A Pilot, Randomized Controlled Trial of HIV Self-Testing and Real-Time Post-Test Counseling/Referral on Screening and Preventative Care Among Men Who Have Sex with Men

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Abstract

HIV self-testing (HST) could be an effective strategy for helping those at high risk test more regularly. However, concerns about HST's lack of follow-up care and referral have so far limited its use. In a pilot, randomized controlled trial, high-risk HIV-negative, or status unknown men who have sex with men (MSM; $N=65$) were recruited from January 2016 to February 2017 and received (1) HST kits by mail, equipped with devices that detected when kits were opened and prompted a follow-up call from a counselor (eTEST); (2) standard HST kits with no follow-up (standard); or (3) informational letters about HIV testing locations (control) at baseline, 3 months, and 6 months. Monthly surveys over 7 months assessed HIV testing, sexually transmitted infection (STI) testing, access to prevention services, and behavioral risk reduction. All participants (100%) in the eTEST and standard HST groups reported HIV testing at least once during the 7-month period compared with 72% of controls. Repeat testing was higher among those in the HST groups versus controls (79% vs. 41%). Participants in the eTEST group were significantly more likely to receive risk reduction counseling, prevention supplies (e.g., condoms and lube), and PrEP referrals during the study period compared with standard HST and controls. No effects on STI testing or PrEP initiation emerged. Delivering HST kits to high-risk MSM at regular intervals could increase HIV testing rates and encourage more regular testing. Providing active post-test referrals alongside HST might also connect high-risk men with some other important services that encourage prevention behaviors.

Keywords: HIV testing, men who have sex with men, counseling

Introduction

OVERALL RATES OF new HIV infections have declined in the United States (US) in recent years, but incidence remains high among men who have sex with men (MSM).^{1,2} Recent estimates suggest that without achieving declines in new infections, one in six MSM in the US will be diagnosed with HIV in their lifetime.³ An estimated 20% of MSM have HIV, but are unaware of it,^{4,5} and modeling studies suggest that 50% of new infections may originate from this population.^{6,7} The CDC recommends HIV testing for MSM at least once every 6 months,⁸ yet only 40–50% of MSM report having been tested in the last year,⁹ with fewer than 20% having been tested more than once during that time.^{10,11} Innovative approaches are needed to encourage more regular testing to facilitate early diagnosis and treatment¹² and decrease HIV incidence.^{13–16}

In July 2012, the first rapid self-test for HIV using oral fluid (OraSure® Technologies, Bethlehem, Pennsylvania) was approved by the US Food and Drug Administration. The test relies on oral fluid sampling, produces results in 20 min, and can be completed entirely by users. These self-tests (HSTs) could increase HIV testing rates beyond relying on clinic-based testing alone given that the most common barriers to testing include its inconvenience (e.g., travel, wait times, and difficulty attending clinics during work hours) and concerns about confidentiality.^{17,18}

HSTs may also be particularly well suited for engaging those who are most at risk or who are difficult to reach with traditional services.^{17,19–23} Some international studies have found higher uptake of HSTs compared with clinic-based testing alone.^{24–26} At least one US study, however, found that HST did not boost testing rates compared with clinic-based testing alone among young MSM.²⁷ A key advantage

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of HST, however, is that it may also boost rates of *repeat* or *regular* testing. Regular testing is particularly critical among high-risk MSM since it could facilitate earlier diagnosis, improving the health outcomes of those infected and reducing onward transmissions.²⁸ Yet, few studies have explored the potential of HSTs to encourage more regular HIV testing among high-risk groups such as MSM in the US.²⁹

Despite its promise, concerns about HSTs have limited its use in the US to date.^{30–33} One key concern is that those who test for HIV at home may not be adequately linked to care if their results are reactive.³⁴ Modeling studies have suggested that HST implemented broadly without sufficient linkage to care may actually increase population-level HIV incidence if users delay seeking care.³⁰ Similarly, HST users who test negative would also likely benefit from being linked with other prevention resources, such as testing for other sexually transmitted infections (STIs), pre-exposure prophylaxis (PrEP), or other prevention tools (e.g., risk reduction counseling and safe sex supplies). Brick-and-mortar testing clinics commonly provide these resources to patients.

