose the study and the survey procedure. The survey entailed a review of a PowerPoint presentation that described a hypothetical LAI PrEP research study. Participants responded to survey questions regarding their attitudes towards various aspects of the hypothetical study, including recruitment, confidentiality, risks, and benefits. Ultimately they indicated their level of comfort in choosing to participate in the hypothetical study.

Hypothetical Research Vignette. The vignette included 21 PowerPoint slides that introduced a hypothetical research study on LAI PrEP. Individual slides were embedded into the questions of the survey, so respondents were not able to skip or miss any of the slides as they progressed through the survey. Initial slides described the paucity of studies on the HIV prevention needs of MSM and transgender women of color. This was followed by descriptions of what was currently known about the safety and efficacy of oral and LAI PrEP and the rationale for a randomized controlled trial, comparing these two treatment modalities. The description of the oral/injectable PrEP study and several survey items were adapted from a prior study on attitudes toward participation in an LAI and oral PrEP randomized controlled trial, conducted with MSM and transgender and gender nonbinary adolescents (Fisher et al., 2017, 2021; Fisher, Puri, et al., 2018). Additional survey questions were created as novel items that were specifically created for the purposes of this survey.

In subsequent slides in the survey, study inclusion criteria were reviewed (e.g., HIV negative/unknown serostatus and having been sexually active with a cisgender male partner in the past year), random assignment, additional medical procedures (e.g., blood samples to test for HIV and PrEP adherence), and potential research benefits and risks. Slides also included information on recruitment of participants, the length of the proposed study (one year), and study limitations.

To ensure appropriateness of content, the survey slides included gender-affirming images of Asian, Black, and Latinx gay men and transgender women that had been developed in consultation with members of a community advisory board, composed of national queer activists of color. The research team made efforts to ensure that these images reflected the racial, ethnic. and gender diversity of MSM and transgender women of color in the U.S.

Survey Items

Sociodemographics. The main survey consisted of a total of 52 items, interspersed among the PowerPoint slides and following the description of the hypothetical research vignette. Sociodemographic items at the beginning and end of the survey supplemented those collected during the screening process. These items included race/ethnicity, gender identity, sexual orientation, education, language(s) spoken at home, and income. In the eligibility screener, we followed the "Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys" (GenIUSS Group, 2014). This two-step question first asks respondents to indicate their sex assigned at birth (M or F), then asks them to indicate their current gender identity.

Sexual Partners, Substance Use, HIV/STI Testing, and Treatment. Participants were asked to provide the number of sexual partners they had in the past year, substance use, whether or not they had previously tested for HIV, whether or not they had been previously tested for other sexually transmitted infections (STIs), whether or not they had previously been treated for an STI, familiarity with PrEP, having previously taken oral PrEP, substance use behaviors in the past year, and whether or not they were taking hormones. To ensure that participants were not familiar with PrEP only as a result of the information we provided in the hypothetical research vignette, we asked these questions before defining PrEP and explaining the nature of the proposed research study. We also included two questions regarding likelihood of getting HIV and level of worry regarding getting HIV, adapted from Napper et al.'s (2012) perceived risk of HIV scale.

Recruitment. A series of questions probed participants' comfort with various forms of recruitment, to which participants responded on a 5-point Likert scale from 1 (very unlikely/uncomfortable/unconcerned) to 5 (very likely/comfortable/concerned). The first question asked: "How likely would you be to respond to an advertisement for a research study that is targeting queer communities of color?" Then participants were asked to indicate their level of comfort in being recruited by a friend or colleague who told them about the study; at a nonprofit organization or clinic that serves communities of color; or at a nonprofit organization or clinic that serves queer communities. Participants were also asked about their level of concern in regard to others coming to know that they were being recruited for the study.

Comfort With Trial Parameters. Participants were asked to respond to a question gauging their comfort in taking a daily pill to reduce their HIV risk, using a 5-point Likert scale from 1 (not at all comfortable) to 5 (very comfortable). The same question was posed in regard to comfort with taking a bimonthly shot. Participants were also asked how strongly they agreed that randomization was a fair way to assign participants to groups; their level of comfort in providing a urine sample and getting tested for HIV every 2 months; and whether or not they were taking hormonal medications.

