Feasibility and Acceptability of an mHealth Patient Navigation Intervention to Increase PrEP Uptake in Racially and Ethnically Diverse Sexual and Gender Minority Youth in Los Angeles (PrEPresent): Pilot Randomized Control Trial

Sam Calvetti, Bryan Lei, Jacob B Stocks, Matthew T Rosso, Manuel Puentes, Ramon Durazo-Arvizu, Lindsay Slay, Michele D Kipke, Lisa B. Hightow-Weidman

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Abstract

Background: Pre-exposure prophylaxis (PrEP) is a powerful tool to prevent the transmission of HIV. Interventions promoting this medication must focus on populations most impacted by systemic barriers to uptake. Historically, young sexual minority men (YSMM) and transgender women have the highest demonstrated rates of new HIV diagnoses, but prevalence within other gender minority populations is now being studied. To date, few interventions have focused exclusively on addressing PrEP uptake with sexual and gender minority (SGM) youth, particularly through mobile health (mHealth) technologies. Built on the successful foundation of the HealthMpowerment (HMP) Platform, PrEPresent aimed to engage with SGM youth across diverse gender and racial and ethnic identities in the Greater Los Angeles area.

Objective: The aim of this study was to evaluate the feasibility and acceptability of a digital peer patient-navigation PrEP uptake application.

Methods: The PrEPresent intervention took place over a 6-month timepoint with visits at baseline, 3 months, and 6 months. The active intervention period lasted from baseline to 3 months. Control participants received an information only version of the app. Intervention participants received an enhanced app with additional features and access to an interventionalist, the PrEPresentative. Intervention participants could meet with the PrEPresentative 4 times over the 3-month period via phone, HIPPA-compliant video conferencing, or in-app text messaging system. PrEP uptake was measured through survey response and UrSure rapid urine test of tenofovir.

Results: PrEPresent comprised of 147 sexual and gender diverse participants – 48.3% (71/147) were Latinx and 18.4% (27/147) were Black/African American. Most (66.6%, 98/147) were transgender or gender diverse and the remainder (33.3%, 49/147) were cisgender men. PrEP was initiated by 14/56 (25.0%) of intervention participants and 11/58 (19.0%) of control participants. 50% (36/72) of intervention participants completed two or more sessions with the interventionalist. Intervention participants had an average of 15.93 logins compared to 6.31 logins for control participants. Average usage of the mHealth platform was 9.51 minutes for intervention participants and 3.03 minutes for control participants.

Conclusions: PrEPresent met primary outcome measure metrics of feasibility and acceptability, demonstrating that mHealth-based peer-navigator support has potential to increase PrEP uptake in racially and ethnically diverse SGM. Despite this, PrEP uptake was low across both arms and usage of the platform was low compared to other iterations of HMP projects. While mHealth offers promising HIV prevention outcomes, fostering active participant app engagement will continue to be crucial in promoting behavior change. With the widescale adoption of on-demand and long-acting injectable PrEP, interventions targeting

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Trial Registration:

ClinicalTrials.gov NCT05281393; https://clinicaltrials.gov/ct2/show/NCT05281393

Key Words:

PrEP; Mobile Health; LGBTQ; Adolescent; Transgender; HIV

Introduction

According to 2022 CDC HIV Surveillance Reports, there is a decreasing trend in the prevalence of new HIV acquisitions within cisgender queer men in the LGBTQ+ community. Despite this, 67% of new HIV acquisitions are still attributed to sexual interactions within that subgroup. Youth, those between the ages of 13 to 34, still make up just over half (56%) of new diagnoses. Particularly, Black and African American young sexual minority men (YSMM) account for 49% of new acquisitions within 13–24-year-olds, and Hispanic/Latino YSMM account for 31% of new acquisitions in that age group [1]. Amongst transgender and non-binary people, the incidence of new HIV diagnoses in transgender women is the most well documented. Transgender women have been identified as having a higher rate of HIV acquisition than any other population subgroup. One count within major United States (US) cities in a 2019-2020 CDC Special Report cited a 42% positivity rate within this population, with 18.9% of the sample living with HIV aged 18-29 [2]. Individual, social, and institutional issues related to homophobia and transphobia create health disparities amongst sexual and gender minority (SGM) people that impact their ability to access and continually engage in HIV prevention and treatment [3,4]. There is a clear need for both YSMM and young transgender women to continue to be prioritized in prevention efforts and studies are now working to understand HIV likelihood and prevalence within transgender and non-binary youth of different genders [5]. Prevention strategies must address the needs of populations understood to be at greatest chance of acquisition while prioritizing the inclusion of all sexual and gender minority youth also at a greater likelihood of HIV transmission.

PrEP Awareness, Utilization, and Uptake - Advancements in PrEP

An important factor in working to end the HIV epidemic is increasing the uptake of pre-exposure prophylaxis (PrEP), a medication that can prevent the transmission of HIV [6]. PrEP awareness amongst SGM youth continues to be high, but uptake is low [7,8]. Barriers to uptake of PrEP can include lack of healthcare access, stigma, and logistical difficulty accessing PrEP [9] as well as a perception of high barriers to accessing PrEP [10]. Low uptake amongst SGM populations has been attributed to different factors, such as a lack of trust in the medical system by transgender people interested in PrEP [11] and social stigma around PrEP disclosure due to negative connotations of PrEP users amongst Black SMM communities [12]. In a 2021 review of previous interventions targeting PrEP uptake, adherence, or persistence in the US, 20 published interventions were identified but only 2 listed uptake as an intended impact [13]. Additional studies are necessary to understand how interventions can increase this health behavior particularly in SGM youth.

