

RESEARCH ARTICLE

Barriers and facilitators of HIV vaccine and prevention study participation among Young Black MSM and transwomen in New York City

Sharise Richardson¹✉, Pich Seekaew²✉*, Beryl Koblin³, Tasha Vazquez³, Vijay Nandi³, Hong-Van Tieu³

1 University of Miami School of Medicine, Miami, Florida, United States of America, **2** Department of Prevention, Thai Red Cross AIDS Research Center, Bangkok, Thailand, **3** Laboratory of Infectious Disease Prevention, Lindsley F. Kimball Research Institute, New York Blood Center, New York, New York, United States of America

✉ These authors contributed equally to this work.

* pich@trcarc.org



OPEN ACCESS

Citation: Richardson S, Seekaew P, Koblin B, Vazquez T, Nandi V, Tieu H-V (2017) Barriers and facilitators of HIV vaccine and prevention study participation among Young Black MSM and transwomen in New York City. PLoS ONE 12(7): e0181702. <https://doi.org/10.1371/journal.pone.0181702>

Editor: Marcia Edilaine Lopes Consolaro, Universidade Estadual de Maringa, BRAZIL

Received: April 1, 2017

Accepted: July 4, 2017

Published: July 19, 2017

Copyright: © 2017 Richardson et al. This is an open access article distributed under the terms of the [Creative Commons Attribution License](https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

Funding: This work was supported by the National Institutes of Mental Health (NIMH) and the National Institute of Allergy and Infectious Diseases (NIAID) U.S. Public Health Service Grant UM1 AI068614 [LOC: HIV Vaccine Trials Network (HVTN)] as part of the HVTN Research and Mentorship Program (RAMP) Scholar Program (SR). The funders had

Abstract

Background

Black men who have sex with men (MSM), and Transwomen (TW) shoulder disproportionate burden of HIV. However, they are unrepresented in HIV vaccine trials. We investigated the perceptions of that factors associated with HIV vaccine trials participation among Black MSM and TW in New York.

Methods

Self-administered online questionnaires were administered to 18–29 years of NYC residents who identified as Black MSM and TW, assessing demographics, awareness and willingness to participate in HIV vaccine trials, barriers and facilitators associated with willingness, and sexual behaviors. Frequency summation was performed to determine barriers and facilitators, and logistic regression analysis was performed to determine factors association with expressed willingness.

Results

Black MSM and TW who reported engaging in risk behaviors had a 61% lower likelihood of participating in HIV vaccine trials when compared to those who did not report engaging in any risk behavior. Facilitators associated with trial participation were: cash compensation, confidentiality regarding participation, public transportation vouchers, gift cards, and food or grocery vouchers as potential facilitators for trial participation. Conversely, fear of side effects from the vaccine, concerns about testing positive on routine HIV testing due to an HIV vaccine, limited knowledge of research trials, and fear of being judged as HIV-positive were perceived as barriers.

no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared no competing interests exist.

Conclusions

These findings provided insights into the considerations and perceptions of Black MSM and TW towards HIV vaccine trials. However, further studies are needed to delineate the complex mechanisms underlying the decision-making process and establish approaches to increase study participation in this population.

Introduction

Men who have sex with men (MSM) and Transgender Women (TW) have been disproportionately affected by the HIV/AIDS epidemic. In 2014 MSM accounted for 83% of all HIV incidence in men and 67% of all HIV incidence in the U.S. Black MSM (BMSM) comprised the largest number of new diagnoses [1] (CDC 2014). Despite an increase in new diagnoses among overall BMSM, young BMSM (aged 13–24) experienced only a slight decline of 2% in new diagnoses since 2010 [2]. TW have also shouldered a large portion of the HIV burden in the U.S. [3] [4]. In a meta-analysis, Herbst et al found that approximately 27% of TW were HIV-infected at study initiation and 12% self-reported having HIV [4]. Moreover, Black TW had higher rates of HIV infection, with 56% being newly diagnosed and 30% self-reporting being HIV-positive [4].

Current state of HIV prevention research

Due to the staggering HIV infection rates in BMSM and TW in the US, HIV prevention measures targeted at these populations are important. The use of antiretroviral drugs to prevent HIV acquisition is a key approach. Pre-Exposure Prophylaxis (PrEP) with the use of daily oral emtricitabine /tenofovir disoproxil fumarate has shown to reduce the risk of HIV acquisition by 86% [5]. However, limited long-term safety information, and issues with drug adherence have prompted research looking into alternative oral agents, long-acting injectable formulations and intermittent dosing schedules for oral PrEP [6, 7].

