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Uptake, Retention, and Adherence to Pre-exposure Prophylaxis (PrEP) in TRIUMPH: A Peer-Led PrEP Demonstration Project for Transgender Communities in Oakland and Sacramento, California

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Background: TRIUMPH (Trans Research–Informed communities United in Mobilization for the Prevention of HIV) was a community-led, transgender-specific pre-exposure prophylaxis (PrEP) demonstration project at 2 community-based clinical sites in California. TRIUMPH used peer health education, community mobilization, and clinical integration of PrEP with hormone therapy to promote PrEP knowledge and acceptability. The goal of this study was to evaluate PrEP uptake, retention, and adherence among TRIUMPH participants and examine site-based differences.

Methods: Eligible participants were adult transgender and gender diverse people interested in PrEP. Participants were seen at baseline and at 1, 3, 6, 9, and 12 months for PrEP provision, clinical visits, and HIV testing. PrEP uptake was defined as dispensation of PrEP, PrEP retention was defined as proportion of expected visits completed among those who initiated PrEP, and PrEP adherence was assessed by measuring tenofovir diphosphate concentrations in dried blood spots. Logistic regression models quantified the association of variables with PrEP outcomes.

Results: TRIUMPH enrolled 185 participants; the median age was 28 years (interquartile range: 23–35), 7% was Black, and 58% was Latinx. PrEP uptake was as follows: 78% in Oakland and 98% in Sacramento; 91% among trans women, 96% among trans men, and 70% among nonbinary participants. Almost half (47%) rarely/never believed about HIV, and 42% reported condomless sex act in the past 3 months. Participants who reported higher numbers of sex partners were more likely to be retained and adherent; other predictors of adherence included not having a primary partner and not experiencing violence in the past 3 months.

Conclusions: This community-led, trans-specific PrEP demonstration project documents high levels of PrEP initiation in a young transgender and gender diverse cohort at risk of HIV acquisition.

Key Words: transgender, pre-exposure prophylaxis, HIV prevention, PrEP adherence, PrEP uptake

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INTRODUCTION

Transgender ("trans") women (individuals with a feminine and/or female gender identity who were assigned male sex at birth) are disproportionately affected by HIV; prevalence and incidence rates for trans women are demonstrated to be among the highest of all risk groups.[1] In the United States, the odds of HIV among trans women was found to be 34-fold higher than the general population.[2] Although the estimated HIV prevalence for adults in the United States is less than 0.5%, an estimated 9.2% of trans people is living with HIV; 14.1% is trans women and 3.2% is trans men.[3] Trans women of color, particularly Black and Latina trans women, experience an extremely high burden of HIV; more than half of trans people diagnosed with HIV are Black (44%) and/or Hispanic/Latinx (26%).[4]

Pre-exposure prophylaxis (PrEP) is a highly effective HIV prevention method when taken as prescribed.[5] However, several studies have reported low rates of PrEP awareness and uptake among trans people. A probability sample of sexually active trans people in the United States found low rates of current PrEP use (3%).[6] Respondents who were transfeminine (individuals assigned male sex at birth but do not identify as men) were less likely to be familiar with PrEP than those who were transmasculine (individuals assigned female sex at birth but do not identify as women); most (72%) reported favorable attitudes toward PrEP.[6] In a recent survey of HIV-negative transgender people in the United States, 17.4% reported ever receiving a PrEP prescription, trans men reported higher PrEP use than trans women, and PrEP discontinuation was reported by 49% of those who reported PrEP use.[7] PrEP uptake was higher among trans men than trans women in some studies,

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although uptake remains suboptimal among trans men considering the level of HIV risk reported.[7,8]

Barriers to PrEP use among trans people include competing life priorities, intersectional stigma (including HIV-related stigma and gender-related stigma), which often results in health care avoidance, and concerns about negative drug–drug interactions between PrEP and hormones.[8–11] Furthermore, there has been a long history of erasure of trans individuals and gender diverse (individuals who identify with a gender other than cisgender male or cisgender female) people in HIV prevention research and programming.[12] Historically, trans women have been subsumed under the behavioral risk group "men who have sex with men (MSM)," obscuring their unique risks and prevention needs and hindering our understanding of accurate prevalence and incidence rates globally.[13,14] Trans women's unique sociocultural issues and contexts of risk are not considered or addressed in prevention programming for men, and trans women often do not feel safe or welcome when accessing these programs.[15] Information about trans men's HIV risk and protective behaviors is only recently coming to light.[16–18]

There is an urgent need for community-led gender-affirming PrEP programs designed specifically for trans people and gender diverse people.[19] Gender-affirming health care includes using patients' preferred names and pronouns, respecting diversity in patients' gender identities and expressions, and creating safe spaces for trans patients, in addition to the provision of hormone therapy and other gender-affirming medical care.[20] The Model of Gender Affirmation (GA) describes an interpersonal, interactive process whereby a person receives social recognition and support for their gender identity and expression.[21] Trans women have low access to care that meets their transgender-specific care needs[22–24] and often encounter stigma when accessing care.[23] The Model of Gender Affirmation demonstrates how meeting transgender women's needs for gender affirmation by increasing access to trans-related services may decrease risk behavior and increase self-care, including engagement in prevention services.[25–28] The Model of Gender Affirmation informed the development of the TRIUMPH PrEP demonstration project, which hypothesized that integrating PrEP delivery into trans-specific health care services in gender-affirming environments, prioritizing trans community leadership, and highlighting the connection between HIV prevention and gender transition–related goals would support PrEP uptake and adherence among transgender and gender diverse people.[19]