PrEP Research Benefits. This set of questions gauged participants' attitudes towards PrEP research benefits. Participants answered the question: "In your opinion, what benefits do you see from participating in this study?" Options included: potential protection from HIV infection, free access to PrEP, access to HIV testing, access to

STI testing, access to condoms/lube, linkage to HIV care if tested positive, potential improvement on research on communities of color, potential improvement on research on queer communities, and potential improvement on research on queer communities of color. Participants could also write in their own response in an Other option.

Altruistic Motivations. Altruistic motivations were gauged by responses to the last three options to the previous question regarding PrEP research benefits: "In your opinion, what benefits do you see from participating in this study?" These options were: (1) potential improvement of research on communities of color; (2) potential improvement of research on queer communities; and (3) potential improvement of research on communities that are both of color and queer.

PrEP Research Risks. Barriers were assessed by asking the question: "In your opinion, what risks do you see from participating in this study?" Potential risk options included discomfort/pain during blood draws; discomfort/pain when receiving shots; concerns over possible side effects of the shot; and currently taking hormones. Participants were again provided the option of writing in their own response in an Other option. Comfort regarding randomization in the hypothetical research study was measured on a 4-point Likert scale, ranging from 1 (very unfair) to 4 (very fair).

Confidentiality Concerns. Participants were asked to indicate their level of concern on a 5-point Likert scale from 1 (very unconcerned) to 5 (very concerned regarding: others finding out that they may test positive for HIV; others knowing that they were participating in the study; others finding out about their gender identity or sexual orientation; and threats to their personal safety, should someone come to know that they were taking PrEP medications).

Likelihood of Participation. The main research outcome was likelihood of participation. To assess likelihood of participating in an LAI PrEP research study, participants were asked: "Based on all the information you have been given, do you think you would choose to participate or not participate in this study?" Participants were asked to respond to their level of agreement on a 4-point Likert scale: (1) probably would not participate; (2) definitely would not participate; (3) probably would participate; and (4) definitely would participate.

Statistical Analysis. All statistical calculations were conducted using the software, SPSS Version 25. Response percentages and means/standard deviations were calculated for sociodemographic and behavioral variables, including previous participation in HIV research, previous testing/treatment for STIs, substance and injection drug use, and having previously heard of or taken PrEP. For Likert-type items, a series of two-way multivariate analysis of variance (MANOVA) tests were conducted, with fixed factors of race/ethnicity and gender. If differences were identified by the F test, we conducted a Scheffe post-hoc analysis to analyze specific differences by race, by gender, or by their interaction. For categorical items, chi-square analysis was conducted to identify differences by race/ethnicity or gender.

To build the multiple linear regression model predicting LAI PrEP research participation, we first calculated bivariate correlations between likelihood of research participation and various predictor variables, including sociodemographic characteristics, barriers/facilitators, and previous HIV/STI testing and treatment histories. Only those variables that had a statistically significant association ($p < .05$) with the

outcome variable were included in the final multivariate linear regression model. Several variables also had a degree of multicollinearity. If two variables were highly correlated (with an $r > 0.8$), the variable with the strongest correlation with research participation choice was selected. For example, in the questions regarding potential improvement for research, the response, "potential improvement for queer communities of color," had the highest correlation with research participation ($r = 0.11$, $p = .098$) and was therefore included in the final regression model.

RESULTS

Sociodemographics. The sample included 216 MSM, transgender women and GNC people of color (Table 1). The majority of respondents were Christian (56.9%), were born in the U.S. (81%), and spoke the following languages at home: English (95.1%), Spanish (14.3%), Mandarin (3.6%), Tagalog (2.7%), and Hindi (2.7%). Among Asian respondents, 41.8% were East Asian; 34.2% were Southeast Asian; 22.8% were South Asian; and 1.3% were Western Asian. The most commonly used substances in the past year were alcohol, marijuana, prescription drugs, and cocaine/methamphetamine. Across racial/ethnic groups, there were no significant differences by age, gender identity, sexual orientation, income, or education. By gender identity, the majority (66.7%) identified as cisgender men, followed by transgender women (21.8%), transgender men (5.6%), and GNC (6.0%).