Not all forms or methods of PrEP are approved to be used by all people. The current approved forms of PrEP for people who were assigned female at birth who have receptive vaginal sex are daily oral Truvada (or generic equivalent) and Apretude injectable [14]. Injectable PrEP was approved to be used in December of 2021 [15]. Descovy, an alternative medication to Truvada approved for pre-exposure prophylaxis in October of 2019, is only approved for use in people who were assigned male at birth [16,17]. Although not FDA-approved, guidance exists for on-demand PrEP (also called 2-1-1), but its efficacy has only been well-studied in gay and bisexual cisgender men [18]. Many transmasculine people meet the eligibility for PrEP, but few acquire a prescription [19,20]. One 2021 study of 715 trans men did find high rates of PrEP utilization in their cohort (22.1%), but also found one in twenty people in the project using PrEP were prescribed Descovy - not currently approved for the sex they were assigned at birth [21]. Because of the availability and accessibility of different types of PrEP for different types of people, patient navigation, empowerment, and education around uptake is essential within SGMY.

Mobile Health (mHealth) Interventions

Mobile health (mHealth) interventions can play a key role in mediating factors that contribute to HIV acquisition amongst SGM youth. These interventions have been shown to be acceptable with many groups in HIV prevention, such as in PrEP adherence with YSMM of color [22], increasing self-HIV testing with transgender youth [23], and access to HIV/STI at home testing kits, condoms and lube, and prevention information with transmasculine people [24]. They have also been demonstrated to have an impact on effecting HIV-related stigma in both people living with HIV and not living with HIV [25]. Despite the existence of interventions to impact these factors affecting new HIV transmissions, there is a lack of information about how mHealth solutions can affect uptake of PrEP, particularly in populations including both YSMM and transgender and non-binary people. A previous study with Black SMM looked at the effect of an mHealth mobile messaging intervention on PrEP uptake, but this project initiated the intervention at the point of care (an STI/HIV testing clinic that offered PrEP services) [26]. Building off existing literature supporting mHealth engagement in preventing HIV transmission while prioritizing PrEP uptake as a health behavior change, PrEPresent, a mHealth application built from the successful foundation of the HealthMpowerment (HMP) Platform [27], aimed to engage with SGM youth across diverse gender and racial/ethnic identities in the Greater Los Angeles area.

Project Aims

PrEPresent is a randomized control trial (RCT) (ClinicalTrials.gov NCT05281393; https://clinicaltrials.gov/ct2/show/NCT05281393**)** seeking to increase PrEP uptake through a tailored mHealth intervention by engaging SGM youth at greater likelihood of HIV acquisition currently outside of the care continuum. In connecting users with a mobile app and a trained intervention peer support navigator, the PrEPresentative, PrEPresent provides educational and motivational support to SGM youth in their decision to initiate PrEP. Specific information about the session content and other components of the intervention are outlined in the research protocol [28]. PrEPresent incorporates the patient activation theory, which focuses on one's ability to manage their own wellness and healthcare [29]. The aim of this project was to evaluate the feasibility and acceptability of the app and intervention with a racially/ethnically diverse sample of 150 SGM youth (ages 16-26) in Los Angeles.

Methods

Institutional Board Approval and Trial Registration:

All phases of PrEPresent were approved by the Children's Hospital Los Angeles Institutional Review Board (IRB # CHLA-20-00596). The project is registered at ClinicalTrials.gov (ClinicalTrials.gov NCT05281393)

Study Design and Population

PrEPresent was conducted in three phases. Formative research to inform app features, content, and resources occurred in Phase 1 of the project. Phase 1A involved qualitative interviews with key informants providing PrEP care in the Los Angeles area. Phase 1B involved four sessions of weekly working groups with 20 SGMY to understand PrEP awareness, acceptance, readiness, and hesitation within the prospective RCT population. Phase 2 involved preliminary usability testing of the PrEPresent platform with 7 SGMY. Phase 3 involved 1:1 randomization of racially and ethnically diverse SGMY into a pilot RCT.

Within the Phase 3 RCT, participants completed study visits at baseline, 3 months, and 6 months; the intervention component took place actively between the baseline and 3-month visits. The majority of study activities took place online. Participants completed a survey at baseline. At the 3- and 6-month

time points, all participants completed a survey as well as a UrSure point-of-care rapid urine test of tenofovir as a biomarker of PrEP usage. Ursure tests kits were either mailed to participants or completed on-site at the research location. UrSure is a validated urine assay with high sensitivity and specificity for tenofovir use within the previous 48 hours. Participants were compensated $50 for each survey they completed, as well as $20 for completing the at-home biomarker testing. If all study components were completed (three surveys and two biomarker tests), participants received a $50 bonus incentive at the end of the project.

From August 2022 to July 2023, 147 youth were recruited into the project. Recruitment sources included an existing cohort of YSMM and transgender and non-binary youth of color in Los Angeles, in-person recruitment via fliers in community-based organizations (CBOs), tabling at community events, and online advertising via social media and dating apps. Eligible participants were: (1) aged 16-26 years; (2) cisgender men, transgender or gender nonconforming people, or identified differently from the gender picked for them at birth; (3) gay, bisexual, or some other same-sex identity, or reported having had sex with anyone with a penis during the previous 12 months; (4) White or Caucasian, Black or African American, Hispanic or Latino or Latinx, or multiracial with one of these identities; (5) living in the Los Angeles metro area; (6) had daily access to an iOS or Android smartphone or tablet with internet access; (7) reported having insertive or receptive sex in the previous 6 months or report a positive STI result in the previous 6 months; (8) not currently on PrEP and have no plan to start or restart PrEP in the following 7 days; and (9) not currently enrolled in another HIV prevention study. Participants from phase 1 or phase 2 of the study were not eligible to enroll in phase 3 of the project. Prospective participants living with HIV or who did not speak English were excluded.

Study Procedures

Following verification of eligibility, participants completed in-person or virtual electronic consent processes. Participants then performed a baseline computer assisted self-interviewing (CASI) via online survey. After survey completion, participants were randomized into a 1:1 ratio of intervention (PrEPresent app) or control (information-only app) arm and prompted to download the study app. Participants were then led by a research assistant through the features of their assigned apps.