The TRIUMPH PrEP Demonstration Project

TRIUMPH (Trans Research–Informed communities United in Mobilization for the Prevention of HIV) project was a collaboration between the University of California, San Francisco, and 2 implementing sites: La Clinica de la Raza in Oakland (a Federally Qualified Health Center; FQHC) and Gender Health Center (a community-based organization; CBO) in Sacramento, California. La Clinica (La Clinica) de la Raza is a primary care clinic primarily serving Latinx communities in Oakland's Fruitvale district. Gender Health Center is a trans-led community hormone and mental health clinic. To reflect the communities being served by TRIUMPH, at any one time, we had a minimum of 10 trans staff and 10 nontrans staff, with trans-identified staff represented at all levels of the study team and clinic staff, including the principal investigator (PI), Co-PI, site PI, Project Director, Research Assistant, and Peer Health Educator levels. More than half of our team members were people of color.

Peer Health Educators

Extensively trained peer health educators (PHEs) led all TRIUMPH activities and provided PrEP navigation, education, and support to participants. As needed, PHEs also provided peer navigation to other needed services, such as legal services for name changes and asylum procedures, mental health services, and transportation.

Drop-In Clinics

Trans-specific PrEP and hormone clinics were held at our clinical sites during 2 late afternoons/early evenings per week. During clinic hours, group discussions were led by PHEs to provide opportunities for participants to share resources, seek support, receive ongoing health education, and brainstorm strategies for increasing PrEP adherence. Adherence support focused on empowering personal choice, self-assessment of HIV risk, desire for feeling safe during sex act, and daily habit formation.

Monthly Groups

Once per month, the PHEs facilitated a social group that incorporated interactive educational discussions focused on health-related topics, including trans-specific health issues, safer sex act, alcohol and substance use, and PrEP. The La Clinica site specifically included elements that were culturally relevant to the trans Latina participants, such as food, music, and topics related to immigration.

Community Mobilization and PrEP Champions

TRIUMPH aimed to increase PrEP knowledge and acceptability among trans communities in Oakland and Sacramento through community mobilization efforts. Community mobilization strategies are particularly effective in increasing empowerment and decreasing stigma among marginalized populations and in disseminating novel information through trusted social networks.[29] Community mobilization efforts consisted of peer-led, gender-affirming, sex-positive PrEP education and social marketing strategies emphasizing the need for trans communities to mobilize to seek full inclusion in society, gender affirmation, prevent HIV, and fully explore the potential benefits of PrEP. We also cultivated PrEP champions through community events that were conceived and produced by TRIUMPH staff, including an annual "*Miss Triunfo*" pageant in Oakland.

METHODS

Study Design

The overall goal of the study was to examine PrEP uptake, retention, and adherence and their predictors during a trans-specific, community-led PrEP demonstration project using a prospective single-arm design comparing 2 clinical sites. The study attempted to enroll all trans people and gender diverse people receiving services through the demonstration project at the TRIUMPH sites.

Settings

La Clinica de la Raza has a long history of serving Latinx communities in Oakland and providing sexual health services including PrEP; they did not have a history of providing gender-affirming hormones or have dedicated transgender health services before implementing TRIUMPH. As part of the program planning phase, all La Clinica staff (including security and janitorial staff) underwent transgender competency training delivered by UCSF staff. La Clinica also had a strong internal champion for TRIUMPH programming, who served as the primary health care provider for the program. La Clinica had an on-site pharmacy that dispensed PrEP to participants. Gender Health Center has a long history of serving trans communities in Sacramento and providing mental health services and hormone therapy; they did not have experience providing sexual health services such as PrEP. As part of the program planning phase, all staff underwent PrEP knowledge training, the clinic built out a phlebotomy laboratory, and a staff member became a licensed phlebotomist. Gender Health Center did not have an on-site pharmacy; study staff dispensed PrEP directly to participants. All TRIUMPH staff at both clinics underwent initial training regarding implementation of TRIUMPH; additional training and support were provided as needed during the implementation.

Study Population and Eligibility Criteria

Recruitment was led by 4 PHEs, all of whom were transgender women of color. The PHEs led community mobilization efforts at community-based venues, events, social networks, and social media, designed to encourage self-referral and referral through social networks to TRIUMPH clinics. To be eligible, participants had to be aged 18 years or older, to be HIV-negative (confirmed by rapid test), to have a gender identity that was different from the sex they were assigned at birth, to be currently sexually active or intending to become sexually active, to express a desire to use PrEP, and to be fluent in English or Spanish. All participants provided informed consent before enrollment.

