ORIGINAL PAPER

TRUST: Assessing the Efficacy of an Intervention to Increase HIV Self-Testing Among Young Black Men Who have Sex with Men (MSM) and Transwomen

Victoria Frye[1] · Vijay Nandi[2] · Mark Q. Paige[2] · Jermaine McCrossin[2] · Debbie Lucy[2] · Marya Gwadz[3] · Patrick S. Sullivan[4] · Donald R. Hoover[5] · Leo Wilton[6,7] · for the TRUST Study Team

Abstract

HIV testing among young Black MSM and transwomen (YBMSM/TW) is the gateway to biomedical HIV prevention or treatment. HIV self-testing (HST) is a method that may increase consistent HIV testing. TRUST, a brief, peer-based behavioral intervention, was designed to increase uptake of consistent (every three months) HST among YBMSM/TW in New York City. To test the efficacy of the intervention, we randomized 200 friend pairs into either the intervention condition (TRUST) or a time and attention control condition. A modified intent-to-treat analysis found that self-reported HST at 3-month follow-up was statistically significantly higher (uOR 2.29; 95% CI 1.15, 4.58) and at 6-month follow-up was marginally statistically significantly higher (uOR 1.94; 95% CI 1.00, 3.75) in the intervention arm as compared with the control arm. There were no statistically significant differences by arm at 9- or 12-month follow-up. TRUST, a culturally-congruent intervention to increase HST among YBMSM/TW, had short-term impact on past-three month HST.
Clinical Trials Registration ClinicalTrial.gov NCT04210271.

Keywords HIV testing · HIV self-testing · Peer intervention · Black men who have sex with men (MSM) · Transwomen

✉ Leo Wilton
   lwilton@binghamton.edu

1 Community Health and Social Medicine, Sophie Davis School of Biomedical Education/CUNY School of Medicine, City College of New York, City University of New York, New York, NY, USA

2 Laboratory of Infectious Disease Prevention, New York Blood Center, New York, NY, USA

3 Silver School of Social Work, New York University, New York, NY, USA

4 Rollins School of Public Health, Emory University, Atlanta, GA, USA

5 Department of Statistics and Biostatistics, Rutgers University, The State University of New Jersey, Piscataway, NJ, USA

6 Department of Human Development, College of Community and Public Affairs (CCPA), State University of New York At Binghamton, 4400 Vestal Parkway East, Binghamton, NY 13902, USA

7 Faculty of Humanities, University of Johannesburg, Johannesburg, South Africa

Introduction

In the United States (US), HIV testing occupies a central role in national and local strategies to curb the HIV epidemic [1–4]. Individuals who receive a positive test result may be linked to medical and social care; if a sustained undetectable viral load is achieved through treatment, these individuals cannot transmit the HIV virus to their sexual partners [5]. Importantly, delayed diagnosis is associated with poorer health outcomes and increased mortality and health care costs for those affected [6–9]. Those who test negative may consider uptake of effective biomedical prevention options, such pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP), alongside other acquisition risk reduction strategies [10]. Collectively, these approaches have the potential for significantly reducing HIV incidence. Yet, the Centers for Disease Control and Prevention (CDC) estimates that 80% of new infections occurring in 2016 were transmitted from the approximately 40% of people living with HIV who had not yet been diagnosed with HIV or who received a diagnosis but were not in care [11]. Because of this, in part, the CDC and others recommend consistent

testing (approximately every 3–6 months) for members of populations [12, 13] more vulnerable to HIV, including men who have sex with other men as well as transgender women (henceforth transwomen).

Gay, bisexual and other men who have sex with men (henceforth MSM) and transwomen who have sex with men continue to bear a disproportionate burden of HIV, with 67% of all new HIV diagnoses in the US occurring among this group in 2016 [14]. Racial disparities in HIV infections among MSM and transwomen remain stark, with Black and Latino MSM representing the majority of new HIV infections [14]. Young Black MSM are six times more likely to be unaware of their HIV infection, compared to other MSM, and face significant structural barriers to testing [7, 15]. Further, some current research suggests that sexually active Black MSM and transwomen could benefit from more frequent HIV testing [13]. Although HIV testing has increased among Black MSM in recent years [16], further increases in testing are needed to optimize uptake of biomedical and behavioral prevention strategies and linkage to medical care and uptake of ART early in HIV infection [17–22]. However, few HIV testing interventions designed specifically for young Black MSM and transwomen have been designed and tested [23, 24]. Further, the availability of novel HIV testing approaches, such as self-testing for those unable or unwilling to visit a testing site, offer opportunities for innovative testing interventions tailored to the needs of young Black MSM and transwomen [25, 26].

HIV self-testing is a method that may increase consistent testing by addressing user concerns around HIV stigma and increasing control over testing timing and context [27, 28], as well as well-founded mistrust of institutions or organizations based in lived experiences of racism and the legacy of medical racism in the US [29–31]. Early concerns among clinicians and HIV prevention/treatment professionals included potential lack of test operator skill and need for training, challenges with linkage to care, and risks inherent in receiving test results alone and unsupported [32]. In our previous research with Black MSM and transwomen, we found that while HIV self-testing was an acceptable option, potential users had concerns around cost, lack of support following a positive result, and correct test operation [33]. Yet, our formative research, in conjunction with our practical experience managing a large HIV testing program, also suggested that self-testing could be an empowering option that could support autonomy and reduce anxiety associated with contact with inhospitable or unsafe service contexts [27]. Moreover, a peer-based self-testing approach builds disclosure of a positive test result to a supportive social network member into the testing process [34–36]. Given that social support is associated with linkage to care and HIV testing, building social support into rapid self-testing may also increase likelihood of care linkage [37, 38]. Our formative

research found that HIV self-testing with a friend was an acceptable option that addressed concerns around individuals receiving positive test results alone and unsupported, potentially experiencing distress alone and/or decreasing the chances of being linked to HIV care [27, 33, 39].

Based on our formative research, program implementation experience, and the literature, we developed a peer-based behavioral intervention to increase the uptake of rapid HIV self-testing (every three months) among young Black MSM and transwomen [39, 40]. We designed the intervention so that friend pairs could learn self-testing together and support each other in future self-testing, as prior research demonstrated that social support is associated with increased testing among Black MSM [34, 35]. Additionally, because of the concern that self-testers might receive a positive result alone and unsupported, shared by both clinicians and potential self-test users, and thus be less likely to link to care, we designed modules where participants identified the specific peer support needed to facilitate linkage to care in the event of an HIV diagnosis. Here, we present results of a randomized controlled pilot trial of the intervention to establish preliminary efficacy.

Methods

Design

Eligible friend pairs, consisting of a "Primary Eligible Participant" (PEP) and the "Friend of the PEP," were randomized together to one of two conditions. In the intervention condition (the TRUST intervention), friend pairs engaged in HIV testing together as friends, using a standard counselor-administered fourth-generation rapid HIV test to establish HIV-negative status and a modified version of couples testing for MSM [41], and included all standard HIV risk reduction (e.g., modes of transmission, role of alcohol and drug use, etc.) and HIV testing (e.g., window period, testing options, etc.) content. Next, they participated in a 30-min TRUST intervention session; namely, a psycho-educational rapid HIV self-test training session, described in more detail below, focused on mobilizing social support, enhancing motivation, increasing knowledge, and acquiring skills to adopt and maintain consistent HIV testing, with focused instruction on HIV self-testing and planning as a friend pair for consistent self-testing and HIV prevention. The time and attention control arm had the friend pairs test for HIV separately, but share their test results prior to participating in a 30-min didactic informational session on self-screening for common health conditions, such as hypertension, diabetes, anxiety and depression, alcohol and drug abuse, and testicular and anal cancer. The intervention and control arm sessions were delivered by trained peer educators

and audio-recorded; the last author monitored fidelity to the intervention by listening to every fifth session and providing feedback on drift and contamination. Both session facilitators and participants knew to which study arm participants were assigned.

Enrollment began in July of 2016 and ended in December of 2017, with the final follow-up surveys occurring in January of 2019. Standardized web-based, self-administered surveys assessed outcomes and covariates at baseline and 3-, 6-, 9-, and 12-months post baseline. Participants received compensation at all study visits: $75 (baseline); $30 (3/6/9 M); $40 (12 M). All participants were provided HIV self-test kits at the baseline visit and at every follow-up session, using a method of their choice (mailed to their home or picked up at the site). This randomized pilot efficacy trial tests the hypothesis that PEPs randomized to the TRUST intervention were more likely to report consistent HIV self-testing, defined as self-testing in the past three months over a 12-month period, as compared with PEPs randomized to the time and attention control arm.