Intervention Arm

After being guided through the app, intervention participants were then encouraged to schedule their first session with the PrEPresentative, the interventionalist peer support navigator. Participants could meet up to 4 times with the PrEPresentative across the 3-month intervention period. The PrEPresentative was trained on a formulated intervention curriculum. The curriculum included guided session topics, a reference library, motivational messaging examples, common solutions to known PrEP barriers, and additional relevant informational content about PrEP for participants. Sessions were conducted via an in-app chat communication feature, phone call, or HIPPA-compliant video call. Each intervention session had to be completed before moving onto the next. Following intervention sessions, the PrEPresentative completed a CRF to track intervention statistics. Session topic content and referrals were recorded, and multiple session topics could be chosen. Session topics were broken into three overarching categories: individual, socio-cultural, and structural. After each session, participants were sent a brief satisfaction survey. Participants were compensated $10 for attending each session, delivered after feedback survey completion. Intervention participants had access to the PrEPresent app and were encouraged to use it actively. App features included a health tracker for habit monitoring, anonymous user forum, activities and goal-setting functions, avatar customization, a care locator, ask the expert section, and interventionalist appointment scheduler.

Control Arm

Control participants were provided with an information-only version of the app and were encouraged

to use it actively. This app only contained a media library with resources regarding PrEP and did not allow access to other features. Control participants were not able to interact with the PrEPresentative.

Outcomes

The primary outcome measure for the RCT was feasibility and acceptability of the PrEPresent mHealth intervention. Feasibility of the intervention was defined as at least 50% of intervention participants completing 2 peer navigation sessions with the PrEPresentative. The intervention sessions were defined as feasible if an overall post session score of 4 or higher (out of seven) was reported on feedback surveys. Acceptability was defined as interventions participants utilizing the mobile app at a higher frequency than control participants. Metrics on feedback about components of the app, such as trustworthiness of information, ease of use, and future app use were utilized to understand app acceptance. A secondary outcome measure was defined as higher levels of PrEP uptake within intervention participants compared to control participants. For the project, PrEP uptake was defined as an adherent UrSure test result or self-report PrEP usage on survey measures.

Statistical Analysis

Descriptive Statistics

Descriptive statistics were calculated for important demographic baseline variables and variables of interest for the entire cohort and stratified by treatment arm. Continuous variables were summarized using medians and interquartile range. Categorical variables were reported using frequencies and percentages. Cronbach's alphas were calculated to assess the internal consistency of non-validated instruments. The total scores of these instruments were calculated by summing the individual question scores. Due to our small sample, statistical analysis did not include power value calculations or tests of statistical significance. The aim of this project was to understand in a pilot test the feasibility and acceptability within our population, and to understand how the app and project were delivered and the engagement in delivery over time.

Software

All statistical analysis was performed using R version 4.2.3.

Results

Demographics and Comparisons

A total of 147 participants were included at baseline. 75 participants were in the control group and 72 were in the intervention group. The mean age across both groups was 22.57(2.48) years. Gender varied greatly among participants. 33.3% of the participants classified themselves as cisgender men, followed by non-binary individuals (28.6%), and trans men (12.9%). Gay (27.9%) and queer (26.5%) were the most common sexual orientations, making up more than 50% of the participants. Almost 62% of participants reported a sexual attraction to more than one gender. Hispanic/Latinx was the most represented group (48.3%), predominantly in the control group (56.0%) compared to the intervention group (40.3%). Black/African American-identified participants made up 20.8% and 16.0% of the intervention and control arm, respectively. Participants were mostly evenly split between those that reported having a partner, spouse boyfriend, or girlfriend (51% overall), and those that were casually dating or single (49%). A detailed breakdown of the demographic characteristics is summarized in Table 1.

Table 1. Baseline demographic characteristics of SGM youth in the PrEPresent study. [a-b]

Characteristic	Total (n=147)	Control (n=75)	Intervention (n=72)
	n (%)	n (%)	n (%)

Age (in months)				
	Mean (SD)	22.57 (2.48)	22.55 (2.52)	22.60 (2.45)
Sex at Birth[a]				
	Male	78 (53.1)	40 (53.3)	38 (52.8)
	Female	66 (44.9)	32 (42.7)	34 (47.2)
	Intersex	1 (0.7)	1 (1.3)	0 (0.0)
Gender				
	Cisgender Man	49 (33.3)	26 (34.7)	23 (31.9)
	Gender Non-Conforming	6 (4.1)	0 (0.0)	6 (8.3)
	Genderfluid	8 (5.4)	4 (5.3)	4 (5.6)
	Genderqueer	6 (4.1)	5 (6.7)	1 (1.4)
	Non-binary	42 (28.6)	20 (26.7)	22 (30.6)
	Trans woman	10 (6.8)	5 (6.7)	5 (6.9)
	Trans Man	19 (12.9)	10 (13.3)	9 (12.5)
	Two-spirit	1 (0.7)	1 (1.3)	0 (0.0)
	Other	6 (4.1)	4 (5.3)	2 (2.8)
Sexuality[b]				
	Bisexual	28 (19)	10 (13.3)	18 (25.0)
	Demisexual	1 (0.7)	0 (0.0)	1 (1.4)
	Gay	41 (27.9)	21 (28.0)	20 (27.8)
	Heterosexual (straight)	1 (0.7)	0 (0.0)	1 (1.4)
	Homosexual	3 (2.0)	2 (2.7)	1 (1.4)
	Lesbian	3 (2.0)	3 (4.0)	0 (0.0)
	Man who has sex with other men	2 (1.4)	1 (1.3)	1 (1.4)
	Pansexual	24 (16.3)	13 (17.3)	11 (15.3)
	Queer	39 (26.5)	22 (29.3)	17 (23.6)
	Same gender-loving	1 (0.7)	1 (1.3)	0 (0.0)
	Other	3 (2.0)	2 (2.7)	1 (1.4)
Race/Ethnicity				
	Black/African American	27 (18.4)	12 (16.0)	15 (20.8)
	Hispanic/Latinx	71 (48.3)	42 (56.0)	29 (40.3)
	White	49 (33.3)	21 (28.0)	28 (38.9)
Relationship Definition				
	Single	49 (33.3)	25 (33.3)	24 (33.3)
	Casually Dating	23 (15.6)	9 (12.0)	14 (19.4)
	Have a partner or Spouse	26 (17.6)	14 (18.6)	12 (16.7)
	Have a boyfriend or girlfriend	49 (33.3)	27 (36.0)	22 (30.6)

[a]2 Decline to answer in control

[b]1 Don’t know in intervention

Sexual Activity and PrEP Readiness

At baseline, the control group reported a mean of 2.69 sexual partners, compared to 2.81 in the intervention group (Table 2). In a collapsed category, 28% of control participants and 35% of intervention participants had more than 3 sexual partners at baseline. At 3 months, in both groups most participants had 1 or 2 sexual partners in the past 3 months (64% total). Average number of sexual partners remained stable across the intervention period. Of participants who reported sexual

activity at baseline and 3 months, high percentages of condomless sex were reported. In an assessment of PrEP readiness, almost 70% of both study arms reported the importance of starting PrEP between 1-5 on a 10-point scale. 64% of control participants and 69% of intervention participants rated their motivation to start PrEP as between 1-5 on a 10-point scale.