Procedures

Study staff were certified HIV test counselors and conducted HIV testing during the eligibility screener and at 1, 3, 6, 9, and 12 months postenrollment. Toward the end of the study, we modified procedures to enable us to continue to enroll participants even though we would not be able to follow-up for the full 12 months; thus, 22 participants reached study end point at 6 months follow-up and did not have the 9-month and 12-month visits per study protocol. PrEP was dispensed by providers at office visits at the Sacramento site and from the on-site pharmacy at the Oakland site. All participants were offered free study drug, regardless of insurance status, but were able to receive PrEP through their insurance provider if they preferred. Clinicians at each site provided standard care for the administration of hormones and PrEP initiation and monitoring. Study procedures were approved by the University of California, San Francisco, Institutional Review Board (16-20251).

Data Collection

Participants completed computer-assisted self-interviewing (CASI) surveys and provided dried blood spots (DBS) collected by phlebotomy at baseline and at 3, 6, 9, and 12 months postenrollment. Participants were reimbursed $30 for completing both the DBS collection and the CASI survey at each time point.

Predictors

Demographics

Gender identity was assessed by asking, "What is your gender identity? Please check all that apply." Response options included the following: "male," "female," "transgender male," "transgender female," "genderqueer/gender nonbinary/gender nonconforming," and "additional category (please specify)." Other demographic characteristics were assessed using standard questions, including sex assigned at birth, race/ethnicity, US-born, housing, and education. *Financial situation* was assessed by asking, "Which of the following statements best describes your financial situation: (Choose one.)" Response options included the following: "I have enough money to live comfortably," "I can barely get by on the money I have," and "I cannot get by on the money I have."

Health Characteristics

Lifetime hormone use was assessed by asking, "Have you ever taken hormones?" (yes/no). If the response was yes, *current hormone use* was then assessed by asking, "Are you currently taking hormones?" (yes/no). *Silicone use* was assessed by asking, "Have you ever injected silicone or other substances (besides hormones) to enhance your gender presentation?" (yes/no).

Sex Partners

Primary relationship status was assessed by asking, "Are you in a primary relationship? By primary partner, we mean someone with whom you feel committed to above anyone else and with whom you have had a sexual relationship." (yes/no). *Number of sex partners* was assessed by asking, "Around how many sexual partners have you had in the last 3 months (either front hole/vaginal or anal sex)?" *Any condomless receptive sex with HIV+ partner* was assessed by asking first, "Of the total partners you have had sex with in

the past 3 months, with how many partners did you have receptive anal sex, where your partner put their penis into your anus?," followed by "Of the # partner(s) you have had receptive anal sex with in the past 3 months, about how many of these partners did not use a condom when having sex with you?," followed by "Of the # partners that did not use a condom, about how many were HIV+ that you know of?" *Sex work* was assessed by asking, "Of the # partners you have had receptive anal sex with, how many partners paid you money or gave you something like drugs, food, clothes, or housing in return for this type of sex?"

Substance Use

Drug use was assessed using the 10-item Drug Abuse Screening Test (DAST).[30] All DAST items are yes/no questions that receive one point for each "yes" response. Possible scores range from 0 to 10. *Alcohol use* was measured using the 10-item Alcohol Use Disorders Identification Test (AUDIT).[31] The range of possible scores on the AUDIT is from 0 to 40, with a score of 15 as the cutoff for hazardous drinking.

Mental Health and Violence

Mental health was assessed using the 4-item Patient Health Questionnaire (PHQ-4), a measure of depression and anxiety with a potential range of scores from 0 to 12; higher scores indicate higher levels of depression and/or anxiety.[32] Recent *violence* was assessed by asking, "In the past 120 days (3 month) were you abused, threatened, or the victim of violence?" (yes/no).

PrEP Interest, Awareness, and HIV Risk Perception

PrEP interest was assessed by providing the participants with a series of statements about reasons they may be interested in PrEP. Participants were able to check all that apply. A count of the total number of endorsed reasons was calculated; potential scores range from 0 to 7. An example item is "To protect myself against HIV." *Previous PrEP awareness* was assessed by asking, "Before today, had you heard about PrEP (also known as Truvada, taking a daily pill) to prevent HIV?" (yes/no). *HIV risk perception* was measured using the following item: "I think my chances of getting infected with HIV are:" Response options were as follows: "zero" (0), "almost zero" (1), "small" (2), "moderate" (3), "large" (4), and "very large" (5). Responses were dichotomized into "not likely (0–2)/likely (3–5)".

Medical Mistrust

Medical mistrust was assessed by asking participants to indicate whether they agreed or disagreed with the item "People like me cannot trust doctors and health care workers." Response options were as follows: "strongly disagree," "disagree," "neutral," "agree," and "strongly agree."

Primary Outcome Measures

PrEP uptake was defined as dispensation of a PrEP pill bottle to the participant. *PrEP retention* was measured longitudinally and defined as the proportion of expected visits completed among those who began PrEP. *PrEP adherence* was measured longitudinally and defined as having protective drug levels (tenofovir diphosphate level $\geq$ 700 fmol per punch by dried blood spot [DBS] analysis) among those who were on PrEP and completing visits.