Since becoming commercially available, OraSure has maintained a 24-h toll-free helpline that provides counseling, guidance on test conduct, and referrals to HIV care for callers.³⁵ However, as of 2015, OraSure estimated that this helpline received calls that amounted to <10% of the number of tests sold, and of these calls, <5% were related to post-test counseling or HIV diagnosis/treatment.³⁶ This passive approach to providing post-test service linkage and counseling may be insufficient, and a more active approach may be needed, especially to ensure that high-risk MSM and hard-to-reach populations receive the other services they need after testing.

We created a system called eTEST that detects when users open the HST kits remotely in real time, allowing us to conduct follow-up counseling and referral with these users over the phone. The system, described in detail elsewhere,³⁷ uses a native smartphone application (iOS, Android) installed on the devices of end users and Bluetooth low-energy (BLE) beacons placed inside each HST test kit. BLE beacons are small devices that use radio waves to broadcast an identifier to nearby devices that have Bluetooth capability (e.g., smartphones), allowing these devices to perform actions when they are within range of the beacon. Once a beacon-equipped HST kit is opened, the eTEST system notifies researchers that a user may have initiated HIV self-testing (HST), prompting counselors to call these users to provide post-test counseling and referrals.

This study reports results from a longitudinal, randomized controlled trial of high-risk MSM who had not tested in the last year. Participants were randomly assigned to receive (1) HST with follow-up (eTEST), (2) HST with no follow-up (standard HST), or (3) reminders for clinic-based testing (control) at baseline, 3 months, and 6 months. Rates of HIV and STI testing as well as receipt of other prevention services (e.g., risk reduction counseling and PrEP) were assessed through surveys collected each month over a 7-month study period. We then tested whether providing active follow-up and referral after HST use (the eTEST condition) increased rates of HIV testing, repeat testing, and participants' rates of following up with other sexual health services (e.g., STI testing, PrEP, and risk reduction counseling) compared with standard HST and controls.

Methods

Participants

Sixty-five MSM in the northeastern US were recruited from gay-oriented smartphone dating apps (e.g., Grindr and Scruff), social networking sites (e.g., Facebook and Instagram), and in-person outreach (e.g., flyers) and enrolled between July 2016 and February 2017. Eligible participants (1) were assigned male sex at birth, (2) were over age 18, (3) were able to read in English, (4) reported condomless anal sex (CAS) with a casual male partner in the past 6 months, (5) had not tested for HIV in the last year, (6) were HIV negative or unsure of their status, and (7) used a smartphone running Android or iOS with a data plan.

Those who reported currently taking PrEP were excluded since they typically receive HIV testing every 3 months as a part of routine PrEP care. As this was a pilot randomized control trial (RCT), *a priori* power analyses were not conducted to determine sample size. Instead, we aimed to recruit enough participants to allow a preliminary examination of condition effects (at least $N=20$ per group) before conducting a fully powered RCT.

Experimental conditions

Participants were assigned to conditions using simple random assignment, using the study's database to generate a random number when a new record was created at participant enrollment. Neither participants nor research staff were blind to condition. Those in the eTEST condition downloaded the eTEST app to their personal smartphones at baseline, and HST kits equipped with BLE beacons were mailed to their home addresses at 3-month intervals. HIV test counselors then called participants who opened their test kits within 24 h to answer any questions and offer referrals to other sexual health services. Consistent with CDC guidelines,³⁸ risk reduction counseling was also offered during these calls, but it was not required to receive tests and could be declined. If provided, risk reduction counseling adopted a person-centered approach commonly used in clinic-based settings.³⁹

In the standard condition, HST kits without beacons were mailed to the home addresses of participants at the same 3-month intervals. These kits provide only OraSure's standard 1–800 number. In the control condition, letters were mailed that reminded participants to get tested for HIV in a local clinic and provided them with information about free clinic-based testing in the area at the same 3-month intervals.