Despite many vaccine trials conducted, six vaccine regimens have made it to clinical efficacy trials [7,8]. The RV144 trial conducted in Thailand was the first to show a reduction in HIV acquisition [9]. Although not demonstrated in the RV144 trial, one potential consequence of receiving vaccines is Vaccine-Induced Sero-Positivity (VISP), which results in false positive to standard HIV serologic tests [10]. This could present several challenges, including disruption of personal relationships and difficulties in obtaining life insurance [10], which could lead to a reluctance to participate in preventive HIV vaccine trials [10, 11].

Minority participation and population targeted recruitment efforts

Though disproportionately affected by HIV, Blacks have been underrepresented in HIV treatment trials [12]. Insufficient representation of young BMSM and TW in HIV prevention trials may minimize the effort in curtailing HIV epidemic, as the results from such trials would limit the generalizability to these populations. Thus, it is imperative to assess factors that contribute to a low participation in HIV vaccine trial.

We conducted an online survey to assess awareness and perceptions of young BMSM and TW in New York City (NYC) in regards to participating in HIV biomedical intervention research studies.

Methods

Recruitment, eligibility, and reimbursement

Eligibility was defined as: self-identify as male, between the ages of 18 and 29, resident in NYC, self-report of anal sex with a man in the past 6 months (insertive and/or receptive), self-identify as Black/African-American, and self-report being HIV-negative. Participants were recruited using banner advertisement placed on several websites (Facebook, Ronaldmatters, Grindr, BGC, and Mused Magazine) frequented by young BMSM and TW living in NYC. Participants were reimbursed with a \$30 Amazon.com gift card upon completion of the survey. The study was approved by the New York Blood Center Institutional Review Board (IRB: 543398).

Survey components

Prescreener and main survey questionnaire overview. Participant eligibility and demographics (age, race/ethnicity, gender and sexual identity) were ascertained by an 8-question prescreening questionnaire that was linked to the banner advertisements ([S1 File](#)). Participants who were eligible and who indicated interest in participating were automatically redirected to the main study questionnaire on SurveyGizmo ([S2 File](#)). The average time to complete the main questionnaire was 21 minutes. No personal identifying information was collected. To preserve the integrity of the questionnaire, responses were limited to one person per IP address. The main study survey consisted of 6 sections: demographics, awareness of HIV prevention approaches, willingness to participate (WTP) in HIV vaccine trials, barriers and facilitators to participating in HIV vaccine trials, and sexual behaviors.

Participant age, race/ethnicity, gender, and sexual identity were asked of participants on the online eligibility prescreening questionnaire. In order to protect participant identification, data on the online prescreening questionnaire including sexual identity and age were not linked with the main questionnaire and thus were not available for analysis.

Demographics. The demographics section contained 10 questions including level of education, annual personal income, religion, Hispanic ethnicity, employment, place of birth, usual place of medical care and date of last HIV test.

Awareness of HIV prevention approaches. We asked participants if they had ever heard of HIV vaccine research and VISPs, participated in HIV vaccine trials, and whether they knew anyone else who has participated in an HIV vaccine trial. We also assessed awareness of PEP and PrEP as well as PrEP trials, use of PEP and PrEP and participation in PrEP trials.

Willingness to participate in HIV vaccine trials. After showing educational information on HIV vaccine trials, participants were asked about their WTP in HIV vaccine trials. Responses were collected on a 4-point Likert scale (not willing, minimally willing, moderately willing, and very willing), and were dichotomized (not willing to participate and willing to participate) for analysis.

Barriers and facilitators to participate in HIV vaccine trials. The facilitators were obtained from the questionnaire "Please rate the importance of the following items in terms of what would make your participation in a research trial easier or harder." The choices were: private transportation to and from appointments, public transportation (bus, metro) vouchers, cash compensation for time, food or grocery vouchers, gift cards, referrals for other community services, condoms and dental dams, hygiene kits (toothbrush, toothpaste, bleach, soaps, shampoo, etc.), clothing, weekday morning study visits, weekday evening study visits, weekend study visits, going to a site close to home, confidentiality regarding participation, other commitments (work, family, etc.), child care or reimbursement for cost of child care.

The barriers were obtained from the questionnaire “What would prevent you from participating in an HIV vaccine trial? (Mark all that apply).” The choices were: access to study site, fear of being judged as HIV positive, fear of being judged of being at risk for HIV infection, fear of being judged for being gay, fear of testing false positive on routine HIV testing, limited knowledge of research trials, fear of needles and injections, fear of side effects from the vaccine, fear of being discriminated against because of race, fear of being discriminated against because of age, nothing: I would be willing to participate.”