Data Analysis

Demographics between sites were compared by the *t* test for continuous variables and the Fisher exact test for categorical variables. Initiation of PrEP was associated with participant characteristics using logistic regression. We report the associated odds ratios with 95% confidence interval. The repeated drug level measurements (DBS level $\geq$ 700 fmol per punch) and proportion of expected visits completed were analyzed using generalized estimating equations with logit link, a working independence specification, and robust variance estimators.[33] We made no adjustment for missing DBS specimens. Analyses were conducted in Stata, version 16.2.[34]

RESULTS

From October 2017 to March 2020, TRIUMPH enrolled 185 transgender and gender diverse participants at 2 sites (see Fig. 1, CONSORT diagram).

Demographic Characteristics

Participants' baseline characteristics are summarized in Table 1. The median age of TRIUMPH participants overall was 28 years (interquartile range 23–35), with a slightly younger cohort enrolled in Sacramento. Most (68%) of the participants had a transfeminine identity (eg, transgender woman or woman) and were categorized as transgender women for these analyses; 13% reported a nonbinary or additional gender (eg, genderqueer) and 6% declined to answer the gender identity question. The Oakland site enrolled a higher proportion of transgender women, whereas the Sacramento site enrolled a higher proportion of transgender men. More than half of participants identified as White Latinx (58%), 19% identified as White non-Latinx, 7% identified as African American, 14% was multiracial, and 2% was Asian/Asian American. Most of the participants enrolled in Oakland were White Latinx (92%) and born outside of the United States (88%), whereas less than a quarter of the participants enrolled in Sacramento were born outside of the United States (22%). Most of the participants reported the completion of a high school degree or less (51%), with participants enrolled in Sacramento reporting significantly higher levels of education. A high proportion of the cohort reported unstable housing (42%), with no significant differences between Oakland and Sacramento. Most of the cohort reported that they can barely (54%) or cannot get by on the money they have (30%), with more participants in Sacramento reported having enough money to live comfortably (25%).