The institutional review boards at all participating institutions approved the study. A DSMB was convened, with members independent of the trial and funding agency, to monitor and support safe and effective conduct of the trial.

Participant Eligibility

Initially, PEPs and Friends of PEPs were eligible if they were: (1) 18–29 years of age; (2) assigned male sex at birth; (3) self-identified as Black, African American, Caribbean Black, African Black, or multiethnic Black; (4) resided in the NYC area; (5) were not HIV positive according to self-report; (6) reported insertive or receptive anal intercourse with a man or transwoman in the last 12 months; (7) were willing to participate in a study for 12 months; (8) could communicate in English; (9) provided informed consent, including participating in the study with a friend and HIV testing together or sharing test results. Participants were ineligible if they were enrolled in any other HIV-related research study involving HIV testing or have been a participant in an HIV vaccine trial.

After the pilot efficacy trial began, we made two changes to the eligibility criteria for PEPs. In January of 2017, we expanded the upper end of the age range criterion from 29 to 34, although the final sample accrued had an average of ~24 for both PEPs and Friend of PEPs. In addition, based on epidemiologic evidence showing stable infection rates among Latino MSM [42], in July of 2017, we expanded the race/ethnicity criterion to include individuals who self-identified as Latino/a/x, but not Black or African American. We note that despite this change, we did not enroll any participants who identified as Latino and did not *also* identify as Black, African-American, Afro-Caribbean or Black African. Thus,

all of the PEPs enrolled indicated that they were Black, African-American, Afro-Caribbean or Black African, either only or in addition to indicating another "race/ethnicity". We also adjusted the Friend of PEP criteria in late 2016; we determined that a number of eligible individuals would have enrolled in the study, as PEPs, if they had been able to include a friend who fell outside the original eligibility criteria for Friends of PEPs, for example, a cisgender female friend. Thus, in July 2016, we expanded the criteria *for the Friend of PEP* so that eligibility included only: 18 years of age or older; HIV negative; and able to communicate in English; these individuals must also have been willing and able to provide informed consent, including HIV testing with a friend and/or sharing test results.

Recruitment and Sample Accrued

Recruitment was conducted via online advertising, face-to-face outreach and referrals by study participants. For online recruitment, individuals clicked on an ad and completed a brief eligibility assessment. If they were eligible and interested in participating in the study with a friend, they completed an online contact card and were provided a link that they could send to a friend to complete the eligibility survey, indicate their interest in participating, and provide contact information. The study staff then retrieved this information and contacted both friends to schedule a study visit. In face-to-face recruitment, potentially eligible individuals were informed about the study and completed a preliminary eligibility assessment. Eligible participants were then asked to provide contact information for study staff follow-up. Finally, eligible and enrolled participants were encouraged to refer up to five people for the study and receive $10 for each person who completed the screening process and was found to be eligible for the study. When an eligible PEP and their eligible friend were matched and both identified a baseline enrollment date, the appointment was made. Both PEPs and their friends confirmed their understanding that, at the baseline enrollment visit, they would be tested for HIV and that their friend would learn the results of the test at the visit.

Among 3143 potential participants who landed on the web-based eligibility screening page, 2579 began the PEP screener. Of these, 451 were determined to be eligible as PEPs and 434 indicated that they were interested in participating in the study. However, of these, 372 provided adequate contact information for study staff to contact them. These eligible and interested PEPs were instructed (either by study staff or as described in the web-based instruction) to e-mail and/or text a unique Friend of PEP web-based eligibility screener link. This resulted in 434 Friend of PEPs starting the web-based eligibility screener, with 353 being eligible and providing adequate contact information. Once matched, as described above, a total of 200 unique friend

pairs or 400 individuals (PEPs and Friend of PEPs) attended the baseline visit and were randomized (See Fig. 1).

Baseline Visit Procedures

After both participants arrived at the site, they engaged in the informed consent process and were asked to provide contact information to assist with study retention. After the informed consent process was complete, participants were randomized as friend pairs in a 1:1 ratio into either the TRUST intervention or the time- and attention-matched control intervention arm using assignments generated by the study data analyst using Sealed Envelope Ltd. 2015 [available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists (Accessed 4 Mar 2016)]. Assignments were in sequentially numbered, sealed, opaque envelopes, which staff opened and recorded the pair's study ID number and assignment into the site's data management system. Neither staff nor participants were blinded to study arm assignment.

Participants then completed the baseline assessment via ACASI, which assessed sociodemographic characteristics, HIV testing history (including self-testing) [43], sexual behaviors, [44] substance use behaviors [45, 46], mental health indicators [47], peer support and engagement with study friend, and other psychosocial factors (e.g., health empowerment, internalized stigma, experiences of racial discrimination [48]) in the prior three months. Questions about sexual behaviors in the prior three months included number of anal or vaginal sex partners, insertive and receptive anal sex, condom use and HIV status of partners. Questions on use of substances in the prior three months included marijuana, stimulants (powder cocaine, crack cocaine, methamphetamine), prescription drugs, poppers, erectile dysfunction drugs, and club drugs. After completing the baseline assessment, participant pairs randomized to the intervention arm engaged in standard HIV testing and counseling *together as a friend pair* and the TRUST intervention session. Participant pairs randomized to the time and attention control arm received standard HIV testing and counseling *separately* and then came together, sharing their test results; they then engaged in the generic self-screening time and attention control arm. After the baseline study visit was complete, each participant received $75 cash and a round-trip transit fare card.

Intervention and Control Arms

The TRUST intervention was developed using a formative mixed methods research phase including in-depth interviews (N = 29) and quantitative surveys (N = 433) to explore relevant domains and evaluate interest in the core intervention mechanisms of self-determined and peer supported HIV self-screening [40]. Results informed the design of

the TRUST intervention, which was framed broadly within socioecological [49], empowerment [50–52], self-efficacy [53] and social support [54] theories, and incorporated core components of motivational interviewing theory [55], specifically exercises to address decisional balance associated with HIV testing [23, 56]. A brief pre-pilot phase enrolled eight friend pairs, after which the TRUST intervention condition was finalized. In this arm, after HIV testing and receiving results together, participant pairs assigned to the TRUST intervention condition engaged in the structured, interactive session that included the following components: (1) Describing their optimal sex life and how HIV testing fit into that; (2) HIV self-testing instruction (e.g., specific and clear instructions on how to operate the self-test; common mistakes and ways to avoid them, etc.); (3) HIV self-test skills building (e.g., peers taught each other how to operate the HIV self-test); (4) identifying and communicating the specific peer support needed to support consistent testing and receipt of test results; (5) planning for risk reduction and consistent self-testing and/or testing over time (together or apart). At the end of the session, participants developed personalized "Staying Negative" plans, specifying how to support each other in staying negative including through self-monitoring and -testing; finally, they selected their self-test delivery approach (mailed to their homes or picked up from the site). Participants were encouraged to support each other in enacting their testing plans, but there were no formal intervention components delivered by staff to the intervention arm pairs after the baseline session.

Time and attention control participant pairs were HIV tested separately, but received their results together, and then were provided the control condition, which offered information about a range of self-screening approaches for common, adverse health conditions, such as testicular cancer, anal cancer, high blood pressure, diabetes, anxiety and depression, alcohol and drug abuse, and HIV. In the control arm, each health condition and available self-screening methods were described didactically.

To reduce the potential bias of the cost of self-test kits as a factor in future HIV testing, all intervention and control participants received two HIV self-test kits at the end of the baseline visit and received free HIV self-test kits every 3 months via their preferred delivery method. There were no other control arm components delivered to control arm participants beyond the baseline session.