FACILITATORS AND BARRIERS TO PARTICIPATION IN AN LAI PREP RESEARCH TRIAL

GROUP DIFFERENCES IN BARRIERS/FACILITATORS TO PARTICIPATION

Sexual Partners, HIV/STI Testing, and Treatment. Participants reported an average number of 6.9 ($SD = 23.4$) sexual partners within the past 12 months; the median for the sample was 2 partners and the mode for the sample was 1 (45.8%). The majority of respondents had not previously participated in an HIV research study (83.9%). By gender, transgender/GNC participants were more likely to have ever been tested for HIV, $\chi^2(3) = p < .01$; were more likely to worry about getting HIV ($p < .05$); and were more likely to take hormonal medications ($p < .01$) than those who were not transgender/GNC. By race/ethnicity, significant differences were found across racial groups, using the MANOVA test, including: ever having been tested for HIV ($p = .005$); ever having been tested for an STI ($p < .01$); and ever having been diagnosed with an STI ($p < .05$). Additionally, significant differences occurred by race/ethnicity in regard to incentives for study participation being sufficient ($p < .01$).

Recruitment. Overall 65% reported that they were somewhat or very likely to respond to an advertisement targeting people of color; there were no significant differences across racial groups for this question. In terms of recruitment site, most participants reported that they were somewhat to very comfortable with being recruited by a friend or colleague who told them about the study (78.0%); at a nonprofit organization or clinic that serves communities of color (78.9%); or at a nonprofit organization or clinic that serves queer communities (63.2%). Concerns regarding

TABLE 1. Sociodemographics of Sample

	Asian (*n* = 70)	Black (*n* = 70)	Latinx (*n* = 76)	Total Sample (*N* = 216)
Age, mean (*SD*)	37.3 (15.1)	33.6 (11.1)	37.7 (13.7)	36.2 (13.5)
Annual Income, *n* (%)				
Less than $20,000	13 (18.6)	12 (5.6)	9 (4.2)	34 (15.7)
Between $20,000 and $50,000	19 (8.8)	29 (13.4)	24 (11.1)	72 (33.3)
Between $50,000 and $75,000	12 (4.6)	15 (6.9)	14 (6.5)	68 (31.5)
Over $75,000	26 (12.0)	15 (6.9)	29 (13.4)	70 (32.4)
Gender Identity, *n* (%)				
Cisgender man	53 (24.5)	38 (17.6)	53 (24.5)	144 (66.7)
Transgender woman	10 (4.6)	22 (8.8)	15 (6.9)	47 (21.8)
Transgender man	3 (1.4)	4 (1.9)	5 (2.3)	12 (5.6)
Genderqueer/GNC	5 (2.3)	5 (2.3)	3 (13.9)	13 (6.0)
Sexual Orientation, *n* (%)				
Gay	30 (42.9)	32 (14.8)	35 (16.2)	97 (44.9)
Lesbian	0 (0)	1 (0.5)	1 (0.5)	2 (0.9)
Bisexual	28 (40.0)	20 (9.3)	31 (14.4)	79 (36.5)
Heterosexual	5 (2.3)	9 (4.2)	1 (0.5)	15 (6.9)
Pansexual, queer, or questioning	7 (10.0)	7 (10.0)	2 (0.9)	16 (7.4)
Education, *n* (%)				
High school degree	5 (2.3)	19 (8.8)	14 (4.6)	40 (18.5)
Some college	19 (8.8)	15 (6.9)	16 (7.4)	50 (23.1)
College degree	26 (12.0)	25 (11.6)	30 (25.5)	81 (37.5)
Graduate degree	19 (8.8)	10 (4.6)	16 (7.4)	45 920.8)
Number of sexual partners in past year, mean (*SD*)	9.2 (32.4)	3.9 (7.0)	7.3 (23.5)	6.9 (23.4)
Substance Use, *n* (%)				
Alcohol	51 (23.6)	60 (2.8)	55 (2.5)	166 (76.9)
Marijuana	21 (9.7)	48 (22.)	47 (21.8)	116 (53.7)
Prescription drugs (opioid painkillers, benzodiazepines)	13 (6.0)	17 (7.9)	17 (7.9)	47 (21.2)
Cocaine and methamphetamine	12 (5.6)	16 (7.4)	20 (9.3)	48 (22.2)
Injection Drug Use, *n* (%)				
In past year	7 (10.0)	3 (1.4)	10 (4.6)	20 (9.3)
Prior to past year	7 (10.0)	6 (2.8)	3 (1.4)	16 97.4)
Never	56 (26.0)	61 (28.2)	63 (29.2)	180 (83.3)
Willingness to Participate in LAI Prep Research Study, *n* (%)				
Choose to participate	48 (68.6)	15 (6.9)	15 (6.9)	164 (75.9)
Do not choose to participate	21 (30.0)	55 (25.4)	60 (2.8)	50 (23.1)