Procedures

Interested participants first completed a brief screening survey online to assess their eligibility. Eligible participants were then contacted by research staff to schedule an appointment to enroll. After acquiring informed consent, research staff guided participants through baseline assessments and then assisted those in the eTEST condition in downloading the app to their smartphone. After their appointments, participants were instructed to complete an online survey each month over the course of the 7-month study period. We adopted this limited interaction online approach so as to avoid frequent study visits or other procedures that could bias primary outcomes. We also chose a monthly follow-up interval given evidence that recall of HIV-relevant

behaviors is improved when assessed at relatively brief intervals.⁴⁰

Participants were paid \$20 for the baseline appointment and \$15 per monthly assessment, with a bonus of \$55 for completing all assessments (for a total \$180 possible). The study protocol was approved by the Brown University Institutional Review Board and registered on ClinicalTrials.gov in August of 2016 (NCT02876926).

Measures

HIV testing over the past month was assessed in monthly questionnaires, including the date, location (e.g., doctor's office, HIV test clinic, or home), and results. For those who indicated taking HST, items inquired about whether the test was provided by the study. Items also assessed testing for other STIs (i.e., syphilis, gonorrhea, and chlamydia) over the past month as well as the date, location, and results of these tests. Questionnaires also assessed whether participants had received counseling about reducing their risk for HIV and other STIs from a professional counselor, nurse, or doctor in the past month as well as whether they received prevention supplies (e.g., condoms and lube) from one of these sources during that time. Finally, these questionnaires assessed whether participants had been referred to a physician for PrEP over the last month by a sexual health professional and whether they had started or been prescribed PrEP during that time.

Monthly surveys also assessed sexual behavior over the past month using an online Timeline Followback (TLFB) procedure.^{41–45} The TLFB asked participants to indicate days in the last 30 in which they engaged in oral, anal, or vaginal sex and then respond to questions about the characteristics of partners they had each day, the acts they engaged in, and whether or not a condom was used for each act.

Analyses

Monthly survey responses were first aggregated across the entire study period for each of the study's key outcomes: HIV testing rates, STI testing rates, receipt of risk reduction counseling, receiving prevention supplies, CAS, PrEP referrals, and being prescribed PrEP. Between-subject ANOVAs with planned contrasts were then used to explore differences in these outcomes between the study groups across the entire 7-month study period. Next, we used survey completion dates to examine rates of each outcome across the 3-month study intervals (baseline, 3 months, and 6 months), which align with current CDC recommendations for HIV testing every 3–6 months among high-risk MSM.⁸ Repeat testing was defined as having tested at least twice in at least two of these intervals over the course of the study period.

To explore the effect of condition outcomes over time, we used generalized estimating equations (GEEs) with binomial distributions and logit link functions for binary outcomes and Poisson distributions and log link functions for count outcomes. All models were analyzed using an intent-to-treat (ITT) approach that involved retaining participants who withdrew from the study and assuming that they did not engage in any key outcome. Significance was defined as p -values ≤ 0.05 . All analyses were conducted in Stata 14.

Results

Attrition, adherence, and study manipulations

See Table 1 for sample demographics and Fig. 1 for participant flow. Of 65 participants enrolled, 8 (12.3%) withdrew or stopped completing monthly surveys before the month 7 survey. The overall monthly survey completion rate in this

TABLE 1. DEMOGRAPHIC AND BEHAVIORAL CHARACTERISTICS OF THE STUDY SAMPLE ($N=65$)