Training of peer educator-facilitators for both arms covered study purpose, ethics, privacy, confidentiality, procedures, and implementation and was delivered by the project investigators. Peer educators-facilitators also received clinical supervision to address issues that may have arisen during delivery of the sessions. Fidelity to the intervention and control arms was monitored via review of a random selection of audio recordings using a standardized form with qualitative
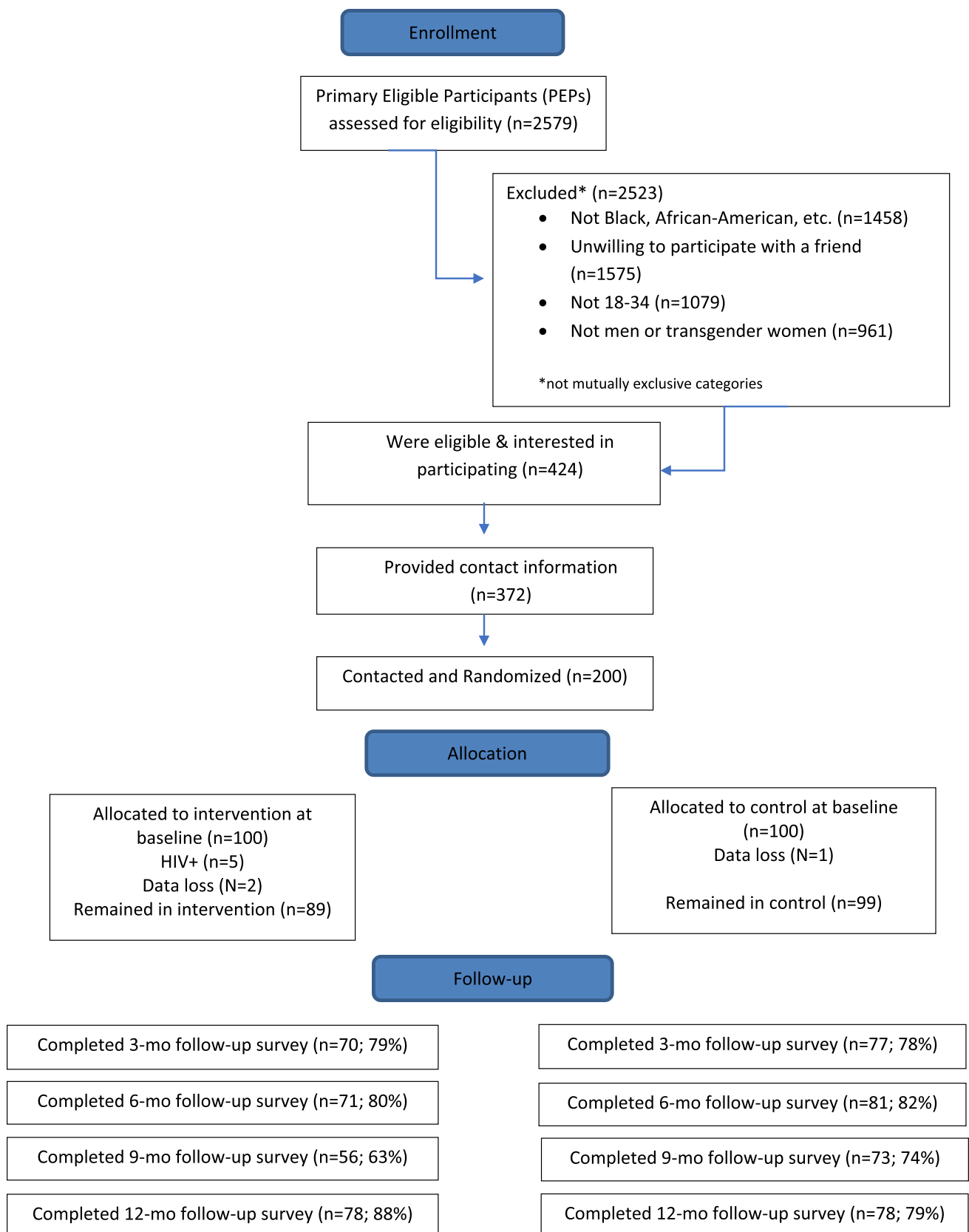
Enrollment

Primary Eligible Participants (PEPs) assessed for eligibility (n=2579)

Excluded* (n=2523)
- Not Black, African-American, etc. (n=1458)
- Unwilling to participate with a friend (n=1575)
- Not 18-34 (n=1079)
- Not men or transgender women (n=961)

*not mutually exclusive categories

Were eligible & interested in participating (n=424)

Provided contact information (n=372)

Contacted and Randomized (n=200)

Allocation

Allocated to intervention at baseline (n=100)
HIV+ (n=5)
Data loss (N=2)
Remained in intervention (n=89)

Allocated to control at baseline (n=100)
Data loss (N=1)

Remained in control (n=99)

Follow-up

Completed 3-mo follow-up survey (n=70; 79%)

Completed 6-mo follow-up survey (n=71; 80%)

Completed 9-mo follow-up survey (n=56; 63%)

Completed 12-mo follow-up survey (n=78; 88%)

Completed 3-mo follow-up survey (n=77; 78%)

Completed 6-mo follow-up survey (n=81; 82%)

Completed 9-mo follow-up survey (n=73; 74%)

Completed 12-mo follow-up survey (n=78; 79%)

Fig. 1 TRUST study consort flow diagram: primary eligible participants only

feedback provided to the peer educator-facilitators throughout the duration of the project.

Outcome Assessment: Follow-Up Surveys and Access to HIV Self-Test Kits

The primary outcome was self-reported consistent HIV self-testing, defined as self-testing for HIV within the past three months, over 12 months of follow-up. The primary outcome and covariates were assessed via follow-up surveys completed by participants either online or at the study site via ACASI. Participants were sent a link to the follow-up surveys by email, which they could complete remotely. Alternatively, participants could come into the study site to complete the follow-up survey. The follow-up assessment included the same questions as in the baseline survey, excluding some sociodemographic information. After the final survey at 12 months, participants who reported testing HIV positive in one of the follow-up surveys were contacted to ensure that they received medical and social care; at each point of contact, all participants were informed that study staff were available to provide resources for linkage to care and social services, as needed for HIV or otherwise.

Power and Statistical Analysis

The study was powered for a treatment effect for the primary binary outcome, consistent HIV self-testing (i.e., every three months) according to self-report. Our initial power calculation, with a 20% difference between the two arms (40% self-testing in the intervention arm and 20% in the control arm; 95% plausible interval for control values 10%, 30%), indicated that a sample size of approximately 188 participants (about 94 pairs) were required in each study arm to achieve ~80% power ($p < 0.05$) [57]. Analysis of outcomes among PEPs only were conducted on a modified intent-to-treat basis using subjects who were eligible and for whom we were able to collect data. After randomization, one PEP participant was discovered to have enrolled in another HIV testing study at the study site and was removed from the study. Because HIV testing was part of both arms of the study, a number of participants (N = 18; 13 Friend of PEPs and 5 PEPs) were found to be HIV positive after randomization. In consultation with our Institutional Review Board (IRB) and Data and Safety Monitoring Board (DSMB), we determined that these individuals could not continue in the study despite having been randomized due to the ethical imperative that we immediately support test result confirmation and linkage to medical and social care. When the participant who tested positive was a Friend of PEP, the PEPs (N = 13) continued in the study, despite not having received the full session, due to the receipt of the reactive test result, and were included in the modified intent to treat analysis. Thus, there were 19 randomized individuals who had baseline data

but no follow-up data and thus were not included in what became a modified intent to treat analysis. Of the 381 remaining participants, 190 were PEPs and were included in the analytic dataset; unfortunately, baseline data for two of these PEPs were lost due to a computer malfunction, leaving 188 PEPs in the analytic dataset (90 in the TRUST intervention arm and 98 in the control arm).

Using this sample, our analysis unfolded in several steps based on prior research [43]. First, descriptive analyses were conducted to assess randomization. Here, for two-group comparisons of continuous measures, Wilcoxon rank sum tests were implemented; for ordinal measures, the Cochran-Armitage test for trend was used to compare baseline characteristics across study arms. In addition, dropouts were compared to completers by baseline behavior and other characteristics to assess whether differential dropout occurred. Generalized estimating equation models using an independent structure and with subject as a cluster were used to assess reported changes from baseline to 3-, 6-, 9-, and 12-month follow-up, excluding participants who reported an HIV-positive test result at any follow-up period. An interaction term that concatenated treatment group and wave was used to calculate odds of HIV self-testing for the intervention arm participants compared with the control group participants. The primary outcome, self-reported occurrence of HIV self-testing by the PEP in the past three months, was compared between intervention and control arms.

We planned to adjust for variables in the final model that were associated at baseline with *both* study arm (indicating that randomization was suboptimal) and the study outcome, self-reported HIV self-testing in the past three months, using a statistical significance cut point of $p < 0.10$. Based on this strategy, we assessed associations among baseline variables that met that criteria (i.e., full-time employment vs. other and AUDIT score) and our outcome HIV self-testing in the past three months. We ran the final test of the intervention GEE model with each factor and then compared the models and found that the inclusion of the covariates did not significantly improve the model fit (and the covariates were not statistically significant in the model). Thus, we present the most parsimonious model for the test of the intervention's effect in an unadjusted model. Finally, we conducted exit interviews with all participants who reported a reactive or indeterminate test results during the follow-up period and who we could locate to ensure that they were connected to HIV care.