Sexual behaviors. We asked participants if they ever received or given money, drugs, gifts or services in exchange for sex in the last 12 months, diagnosed with sexually transmitted infections (STIs) (gonorrhea, chlamydia, syphilis) in the past 12 months, and used drugs (injectable drugs, cocaine, methamphetamine/amphetamine) in the past 12 months. Additionally, we asked the participants regarding their sexual position(s) (insertive, receptive) and if they used condoms in the past 6 months

Statistical analysis

Frequencies of demographic and behavioral characteristic responses were described via univariate logistic regression analyses through TABULATE command in Stata Version 14.0 for Mac (StataCorp 1985–2015, College Station, Texas).

The facilitators and barriers were determined by calculating the sum of frequency of all the choices, and the 5 factors with the highest frequencies were selected.

The primary outcome was WTP in HIV vaccine trials. The outcome was dichotomized into “willing to participate” (participants who responded “moderately willing” and “very willing” to participate in HIV vaccine trials were) and “not willing to participate” (participants who responded “not willing” and “minimally willing” to participate in HIV vaccine trials).

Participants were assigned a Risk Score (RS) of 1 if they had responded yes to one or two of the following five risk behaviors: received money, gifts, drugs for sex; gave money, gifts, or drugs for sex; STIs in past 12 months; any condomless receptive anal intercourse (RAI) in the past 6 months; and any condomless insertive anal intercourse (IAI) in the past 6 months. Those with three or more of the risk behaviors were assigned a RS of 2, the maximum possible RS. Those without any of the risk behaviors were assigned a RS of 0.

Bivariate logistic regression analyses were conducted to determine specific variables that were significantly associated with the outcome (WTP in HIV vaccine trials) using Pearson’s Chi-square test or Fisher’s Exact test among those who reported not having ever participated in HIV vaccine trials in the past. Demographic and behavioral variables that were considered for inclusion were the following: education, employment status, income, place of birth, religion, usual place of medical care, last HIV test, risk behaviors, PrEP usage in the past, PEP usage in the past, and past research participation. Variables with $p < 0.05$ were considered significantly associated with the outcome and entered into the multivariable logistic regression model. Collinearity between each significant variable was assessed using Pearson’s Chi-square and Fisher’s Exact test, and the Hosmer and Lemeshow’s goodness of fit test was used to evaluate fit of the final model. All statistical analyses were evaluated for statistical significance at $\alpha = 0.05$, using two-sided tests and performed using Stata Version 14.0 for Mac (StataCorp 1985–2015, College Station, Texas).

Results

Population demographics and characteristics

A total of 192 completed the prescreener questionnaire, of whom 45% ($N = 85$) were between the ages of 18–23, 54.5% ($N = 103$) were between 24 and 29, and 0.5% ($N = 1$) was older than

Table 1. Sociodemographics, risk behaviors and past research experience (N = 189).

	N(%)	
Age		
18–23	85(45.0)	
24–29	103(54.5)	
30	1(0.5)	
Ethnicity		
Hispanic African-American	74(39.2)	
Non-Hispanic African-American	115(60.8)	
Education		
Less than high school diploma	12(6.3)	
High school diploma	30(15.9)	
College or higher	147(77.8)	
Employment		
Working full-time	110(58.2)	
Working part-time	38(20.1)	
Not working	41(21.7)	
Annual Income		
Less than \$10,000	41(21.7)	
\$10,000–19,999	30(15.9)	
\$20,000–39,999	64(33.9)	
\$40,000 or more	54(28.6)	
Place of Birth		
United States (U.S.)	172(91.0)	
Non-U.S.	17(9.0)	
Religion		
Christian	149(78.8)	
Non-Christian	40(21.2)	
Usual Place of Medical Care		
Private doctor	121(64.0)	
Health department/ER ^a	36(19.1)	
Community clinic	32(16.9)	
Last HIV Test		
Less than 6 months	151(79.9)	
More than 6 months or never	38(20.1)	
Risk Behaviors		
Received money, gifts, drugs for sex in the past 12 months	26(13.8)	
Gave money, gifts or drugs for sex in the past 12 months	10(5.3)	
STIs in past 12 months	24(12.7)	
Condomless anal intercourse in past 6 months		
	Any Condomless RAI ^b	
	Yes	50(47.17)
	No	56(52.83)
	Any Condomless IAI ^c	
	Yes	55(47.83)
	No	60(52.17)
Risk Score		
1. 0	67(43.2)	
2. 1	80(51.6)	

(Continued)

Table 1. (Continued)

	N(%)
3.2	8(5.2)
Expressed Willingness to Participate in HIV Vaccine Trials	
Not willing	26(13.8)
Minimally willing	52(27.5)
Moderately willing	38(20.1)
Very willing	73(38.6)