Characteristics	Control ($N=22$) N (%)	Standard ($N=22$) N (%)	eTEST ($N=21$) N (%)	χ^2 or F^1
Age (range, 18–72; $M \pm SD$) ² , years	35.5 (15.2)	35.8 (16.3)	34.1 (13.9)	0.1
Race				
White	14 (66.7)	20 (95.2)	16 (84.2)	8.4
Black or African American	4 (19.1)	0 (0.0)	1 (5.3)	
Asian	1 (9.5)	1 (4.8)	2 (10.5)	
Multi-racial	1 (4.8)	0 (0.0)	0 (0.0)	
Ethnicity (Hispanic or Latino)	2 (9.1)	1 (4.8)	2 (9.5)	0.4
Currently in exclusive relationship ³	2 (9.1)	5 (22.7)	7 (33.3)	3.4
Low income ⁴	4 (18.2)	2 (9.1)	4 (18.2)	3.7
No college degree	6 (27.3)	10 (47.6)	12 (54.1)	1.3
Unemployed	1 (4.6)	4 (19.1)	2 (9.5)	2.8
Identity other than gay or bisexual	0 (0.0)	0 (0.0)	1 (4.8)	1.9
Never tested for HIV in lifetime	2 (9.1)	3 (13.6)	4 (19.1)	0.2
Years since most recent HIV test ¹	2.1 (1.1)	3.1 (1.6)	2.7 (1.0)	0.2
Hazardous drinkers ⁵	11 (57.9)	9 (45.0)	14 (73.7)	2.3
Type of test taken during the 7-month study period				
Did not test	6 (27.3)	0 (0.0)	0 (0.0)	
Clinic test only	14 (63.6)	2 (9.1)	1 (4.8)	
Home-based test only	1 (4.6)	12 (54.5)	9 (42.9)	
Both clinic and home-based tests	1 (4.6)	8 (36.4)	11 (52.4)	

¹All $p > 0.05$.

²Shown in M and SD . Represents those with a household annual income $< \$30,000$ /year.

³Represents participants who reported currently being in a sexually exclusive monogamous relationship with one partner.

⁴Some participants reported having tested between their screening and enrolling in the study.

⁵Defined as reporting drinking > 5 drinks on a single occasion or an average of ≥ 14 drinks per week in the past month.

FIG. 1. Flow of eTEST participants.

full sample was 89% (SD , 23%; range, 14–100%). Attrition rate did not differ by study condition, $\chi^2(2) = 1.31$, $p > 0.05$ (eTEST: 12%, standard: 9%, control: 9%). Survey completion rates also did not differ across study conditions, $F(2, 62) = 1.17$, $MS = 0.61$, $p > 0.05$. No participants reported receiving reactive or positive HIV test results during the study period. However, eight participants (12.3%) reported having been diagnosed with an STI other than HIV over the course of the study period. STI rates did not differ across study conditions, $\chi^2(2) = 0.18$, $p > 0.05$.

Of participants in an HST condition (eTEST or standard), 93.1% reported using a study-provided kit to test themselves for HIV at some point during the study. Of those in the eTEST condition, the app and sensor system successfully detected a kit opening 73.4% of the time across the entire study period when participants reported using study-provided HST that month. Post hoc analyses suggest that the detection rate declined substantially across the study period (baseline: 95%; 3 months: 57%; and 6 months: 47%), suggesting that the most likely reason for detection failure was participants having deleted the app from their devices or changing smartphones during the study. eTEST participants were successfully reached for follow-up phone counseling and referral within 24 h after 100% of detected tests. The average amount of time after the app detected an opening until participants received a call from a counselor was less than an hour (in hours: M , 0.90; SD , 1.75; range, 0.3–7.5).

HIV testing

All (100%) participants in the eTEST and standard HST conditions reported testing for HIV at some point during the study period using either HST or an in-person test compared with 72% of control participants, a statistically significant between-group effect, $F(2, 62) = 7.69$, $MS = 0.54$, $p = 0.001$.

GEE models similarly showed a significant effect of experimental condition on HIV testing over time. The odds of HIV testing in each of the study's 3-month intervals were 4.4 times higher among participants in an HST group (either eTEST or standard) compared with controls ($SE = 0.41$, $p < 0.001$).