Results

The mean age of PEPs was 23.4 years (SD = 3.5 years). Most (85.6%) self-identified as cisgender male; 11.7% as a transwoman; and 2.1% as female. Three-fifths (59.9%)

self-identified as gay or same gender loving and nearly a third (30.3%) as bisexual; just one in ten (10.1%) were employed full-time and over half (65.4%) earned less than $10,000 per year. Almost three-quarters (73.4%) had a high school degree, GED, or a lower level of education (Table 1). In the three months before baseline, nearly a third (32.5%) reported condomless receptive anal intercourse and 38.8% reported condomless insertive anal intercourse. Over half (53.7%) reported sex while using drugs in the past three months and 16.5% reported five or more casual male or transwoman sexual partners in the past 3 months. Just 6.4% reported a new STI in the past 12 months and 9% were on PrEP (Table 2). No statistically significant differences at $p < 0.10$ were found between intervention and control arm participants on key demographic or behavioral characteristics, except for employment (16% vs. 5%, X^2 statistic $= 5.88$, 1 df, $p = 0.02$) and mean AUDIT scale scores (9.8 vs. 7.7; X^2 statistic $= 0.989$, 1 df $p < 0.05$). Five or more partners (X^2 statistic $= 2.90$, 1 df) and worry about HIV (X^2 statistic $= 2.0$, 1 df) were associated at $p > 0.10$.

At baseline, most participants (92.5%) reported lifetime HIV testing and just less than half (43.1%) reported HIV testing in the past 3 months. Less than one in five (14.4%) reported lifetime HIV self-testing, although a third of these participants had self-tested in the three months prior to enrollment. Almost half of participants (45.2%) indicated that they were very likely to self-test in the next three months. Differences in past three months HIV self-testing did not vary significantly by arm (Table 3).

Retention rates for both PEPs and Friends of PEPs over the follow-up period were: 89% at 3-month, 83% at 6-month, 81% at 9-month and 82% at 12-month follow up visits. Retention for PEPs only, were 79% at 3-month, 80% at 6-month, 63% at 9-month and 88% at 12-month follow up visits. Those PEPs not completing 3-month follow-up were more likely to be financially insecure ($p \leq 0.001$), unemployed ($p = 0.004$), and to have lower incomes ($p = 0.014$) at baseline. There were no differences in lifetime or prior 3-month self-testing at baseline by retention at 3, 6, 9 and 12 months.

Self-reported HIV self-testing at 3- and 6-month follow-up was significantly higher in the intervention arm as compared with the control arm. Participants in the TRUST intervention arm had twice the odds of reporting HIV self-testing in the past three months at the 3-month follow-up (uOR 2.29; 95% CI 1.15, 4.58) and almost twice the odds at the 6-month follow-up point (uOR 1.94; 95% CI 1.00, 3.75). The proportion of participants in the TRUST intervention arm who reported self-testing was 2% at baseline in the intervention arm, 57% at 3-months ($p = 0.02$), 54% at 6-months ($p \leq 0.05$), 39% at 9-months ($p = 0.34$), and 48% at 12-months ($p = 0.49$). This compares with the control arm where self-testing was 7% at baseline, 42% at 3-months and

6-months, 39% at 9-months, and 41% at 12-months. The difference in past 3-month self-testing was statistically significant by arm at 3-month follow-up ($p < 0.05$) and was marginally statistically significant at 6-month follow up ($p \leq 0.05$), but were not statistically significant at 9- and 12-months (Table 4).

Of the 188 PEPs, two reported testing HIV positive during follow-up. The participant who had been randomized to the TRUST intervention arm reported using the HIV self-test to identify the new infection; the participant had been randomized to the control condition did not report using the self-test. Of note, another five Friends of PEPs self-reported testing positive during the follow-up period; three had been randomized to the control condition and two to the TRUST intervention arm. None of these individuals reported using the HIV self-test to identify the new infection.

Discussion

Increasing consistent HIV testing is a critical component of the national prevention strategy in the US, where antiretroviral therapy and PrEP are available [58]. HIV self-testing has taken on increased importance in the context of the COVID-19 pandemic. [59] In this HIV self-testing RCT, the intervention approach utilized peer support, motivational enhancement and facilitated training approaches to increase consistent HIV testing using the self-test. Self-testing increased in both study arms among this sample; however, intervention arm participants were more likely to self-test at 3- and 6-months post-intervention as compared with control participants. Thus, the TRUST intervention demonstrated efficacy to increase consistent self-testing, which conforms to CDC recommendations for testing every three-to-six months for higher-risk groups [60]. The control arm in this study provided a strong test of the intervention, as it provided participants with information about HIV self-testing, was delivered to friend pairs, and included the provision of HIV self-test kits as baseline and every three months, to control for HIV self-test kit access.

We found that the effect of the TRUST intervention diminished over time within our study follow-up timeframe, which may be due to several factors. The intervention may have worn off, despite the follow-up contact required for the study design. As well, there may have been regression to the mean, a common occurrence in clinical trials [61]. Alternatively, it is possible that the effect of the intervention may have been evident over longer periods of time had follow-up continued past 12 months. Further research is needed to determine if more booster messages or sessions could, in a cost-effective manner, extend the positive impact of the intervention [24]. Also of importance is that the control arm's rate of HIV self-testing increased dramatically.

Table 1 Baseline sociodemographic characteristics by study arm, TRUST study 2016–18

	Total		Intervention		Control		Test statistic, df, p-value
	Primary (N=188)	Friend (N=188)	Primary (N=89)	Friend (N=90)	Primary (N=99)	Friend (N=98)	
Sociodemographics							
Age (Mean, SD)[a]	23.4 (3.5)	23.8 (5.7)	23.5 (3.7)	23.5 (4.8)	23.3 (3.4)	24 (6.4%)	t-test statistic=0.386, 186 df, p-value=0.700
Gender identity							Fisher's exact test, p-value=0.122
Female	4 (2.13%)	42 (22.7%)	2 (2.22%)	25 (26.6%)	2 (2.04%)	17 (18.7%)	
Male	161 (85.6%)	118 (63.8%)	81 (90%)	56 (60.5%)	80 (81.63%)	61 (67%)	
Male to female (MTF) transgender	22 (11.7%)	19 (10.3%)	6 (6.67%)	10 (10.6%)	16 (16.33%)	9 (9.9%)	
Other	1 (0.53%)	6 (3.2%)	1 (1.1%)	2 (2.1%)	0 (-)	4 (4.4%)	
Race/ethnicity							X^2 statistic=0.996, 3 df, p-value=0.802
African-American	99 (53.5%)	88 (49.2%)	50 (56.18%)	48 (51.6%)	49 (51.04%)	40 (46.5%)	
African/Other	56 (30.3%)	54 (30.2%)	25 (28.09%)	24 (25.8%)	31 (32.29%)	30 (34.9%)	
Afro Latino	13 (7.0%)	29 (16.2%)	7 (7.87%)	17 (18.3%)	6 (6.25%)	12 (14%)	
Caribbean	17 (9.2%)	8 (4.5%)	7 (7.87%)	4 (4.3%)	10 (10.42%)	4 (4.7%)	
Sexual identity							Fisher's exact test, p-value=0.164
Gay/same gender loving/queer	111 (59.9%)	103 (56.0%)	55 (61.8%)	51 (54.8%)	56 (57.1%)	52 (57.1%)	
Bisexual	57 (30.3%)	49 (26.6%)	26 (29.2%)	26 (28.0%)	31 (31.6%)	23 (25.3%)	
Questioning or unsure	3 (1.6%)	2 (1.1%)	3 (3.4%)	1 (1.1%)	0 (-)	1 (1.1%)	
Heterosexual/straight/other	16 (8.5%)	30 (16.3%)	5 (5.6%)	15 (16.1%)	11 (11.2%)	15 (16.5%)	
High school education or higher	137 (72.9%)	133 (73.1)	65 (73%)	64 (68.8%)	72 (72.7%)	69 (77.5%)	X^2 statistic=0.002, 1 df, p-value=0.962
Total personal income less than 10 K/year	124 (66%)	129 (70.1%)	56 (62.9%)	65 (69.9%)	68 (68.7%)	64 (70.3%)	X^2 statistic=0.694, 1 df, p-value=0.405
Full-time employment	19 (10.11%)	22 (11.9%)	14 (15.56%)	12 (21.8%)	5 (5.1%)	10 (11%)	X^2 statistic=5.88, 1 df, p-value=0.018
Financial insecurity (not enough money for food, rent, etc.)							X^2 statistic=4.21, 3 df, p-value=0.240
Never	44 (23.4%)	38 (20.5%)	24 (26.67%)	21 (22.3%)	20 (20.41%)	17 (18.7%)	
Once in a while (1–2 times)	39 (20.74%)	52 (28.1%)	16 (17.78%)	26 (27.7%)	23 (23.47%)	26 (28.6%)	
Fairly often (3–5 times)	50 (26.6%)	36 (9.5%)	28 (31.11%)	21 (22.3%)	22 (22.45%)	15 (16.5%)	