^a ER: Emergency Room

^b RAI: Receptive anal intercourse

^c IAI: Insertive anal intercourse

<https://doi.org/10.1371/journal.pone.0181702.t001>

29. 189 participants were enrolled from April to June 2014 with 39.2% identifying as Hispanic (Table 1). Most of the participants were born in the U.S. (N = 172; 91.0%) and identified as Christian (N = 149; 78.8%). Over three-quarters (N = 147; 77.8%) had a college degree or higher, 58.2% (N = 110) of the participants worked full-time, and 33.9% (N = 64) reported having an annual income between \$20,000 and \$39,999. Most (N = 121; 64%) cited their private doctor as their place for usual medical care, while others reported going to the health department/emergency room (ER) (N = 36; 19.1%) for care.

79.9% (N = 151) of the participants reported having been tested for HIV within the last 6 months. A small proportion of the participants engaged in high-risk behaviors in the last 12 months, including receiving money, gifts, drugs for sex (N = 26; 13.8%); giving money, gifts, drugs for sex (N = 10; 5.3%); having been diagnosed with STIs in the past 12 months (N = 24; 12.7%). Furthermore, 47.2% (N = 50) and 47.8% (N = 55) of the participants reported engaging in condomless RAI and condomless IAI, respectively. Based on our analysis, 51.6% (N = 80) and 5.2% (N = 8) of the participants had a RS of 1 and 2, respectively. However, 43.2% (N = 67) had a RS of 0 (Table 1).

HIV biomedical trials awareness and experiences

Almost three-quarter of the participants reported having heard of HIV vaccine trials (N = 141; 74.6%); only 8 (5.7%) of those ever participated in any of the HIV vaccine trials (Table 2). Six of those 8 reported good to excellent experience when enrolled in the trial. Only a small fraction (N = 18; 9.5%) reported knowing anyone who has participated in HIV vaccine trials.

Table 2. Knowledge and awareness of HIV vaccine and other biomedical prevention trials.

	Yes(%)
Ever heard of HIV vaccine trials (n = 184)	141(74.6)
Ever participated in any HIV vaccine trials (n = 141)	8(5.7)
Know anyone who has participated in HIV vaccine trials (n = 189)	18(9.5)
Ever heard of vaccine-induced seropositivity (n = 178)	36(20.2)
Ever heard of PEP (n = 186)	92(49.5)
Ever used PEP (n = 92)	11(12.0)
Ever heard of PrEP (n = 186)	113(60.8)
Ever used PrEP (n = 113)	14(12.4)
Ever heard of PrEP trials (n = 113)	28(24.8)
Ever participated in any PrEP trials (n = 113)	10(8.9)

<https://doi.org/10.1371/journal.pone.0181702.t002>

When assessing PrEP and PEP awareness, 60.8% (N = 113) had heard of PrEP, while 49.5% (N = 92) had heard of PEP. Of those reported having heard of PrEP and PEP, only 12.4% (N = 14) and 12% (N = 11) had ever used PrEP and PEP, respectively. Among PrEP users (N = 14), 10 (71.4%) had a RS \geq 1. Among PEP users (N = 11), 10 (90.9%) had a RS \geq 1. For former PrEP trial participants (N = 10), half reported having good to excellent experience, while half reported having only a fair experience.

Factors associated with willingness to participate in HIV vaccine trials

In the bivariate analysis, we found significant association between WTP in HIV vaccine trials and demographic characteristics (education, employment, annual income, place of birth, religion, usual place of medical care) (Table 3). However, none of the risk behaviors, when calculated as a singular factor, were significantly associated with the outcome; only RS was found to be significant. Multivariable logistic regression analysis found that participants reported they would be less willing to participate in HIV vaccine trials (Table 3) if they had a Risk Score of 1 (OR = 0.39; $p = 0.009$) compared to a Risk Score of 0. We found no association between WTP in HIV vaccine trials and education, employment status, religion, income, place of birth, usual place of medical care, last HIV test, PrEP or PEP usage, and past HIV vaccine research participation (Table 3).

Barriers and facilitators

Cash compensation, confidentiality regarding participation, public transportation vouchers, gift cards, and food or grocery vouchers were ranked highest as facilitators when considering participating in biomedical prevention trials (Table 4). The most common barriers were the following: fear of side effects from the vaccine, VISP, limited knowledge of research trials, and fear of being judged as HIV-positive. Interestingly, 37.6% (N = 71) reported that they had no barriers that would prevent them from participating in the HIV vaccine trials. Among those with no barriers, 90.1% (N = 64) had heard of HIV vaccine trials, but only 6.3% of these (N = 4) had ever participated in HIV vaccine trials (Data not shown).