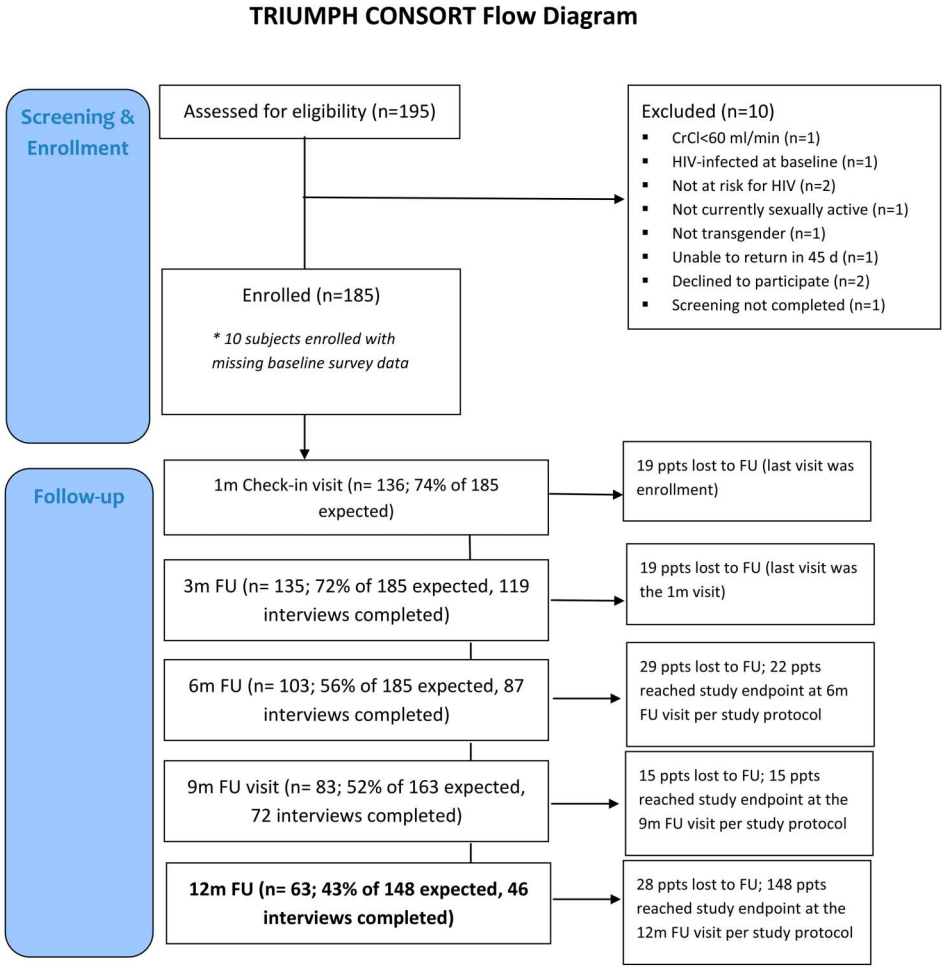

FIGURE 1. TRIUMPH CONSORT flow diagram. full color online

Health Characteristics at Baseline

About three-quarters of TRIUMPH participants had ever used hormones (76%) and one-fifth (20%) had ever used silicone, with significant differences between the Oakland and Sacramento sites in lifetime hormone use (87% and 68%, respectively, $P < 0.01$) and lifetime silicone use (32% and 10%, respectively, $P < 0.001$). Overall, 69 participants (40%) reported having a primary partner, with a median number of 2 sexual partners in the previous 3 months. Condomless anal sex act in the previous 3 months was reported by 59 participants (41%) in the overall sample; 33 (20%) participants reported being currently engaged in sex work. No significant differences existed between sites in terms of participants' sexual behavior. Overall, 11 participants (6%) had AUDIT scores that reached the threshold for hazardous drinking, and rates were roughly equivalent among participants at both sites. Participants in Sacramento reported a significantly higher median number of mental health symptoms than those in Oakland (3 vs. 0). Experiences of violence in the 3 months before the baseline survey were reported by 28 participants (16%) and were not significantly different between sites. Previous PrEP awareness was 80% overall and was higher among participants in Sacramento than those in Oakland (86% vs. 72%, respectively, $P < 0.05$) as was PrEP interest (median score of 3 vs. 1, respectively, $P < 0.001$). HIV risk perception was significantly higher among participants in Oakland ($P < 0.01$).

PrEP Uptake

Of 185 participants, 8 (4%) were already on PrEP at enrollment. Of the remaining 177, 162 (87%) initiated PrEP and 15 (8%) did not initiate PrEP during the study. PrEP uptake was as follows: 91% among trans women, 96% among trans men, and 70% among nonbinary participants; 78% in Oakland and 98% in Sacramento. Of the 15 who did not initiate PrEP, 12 were White Latinx, 1 was White non-Latinx, and 2 were missing race information. Most of those who did not initiate PrEP were not US-born (73%) and were enrolled at the Oakland site (87%). Those who had not been aware of PrEP before enrollment in TRIUMPH were less likely to initiate PrEP than those who were already aware of PrEP (OR 0.25, $P = 0.019$).

PrEP Retention

Transgender women, those who were White Latinx and not US-born, and participants enrolled in Oakland completed a significantly higher proportion of visits (Table 2). Furthermore,

TABLE 1. Sociodemographic Characteristics of Individuals Enrolled in TRIUMPH (N = 185) at Baseline, Overall and by Site

	Overall	Oakland	Sacramento	*P*
Age (median, IQR)	28 (23–35)	33 (26–41)	26 (22–32)	<0.0001
Gender identity				<0.0001
Transgender female, n (%)	126 (68)	64 (82%)	62 (58%)	
Transgender male	27 (15%)	2 (3%)	25 (23%)	
Nonbinary/additional gender	21 (11%)	10 (13%)	11 (10%)	
Declined	11 (6%)	2 (3%)	9 (8%)	
Sex assigned at birth				<0.0001
Male	139 (79%)	72 (94%)	67 (68%)	
Female	36 (21%)	5 (7%)	31 (32%)	
Race/ethnicity				<0.0001
African American/Black	12 (7)	2 (3%)	10 (10%)	
Asian/Asian American	4 (2%)	0 (0%)	4 (4%)	
Multiracial	24 (14%)	3 (4%)	21 (22%)	
White, Latinx	99 (58%)	70 (92%)	29 (30%)	
White, non-Latinx	33 (19%)	1 (1%)	32 (33%)	
US-born	84 (49%)	9 (12%)	75 (78%)	<0.0001
Education				<0.0001
Less than high school	42 (25%)	32 (43%)	10 (11%)	
Finished high school or got GED	44 (26%)	22 (29%)	22 (23%)	
Technical or vocational school	17 (10%)	14 (19%)	3 (3%)	
Some college, AA, or technical degree	50 (29%)	4 (5%)	46 (48%)	
College degree or above	17 (10%)	3 (4%)	14 (15%)	
Housing				0.2151
Stable	100 (58%)	40 (53%)	60 (63%)	
Unstable	72 (42%)	36 (47%)	36 (38%)	
Financial situation				0.0013
I have enough money to live comfortably	27 (16%)	3 (4%)	24 (25%)	
I can barely get by on the money I have	90 (54%)	46 (64%)	44 (46%)	
I cannot get by on the money I have	51 (30%)	23 (32%)	28 (29%)	
Hormone use				
Ever	132 (76%)	65 (87%)	67 (68%)	0.0065
Current	101 (58%)	45 (60%)	56 (57%)	0.7567
Silicone use	34 (20%)	24 (32%)	10 (10%)	0.0005
Current primary partner	69 (40%)	24 (32%)	45 (46%)	0.0851
Number of sex partners (median, IQR)	2 (1–4)	2 (1–4)	2 (1–5)	0.2732
Condomless sex act				
Any condomless receptive anal sex act, past 3 mo	56 (39%)	26 (43%)	30 (36%)	0.3922
Any condomless insertive anal sex act, past 3 mo	11 (9%)	6 (11%)	5 (7%)	0.5237
Any condomless sex act, past 3 mo	59 (41%)	27 (45%)	32 (39%)	0.4929
Sex work, current	33 (20%)	19 (25%)	14 (15%)	0.1178
Substance use—DAST score (median, IQR)	0 (0–1)	0 (0–0)	0 (0–2)	0.0041
Alcohol use—AUDIT score (median, IQR)	3 (1–6)	4 (0–10)	3 (1–5)	0.1645
Hazardous drinking	11 (6%)	6 (8%)	5 (5%)	0.5368
Mental health—PHQ (median, IQR)	2 (0–4)	0 (0–2)	3 (0–6)	0.0001
Violence, past 3 mo	28 (16%)	10 (13%)	18 (18%)	0.4095
PrEP interest	2 (1–3)	1 (1–3)	3 (1–4)	0.0001
Previous PrEP awareness	134 (80%)	52 (72%)	82 (86%)	0.0307
Medical mistrust (median, IQR)	2.8 (2.0–3.2)	2.8 (2.2–3.2)	2.7 (2.0–3.0)	0.3757
HIV risk perception				
Likely	18 (11%)	15 (20%)	3 (3%)	0.0085
Not likely	154 (90%)	59 (80%)	95 (97%)	