Table 1 (continued)

	Total		Intervention		Control		Test statistic, df, p-value
	Primary (N=188)	Friend (N=188)	Primary (N=89)	Friend (N=90)	Primary (N=99)	Friend (N=98)	
Very often (6 or more times)	55 (29.26%)	59 (31.9%)	22 (24.4%)	26 (27.7%)	33 (33.67%)	33 (36.3%)	
Health insurance							X^2 statistic=0.5, 1 df, p-value=0.480
Currently has health insurance	149 (79.26%)	137 (74.1%)	73(82.0%)	65 (69.2%)	76 (76.8%)	72 (79.1%)	
Usual health care							X^2 statistic=3.11, 3 df, p-value=0.375
Medical doctor's office	76 (40.4%)	72 (38.9%)	37 (41.1%)	41 (43.6%)	39 (39.8%)	31 (34.1%)	
Emergency room	47 (25.0%)	45 (24.3%)	26 (28.9%)	27 (28.7%)	21 (21.4%)	18 (19.8%)	
Community or Free clinic, HIV/STI (sexually transmitted infection) counseling and testing site, Health department	57 (30.3%)	59 (32.1)	25 (27.8%)	23 (–)	32 (32.7%)	37 (40.7%)	
Alternative practitioner (e.g., herbalist), Drug treatment program, other	8 (4.3%)	8 (4.3%)	2 (2.2%)	3 (3.2%)	6 (6.1%)	5 (5.5%)	

[a]Primary: Minimum=18; Maximum=33. Friend: Minimum=18; Maximum=54

Statistical tests contrast Primary treatment assignment

[b]Chi-square test not performed due to small cell counts

Because our study design controlled not only for time and attention, but also for format (peer-based), core content (awareness of the HIV self-test) and access (provision of HIV self-tests every three months), it is not possible to indicate that a significantly shorter and less resource-intensive intervention could achieve the same results. Further research using a multi-factorial design could answer such a question.

HIV self-testing is a critical option that can help to increase consistent HIV self-testing. The HIV self-test is believed to reduce anticipated stigma that acts as an important barrier to HIV testing [62]. As well, HIV self-testing allows users to test in privacy and on their own schedule. However, HIV self-testing does not necessarily reduce fear of a positive result and eventually reactive test results must be confirmed using a second rapid test or other method. Fear of this confirmation of HIV positive status may still prevent individuals from accessing care [44]. It is possible that HIV self-testing and/or consistent self-testing will increase openness to PrEP, through several mechanisms. The feelings of increased self-efficacy to self-screen that may come from consistent or even semi-annual use of an HIV self-test kit may facilitate uptake of user-driven prevention methods, such as PEP and PrEP. Future research could combine the TRUST intervention with transition to PrEP components embedded during the follow-up period to explore these possibilities.

There are several key limitations to our study. First, our outcomes were self-reported and increases in HIV self-testing may have reflected socially desirable responding; this could have been more acute in the intervention arm,

Table 2 Baseline sexual and drug use behavior and psychosocial factors by study arm, TRUST study 2016–2018

	Total		Intervention		Control		p-value
	Primary (N=188)	Friend (N=188)	Primary (N=89)	Friend (N=90)	Primary (N=99)	Friend (N=98)	
Sexual and drug use risk behavior							
Condomless receptive anal intercourse P3M	61 (32.5%)	62 (33.5%)	26 (28.9%)	25 (26.6%)	35 (35.7%)	37 (40.7%)	X^2 statistic=1.14, 1 df, p-value=0.286
Condomless insertive anal intercourse P3M	73 (38.8%)	60 (32.4%)	36 (40%)	23 (24.5%)	37 (37.8%)	37 (40.7%)	X^2 statistic=0.02, 1 df, p-value=0.895
Sex while using drugs P3M	101 (53.7%)	76 (41.1%)	49 (54.4%)	34 (36.2%)	52 (53.1%)	42 (46.2%)	X^2 statistic=0.003, 1 df, p-value=0.957
New STI P12M	50 (27.7%)	56 (30.6%)	52 (28.9%)	27 (28.7%)	48 (25.5%)	29 (32.6%)	X^2 statistic=0.04, 1 df, p-value=0.495
Five or more casual male and/or TGF sex partners	31 (16.49%)	16 (8.7%)	19 (21.11%)	7 (7.5%)	12 (12.24%)	9 (9.9%)	X^2 statistic=2.90, 1 df, p-value=0.102
HIV risk perception							
How likely are you to get HIV?	2.0 (1.2)	1.9 (1.3)	2.0 (1.2)	1.7 (1.0)	2.0 (1.2)	2.2 (1.5)	X^2 statistic=0.12, 1 df, p-value=0.729[a]
How worried are you about getting HIV?	3.4 (1.9)	3.2 (1.9)	3.6 (1.9)	3.0 (1.9)	3.2 (2.0)	3.3 (1.9)	X^2 statistic=2, 1 df, p-value=0.101 [a]
Current PrEP use	17 (9%)	20 (10.8%)	8 (8.9%)	6 (6.4%)	9 (9.2%)	14 (15.4%)	X^2 statistic=2.41, 1 df, p-value=0.120
AUDIT score mean (SD)	8.8 (5.9)	8.3 (4.7)	9.8 (6.5)	8.4 (5.1)	7.7 (5.1)	8.2 (4.3)	X^2 statistic=.989, 1 df, p-value=0.046 [a]
Drug use P3M							
Marijuana	133 (70.7%)	122 (66.3%)	62 (69.7%)	66 (71.0%)	71 (71.7%)	56 (61.5%)	X^2 statistic=0.096, 1 df, p-value=0.757
Stimulants	25 (13.3%)	17 (9.2%)	13 (14.6%)	6 (6.5%)	12 (12.1%)	11 (12.1%)	X^2 statistic=0.2511, 1 df, p-value=0.616
Club drugs/poppers	32 (17.0%)	27 (14.7%)	17 (19.1%)	11 (11.8%)	15 (15.2%)	16 (17.6%)	X^2 statistic=0.518, 1 df, p-value=0.472
Prescription/other	17 (9.0%)	12 (6.5%)	12 (13.5%)	6 (6.5%)	5 (5.1%)	6(6.6%)	0.969
Psychological Distress (2-item PHQ: low interest; depressed)	1.6 (0.8)	1.6 (0.8)	1.6 (0.7)	1.7 (0.9)	1.7 (0.9)	1.6 (0.7)	X^2 statistic=.016, 1 df, p-value=0.687 [a]

Table 2 (continued)

	Total		Intervention		Control		p-value
	Primary (N=188)	Friend (N=188)	Primary (N=89)	Friend (N=90)	Primary (N=99)	Friend (N=98)	
Mental Health (2-item: happy; calm and peaceful)	2.4 (1.1)	2.5 (1.3)	2.4 (1.1)	2.5 (1.4)	2.4 (1.1)	2.6 (1.3)	X^2 statistic = .057, 1 df, p-value = 0.812 [a]
Peer support							
Outness (# of friends know gay/sex with men/ attracted to men or TGW [none-all; 5-pt scale])	3.6 (1.1)	3.5 (1.1)	3.6 (1.0)	3.4 (1.1)	3.7 (1.1)	3.7 (1.1)	X^2 statistic = 0.486, 1 df, p-value = 0.486 [a]
Peer norms @ safe sex & testing (4-pt scale)	2.9 (0.7)	2.8 (0.7)	2.9 (0.7)	2.8 (0.8)	2.8 (0.7)	2.8 (0.7)	X^2 statistic = 0.214, 1 df, p-value = 0.643 [a]
HST Peer Norms (most friends approve of HST, etc.; 4-pt scale)	3.3 (0.6)	3.2 (0.6)	3.3 (0.6)	3.2 (0.6)	3.3 (0.6)	3.2 (0.6)	Statistic = 0.220, 1 df, p-value = 0.639 [a]
Social Support (count on person; accepts me; trust with my HIV results)	3.5 (0.6)	3.4 (0.7)	3.5 (0.6)	3.4 (0.8)	3.4 (0.6)	3.5 (0.7)	X^2 statistic = 0.481, 1 df, p-value = 0.488 [a]
Health empowerment	3.3 (0.5)	3.2 (0.5)	3.3 (0.5)	3.1 (0.6)	3.2 (0.5)	3.2 (0.4)	Statistic = 1.67, 1 df, p-value = 0.196 [a]
Internalized homophobia	1.7 (0.7)	1.7 (0.7)	1.8 (0.7)	1.7 (0.7)	1.7 (0.7)	1.6 (0.7)	Statistic = 0.163, 1 df, p-value = 0.687 [a]