Discussion

58.7% of the participants were willing to participate in HIV vaccine trials, which is comparable to previous studies conducted in young adults in Tanzania and MSM in India (50.6% and 48.1%, respectively) [13, 14], but lower than the 76.7% observed in China [15]. This number is slightly higher than the 46% reported in a study conducted in 3 U.S. cities. However, the population in the study was broadly recruited and included injecting drug users and MSM, while this study focused only on BMSM and TW [16].

Our results differed from those of past studies, which have shown high-risk MSM were more likely to express WTP in HIV vaccine trials than lower risk MSM. Our study included only young MSM and TW aged from 18–30 years, whereas the median age for the other studies was higher: participants in studies conducted by Newman et al. at two sites in the U.S. had a median age of 33 and 37 years. Additionally, the study populations were both male and female, and did not exclusively focus on MSM and TW [15, 17, 18]. Another study with contradictory results was among the Thai Army who were male and aged between 21–29, suggesting higher willingness among high-risk individuals to participate in HIV vaccine trials when compared to those with lower risk [19]. Therefore, it is worth exploring whether high-risk young BMSM and TW face unique challenges, such as gender-affirming care settings, and a lack of legal protections for human rights, that deter them from engaging in trials [20, 21]. A

Table 3. Factors associated with Willingness to participate in HIV vaccine trials among those who have not participated in HIV vaccine trials in the past (N = 189) and multivariable logistic regression examining the association between willingness to participate in HIV vaccine trials and sociodemographic characteristics and risk score (N = 155).

		Not willing to participate (N = 78) N (%)	Willing to participate (N = 111) N (%)	P-value	OR (95% CI)	P-value
Education						
				0.02		
	Less than high school diploma	7(58.3)	5(41.7)		Reference	Reference
	High school diploma	18(60.0)	12(40.0)		0.67(0.15–3.08)	0.61
	College or higher	53(36.1)	94(63.9)		1.51(0.38–5.96)	0.56
Employment						
				0.001		
	Working full-time	33(30.0)	77(70.0)			
	Working part-time	24(63.2)	14(36.8)			
	Not working	21(51.2)	20(48.8)			
Annual Income						
				<0.001		
	Less than \$10,000	21(51.2)	20(48.8)			
	\$10,000–19,999	21(70.0)	9(30.0)			
	\$20,000–39,999	21(32.8)	43(67.2)			
	\$40,000 or more	15(27.8)	39(72.2)			
Place of Birth						
				0.04		
	United States	67(38.9)	105(61.1)		1.75(0.57–5.36)	0.33
	Non-U.S.	11(64.7)	6(35.3)		Reference	Reference
Religion						
				0.007		
	Christian	54(36.2)	95(63.8)			
	Non-Christian	24(60.0)	16(40.0)			
Usual Place of Medical Care						
				0.02		
	Private doctor	41(33.9)	80(66.1)			
	Health department/ER ^a	21(58.3)	13(41.7)			
	Community clinic	16(50.0)	16(50.0)			
Last HIV Test						
				0.05		
	Less than 6 months	57(37.8)	94(62.3)		1.16(0.52–2.60)	0.71
	More than 6 months/never	21(55.3)	17(44.7)		Reference	Reference
Risk Behaviors						
				0.33		
	Exchange money, gifts, drugs for sex in the past 12 months	13(50.0)	13(50.0)			
	Gave money, gifts or drugs for sex in the past 12 months	6(60.0)	4(40.0)	0.32*		
	STIs in past 12 months	13(54.2)	11(45.8)	0.17		
	Condomless anal intercourse in past 6 months					
	Any condomless RAI ^b			0.85*		
	Yes	24(48.0)	26(52.0)			
	No	25(44.6)	31(55.4)			
	Any condomless IAI ^c			0.19*		
	Yes	31(56.4)	24(43.6)			
	No	26(43.3)	34(56.7)			

(Continued)

Table 3. (Continued)

		Not willing to participate (N = 78) N (%)	Willing to participate (N = 111) N (%)	P-value	OR (95% CI)	P-value
Risk Score				0.01		
1. 0		22(32.8)	45(67.2)		Reference	Reference
2. 1		45(56.2)	35(43.8)		0.39(0.19–0.79)	0.01
3. 2		5(62.5)	3(37.5)		0.37(0.08–1.84)	0.23
PrEP^d or PEP^e Usage Ever In the Past						
	PrEP			1.00		
	Yes	5(35.7)	9(64.3)			
	No	33(33.3)	66(66.7)			
	PEP			0.34*		
	Yes	4(36.4)	7(63.6)			
	No	45(55.6)	36(44.4)			
Past Research Participation						
	HIV vaccine trials			0.26*		
	Yes	1(12.5)	7(87.5)			
	No	48(36.1)	85(63.9)			