Patient Activation

The Patient Activation Measure (PAM-13) was used, with a Cronbach's alpha of 0.93, to measure patient activation within the sample at each survey timepoint [29]. Both study arms scored within the high-level activation category (category 4, defined as 67.1-100 points) at baseline. Patient activation scores remained stable across both groups over the 3 months (Table 2).

PrEP Knowledge, Uptake, and Adherence

Only 14 participants reported not having heard of PrEP before initiating the RCT (7 control and 7 intervention participants). Although most participants had heard about oral PrEP (87% of control participants and 86% of intervention participants), there was less overall knowledge of 2-1-1 or injectable indications. Both groups had similar rates of lifetime prior PrEP use, with 18.7% of control participants previously using PrEP and 22.2% of intervention participants. Participants were most likely to hear about PrEP from their friends (48%), a doctor (36%), social media (35%), or an HIV counselor (24%). PrEP uptake was initiated by 14 intervention participants at the 3-month mark (25%) and 11 participants in the control group (19.0%). Almost all participants reported using the daily oral pill, but one control participant reported using injectable prep. Information on PrEP type is missing for 3 control participants, as they tested adherent on Ursure testing but did not report PrEP usage in their 3-month survey data. All participants were administered UrSure rapid adherence tests at their 3-month study visit, regardless of reported PrEP uptake status. PrEP bio-marker testing had a low rate of return across both arms. At the 3-month mark of the 58 control participants who completed the survey, only 35 participants completed the biomarker testing (60.3%) and of the 56 intervention participants, only 34 completed the testing (60.7%). Reported adherence levels according to tests were low across the sample, with 88.2% of intervention participants and 80.0% of control participants demonstrating non-adherence based on test results at 3 months. Of the 11 control participants with PrEP uptake, 9 completed biomarker testing and 5 were found to be adherent (55%), compared to 14 intervention participants, of which 10 completed biomarker testing and 4 were found to be adherent (40%).

Table 2. PrEP eligibility, readiness, knowledge, and uptake among participants from baseline to 3 months.[a-d]

			Baseline Control (n=75)	Baseline Intervention (n=72)	3 Month Control (n=58)	3 Month Intervention (n=56)
			n (%)	n (%)	n (%)	n (%)
PrEP Readiness Ruler						
	On a scale from 1 to 10, how important is starting PrEP to you right now?					
		1-5	51 (68.0)	50 (69.4)		
		6-10	24 (32.0)	22 (30.6)		
	On a scale from 1 to 10, how motivated do you feel to start PrEP right now?					
		1-5	48 (64.0)	50 (69.4)		
		6-10	27 (36.0)	22 (30.6)		

PrEP Knowledge					
	Before today, what types of PrEP had you heard about? (Check all that apply)				
	Oral PrEP	65 (86.7)	62 (86.1)		
	Oral PrEP Episodic	24 (32.0)	28 (38.9)		
	Injectable	21 (28.0)	15 (20.8)		
	Other	1 (1.3)	0 (0.0)		
	I have never heard of PrEP	7 (9.3)	7 (9.7)		
	Where did you hear about or get information on how to use PrEP in the last 6 months?[a]				
	Pharmacist	3 (4.4)	2 (3.1)		
	Doctor	24 (35)	24 (36.9)		
	Friends	26 (38)	38 (58.5)		
	HIV counselor	12 (18)	20 (30.8)		
	Social media	26 (38)	20 (30.8)		
	Other	15 (22)	11 (16.9)		
Sexual Activity					
	Number of Sexual Partners (Last 3 Months)[b]				
	Mean (SD)	2.69 (4.24)	2.81 (2.90)	2.38 (2.97)	2.62 (3.61)
	Reported Sexual Partners				
	None	3 (4.0)	3 (4.2)	6 (10.3)	4 (7.3)
	1	37 (49.3)	25 (34.7)	30 (51.7)	23 (41.8)
	2	14 (18.7)	19 (26.4)	8 (13.8)	10 (18.2)
	3+	21 (28.0)	25 (34.7)	14 (24.1)	18 (32.7)
	Condomless Sex				
	Anal Receptive Condomless	22 / 31 (71.0)	17 / 26 (65.4)	19 / 24 (79.2)	17 / 20 (85.0)
	Anal Insertive Condomless	11 / 15 (73.3)	5 / 8 (62.5)	14 / 16 (87.5)	5 / 7 (71.4)
	Vaginal Receptive Condomless	8 / 9 (88.9)	17 / 21 (81.0)	14 / 22 (87.5)	13 / 21 (81.2)
	Vaginal Insertive Condomless	8 / 8(100)	8 / 9 (88.9)	4 / 5 (80.0)	6 / 7 (85.7)
Patient Activation Score					
	Mean (SD)	78.02 (16.61)	77.74 (20.55)	77.06 (18.79)	80.13 (16.54)
PrEP Uptake					
	Pre-Baseline PrEP Uptake (Lifetime)	14 (18.7)	16 (22.2)		
	PrEP Uptake (3 Month)			11 (19.0)	14 (25.0)
	PrEP Type (Select All that Apply)				
	Daily oral pill	14 / 14 (100.0)	15 / 17 (88.2)	7 / 11 (63.6)	14 / 14 (100.0)
	Injectable PrEP	0 / 14 (0.0)	1 / 17 (5.9)	1 / 11 (9.1)	0 / 14 (0.0)
	2-1-1	0 / 14 (0.0)	1 / 17 (5.9)	0 / 11 (0.0)	0 / 14 (0.0)
	Undetermined[d]			3 / 11 (27.2)	
	PrEP UrSure Adherence Test Results				