GED, general educational development; IQR, interquartile range.

TABLE 2. Predictors of Retention in TRIUMPH

	Proportion of visits completed	OR (CI)	Overall *P*	*P* vs. Ref
Site				
Oakland	76	Ref	0.002	
Sacramento	62	0.52 (0.35 to 0.79)		0.002
Age		1.02 (1.00 to 1.04)		0.09
Gender identity				
Transgender female	72	Ref		0.004
Transgender male	61	0.61 (0.39 to 0.96)	0.034	
Nonbinary/additional gender	51	0.41 (0.24 to 0.73)	0.002	
Declined	51	0.41 (0.16 to 1.04)	0.06	
Sex assigned at birth				
Male	70	Ref		0.088
Female	62	0.70 (0.46 to 1.05)	0.088	
Race/ethnicity				
African American/Black	65	Ref		0.008
Asian/Asian American	45	0.46 (0.18 to 1.17)	0.104	
Multiracial	66	1.08 (0.44 to 2.67)	0.862	
White, Latinx	73	1.48 (0.67 to 3.26)	0.328	
White, non-Latinx	62	0.89 (0.39 to 2.06)	0.788	
US-born				
Yes	63	Ref		0.016
No	74	1.64 (1.10 to 2.46)	0.016	
Education				
Less than high school	69	Ref		0.434
Finished high school or got GED	65	0.83 (0.47 to 1.46)	0.508	
Technical or vocational school	77	1.47 (0.61 to 3.54)	0.387	
Some college, AA, or technical degree	65	0.80 (0.47 to 1.37)	0.414	
College degree or above	75	1.34 (0.63 to 2.86)	0.452	
Housing				
Stable	67	Ref	0.63	0.63
Unstable	69	0.90 (0.60 to 1.36)		
Financial situation				
I have enough money to live comfortably	72	Ref		0.673
I can barely get by on the money I have	67	0.77 (0.44 to 1.37)	0.375	
I cannot get by on the money I have	68	0.83 (0.44 to 1.55)	0.552	
Hormone use				
Ever				
No	65	0.85 (0.53 to 1.36)	0.5	
Yes	69	Ref		0.5
Current				
No	68	Ref		0.91
Yes	68	0.98 (0.65 to 1.47)	0.91	
Silicone use				
Yes	73	Ref		0.294
No	67	0.76 (0.45 to 1.27)	0.294	
Current primary partner				
No	69	1.13 (0.77 to 1.67)	0.534	
Yes	66	Ref		0.534
Number of sex partners		1.02 (1.00 to 1.03)		0.027
Any condomless receptive sex act with HIV+ partner (past 3 mo)				
Yes	43	0.38 (0.14 to 1.01)	0.053	

(*continued on next page*)

TABLE 2. (*Continued*) Predictors of Retention in TRIUMPH

	Proportion of visits completed	OR (CI)	Overall *P*	*P* vs. Ref
No	67	Ref		0.053
Sex work, current				
No	67	0.72 (0.42 to 1.24)	0.241	
Yes	73	Ref		0.241
Substance use		0.93 (0.86 to 1.00)		0.055
Hazardous alcohol use				
No	68	Ref		0.944
Yes	67	0.97 (0.41 to 2.28)	0.944	
Mental health		0.98 (0.92 to 1.05)		0.604
Violence, past 3 mo				
Yes	69	Ref		0.864
No	68	0.95 (0.54 to 1.67)	0.864	
PrEP interest		0.91 (0.79 to 1.05)		0.196
Previous PrEP awareness				
No	66	0.88 (0.52 to 1.49)	0.632	
Yes	69	Ref		0.632
Medical mistrust		1.01 (0.81 to 1.26)		0.924
HIV risk perception				
Not likely	56	0.58 (0.33 to 1.01)	0.054	
Likely	69	Ref		0.054

GED, general educational development.

participants who reported a higher number of sex partners completed a significantly higher proportion of visits (OR 1.02 per partner (95% CI: 1.00 to 1.03), $P < 0.05$). Those who reported higher levels of substance use and who believed they were not likely to be at risk of HIV trended toward completing a significantly lower proportion of visits ($P < 0.06$).