(*) = Fisher’s Exact Test

^a ER: Emergency Room

^b RAI: Receptive anal intercourse

^c IAI: Insertive anal intercourse

^d PrEP: Pre-Exposure Prophylaxis

^e PEP: Post-Exposure Prophylaxis

<https://doi.org/10.1371/journal.pone.0181702.t003>

prior study indicated that PrEP awareness was associated with previous history of STIs [22]; however, this association was not observed in our study.

We found that three-quarters of young BMSM and TW in our study were aware of HIV vaccine trials, but only 5.7% ever participated. This may be due to the fact that only 9.5% knew

Table 4. Barriers and facilitators to HIV vaccine trial participation (N = 189).

	N(%)
Top 5 Facilitators	
Cash compensation for my time	142(75.1)
Confidentiality regarding my participation	122(64.6)
Public transportation vouchers	121(64.0)
Gift cards	110(58.2)
Food or grocery vouchers	96(50.8)
Top 5 Barriers	
Fear of side effects from the vaccine	84(44.4)
Nothing	71(37.6)
Fear of testing false positive on routine HIV testing	57(28.0)
Limited knowledge of research trials	53(28.0)
Fear of being judged as HIV positive	43(22.8)

<https://doi.org/10.1371/journal.pone.0181702.t004>

someone who had participated in the HIV vaccine trials, limiting referral among the participants and their social networks. Earlier studies noted the importance of familial and social support on HIV vaccine trials participation [14, 15].

Our study showed that cash compensation, confidentiality regarding participation, public transportation vouchers, gift cards, and food or grocery vouchers were top facilitating factors for participating in HIV vaccine trials. Our findings were similar to those found in studies conducted in China and Thailand, which had determined that financial incentives were associated with HIV vaccine participation [15, 19]. Since cash compensation was a significant factor for this population [15, 19], our result may indicate that young BMSM experienced financial insecurity. Conversely, we found that fear of side effects from the vaccine, false positive results on routine HIV testing, limited knowledge of research trials, and fear of being judged as HIV positive were perceived as barriers, which also echoed in other studies as major [23, 24]. This suggests that more education should be conducted to young BMSM and TW communities about HIV vaccine trials with full discussion of side effects and VISP. Coupled with what previous studies suggested regarding social support, it may also be beneficial if the studies are constructed based on a referral system, with financial incentives.

Another possible reason underlying low enrollment of BMSM and TW in research studies may be due to historical precedence, thus it may be valuable to explore social constructs around racial issues related to biomedical research. While it is important to educate and inform potential research participants, it is imperative to provide social and psychological support as previous studies suggested that these are important components that are highly correlated with WTP [14, 15]. A recent HPTN 073 showed that a theory-based, culturally tailored programs for Black MSM, such as counseling, led to high uptake (79% at week 0 and 68% at 26 weeks) as well as high adherence (85% at 4 weeks and 78% at 26 weeks) to PrEP [25].

This study has several limitations. There is a lack of generalizability to BMSM and TW in other metropolitan or rural areas, as well as races, ethnicities, and age. Additionally, we did not stratify BMSM and TW for our analyses, thus we could not capture specific risks and results for each group. Moreover, the WTP is based on a hypothetical setting, thus the findings may not accurately apply to actual trials. [26] Furthermore, due to the small sample size, the power of the results is limited. Also, the data may be subject to self-reporting bias, though the online survey system should limit this bias.

Nevertheless, our findings revealed factors that could enhance enrollment of young BMSM and TW in HIV vaccine trials. Future studies should investigate factors such as cultural-social barriers, and ways to expand study participation through social support and peer referrals. Furthermore, qualitative studies are important to understand complex mechanisms that online questionnaire are unable to capture, which could contribute to or contradict our findings with regard to why lower risk individuals were more willing to participate in HIV vaccine trials than their high-risk counterparts.

Conclusion

Young Black MSM and transwomen have been disproportionately burdened by the HIV epidemic, and the generalizability from the results of biomedical prevention studies may be compromised due to the lack of their enrollment. This study examined the key factors as well as risk characteristics that influenced young Black MSM and TW in NYC on HIV vaccine trial participation, aiming to find potential ways to enhance the involvement of Black MSM and TW community in HIV vaccine trials. We found that low-risk persons were much more likely to express willingness to participate in HIV vaccine trials when compared to high-risk persons, and our results also indicated that financial incentives could potentially increase the

enrollment in in such studies. Caution may be advised if monetary reimbursement serves as an undue influence. Additionally, more efforts should be invested in creating referral system and supportive environment to increase the engagement of Black MSM and transwomen in HIV vaccine research trials.