Note. LAI: long-acting injectable. Because of missing or incomplete data, sum of columns may not always add up to 216.

others coming to know that they were being recruited for the study varied by race/ethnicity, $F(2, 216) = 3.98$; $p < .05$. Post-hoc analyses using the Scheffe test indicated that Asian participants were more likely to report being concerned about others coming to know that they were being recruited for the study over Black ($p < .05$) and Latinx ($p < .05$) respondents.

Comfort With Trial Parameters. The majority of participants (70.9%) believed randomization was a fair way to assign participants to groups. The majority felt comfortable providing a urine sample and getting tested for HIV every 2 months (86.1%). Of those who reported taking hormonal medications (24.5%), almost all reported being concerned about taking PrEP (either oral or LAI) while also taking hormones (91.1%). These variables did not vary by race/ethnicity or gender.

PrEP Research Benefits. Respondents indicated that benefits to research participation were potential protection from HIV infection (56.5%), access to HIV testing (52.9%), free access to PrEP (45.7%), linkage to HIV care if tested positive (41.7%), potential improvement of research on queer communities of color (40.8%), access to STI testing (39.5%), and access to condoms and lube (34.1%). There were significant differences by race/ethnicity in regard to viewing free access to PrEP, $\chi^2(2) = 3.23$; $p < .05$, and access to HIV testing, $\chi^2(2) = 6.1$; $p < .05$, as a benefit. Post hoc comparisons using the Scheffe test indicated that there were significant differences by race/ethnicity with Black respondents being significantly less likely than Latinx respondents ($p < .05$) to view free access to PrEP as a benefit or to view access to HIV testing as a benefit ($p < .05$).

Altruistic Motivations. From the total sample, 38.6% reported that they thought the study would lead to potential improvement on research on communities of color; 38.6% reported that they thought the study would lead to potential improvement on research on queer communities; and 40.8% reported that they thought the study would lead to potential improvement on research on queer communities who were also of color. None of these survey items differed by race/ethnicity or gender.

PrEP Research Risks. Barriers to research participation were short-term side effects (59.64%), long-term impacts (52.9%), discomfort or pain during blood draws (41.7%), discomfort or pain when receiving shots (41.3%), and potential loss of confidentiality (24.4%). Most participants (82.3%) reported that if they participated in the hypothetical study, they would worry about the possible side effects of taking PrEP pills for some/all of the time. In terms of side effects of the LAI PrEP shot, 80.3% said they be worried some/all of the time about side effects. Significant differences existed by race/ethnicity in regard to concerns over discomfort or pain when receiving shots, $F(2, 216) = 3.27$; $p < .05$, and concern over side effects, $F(2, 216) = 2.74$; $p < .05$. By race/ethnicity, Latinx respondents were more likely than Asian respondents to be concerned about discomfort or pain when receiving shots ($p < .05$) and were more likely to be concerned over side effects ($p < .05$).