[a] Kruskal-Wallis test

[#] Chi-square test not performed due to small cell counts

Statistical tests contrast the Primary's treatment assignment groups

which focused intensively on HIV self-testing, although self-screening for HIV with the self-test was described in the control arm and control arm participants also received HIV self-test kits every three months. Generalizability of the findings was a limitation as the study was conducted in New York City and limited to individuals who self-selected into the study and were willing to engage in HIV testing with a friend. Further research is needed on HIV self-testing acceptability and utilization for young Black MSM and transwomen from other geographic regions in the US, especially those areas that have high HIV incidence. We observed loss to follow-up by select socioeconomic characteristics. Although this did not vary by arm, it is concerning as it suggests that retention is compromised by poverty in this population. Although neither a new nor surprising finding [63], it speaks to the need to include intervention strategies to support access to material resources and to keep participants engaged over time in HST programming. The recall period for study assessments may have influenced participants under- or over-reporting outcome variables. Along this line, study participants may have known which arm they were assigned to and may have engaged in socially desirable responding; however, we note that both arms received information on HIV self-testing and test kits every three

Table 3 Baseline HIV testing by study arm, TRUST study 2016–18

	Total		Intervention		Control		p-value
	Primary (N=188)	Friend (N=188)	Primary (N=89)	Friend (N=90)	Primary (N=99)	Friend (N=98)	
HIV testing							
Ever HIV tested	174 (92.5%)	173 (93.5%)	83 (92.2%)	88 (93.6%)	91 (92.86%)	85 (93.4%)	X^2 statistic = .01, 1 df, p-value = 0.920
Number of times tested (lifetime)							X^2 statistic = 1.35, 3 df, p-value = 0.719
1–2 times	28 (16.1%)	42 (52.5%)	12 (14.5%)	21 (24.1%)	16 (17.6%)	14 (16.5%)	
3–4 times	44 (25.3%)	25 (31.2%)	24 (28.9%)	14 (16.1%)	20 (22.0%)	26 (30.6%)	
5–9 times	35 (20.1%)	12 (15.0%)	15 (18.1%)	26 (29.9%)	20 (22.0%)	20 (23.5%)	
10 or more times	67 (38.5%)	1 (1.2%)	32 (38.5%)	26 (29.9%)	35 (38.5%)	25 (29.4%)	
Most recent test							Fisher's exact test p-value = 0.806
In the last 3 months	84 (48.3%)	80 (46.2%)	40 (48.19%)	39 (44.3%)	44 (48.3%)	41 (48.2%)	
4–6 months ago	47 (27.0%)	42 (24.3%)	20 (24.1%)	25(28.4%)	27 (29.7%)	17 (20%)	
7–12 months ago	29 (16.7%)	17 (9.8%)	16 (19.28%)	4 (4.6%)	13 (14.3%)	13 (15.3%)	
Don't know but in the last year	3 (1.7%)	4 (2.3%)	1 (1.2%)	1 (1.1%)	2 (2.2%)	3 (3.5%)	
More than 1 year ago	6 (3.4%)	26 (15%)	4 (4.8%)	16 (18.2%)	2 (2.2%)	10 (11.8%)	
Don't know but more than a year ago	5 (2.9%)	4 (2.3%)	2 (2.4%)	3 (3.4%)	3 (3.3%)	1 (1.2%)	
If not in P3M, why?	N=90	N=93	N=43	N=49	N=47	N=44	#
It was not time for me to test again	30 (33.3%)	26 (28.0%)	9 (20.9%)	10 (20.4%)	21 (44.7%)	16 (36.4%)	
I think I'm at low risk for HIV	16 (17.8%)	13 (14.0%)	5 (11.6%)	9 (18.4%)	11 (23.4%)	4 (9.1%)	
I'm afraid to find out I have HIV	7 (17.8%)	3 (3.2%)	3 (7.0%)	1 (2.0%)	4 (8.5%)	2 (4.5%)	
I did not have time	27 (30.0%)	22 (23.7%)	15 (34.9%)	10 (20.4%)	12 (25.5%)	12 (27.3%)	
I did not know where to go for a test	8 (8.9%)	3 (3.2%)	3 (7.0%)	1 (2.0%)	5 (10.6%)	2 (4.5%)	
I did not have enough money or insurance for a test	3 (3.3%)	0 (–)	2 (4.7%)	0 (–)	1 (2.1%)	0 (–)	
I did not want other people to know that I got a test	1 (1.1%)	1 (1.1%)	0 (–)	0 (–)	1 (2.1%)	1 (2.3%)	

Table 3 (continued)

If not in P3M, why?	N = 90	N = 93	N = 43	N = 49	N = 47	N = 44	#
If I test positive, I wouldn't know where to go for treatment or how to pay for it	1 (1.1%)	3 (3.2%)	1 (2.3%)	1 (2.0%)	0 (–)	2 (4.5%)	
If I test positive, I will be rejected by my friends or family	3 (3.3%)	–	1 (2.3%)	0 (–)	2 (4.3%)	0 (–)	
I don't want my result reported to the health department	2 (2.2%)	2 (2.2%)	0 (–)	0 (–)	2 (4.3%)	2 (4.5%)	
I had a bad experience the last time I got tested	1 (1.1%)	0 (–)	0 (–)	0 (–)	1 (2.1%)	0 (–)	
Other	10 (11.1%)	4 (4.4%)	8 (18.6%)	2 (4.0%)	2 (4.3%)	2 (4.5%)	
HIV self–test ever?							X² statistic = 0.64, 1 df, p–value = 0.423
Yes	27 (14.4%)	20 (10.6%)	11 (12.2%)	10 (1.1%)	16 (16.3%)	10 (10.2%)	
No	161 (85.6%)	168 (89.4%)	79 (87.8%)	80 (87.9%)	82 (83.7%)	88 (89.8%)	
If HST ever, what type?	N = 27	N = 20	N = 11	N = 10	N = 16	N = 10	#
HomeAccess® HIV-1 Test System	1 (3.7%)	0 (–)	1 (9.1%)	0 (–)	0 (–)	0 (–)	
OraQuick® In-Home HIV Test (you swab your mouth, use the testing device yourself and read the results in 20 min)	23 (85.2%)	16 (80.0%)	9 (81.8%)	8 (80.0%)	14 (87.5%)	8 (80.0%)	
SureCheck® HIV Home Test	0 (–)	4 (20.0%)	0 (–)	3 (30.0%)	0 (–)	1 (10.0%)	
A test that is used at testing clinics or by health professionals	1 (3.7%)	0 (–)	0 (–)	0 (–)	1 (6.3%)	0 (–)	
I don' know	3 (11.1%)	2 (10.0%)	1 (9.1%)	0 (–)	2 (12.5%)	2 (20.0%)	
Other	1 (3.7%)	0 (–)	0 (–)	0 (–)	1 (6.3%)	0 (–)	
HST P3M?							Fisher's exact test p-value = 0.173
Yes	9 (4.8%)	3 (1.6%)	2 (2.2%)	1 (1.1%)	7 (7.4%)	2 (2.2%)	
No	179 (95.2%)	182 (93.4%)	88 (97.8%)	93 (98.9%)	91 (92.9%)	89 (97.8%)	
HST intention							X² statistic = 2.15, 3 df, p-value = 0.542
Very unlikely	26 (13.8%)	18 (9.7%)	13 (14.4%)	10 (10.6%)	13 (13.3%)	8 (8.8%)	

Table 3 (continued)