		Adherent			5 / 35 (14.3)	4 / 34 (11.8)
		Non-adherent			28 / 35 (80.0)	30 / 34 (88.2)
		Intermediate			2 / 35 (5.7)	0 / 34 (0.0)
	UrSure Adherence Among PrEP Users					
		Adherent			5 / 9 (55.6)	4 / 10 (40.0)
		Non-adherent			4 / 9 (44.4)	6 / 10 (60.0)

[a]n=68 for control, n=65 for intervention due to skip logic
[b]1 missing for 3 Month Intervention
[c]Denominator represents number of participants who indicated each sexual activity
[d]Undetermined participants tested adherent on UrSure Biomarker but did not report PrEP Use at 3 Months

Intervention

Session content and information

The intervention's acceptability and feasibility is summarized in Table 3, including session delivery method, topic coverage, participant referrals, session satisfaction, and satisfaction with the PrEPresentative. 58 (80.6%) participants attended the first session, 36 participants (50%) attended 2 sessions, 19 (26.3%) attended three sessions and 5 (6.9%) attended four sessions. Phone sessions and in-app message-based intervention sessions were similarly utilized (42.4% and 41.5%), but most sessions took place outside of the app (video or phone call, 58.5% of all sessions). Motivation was discussed in 88.1% of sessions, with PrEP knowledge following as the second most discussed topic. HIV knowledge was discussed in 19.5% of sessions, with sexual health being discussed in 34.7%. Substance use, transportation, food insecurity, and housing were either not discussed or discussed across only one session. Referrals were provided to participants in 33.9% of sessions. The most common referrals were to PrEP clinics, with the second most common being to PrEP educational materials. Nine referrals to PrEP navigators were made.

Intervention Satisfaction

In post-session satisfaction surveys, the post-session satisfaction mean across sessions was 6.23 on a 7-point scale with a Cronbach's alpha of 0.85. Two-fifths of participants reported being very satisfied, with an additional 39% mostly satisfied, demonstrating a consistent level of satisfaction among the attendees. Satisfaction for the interventionalist was high, with 56.4% of participants indicating they were very satisfied and 29.1% indicating they were mostly satisfied with the care navigator. While a majority remained engaged and satisfied, about 9.1% of participants were indifferent or mildly dissatisfied, and a small fraction (5.5%) did not speak with the PrEPresentative.

Table 3. Session attendance, delivery, acceptability and feasibility of the PrEPresent intervention (n=72).[a]

		Total Sessions (n=118)	Session 1 (n=58)	Session 2(n=36)	Session 3(n=19)	Session 4(n=5)
		n (%)	n (%)	n (%)	n (%)	n (%)
Attendance			58 (80.6)	36 (50)	19 (26.3)	5 (6.9)
Session Delivery						
	Video Call	19 (16.1)	10 (17.2)	4 (11.1)	3 (15.8)	2 (40.0)
	Text	49 (41.5)	20 (34.5)	17 (47.2)	9 (47.4)	3 (60.0)
	Phone	50 (42.4)	28 (48.3)	15 (41.7)	7 (36.8)	0 (0.0)
Session Topics						

	Individual					
		Motivation	104 (88.1)	53 (91.4)	32 (88.9)	15 (78.9)	4 (80.0)
		Adherence	12 (10.2)	2 (3.4)	5 (13.9)	3 (15.8)	2 (40.0)
		Substance Use	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Transportation	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
		Food Insecurity	1 (0.8)	1 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)
		Sexual Health	41 (34.7)	28 (48.3)	7 (19.4)	5 (26.3)	1 (20.0)
		Self-efficacy	24 (20.3)	13 (22.4)	6 (16.7)	4 (21.1)	1 (20.0)
		Patient Activation	49 (41.5)	26 (44.8)	13 (36.1)	9 (47.4)	1 (20.0)
		PrEP Knowledge	66 (56.0)	56 (96.6)	8 (22.2)	1 (5.3)	1 (20.0)
		HIV Knowledge	23 (19.5)	17 (29.3)	4 (11.1)	1 (5.3)	1 (20.0)
		Other, specify	55 (46.6)	26 (44.8)	16 (44.4)	10 (53)	3 (60.0)
	Socio-cultural						
		Relationships	15 (12.7)	10 (17)	4 (11.1)	1 (5.3)	0 (0.0)
		Other, specify	4 (3.4)	2 (3.4)	1 (2.8)	1 (5.3)	0 (0.0)
	Structural						
		Housing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Stigma	2 (1.7)	2 (3.4)	0 (0.0)	0 (0.0)	0 (0.0)
		Insurance	19 (16.1)	14 (24.1)	4 (11.1)	1 (5.3)	0 (0.0)
		Work/Employment	3 (2.5)	0 (0.0)	1 (2.8)	2 (10.5)	0 (0.0)
		Other, specify	5 (4.2)	2 (3.4)	1 (2.8)	2 (10.5)	0 (0.0)
Referrals[a]			40 (33.9)	24 (41.4)	13 (36.1)	3 (15.8)	0 (0.0)
	PrEP Navigator		9 (7.5)	6 (10.3)	3 (8.1)	0 (0.0)	0 (0.0)
	PrEP Clinic		21 (17.8)	15 (25.9)	8 (22.2)	1 (5.3)	0 (0.0)
	PrEP Educational Materials		13 (11.0)	8 (13.8)	4 (11.1)	1 (5.3)	0 (0.0)
	Sexual Health Resource		1 (0.8)	1 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)
	STI/HIV Testing		4 (3.3)	2 (3.4)	1 (2.7)	1 (5.3)	0 (0.0)
	Community Clinic		1 (0.8)	0 (0.0)	1 (2.7)	0 (0.0)	0 (0.0)
Post Intervention Session Satisfaction							
	Mean (SD)		6.23 (1.09)	6.23 (1.01)	6.25 (1.15)	6.15 (1.20)	6.35 (1.04)
PrEPresent Care Navigator Satisfaction							
	Very satisfied		31 / 55 (56.4)				
	Mostly satisfied		16 / 55 (29.1)				
	Indifferent or mildly dissatisfied		5 / 55 (9.1)				
	I did not talk to the Care Navigator		3 / 55 (5.5)				

[a]No referrals were made to the following: PrEP Income Support, PEP, Gender Affirming Resources, Transportation Services, Housing Services, Substance Use Services, Domestic Violence Support, Mental Health Resources, Legal Aid, COVID Services, Social/Community Support, Food Pantry, Insurance Navigation, or Immigration Services.