Confidentiality Concerns. Participants reported concerns with confidentiality on a number of issues. Most were concerned about others finding out that they may test positive for HIV (68.6%). Many (59.2%) indicated that they were somewhat/very concerned about others finding out about them participating in the study. In terms

of recruitment, 121 (54.3%) indicated that they were somewhat/very concerned about others knowing that they were being recruited for the study. Additionally, 106 (47.5%) indicated that they were somewhat/very concerned that others might found out about their gender identity or sexual orientation; and 116 (52.0%) indicated that they were somewhat/very concerned about threats to their personal safety, should someone come to know that they were taking PrEP medications. Almost half (47.5%) of respondents indicated that they would be anxious if they participated in the study.

Significant differences existed by race/ethnicity in regard to concerns over potential loss of confidentiality, $F(2, 216) = 5.04$; $p < .01$. By race/ethnicity, Latinx respondents were more likely than Asian respondents to be concerned about potential loss of confidentiality ($p < .05$). Participants also varied in their comfort with being recruited at an organization that serves communities of color, $F(2, 216) = 5.10$; $p < .05$. Asian respondents were less likely to be comfortable than Black ($p < .01$) and Latinx ($p < .05$) respondents. By gender, cisgender participants were more comfortable with being recruited by a friend or colleague than transgender/GNC participants, $F(1, 215) = 4.8$; $p < .05$.

Associations Between Barriers/Facilitators and Likelihood of Research Participation

Likelihood of Participation. A total of 167 participants (74.9%) reported that they would definitely/probably participate in a LAI PrEP research trial. Specifically, 32.3% reported that they would definitely participate; 42.6% reported that they would probably participate; 18.4% reported that they would probably not participate; and 5.4% reported that they would definitely not participate. The majority of participants (91.5%) felt that the hypothetical research study would specifically serve the needs of MSM and transgender women of color. Likelihood of research participation did not significantly vary by race/ethnicity or gender.

Bivariate Correlations. Statistically significant positive bivariate correlations emerged between likelihood of participation and the following facilitators: ever having been tested for HIV, ever having been tested for an STI ever participated in HIV research, ever having heard of PrEP, comfort with taking a pill daily, comfort with providing a urine sample, and belief that randomization is fair; as well as several aspects of recruitment, namely comfort with being recruited at an organization serving communities of color, comfort with being recruited at an organization serving queer communities, and comfort with being recruited by a friend or colleague. Under barriers, statistically significant concerns were concerns that others would find out about their recruitment into the study and concerns over the side effects from the shot. Additionally, under sociodemographic variables, only being a transgender woman was significantly correlated with research participation (Table 2). In total 13 variables were significantly correlated with likelihood of research participation. Age was not found to be statistically significantly correlated at the bivariate level with likelihood of research participation, so was not included in later regression models.

Regression Analyses. From the 13 variables, two variables were highly correlated: ever having been tested for HIV and ever having been tested for STIs. We only included the variable with a stronger correlation to participation: ever having been tested for HIV. A multiple linear regression was conducted with the 12 remaining

TABLE 2. Survey Item and Bivariate Correlation With Likelihood of Participating in Hypothetical LAI PrEP Study ($N = 216$; $df = 214$)