If HST ever, what type?	N=27	N=20	N=11	N=10	N=16	N=10	#
Somewhat unlikely	15 (8%)	36 (19.5%)	7 (7.8%)	21 (22.3%)	8 (8.2%)	15 (16.5%)	
Somewhat likely	62 (33%)	65 (35.1%)	25 (27.8%)	34 (36.2%)	37 (37.8%)	31 (34.1%)	
Very likely	85 (45.2%)	66 (35.7%)	45 (53%)	29 (30.9%)	41 (40.8%)	37 (40.7%)	
HST intention? (with buddy)							X^2 statistic=1.55, 3 df, p-value=0.671
Very unlikely	20 (12.4%)	19 (12.9%)	7 (9.2%)	11 (14.9%)	13 (15.3%)	8 (11%)	
Somewhat unlikely	17 (10.5%)	17 (11%)	9 (11.6%)	8 (10.8%)	8 (9.4%)	9 (12.3%)	
Somewhat likely	66 (40.7%)	55 (37.9%)	32 (42.6%)	28 (37.8%)	34 (51.5%)	27 (37%)	
Very likely	59 (36.4%)	56 (37.9%)	29 (37.7%)	27 (36.5%)	30 (35.3%)	29 (39.7%)	
HIV test self-efficacy	3.2 (0.6)	3.1 (0.6)	3.3 (0.6)	3.0 (0.7)	3.1 (0.6)	3.3 (0.6)	X^2 statistic=2.71, 1 df, p-value=0.100[a]
HIV testing knowledge	2.8(0.5)	2.9(0.5)	2.7(0.6)	2.8(0.6)	2.8(0.4)	2.9(0.5)	X^2 statistic=0.606, 1 df, p-value=0.436 [a]
HIV testing plan ("I have a regular testing plan")							X^2 statistic=2.53, 3 df, p-value=0.470
Strongly agree	79 (42.7%)	71 (39.2%)	43(48.31%)	37 (39.8%)	36 (37.5%)	34 (38.6%)	
Agree	96 (51.89%)	92 (50.8%)	42 (47.19%)	47 (50.5%)	54 (56.25%)	45 (51.1%)	
Disagree	6 (3.24%)	9 (5%)	2 (2.25%)	5 (5.4%)	4 (4.17%)	4 (4.6%)	
Strongly disagree	4 (2.16%)	9 (5%)	2 (2.25%)	4 (4.3%)	2 (2.08%)	5 (5.7%)	

Statistical tests contrast the Primary's treatment assignment groups

[a]Kruskal-Wallis test

[#]Chi-square test not performed due to small cell counts

Table 4 HIV self-testing outcomes by study arm, TRUST, 2016–2018

Comparison	Unadjusted odds ratio	95% Confidence interval	p-value
Intervention at 3 M vs control at 3 M	2.29	1.15, 4.58	0.0191
Intervention at 6 M vs control at 6 M	1.94	1.00, 3.75[a]	0.0498
Intervention at 9 M vs control at 9 M	1.41	0.69, 2.88	0.3443
Intervention at 12 M vs control at 12 M	1.14	0.60, 2.14	0.6915

Outcome: Last 3 month Self-testing (self-reported yes)

[a]Exact 95% CI=1.0005, 3.7534

months and all assessments were done via self-interview on a computer (with an emphasis on the need for accurate self-report), which may have mitigated against socially desirable responding. In planning the study, we considered alternatives to self-reported outcome data to address this concern; however, our formative research suggested that options considered (e.g., mailing or photographing used test paddles) were not well-received by participants.

Conclusions

This study is one of the first to demonstrate the efficacy of a peer-based, theoretically-informed HIV self-testing intervention for young Black MSM and transwomen. The TRUST intervention had a positive impact on likelihood of HIV self-testing at three and six months after the intervention. Our findings suggest the importance of enhancing awareness of and access to HIV self-testing as a promising complementary method of increasing HIV testing among subpopulations unlikely to test at all and/or test consistently [64, 65]. HIV self-testing is a promising way to acknowledge the diversity of testing preferences and strengthen access to a broader set of prevention methods for young Black MSM and transwomen.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no competing interests.

References

1. Singh S, Song R, Johnson AS, McCray E, Hall HI. HIV incidence, prevalence, and undiagnosed infections in U.S. men who have sex with men. Ann Intern Med. 2018;168(10):685–94.

2. Burns PA, Mena LA, Crosby RL. Foretelling the future: predicting STI diagnosis and its implications for ending the HIV epidemic among black men who have sex with men. J Urban Health. 2020. https://doi.org/10.1007/s11524-019-00413-w.

3. Scott H, Vittinghoff E, Irvin R, et al. Development and validation of the personalized sexual health promotion (SexPro) HIV risk prediction model for men who have sex with men in the United States. AIDS Behav. 2020;24(1):274–83.

4. Chandler CJ, Bukowski LA, Matthews DD, et al. Examining the impact of a psychosocial syndemic on past six-month HIV screening behavior of black men who have sex with men in the United States: results from the POWER study. AIDS Behav. 2020;24(2):428–36.

5. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV epidemic: a plan for the United States. JAMA. 2019;321(9):844–5.

6. Nakagawa F, Lodwick RK, Smith CJ, et al. Projected life expectancy of people with HIV according to timing of diagnosis. Aids. 2012;26(3):335–43.

7. Mannheimer SB, Wang L, Wilton L, et al. Infrequent HIV testing and late HIV diagnosis are common among a cohort of black men who have sex with men in 6 US cities. J Acquir Immune Defic Syndr. 2014;67(4):438–45.

8. Mayer KH, Wang L, Koblin B, et al. Concomitant socioeconomic, behavioral, and biological factors associated with the disproportionate HIV infection burden among Black men who have sex with men in 6 U.S. cities. PLoS ONE. 2014;9(1):e87298.

9. Nelson LE, Wilton L, Moineddin R, et al. Economic, legal, and social hardships associated with HIV risk among black men who have sex with men in six US cities. J Urban Health. 2016;93(1):170–88.

10. Wheeler DP, Fields SD, Beauchamp G, et al. Pre-exposure prophylaxis initiation and adherence among Black men who have sex with men (MSM) in three US cities: results from the HPTN 073 study. J Int AIDS Soc. 2019;22(2):e25223.

11 Harris NS, Johnson AS, Huang Y-LA, et al. Vital signs: status of human immunodeficiency virus testing, viral suppression, and HIV preexposure prophylaxis—United States, 2013–2018. Morbid Mortal Weekly Rep. 2019;68(48):1117.

12. Centers for Disease Control and Prevention. HIV testing in the United States. National center for HIV/AIDS, viral hepatitis, STD, and TB prevention 2016; https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-testing-us-508.pdf, 2019.

13. DiNenno EA, Prejean J, Irwin K, et al. Recommendations for HIV screening of gay, bisexual, and other men who have sex with men—United States, 2017. MMWR Morb Mortal Wkly Rep. 2017;66(31):830.

14. Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States 2010–2015. HIV Surveillance Supplemental Report 2018; https://www.cdc.gov/hiv/group/msm/index.html, 2019.

15. Levy ME, Wilton L, Phillips G 2nd, et al. Understanding structural barriers to accessing HIV testing and prevention services among black men who have sex with men (BMSM) in the United States. AIDS Behav. 2014;18(5):972–96.

16. Dailey AF, Hoots BE, Hall HI, et al. Vital signs: human immunodeficiency virus testing and diagnosis delays—United States. MMWR Morb Mortal Wkly Rep. 2017;66(47):1300.

17. Habarta N, Wang G, Mulatu MS, Larish N. HIV testing by transgender status at centers for disease control and prevention-funded sites in the United States, Puerto Rico, and US Virgin Islands, 2009–2011. Am J Public Health. 2015;105(9):1917–25.

18. Hergenrather KC, Emmanuel D, Durant S, Rhodes SD. Enhancing HIV prevention among young men who have sex with men: a systematic review of HIV behavioral interventions for young gay and bisexual men. AIDS EducPreven. 2016;28(3):252–71.

19. Seth P, Walker T, Hollis N, et al. HIV testing and service delivery among Blacks or African Americans–61 health department jurisdictions, United States, 2013. MMWR Morb Mortal Wkly Rep. 2015;64(4):87–90.

20 Nanin J, Drumhiller K, Gaul Z, Sutton MY. HIV testing among black and Hispanic/Latino men who have sex with men in New York city: a mixed-methods study. Arch Sex Behav. 2020;49:2019–27.

21. Matthews DD, Sang JM, Chandler CJ, et al. Black men who have sex with men and lifetime HIV testing: characterizing the reasons and consequences of having never tested for HIV. Prevent Sci. 2019;20(7):1098–102.

22. Drumhiller K, Murray A, Gaul Z, Aholou TM, Sutton MY, Nanin J. "We deserve better!": perceptions of HIV testing campaigns among black and Latino MSM in New York City. Arch Sex Behav. 2018;47(1):289–97.

23. Outlaw AY, Naar-King S, Parsons JT, Green-Jones M, Janisse H, Secord E. Using motivational interviewing in HIV field outreach with young African American men who have sex with men: a randomized clinical trial. Am J Public Health. 2010;100(Suppl 1):S146–51.