Platform Usage and Satisfaction

Overall, intervention participants utilized the PrEPresent app more than control participants. The mean total logins on the platform was 6.31 (9.27) in the control group and 15.93 (15.85) in the

intervention group (Table 4). A similar trend was observed in the mean total minutes spent on the platform, with control group participants spending 3.03 (5.70) minutes on average compared to 9.51 (11.47) minutes in the intervention group. Platform satisfaction was also rated more highly among intervention participants, with 41.1% stating they were very satisfied compared to 25.9% of control participants. More than two-thirds of intervention participants stated PrEPresent helped them deal with the challenges they've faced getting on PrEP compared to 43.1% of control participants (Table 4.) Satisfaction around the app platform was universally high across both RCT arms though overall usage of the platform was low. Around 70% of participants agreed or strongly agreed that the platform was easy to use. At least 70% of participants in both arms stated PrEPresent helps them make healthier choices at a 4 or above on a 0–7-point sliding scale. There were high ratings on levels of trust for the information presented in the app, with no intervention participants disagreeing or strongly disagreeing that they trust the information in PrEPresent. Most participants would use the app in the future.

Table 4. 3-Month mHealth platform engagement and usability measurements. [a]

			Total Control (n=75)	Total Intervention (n=72)	3 Month Control (n=58)	3 Month Intervention (n=56)
			n (%)	n (%)	n (%)	n (%)
Platform Usage						
	Total Logins					
		Mean (SD)	6.31 (9.27)	15.93 (15.85)		
		Median (IQR)	2.00 (1.00, 7.50)	11.00 (4.00, 22.25)		
	Total Minutes					
		Mean (SD)	3.03 (5.70)	9.51 (11.47)		
		Median (IQR)	0.86 (0.04, 2.73)	5.30 (2.01, 13.06)		
Overall, how satisfied are you with PrEPresent?						
	Very satisfied				15 (25.9)	23 (41.1)
	Somewhat satisfied				30 (51.7)	22 (39.3)
	Somewhat unsatisfied				12 (20.7)	10 (17.9)
	Not Satisfied				1 (1.7)	1 (1.8)
Has PrEPresent helped you deal with the challenges you've faced getting on PrEP?						
	Decline to answer				20 (34.5)	13 (23.2)
	No, it really didn't help				13 (22.4)	9(16.1)
	Yes, it helped				17 (29.3)	28 (50.0)
	Yes, it helped a great deal				8 (13.8)	6 (10.7)
PREPRESENT was easy to use						
	Strong Disagree				0 (0.0)	2 (3.6)
	Disagree				4 (6.9)	5 (8.9)
	Undecided				13 (22.4)	9 (16.1)
	Agree				24 (41.4)	23 (41.1)
	Strongly Agree				17 (29.3)	17 (30.4)

	Strong Disagree				0 (0.0)	2 (3.6)
PREPRESENT was hard to use						
	Strongly Disagree				15 (25.9)	12 (21.4)
	Disagree				36 (62.1)	35 (62.5)
	Agree				5 (8.6)	7 (12.5)
	Strongly Agree				2(3.4)	2 (3.6)
I trust the information in PREPRESENT						
	Strongly Disagree				1 (1.7)	0 (0.0)
	Disagree				1 (1.7)	0 (0.0)
	Agree				26 (44.8)	26 (46.4)
	Strongly Agree				30 (51.7)	30 (53.6)
I would use PREPRESENT in the future if it were available						
	Strongly Disagree				3 (5.2)	6 (10.7)
	Disagree				14 (24.1)	7 (12.5)
	Agree				34 (58.6)	32 (57.1)
	Strongly Agree				7 (12.1)	11 (19.6)
PREPRESENT helps me make healthier choices in my life.[a]						
	0-3				15 (25.9)	17 (30.4)
	4-7				43 (75.2)	39 (69.6)

[a] Zero-Seven-point sliding scale.

Discussion

Overall, within a sample of racially and ethnically diverse SGM youth, PrEPresent met the objectives for feasibility and acceptability in the Phase 3 RCT. 66.7% of participants were gender and sexual minority youth of color, and 66.7% of the sample were transgender or nonbinary. Despite hitting these metrics, the project did not see high rates of PrEP uptake within the community when compared to other PrEP uptake projects [30-35]; or when compared against documented PrEP usage within similar cohorts outside of intervention settings [8,21]. Additionally, usage of the mHealth platform was overall low across both study arms compared to other iteration of the HMP platforms [27,36-38]. The information from the outcomes of this project is valuable in understanding how future projects should engage SGMY in HIV prevention efforts, particularly using health technology.