	Mean (*SD*)	*n* (%)	Correlation
LAI Research Participation Facilitators			
Previous testing and treatment			
Ever been tested for HIV	—	187 (86.6)	–0.145*
Ever been tested for STI	—	152 (70.3)	–0.143*
Ever been treated for STI	—	43 (19.9)	–0.085
Ever participated in HIV research	—	35 (16.2)	–0.146*
Concern over HIV			
Self-reported likelihood of getting HIV[a]	2.2 (1.1)	134 (62.0)	0.092
Level of worry about getting HIV[b]	2.7 (1.1)	122 (56.5)	0.037
Comfort with trial parameters			
Previously heard of PrEP	—	161 (72.2)	0.13*
Previously taken PrEP	—	47 (21.1)	0.01
Comfort with taking a pill daily[c]	3.8 (1.2)	185 (85.7)	0.27***
Comfort with providing a urine sample	4.0 (1.3)	229 (86.1)	0.41**
Belief that randomization is fair[d]	2.9 (0.9)	154 (71.3)	0.13*
PrEP research benefits			
Potential protection from HIV infection	—	126 (56.5)	0.02
Free access to PrEP	—	102 (45.7)	0.08
Access to HIV testing	—	118 (52.9)	–0.01
Access to STI testing	—	88 (39.5)	0.09
Access to condoms/lube	—	76 (34.1)	–.09
Linkage to HIV care if test positive	—	93 (41.7)	0.08
Altruistic motivations			
Improvement of research on communities of color	—	86 (38.6)	0.06
Improvement of research on queer communities	—	86 (38.6)	0.10
Improvement of research on queer communities of color	—	91 (40.8)	0.11
Recruitment			
Comfort with being recruited at an org serving communities of color	3.4 (1.3)	170 (78.2)	0.29**
Comfort with being recruited at an org serving queer communities	3.4 (1.3)	98 (76.8)	0.34**
Comfort with being recruited by a friend or colleague	3.4 (1.3)	170 (78.2)	0.25***
LAI Research Participation Barriers			
Concerns regarding confidentiality			
Potential loss of confidentiality	—	60 (27.8)	0.01
Concern that others would find out about recruitment in study[c]	2.6 (1.3)	118 (54.6)	–0.14*
Concern that others would find out about participation in study[c]	2.8 (1.3)	132 (59.2)	–0.02
Concern that others would find out about sexual or gender identity	2.5 (1.4)	104 (48.2)	–0.06
Concern regarding threats to personal safety if someone knew they were taking PrEP	2.6 (1.3)	111 (51.3)	–0.06
LAI Research Participation Barriers			
PrEP research risks			
Discomfort/pain during blood draws	—	93 (41.7)	–0.12
Discomfort/pain during shots	—	92 (41.3)	–0.50
Concerns over possible side effects of shot	—	172 (79.6)	–0.23**
Currently taking hormones	—	56 (25.1)	0.05

Note. LAI: long-acting injectable. [a]Percentage indicates endorsement of being somewhat to extremely likely of becoming infected with HIV.[b]Worries sometimes, a lot, or all the time; [c]Somewhat to very fair; [d]Somewhat to very comfortable; [e]Somewhat to very concerned. *$p \leq .05$. **$p \leq .01$. ***$p \leq .001$.

individual items found to be significantly correlated with the likelihood of participation regressed onto the outcome of likelihood of research participation (Table 3). The regression yielded an adjusted $R^2 = 0.239$, $F(12, 203) = 6.60$, $p < .000$; Durban-Watson = 1.99, indicating that 23.9% of the variance can be explained by our multiple linear regression model. Significant beta scores in the adjusted linear regression model for the following variables continued to exert independent effects when other variables were held constant: ever participated in an HIV research study; comfort with taking a pill daily; comfort with providing a urine sample; and concerns over potential side effects of the shot.

DISCUSSION

As evidenced by our findings, racial/ethnic minorities may choose to opt out of research regarding LAI PrEP because of concerns regarding confidentiality, discomfort in providing a urine sample and concerns over side effects. As HIV disproportionally impacts people of color, it is vital to include Black, Latinx, and Asian individuals within HIV prevention research trials in order to more fully understand the unique needs of these communities.

Our findings also indicate that the needs of Asian communities to utilize LAI PrEP differ from other communities of color. This may be related to cultural distinctions regarding gender and sexuality within Asian communities and familial stress regarding stigma related to these identities. Our findings highlight that fewer Asians reported having previously been tested for HIV or STIs, as compared to Black and Latinx participants. Similarly, fewer Asian respondents reported having previously heard of PrEP. Given the heightened possibility for stigma regarding gender identity and sexual orientation within Asian communities (Calabrese et al., 2014), encouraging Asian participants to participate in research should be approached in a culturally sensitive manner, perhaps by involving Asian peer educators and locating data collection in trusted community spaces.