24. Wilton L, Herbst JH, Coury-Doniger P, et al. Efficacy of an HIV/STI prevention intervention for black men who have sex with men: findings from the many men, many voices (3MV) project. AIDS Behav. 2009;13(3):532–44.

25. OraSure Technologies I. Oraquick In-home HIV test. 2012. https://www.oraquick.com/. Accessed 28 Nov 12.

26. Tobin K, Edwards C, Flath N, Lee A, Tormohlen K, Gaydos CA. Acceptability and feasibility of a Peer Mentor program to train young Black men who have sex with men to promote HIV and STI home-testing to their social network members. AIDS Care. 2018;30(7):896–902.

27. Frye V, Wilton L, Hirshfield S, et al. Preferences for HIV test characteristics among young, Black Men Who Have Sex With Men (MSM) and transgender women: Implications for consistent HIV testing. PLoS ONE. 2018;13(2):e0192936.

28. Lightfoot MA, Campbell CK, Moss N, et al. Using a social network strategy to distribute HIV self-test kits to African American and Latino MSM. J Acquir Immune DeficSyndr. 2018;79(1):38–45.

29. Arnold EA, Rebchook GM, Kegeles SM. 'Triply cursed': racism, homophobia and HIV-related stigma are barriers to regular HIV testing, treatment adherence and disclosure among young Black gay men. Culture, health & sexuality. 2014;16(6):710–22.

30. Washington HA. Medical apartheid: The dark history of medical experimentation on Black Americans from colonial times to the present. New York: Doubleday Books; 2006.

31. Watson CC, Wilton L, Lucas JP, et al. Development of a black caucus within the HIV prevention trials network (HPTN): representing the perspectives of black men who have sex with men (MSM). Int J Environ Res Public Health. 2020;17(3):871.

32. Myers JE, El-Sadr WM, Zerbe A, Branson BM. Rapid HIV self-testing: long in coming but opportunities beckon. AIDS. 2013;27(11):1687–95.

33 Frye V, Wilton L, Hirshfield S, et al. "Just because it's out there, people aren't going to use it." HIV self-testing among young, black MSM, and transgender women. AIDS Patient Care STDs. 2015;29(11):617–24.

34. Scott HM, Pollack L, Rebchook GM, Huebner DM, Peterson J, Kegeles SM. Peer social support is associated with recent HIV testing among young black men who have sex with men. AIDS Behav. 2014;18(5):913–20.

35. Lauby JL, Marks G, Bingham T, et al. Having supportive social relationships is associated with reduced risk of unrecognized HIV infection among black and Latino men who have sex with men. AIDS Behav. 2012;16(3):508–15.

36. Dangerfield DT 2nd, Ober AJ, Smith LR, Shoptaw S, Bluthenthal RN. Exploring and adapting a conceptual model of sexual positioning practices and sexual risk among HIV-negative black men who have sex with men. J Sex Res. 2018;55(8):1022–32.

37. Lelutiu-Weinberger C, Wilton L, Koblin BA, et al. The role of social support in HIV testing and PrEP awareness among young black men and transgender women who have sex with men or transgender women. J Urban Health. 2020;97:715–27.

38. Hermanstyne KA, Green HD Jr, Cook R, et al. Social network support and decreased risk of seroconversion in black MSM: results of the BROTHERS (HPTN 061) study. J Acquir Immune Defic-Syndr. 2018;78(2):163–8.

39. Naeem S, Frye V, Nandi V, et al. Who is using the HIV self-test among young black men who have sex with men (MSM) and transwomen in New York City? J Natl Med Assoc. 2020;112(3):284–8.

40. Paige M, Wilton L, Lucy D, Ortiz G, Nandi V, Koblin B. An intervention to teach young MSM and transgender women of color how to HIV self-test with a friend: lessons learned in project TRUST [poster]. Paper presented at: 22nd international AIDS conference, Amsterdam, Netherlands 2018.

41. Sullivan PS, White D, Rosenberg ES, et al. Safety and acceptability of couples HIV testing and counseling for US men who have sex with men: a randomized prevention study. J IntAssocProvid AIDS Care (JIAPAC). 2014;13(2):135–44.

42. Control CfD, Prevention. CDC fact sheet: HIV among Latinos. US Department of Health and Human Services, Centers for Disease Control and …; 2017.

43. Frye V, Nandi V, Hirshfield S, et al. Brief Report: randomized controlled trial of an intervention to match young black men and transwomen who have sex with men or transwomen to HIV testing options in New York City (all about me). J Acquir Immune DeficSyndr. 2020;83(1):31–6.

44. Koblin BA, Nandi V, Hirshfield S, et al. Informing the development of a mobile phone HIV testing intervention: intentions to use specific HIV testing approaches among young black transgender women and men who have sex with men. JMIR Public Health Surveil. 2017;3(3):e45.

45. Maina G, Strudwick G, Lalani Y, Boakye F, Wilton L, Nelson LE. Characterizing the structure and functions of social networks of men who have sex with men in Ghana, West Africa: implications for peer-based HIV prevention. J Assoc Nurses AIDS Care JANAC. 2018;29(1):70–82.

46. Maisto SA, Carey MP, Carey KB, Gordon CM, Gleason JR. Use of the AUDIT and the DAST-10 to identify alcohol and drug use disorders among adults with a severe and persistent mental illness. Psychol Assess. 2000;12(2):186–92.

47. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–13.

48. Choi KH, Paul J, Ayala G, Boylan R, Gregorich SE. Experiences of discrimination and their impact on the mental health among African American, Asian and Pacific Islander, and Latino men who have sex with men. Am J Public Health. 2013;103(5):868–74.

49. Bronfenbrenner U. The ecology of human development: experiments by nature and design. Boston, MA: Harvard College; 1979.

50. Perkins DD. Speaking truth to power: empowerment ideology as social intervention and policy. Am J Community Psychol. 1995;23(5):765–94.

51. Perkins DD, Zimmerman MA. Empowerment theory, research, and application. Am J Community Psychol. 1995;23(5):569–79.

52. Zimmerman MA. Empowerment theory. Handbook of community psychology. New York: Springer; 2000. p. 43–63.

53. Bandura A. Human agency in social cognitive theory. Am Psychol. 1989;44(9):1175.

54. Lakey B, Drew JB. A social-cognitive perspective on social support. Sourcebook of social support and personality. New York: Springer; 1997. p. 107–40.

55. Miller WR, Rose GS. Toward a theory of motivational interviewing. Am Psychol. 2009;64(6):527.

56. Lundahl BW, Kunz C, Brownell C, Tollefson D, Burke BL. A meta-analysis of motivational interviewing: twenty-five years of empirical studies. Res Soc Work Pract. 2010;20(2):137–60.

57. Raudenbush SW, Spybrook J, Congdon R, et al. Optimal design software for multi-level and longitudinal research (Version 3.01) [Software]. 2011.

58. Li Z, Purcell DW, Sansom SL, Hayes D, Hall HI. Vital signs: HIV transmission along the continuum of care—United States, 2016. Morb Mortal Wkly Rep. 2019;68(11):267.

59. Santos GM, Ackerman B, Rao A, et al. Economic, mental health, HIV prevention and HIV treatment impacts of COVID-19 and the COVID-19 response on a global sample of cisgender gay men and other men who have sex with men. AIDS Behav. 2020;11:1–11.

60. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. J MMWR RecommRep. 2006;55:1–17.

61. Harawa NT, Guentzel-Frank H, McCuller WJ, et al. Efficacy of a small-group intervention for post-incarcerated black men

who have sex with men and women (MSMW). J Urban Health. 2018;95(2):159–70.

62. Goldenberg T, Stephenson R, Bauermeister J. Community stigma, internalized homonegativity, enacted stigma, and HIV testing among young men who have sex with men. J Commun Psychol. 2018;46(4):515–28.

63. Akl EA, Briel M, You JJ, et al. Potential impact on estimated treatment effects of information lost to follow-up in randomised controlled trials (LOST-IT): systematic review. BMJ. 2012;344:e2809.

64. Rael CT, Giguere R, Lopez-Rios J, et al. Transgender women's experiences using a home HIV-testing kit for partner-testing. AIDS Behav. 2020;24:272–2741.

65. Johnson MC, Chung R, Leung SJ, Edelstein Z, Yuan Y, Flavin SM. Combating stigma through HIV self-testing: New York state'shiv home test giveaway program for sexual minorities. J Public Health ManagPract. 2020. https://doi.org/10.1097/PHH.0000000000001138.