PrEP Uptake and Adherence

Although PrEP uptake within the intervention group was 25% and PrEP uptake in the control group was 19.0%, these are lower uptake percentages compared to other interventions accessing PrEP initiation. In a 2016 active PrEP Patient Navigation study, 34% of all participants initiated PrEP by 12 weeks, 29% of the control group and 40% of the intervention group [31]. In a non-incentivized PrEP Uptake project that removed costs to provider visits and labs amongst Black YSMM, 34% of the sample initiated PrEP but 17% discontinued the medication [32]. A motivational interviewing intervention at time of STI testing notes a 52.3% intervention PrEP prescription rate versus 27.9% in the control group (P=.005) [33]. A few studies have noted intervention-level PrEP uptake levels similar to PrEPresent but with greater difference between control and intervention groups. A 2019 culturally tailored counseling PrEP intervention found that of 25 control participants, none initiated PrEP compared to 6 of 25 intervention participants (p=.02) [30] and a 2021 RCT of Partner Notification Services and Social Network strategy found a significant 24% vs. 11% (p=0.04) different between intervention and control in Black SMM [35]. Of comparable mHealth studies that

have been published some have seen similar levels of PrEP uptake and others have seen higher rates of uptake post intervention in certain participants. In the TechStep project, there was no difference between intervention arms (text plus, text only, webapp +, webapp only) and control groups in PrEP uptake with transgender and gender expansive youth [39]. In a mobile messaging mHealth app for SMM, high risk HIV-negative groups had a higher odds of HIV testing and PrEP usage, but these behavioral changes were not noted for the low-risk HIV negative participants [40]. In the theory-driven MyChoices app, HIV testing was higher within the intervention group, but no difference in PrEP uptake was noted. Future mHealth projects targeting PrEP uptake powered for efficacy are required to understand how mobile health can impact overcome barriers SGM youth face to starting PrEP.

Although adherence was not an outcome for this project, positive adherence testing on the UrSure test was used as an indicator of PrEP uptake in conjunction with self-reported survey data. Biological markers of PrEP use continue to be important in conjunction with self-reported PrEP usage information in understanding uptake and adherence, as evidenced in both clinical and research settings [41,42]. Participants were encouraged to complete the at-home UrSure test at the time of their follow up survey, but many completed only the online survey portion. The specimen collection was additionally incentivized, and participants could earn a bonus incentive for completing all study components. It is important to note that despite this, completion of the at-home UrSure urine test for PrEP adherence was low across both arms. Of those who completed the 3-month surveys, only around 60% also completed the Ursure testing (for both arms) . This accounted for 47% of the total initial sample from baseline. In a study accessing feasibility of urine testing for PrEP adherence, it was found to be theoretically more acceptable than phlebotomy draw, finger prick, or hair test among a sample of young people from a PrEP program [43]**.** In a 2023 qualitative feedback study on self-collected STI testing from a similar participant base, low levels of return in this project were noted for those who had less concerns about positive HIV and STI diagnosis [44]. It is possible that due to the low PrEP uptake in our cohort, participants were not as interested in understanding their PrEP adherence levels, as most participants reported they were not taking the medication. Rates of adherence on the Ursure tests were also low amongst our participants**.** The UrSure point of care test measures adherence of medication taken in the last 48-72 hours. Post-intervention qualitative feedback with PrEPresent participants around PrEP adherence testing may provide insights into motivators and barriers to test completion, as well as to understand which versions of PrEP adherence testing (urine, dried blood spot, hair strand) may be most acceptable to this participant population. In the same qualitative study mentioned earlier, participants highlighted desires for video-based instructions, which may help specimen collection and return [44]. Biological markers of adherence delivered key insights into PrEP uptake across the cohort, and future studies may pilot test adherence testing protocols with members of YCABs to supplement understandings of acceptability and troubleshoot sample collection before utilization. Projects must also note that evolving PrEP landscapes and the usage of 2-1-1 PrEP may impact results regarding adherence across different forms of testing, and this should also be considered when understanding feasibility of biological testing**.**

Intervention Feasibility and Acceptability

Within intervention session attendance, 50% of participants attended a second session, meeting the metric for feasibility. Completion of the fourth session was low, at only 5 participants (6.9%). Four intervention sessions were offered to participants within the 3-month active intervention period, and scheduling this number of sessions in that time may not have seemed practical for the participant population. Percentage of referrals dropped in the third and fourth sessions, possibly indicating that a reduced amount of session may still meet participant needs [33,35,45]. It is possible that even just an initial session delivering PrEP information to SGMY is supportive in their decision to pursue a PrEP prescription, as motivation and PrEP knowledge were the most discussed intervention session topics

during the first session. Post-session satisfaction across sessions remained high and scored well-above our target average of 4 for feasibility. Overall satisfaction with the PrEPresentative was also incredibly high, with the majority of participants rating their satisfaction as “very satisfied”. These results demonstrate that in a population of SGMY, a peer-support navigation intervention for PrEP uptake is acceptable and feasible.

Delivery of the intervention sessions varied across participants and sessions. Though originally video conferencing had been intended as the main form of intervention delivery, YCAB feedback indicated that multiple messaging options may be more advisable, particularly because of the overall increase in video meetings throughout the COVID-19 pandemic. Future interventions should utilize community feedback to understand desires for deliveries as well as train interventionalist on multiple methods for participant engagement. Text or phone call-based sessions may support meeting participants where they are at.

One reason acceptability and feasibility of the intervention may have been so high despite low platform usage is because PrEPresent prioritized community-based collaboration throughout all phases of the project. App feedback was overwhelmingly positive, with most participants trusting the information in the app and agreeing that it helped them make better choices. Youth working groups and youth advisory boards (YAB) comprised of racially and ethnically diverse SGMY engaged with the project to understand the similarities and differences between YSMM and transgender and non-binary populations and how an mHealth intervention could best serve them both. Members of the research team, from research assistants to the interventionalist, represent different components of the community represented within this sample. Uplifting community voices should continue to be prioritized in prevention strategies to meet community members' needs.

Platform Usage and Satisfaction

Usage of the PrEPresent intervention was overall low, as compared to other iterations of mHealth projects built on the HMP Platform [25,27,36]. Intervention participants did have similar login rates to the app to other mobile health platforms [27,38], which may be due to utilizing scheduling features to meet with the interventionalist. Most intervention participants chose to engage with the PrEPresentative outside of the app (through phone or video calls), but this alone does not fully explain the low time spent within the app. The project team worked to adapt the platform to make it interactive but certain features shown to be acceptable or increase engagement in other mHealth interventions were not integrated. Features such as usage based points or digital currency [36], app-based health monitoring and tailored messaging [24,46], serious gaming or enhanced gamification [47,48], peer mentor engagement [49], and access to HIV prevention materials such as home tests or condoms and lube [24,46] have been demonstrated to engage similar participant populations in mHealth studies. Reviews of published mHealth findings have found links between higher app usage and behavior change [50]. Mhealth interventions hoping to combine app-based features with external features demonstrated to improve adherence to medication or initiation of care such as two-way SMS or peer health navigators may consider additional in-app incentives to encourage user engagement and should prioritize the collection of app paradata to explore participant usage.