PrEP Adherence

Transgender women in our study were more likely to have protective drug levels (58%) than participants with other gender identities (48% for transgender men and 34% for nonbinary people and those other gender identities, $P < 0.05$; Table 3). Other predictors of protective drug levels were not having a current primary partner (60%) and having a higher number of sex partners [OR 1.02 per partner (1.00–1.03), $P < 0.05$]. Participants who had not experienced violence in the previous 3 months were 2.24 times more likely to have protective drug levels than those who had experienced violence in the previous 3 months (95% CI: 1.10 to 4.57, $P < 0.05$). We observed zero incident HIV infections during the course of the demonstration project.

CONCLUSIONS

We examined PrEP uptake, PrEP retention, and PrEP adherence among participants in a peer-led, trans-specific PrEP demonstration project at 2 distinct California community-based clinical sites. We document high levels of PrEP initiation in a young transgender and gender diverse cohort at risk of HIV acquisition. We enrolled a high number of Latinx trans women, reflecting both the demographics of California and the strong reputation that our Oakland site, La Clinica de la Raza, has for serving Latinx communities. Although PrEP uptake (defined at dispensation of PrEP medication to participants) was high at both sites, Gender Health Center in Sacramento had a particularly high uptake rate. This may be due to lower barriers to dispensation to participants at Gender Health Center, given that study staff were able to dispense medication directly to participants rather than operating through an on-site pharmacy. Alternatively, this may reflect the higher levels of PrEP awareness and interest expressed by participants at Gender Health Center at baseline.

Levels of PrEP adherence overall were encouraging, given that variables related to HIV risk were associated with better adherence. We observed better adherence among trans women, those without a current primary partner, and those with higher numbers of sex partners. Furthermore, participants who reported higher perceived HIV risk were more likely to be adherent. Substance use and violence, rates of which are disproportionately high among trans people, significantly affected retention and adherence, respectively.[35,36] Those who reported substance use were less likely to be retained, whereas those who reported recent experiences of violence were less likely to adhere to PrEP. These findings corroborate other studies that have found that substance use and gender-based violence can impede uptake of and adherence to HIV prevention tools and services.[37,38] Studies with other populations, such as men who have sex with men, have also found that those who use substances were able to adhere to PrEP,[39] but those who are exposed to violence have lower levels of adherence.[40] Overall, our findings underscore the urgent need for trans-specific substance use interventions and PrEP programming that is trauma informed to be responsive to the high rates of violence experienced by our communities.[35,41]

TABLE 3. Predictors of Protective PrEP Drug Levels in TRIUMPH

	% DBS ≥ 4 Pills per Week	OR (CI)	Overall *P*	*P* vs. Ref
Site				
Sacramento	56	1.24 (0.72 to 2.14)	0.432	
Oakland	50	Ref		0.432
Age		1.02 (1.00 to 1.04)		0.090
Gender identity				
Transgender female	58	Ref		0.045
Transgender male	48	0.69 (0.31 to 1.51)	0.353	
Nonbinary/additional gender	34	0.38 (0.17 to 0.88)	0.024	
Declined	28	0.28 (0.07 to 1.08)	0.064	
Sex assigned at birth				
Female	43	0.56 (0.28 to 1.11)	0.097	
Male	57	Ref		0.097
Race/ethnicity				
Multiracial	50	0.65 (0.21 to 2.02)	0.457	
African American	61	Ref		0.584
White, Latinx	51	0.68 (0.24 to 1.93)	0.47	
Asian	67	1.30 (0.13 to 13.01)	0.823	
White, non-Latinx	65	1.19 (0.36 to 3.92)	0.773	
US-born				
Yes	59	Ref		0.204
No	51	0.70 (0.41 to 1.21)	0.204	
Education				
College degree or above	59	2.03 (0.82 to 4.99)	0.125	
Some college, AA, or technical degree	60	2.16 (1.06 to 4.37)	0.033	
Less than high school	41	Ref		0.212
Finished high school or got GED	59	2.05 (0.96 to 4.36)	0.063	
Technical or vocational school (no degree)	54	1.65 (0.54 to 5.03)	0.382	
Housing				
Stable	59	Ref		0.111
Unstable	48	0.65 (0.38 to 1.10)	0.111	
Financial situation				
I have enough money to live comfortably	65	Ref		0.248
I cannot get by on the money I have.	55	0.66 (0.31 to 1.41)	0.289	
I can barely get by on the money I have.	51	0.56 (0.28 to 1.11)	0.095	
Hormone use				
Ever				
Yes	52	Ref		0.107
No	66	1.78 (0.88 to 3.60)	0.107	
Current				
Yes	53	0.88 (0.50 to 1.53)	0.646	
No	56	Ref		0.646
Silicone use				
Yes	No	56	1.30 (0.66–2.54)	0.451
No	Yes	49	Ref	
Current primary partner				
Yes	46	Ref		0.027
No	60	1.73 (0.99 to 2.99)	0.052	
Number of sex partners (past 3 mo)		1.02 (1.00 to 1.03)		0.011
Any condomless receptive sex act with HIV+ partner (past 3 mo)				
Yes	40	0.61 (0.17 to 2.17)	0.449	
No	52	Ref		0.449
Sex work, current				
Yes	60	Ref		0.418