Confidentiality concerns were a primary barrier to likelihood of participating in this hypothetical PrEP research trial. Previous research has found that medical and institutional mistrust is a common barrier to participation in health research for people of color due to inaccurate information, language barriers, underlying biases, and fear of their legal status in the U.S. becoming known (CDC, 2020b; Katz et al., 2007; Scharff et al., 2010). As indicated in our own findings, sexual and gender minority individuals may choose not to participate in health research due to fear of being outed regarding their sexual or gender identities (Macapagal et al., 2017). Cultural and religious norms within communities of color may exacerbate the stigma experienced by individuals who are MSM or transgender/GNC, also extending to the anticipated stigma they may experience for participating in an HIV prevention research trial. Addressing these issues of confidentiality will require researchers to ensure that they have put protections in place to safeguard research participants from unintended negative consequences. Such measures may include the usage of trusted community members and institutions in helping establish rapport between researchers and participants.

Recruitment of minority populations for health research may be more successful with the involvement of community-based organizations, which may help to engage community support and instill trust in research methods and confidentiality. Community-level recruitment may be important to overcoming the barriers that prevent minority individuals from partaking in sensitive health research (Azhar et al.,

TABLE 3. Multiple Regression Model Predicting Likelihood of Research Participation

	Unstandardized coefficients				
(Constant)	B	*SE*	Standardized coefficients (β)	*t*	Significance
Transgender woman	0.150	0.152	0.062	0.977	0.330
Ever been tested for HIV	–0.134	0.209	–0.040	–0.639	0.524
Ever participated in HIV research	–0.398	0.189	–0.129	–2.101	0.037*
Previously heard of PrEP	0.037	0.164	0.015	0.225	0.822
Comfort with taking a pill daily	0.106	0.053	0.139	2.014	0.045*
Comfort with providing a urine sample	0.195	0.050	0.277	3.921	0.000***
Belief that randomization is fair	–0.025	0.057	–0.029	–0.438	0.662
Comfort with being recruited at an org serving communities of color	–0.001	0.062	–0.002	–0.021	0.983
Comfort with being recruited at an org serving queer communities	0.082	0.061	0.123	1.335	0.183
Comfort with being recruited by a friend or colleague	0.041	0.054	0.064	0.755	0.451
Concern that others would find out about recruitment in study	–0.007	0.035	–0.012	–0.187	0.852
Concerns over possible side effects of shot	–0.141	0.055	–0.167	–2.579	0.011*

SE: standard error. *$p \leq .05$. **$p \leq .01$. ***$p \leq .001$.

2021), yet needs to be coupled with concerns over protecting confidentiality within the social networks in which participants may frequently interact.

Facilitators for participation in LAI PrEP research included the potential for protection from HIV infection, access to PrEP, and access to HIV/STI testing. This may indicate that communities of color seek out services that may otherwise be unavailable to them because of insurance, cost, stigma, or location. Barriers to participation included potential for short- and long-term side effects, loss of confidentiality, and discomfort from the injection procedure. Clarifying what the research procedure entails and priming individuals to the experience of receiving the shot may assist in alleviating the anxiety that may accompany drug research trial participation. Providing education about PrEP may alleviate fears and increase overall participation in HIV research, as well as improve ultimate uptake of the biomedical intervention for wider populations. Fears concerning the protection of confidentiality should also be addressed with all potential research participants, but with Asian MSM and transgender women in particular.

Only folks who reported being assigned male sex at birth were eligible for the study. This is why eligibility criteria for the study included people who were assigned male sex at birth, but currently identified as transgender men. Previous research has demonstrated that self-reported gender identity, such as the usage of "transgender man," may not be congruent with mainstream interpretations that categorize people under this label, namely as someone who was assigned female sex at birth and now identifies as male (Azhar et al., 2021). The divergent adoption and interpretation of these labels may reflect an ambivalence or blurring of gender identities within queer

communities. Given that some of our respondents speak another language at home, this may also be a question of not understanding the way in which this term is typically used in English or may reflect a variation in how this gender identity is socially constructed across diverse communities of color.