COVID-19

PrEPresent was developed and tested within the context of changing health landscapes associated with the COVID-19 pandemic. Foundational research for the project occurred in 2021, when many aspects of medical care delivery and daily life were still impacted by COVID-19. Characterizations of PrEP usage and continuations during the COVID-19 pandemic are still continuing to be understood, with one metanalysis citing studies with 30% reduction of PrEP use in similar US- based samples [51]. Still, other projects covered in this analysis cited stable PrEP usage or an increase in initiation throughout the pandemic globally. While it is difficult to understand the exact impact of

COVID-19 on our participant population's interest and willingness to uptake PrEP, there is documentation that perceived risk of HIV and changes in sexual behaviors occurred during that time [52,53]. One article citing clinical strategies to adjust to pandemic PrEP access noted that newly offered telehealth access for services remained in use even after COVID-19 cases had stabilized [54]. An overview of PrEP Access through telehealth published in 2022 found both publicly funded clinical settings and private companies utilizing telehealth for PrEP delivery, in asynchronous or synchronous methodologies, and highlighting the usage of a California state funded tele-PrEP delivery program (one of five states offering this service) [55]. Given that the study was deployed in the post-COVID-19 pandemic period, particularly in a state offering online PrEP access, the novelty of an app-delivered peer support navigator for PrEP uptake may have been less appealing during this time where many services had shifted to offer electronically based care.

Limitations

Although the study was not powered to access efficacy within the pilot project, PrEPresent did demonstrate that SGM youth find an mHealth peer navigation intervention about PrEP uptake feasible and acceptable. While PrEPresent did recruit a racially diverse sample of SGM youth participants from the Los Angeles area, the study is not powered to look at comparisons between the outcomes for different racial/ethnic groups. Because of the specific eligibility criteria around race and ethnicity, the outcomes cannot be generalized across different racial/ethnic groups who may also be at greater likelihood of HIV acquisition. Because recruitment for the project took place in a largescale US city, results may not be generalizable to other geographic areas where factors impacting PrEP uptake may differ, such as access to insurance coverage or clinical spaces specializing in PrEP services.

Future Directions

As demonstrated in the outcomes of this project, one limitation of many mHealth interventions is engagement in the application or web-based tool [50]. In a similar mHealth study, while community events, group sessions, access to services, and usage of their mobile health app were all utilized, app usage averaged about 3.35 minutes per user and PrEP outcomes were not significant [56]. Understanding the best features to drive long-term usage and interest in app platforms and to track and analyze the usage of those features will move app-based PrEP interventions towards higher rates of use, which are tied to better prevention outcomes. Engagement linked to features available through mHealth platforms will also need to consider scalability (the ability to offer the app and features to larger amounts of people) in terms of translational efforts in being integrated into clinical care [40,57]. Future studies will need to prioritize the components of their interventions that work best within their participant population, such as interventionalist visits in this study, to understand how to guide engaging mHealth projects into translatable tools for HIV prevention.

To date, few studies have focused exclusively on PrEP uptake through guided patient navigation using an mHealth platform. Patient activation was a measurement of interest in this study for understanding movement towards behavior change across the intervention with SGM youth and a basis for the intervention guidelines. At baseline, both control and intervention participants scored within the highest category of patient activation indicating high levels of self-management health behaviors such as medication management and healthcare participation with little change during the study. Future projects tailored towards PrEP uptake utilizing a patient navigator may want to purposefully recruit participants with different patient activation levels to understand the impact of this method of intervention on people at different stages of health management.

Throughout the course of this project's development, changes in the types of PrEP available from foundational research to RCT execution occurred. Future mHealth applications supporting PrEP uptake and adherence will need to be developed within the evolving context of PrEP usage amongst

sexual and gender minority communities [58,59]. Across the US, injectable PrEP usage alone increased from 1.1% to 2.5% of all PrEP prescriptions from 2022 to 2023 [60]. Currently, two Phase III clinical trials are being conducted on a longer acting injectable PrEP options Lenacapavir, delivered in-clinic twice-yearly [61]. Injectable PrEP may have a lower barrier to uptake and adherence, particularly for those accessing the medication through Medicare coverage, as a new National Coverage Determination expanded coverage to both oral and injectable PrEP medications with no cost-sharing [62]. With the introduction of injectable PrEP and the popularity of on-demand PrEP, daily PrEP adherence may not be as relevant of a metric for HIV prevention moving forward. Instead, initiation, persistence, and clinical appointment attendance may need to be addressed through innovative app features.

Conclusion

Results from the PrEPresent study indicate that SGM youth at greater likelihood of HIV acquisition are willing to engage with a peer-support navigator through an mHealth platform to understand more about their relationship to PrEP and PrEP uptake. Access to this type of mHealth app in combination with peer navigation may increase PrEP uptake in those outside of the PrEP care continuum. Of those organized into the intervention arm, the app and PrEPresentative were satisfactory although overall engagement was low. Additional mHealth studies around prevention should continue to include and elevate the voices of their participant populations through community-engagement processes to ensure they meet the needs of sexual and gender minority people.

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Conflicts of Interest:

None declared.

Abbreviations:

CDC: US Centers for Disease Control and Prevention
HIPPA: Health Insurance Portability and Accountability Act
LGBTQ+: Lesbian, gay, bisexual, transgender, and queer

mHealth: Mobile Health
PrEP: Pre-exposure Prophylaxis
RCT: Randomized control trial
SGM: Sexual and gender minority
YSMM: Young sexual minority men

Data availability:

The data sets generated and analyzed during this study will be available from the corresponding author upon reasonable request.

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