(*continued on next page*)

TABLE 3. (*Continued*) Predictors of Protective PrEP Drug Levels in TRIUMPH

	% DBS ≥ 4 Pills per Week	OR (CI)	Overall *P*	*P* vs. Ref
No	54	0.76 (0.39 to 1.48)	0.418	
Substance use		0.93 (0.86 to 1.01)		0.055
Hazardous alcohol use				
Yes	52	0.89 (0.40 to 1.97)	0.767	
No	55	Ref		0.767
Mental health		0.98 (0.92 to 1.05)		0.604
Violence, past 3 mo				
Yes	38	Ref		0.027
No	58	2.24 (1.10 to 4.57)	0.027	
PrEP interest		0.94 (0.82 to 1.08)		0.418
Previous PrEP awareness				
No	51	0.86 (0.44 to 1.69)	0.66	
Yes	55	Ref		0.66
Medical mistrust		1.01 (0.81 to 1.26)		0.924
HIV risk perception				
Likely	63	1.92 (0.97 to 3.80)		0.063
Not likely	46	Ref	0.063	

GED, general educational development.

As predicted by the Model of Gender Affirmation, TRIUMPH demonstrated that a gender-affirming, trans-specific PrEP demonstration project can support trans communities at risk of HIV acquisition to use PrEP effectively. At the beginning of the project, we anticipated possible enrollment challenges at La Clinica because they had not previously served trans people, whereas Gender Health Center in Sacramento was a trans-specific mental health and hormone clinic. Interestingly, we observed better retention among trans Latinas at La Clinica, where TRIUMPH was renamed *Triunfo* by participants, tailored to be culturally specific to trans Latinas, thereby fostering a sense of community. At both sites, PHEs established trust with TRIUMPH participants to increase buy-in from local trans communities. Important elements of TRIUMPH programming were community leadership of the project, trans-affirming, compassionate clinical staff, and the provision of PrEP in conjunction with hormone provision and maintenance. TRIUMPH fostered PrEP awareness and acceptability among local trans communities through group education and mobilization events.

To effectively deliver HIV prevention services to trans communities, support beyond clinical services is critical. Participants often needed extensive support from PHEs beyond PrEP navigation, such as legal services for name changes and asylum procedures and mental health services and transportation. These supplementary services provided more holistic support for participants that extended beyond hormones and PrEP. Furthermore, we found that no shows and appointment cancellations occurred frequently. Accommodating rescheduled participants was facilitated by our open clinic models; however, flexibility was restrained due to limited clinician time.

By not relying solely on clinical sites that have a long history of providing transgender health care in only one city, TRIUMPH demonstrated that through community leadership and capacity building, community-based FQHCs with an interest in providing PrEP to trans people can be successful in reaching this population. This approach increases the generalizability of our findings, providing actionable information for various types of clinics and organizations across the country. Qualitative implementation data collected from both sites will provide additional insight into barriers and facilitators to program implementation and PrEP uptake and initiation among TRIUMPH participants.

This was a cross-sectional cohort study that collected self-reported data on potential mediating factors. As the study took place in Oakland and Sacramento, California, 2 sites with limited gender-affirming care services compared with other cities in California such San Francisco and Los Angeles. These results may not be generalizable to other cities in the United States with smaller trans populations and fewer services. We observed a significant attrition rate; 43% of the sample was retained for the full 12 months. This may reflect the high levels of unstable housing in our cohort, high rates of substance use and experiences of violence, and variable sexual health needs of the communities served over the course of a year.

Because HIV prevention needs and preferences change over time, we did not expect the full cohort to persist on PrEP for the entire 12-month duration of the study. Many of our participants' sexual behavior waxed and waned over the course of the study, and their preferences for prevention methods may have also changed. Prevention programs for transgender people and gender diverse people should be responsive to these changes, offering ongoing education about prevention options and flexibility for engagement in programming. Future research should explore optimization of flexible programming and address structural barriers to PrEP retention and adherence among transgender communities at risk of HIV acquisition (Table 3).

Although it is important to continue to develop trans-specific services, existing health programming should also be expanded to include effective and affirming programming for trans people.[16,42] Even when expanded from programming designed for cisgender people, multilevel, gender-affirming interventions that consider culturally unique barriers to health care access are needed to maximize effectiveness with trans people and gender diverse people. Trans leadership in the development of HIV prevention programming increases the impact of these services. The TRIUMPH project successfully demonstrated PrEP implementation among trans communities and the conduct of culturally relevant research by and for trans communities.

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