LIMITATIONS

One of the main limitations to this survey is the usage of an online sample, which has repercussions for the external validity of findings. The usage of the Qualtrics recruitment mechanism of panels may have created selection bias by including those individuals who are more active on the survey platform and eclipsing those who are not likely to complete Qualtrics surveys at all. Given more recent developments in LAI PrEP research, our hypothetical research study vignette may not mirror the latest science regarding LAI PrEP.

Additionally, social desirability bias may influence participants to provide misinformation in regard to their sexual or drug use history, although these limitations also exist with in-person surveys. For some variables, our sample size may not have been large enough to be able to detect smaller differences across racial groups. Another limitation is that we presented a hypothetical study model in Qualtrics, which may have resulted in different attitudes than participants would have provided if they were actually participating in a research trial in real time. An additional limitation to our findings is the fact that we pooled together data from both MSM and transgender/GNC people in our sample. We agree that there is danger in combining categorical labels of sexual orientation, gender identity, and gender expression. While we did separate out these groups in our statistical analysis, we may have eclipsed some of the particular issues that are specific to each group by combining them in one sample.

IMPLICATIONS FOR HEALTH POLICY AND PRACTICE

PrEP continues to be an under-utilized resource in the U.S. (Kanny et al., 2019). Nationally, research has documented that oral PrEP has been underutilized by MSM and transgender/nonbinary people of color (Alvarez et al., 2006; Kuhns et al., 2017; Rabionet et al., 2009). Given shame and stigma of queer identities and the fear of someone potentially discovering their pills, members of communities of color may feel more comfortable with utilizing an injectable form of PrEP. The adoption of LAI PrEP may therefore have meaningful consequences for communities of color and may help reduce HIV incidence in those communities most impacted by HIV.

Health care providers and researchers must be better equipped to cater to the needs of MSM and transgender women of color in order to ensure that they feel safe in requesting information on PrEP research or PrEP usage. The protection of confidentiality remains a key concern in increasing the level of trust that participants feel in participating in health research and accessing experimental medications. Health care providers may need to receive training on cultural humility in working with MSM and transgender women of color. Greater recruitment of participants may be ensured through training researchers to maintain trust by priming participants with a strong sense of study expectations, risks, and benefits. Including minority researchers in the design and execution of HIV research can also bring a different perspective

to the manner by which health disparities are being addressed by the targeted study population (Wood et al., 2019).

Another key issue to addressing the uptake of PrEP is ensuring access. Local health departments and community-based organizations have already attempted to make oral PrEP more accessible for people of color. For example, in San Francisco, where nearly half of the residents are people of color (Horvath et al., 2019), the San Francisco City Clinic offers low to no cost PrEP services and encourages individuals to receive PrEP. For individuals who may not have insurance coverage and earn under $63,800 a year, the San Francisco City Clinic also helps residents register for programs that offer free PrEP cost coverage (U.S. Census Bureau, 2020). Even with these programs, lack of access to oral PrEP appears to remain a primary motivator for participants' likelihood of participating in a LAI PrEP research trial.

Our research findings underscore the need for more gender-affirming approaches to HIV prevention research for transgender women. As others have noted, the HIV prevention needs of transgender women and GNC people are distinct from gay and bisexual men (Kuhns et al., 2017). In bivariate correlations, transgender women were less likely to participate in an LAI PrEP research trial, although this relationship lost statistical significance in the final adjusted model. Given the heightened HIV vulnerability that transgender women of color face, better understanding the unique HIV prevention needs of this population will be pivotal to future HIV prevention efforts. As our evidence support the acceptability of LAI PrEP usage in research trials for MSM, transgender women, and gender-nonconforming people of color, patients' decisions to initiate one method over the other should still be based on their preferences, needs, and desires (San Francisco City Clinic, n.d.).

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