Supporting information

S1 File. Prescreener questionnaire.

(PDF)

S2 File. Main survey.

(PDF)

Acknowledgments

The authors would like to thank Philipp Mann, Mary Allen, Kathy Mngadi, Kennedy Ot wombe and Michele Andrasik for the thorough comments and revisions of this paper.

Author Contributions

Conceptualization: Sharise Richardson, Hong-Van Tieu.

Data curation: Sharise Richardson, Pich Seekaew, Tasha Vazquez, Hong-Van Tieu.

Formal analysis: Pich Seekaew.

Funding acquisition: Sharise Richardson, Hong-Van Tieu.

Investigation: Sharise Richardson, Hong-Van Tieu.

Methodology: Sharise Richardson, Beryl Koblin, Tasha Vazquez, Vijay Nandi, Hong-Van Tieu.

Project administration: Vijay Nandi.

Resources: Beryl Koblin, Hong-Van Tieu.

Supervision: Beryl Koblin, Vijay Nandi, Hong-Van Tieu.

Validation: Beryl Koblin, Hong-Van Tieu.

Writing – original draft: Sharise Richardson, Pich Seekaew.

Writing – review & editing: Pich Seekaew, Beryl Koblin, Hong-Van Tieu.

References

1. Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2015. HIV Surveillance Report 2016 December 2016; 17: 4. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html> Accessed January 26, 2017.
2. Purcell DW, Johnson CH, Lansky A, Prejean J, Stein R, Denning P, et. al. Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. *Open AIDS J.* 2012; 6:98–107. <https://doi.org/10.2174/1874613601206010098> PMID: 23049658
3. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *Lancet Infect Dis.* 2013; 13(3):214–222. [https://doi.org/10.1016/S1473-3099\(12\)70315-8](https://doi.org/10.1016/S1473-3099(12)70315-8) PMID: 23260128
4. Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepz N. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS Behav.* 2008; 12(1):1–17. <https://doi.org/10.1007/s10461-007-9299-3> PMID: 17694429

5. McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure Prophylaxis to Prevent the Acquisition of HIV-1 Infection (PROUD): Effectiveness Results from the Pilot Phase of a Pragmatic Open-label Randomised Trial. *Lancet*. 2016; 387(10013): 53–60. [https://doi.org/10.1016/S0140-6736\(15\)00056-2](https://doi.org/10.1016/S0140-6736(15)00056-2) PMID: 26364263
6. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *N Engl J Med*. 2011; 365(6):493–505. <https://doi.org/10.1056/NEJMoa1105243> PMID: 21767103
7. Saunders KO, Rudicell RS, Nabel GJ. The design and evaluation of HIV-1 vaccines. *AIDS*. 2012; 26(10):1293–1302. <https://doi.org/10.1097/QAD.0b013e32835474d2> PMID: 22706011
8. Hammer SM, Sobieszczyk ME, Janes H, Karuna ST, Mulligan MJ, Grove D, et al. Efficacy trial of a DNA/rAd5 HIV-1 preventive vaccine. *N Engl J Med*. 2013; 369(22):2083–2092. <https://doi.org/10.1056/NEJMoa1310566> PMID: 24099601
9. Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, Kaewkungwal J, Chiu J, Paris R, et al. Vaccination with ALVAC and AIDSVAX to prevent HIV-1 infection in Thailand. *N Engl J Med*. 2009; 361(23):2209–2220. <https://doi.org/10.1056/NEJMoa0908492> PMID: 19843557
10. Voronin Y, Zinszner H, Karg C, Brooks K, Coombs R, Hural J, et al. HIV Vaccine- Induced Sero-Reactivity: a Challenge for Trial Participants, Researchers, and Physicians. *Vaccine*. 2015; 33(10):1243–9. <https://doi.org/10.1016/j.vaccine.2014.10.040> PMID: 25649349
11. Khurana S, Needham J, Park S, Mathieson B, Busch M, Nemo G, et al. Novel Approach for Differential Diagnosis of HIV Infections in the Face of Vaccine-Generated Antibodies: Utility for Detection of Diverse HIV-1 Subtypes. *J Acquir Immune Defic Syndr*. 2006; 43(3): 304 <https://doi.org/10.1097/01.qai.0000242465.50947.5f> PMID: 17019363
12. Castillo-Mancilla JR, Cohn SE, Krishnan S, Cespedes M, Foris-Moore M, Schulte G, et al. Minorities Remain Underrepresented in HIV/AIDS Research Despite Access to Clinical Trials. *HIV Clin Trials*. 2015; 15(1): 14–26
13. Mbunda T, Bakari M, Tarimo EAM, Sandstrom E, Kulane A. Factors That Influence the Willingness of Young Adults in Dar Es Salaam, Tanzania, to Participate in Phase I/II HIV Vaccine Trials. *Glob Health Action*. 2014; 7: 22853
14. Newman PA, Chakrapani V, Weaver J, Shunmugam M, Rubincam C. Willingness to Participate in HIV Vaccine Trials among Men Who Have Sex with Men in Chennai and Mumbai, India. *Vaccine*. 2014; 32(44): 5854–861. <https://doi.org/10.1016/j.vaccine.2014.08.043> PMID: 25173475
15. Chu Z, Xu J, Reilly KH, Lu C, Hu Q, Ma N, et al. HIV Related High Risk Behaviors and Willingness to Participate in HIV Vaccine Trials among China MSM by Computer Assisted Self-Interviewing Survey. *Biomed Res Int*. 2013
16. Strauss RP, Sengupta S, Kegeles S, McLellan E, Mertzger D, Eyre S, et al. Willingness to Volunteer in Future Preventive HIV Vaccine Trials: Issues and Perspectives From Three U.S. Communities. *J Acquir Immune Defic Syndr*. 2001; 26(1): 63–71. PMID: 11176270
17. Newman PA, Duan N, Rudy ET, Roberts KJ Swendeman D. Posttrial HIV Vaccine Adoption: Concerns, Motivators, and Intentions Among Persons at Risk For HIV. *J Acquir Immune Defic Syndr*. 2004; 37(3): 1393–403. PMID: 15483469
18. Newman PA, Lee SJ, Duan N, Rudy E, Nakazono TK, Boscardin J, et al. Preventive HIV Vaccine Acceptability and Behavioral Risk Compensation among a Random Sample of High-Risk Adults in Los Angeles (LA VOICES). *Health Serv Res*. 2009; 44(6): 2167–179. <https://doi.org/10.1111/j.1475-6773.2009.01039.x> PMID: 19780857
19. Jenkins RA, Torugsa K, Markowitz L, Mason C, Jamroentana V, Brown A, et al. Willingness to Participate in HIV-1 Vaccine Trials among Young Thai Men. *J Sex Transm Dis*. 2000; 76(5): 386–92.
20. Poteat T, Wirtz AL, Radix A, Borquez A, Silva-Santisteban A, Deutsch MB, et al. HIV Risk and Preventive Interventions in Transgender Women Sex Workers. *Lancet*. 2015; 385(9964):274–86. [https://doi.org/10.1016/S0140-6736\(14\)60833-3](https://doi.org/10.1016/S0140-6736(14)60833-3) PMID: 25059941
21. Wansom T, Guadamuz TE, Vasan S. Transgender Populations and HIV: Unique Risks, Challenges and Opportunities. *J Virus Erad*. 2016; 2(2):87–93. PMID: 27482441
22. Bauermeister J, Meanley S, Pingel E, Soler JH, Harper GW. PrEP Awareness and Perceived Barriers Among Single Young Men Who Have Sex with Men. *Curr HIV Res*. 2014; 11(7): 520–27.
23. Newman PA, Daley A, Halpenny R, Loutfy M. Community Heroes or “high-risk” Pariahs? Reasons for Declining to Enroll in an HIV Vaccine Trial. *Vaccine*. 2008; 26(8): 1091–097. <https://doi.org/10.1016/j.vaccine.2007.12.016> PMID: 18237829
24. Dhalla S, and Poole G. Barriers of Enrolment in HIV Vaccine Trials: A Review of HIV Vaccine Preparedness Studies. *Vaccine*. 2011; 29(35): 5850–859. <https://doi.org/10.1016/j.vaccine.2011.06.055> PMID: 21740947

25. Wheeler DP, Fields S, Nelson LE, Wilton L, Hightow-Weidman L, Shoptaw S. HPTN: 073 PrEP Uptake and Use by Black Men Who Have Sex With Men in 3 US Cities. CROI 2016
26. Buchbinder SP, Metch B, Holte SE, Scheer S, Coletti A, Vittinghoff E. Determinants of Enrollment in a Preventive HIV Vaccine Trial. *J Acquir Immune Defic Syndr*. 2004; 36(1): 604–12. PMID: [15097304](https://pubmed.ncbi.nlm.nih.gov/15097304/)