There were no significant differences that emerged in HIV testing between the eTEST and standard HST conditions. Rates of repeat testing also significantly differed across study conditions, $F(2, 62) = 5.33$, $MS = 1.06$, $p < 0.007$. Planned contrasts suggested that this effect was primarily due to lower rates of repeat testing specifically in the control condition, $F(2, 62) = 24.5$, $p < 0.001$ (eTEST: 81.0%, standard: 77.2%, control: 40.9%). Rates of repeat testing at both of the later intervals (3 and 6 months) did not differ across the eTEST and standard groups, $F(1, 41) = 0.62$, $p > 0.05$ (eTEST: 52.9%, standard: 60%). See Fig. 2.

Referral and other prevention outcomes

Rates of testing for other STIs did not differ across any of the study conditions, $F(2, 62) = 0.29$, $MS = 0.07$, $p > 0.05$, or within each study interval, $OR = 1.11$, $SE = 0.50$, $p > 0.05$, Fig. 3. However, rates of receiving any counseling about reducing HIV risk behaviors during the study period were significantly different across the groups, $F(2, 62) = 3.97$, $MS = 0.81$, $p = 0.023$. Contrasts suggested that those in the standard HST group were significantly less likely to receive any risk reduction counseling compared with those in the eTEST and control conditions, $F = 6.3$, $p = 0.014$. A similar pattern was observed with respect to receiving prevention supplies (e.g., condoms and lube) throughout the study period. Those in the standard HST condition were significantly less likely to receive supplies at some point during the study period compared with control or eTEST participants, $F(2, 62) = 4.1$, $p = 0.046$.

FIG. 2. Rates of HIV testing among 65 MSM in the northeastern United States, 2016–2017, by study condition across the 7-month study period (left panel) and within 3-month study intervals (right panel). *Note: eTEST participants received follow-up phone calls after the eTEST system detected that they had opened their HST kits.

Although there were no significant differences in sexual risk behavior across the conditions in the 30 days before enrollment ($F[2, 63]=0.32$, $MS=0.72$, $p>0.05$), the average number of CAS events with new partners per month was significantly lower among eTEST participants across each study testing interval when compared with the control and standard group conditions ($IRR=0.20$, $SE=0.09$, $p<0.001$, Fig. 4). Finally, PrEP referral rates across the study period significantly differed between the study conditions, $F(2, 62)=3.44$, $MS=1.04$, $p<0.038$. Contrasts suggested that eTEST participants were more likely to have received these referrals than either control ($\mu_0-\mu_2=-0.24$, $SE=0.12$, $p<0.043$) or HST participants ($\mu_1-\mu_2=-0.29$, $SE=0.12$, $p<0.017$). Although rates of actually having been prescribed PrEP were slightly higher among eTEST participants than the other conditions, these differences were minimal and nonsignificant.

Discussion

Findings from this 7-month longitudinal study showed that delivering HST kits to high-risk MSM who tested less often than recommended is an effective way to boost overall rates of testing in this population. Among these participants,

this approach led to complete HIV testing coverage. These findings are consistent with a number of other studies showing that home delivery of HST kits can improve overall rates of HIV testing among MSM.^{27,46,47} They also suggest that home delivery of self-tests may boost testing rates over other technology-mediated testing tools, such as those that facilitate scheduling clinic-based testing appointments for HIV testing. One such study showed that 50.8% of all visitors to such a website and 87% of those who scheduled an appointment were successfully tested for HIV.⁴⁸

The current study, however, also extends past research by showing that delivering HST kits at regular intervals could also encourage more regular testing. Nearly four of five high-risk MSM who received HST kits at 3-month intervals tested at least twice during a 7-month study period. However, exploring rates of repeat testing at later intervals (3 and 6 months) showed that these rates were not higher among those who received follow-up calls (eTEST participants) compared with standard condition participants, suggesting that providing active follow-up calls that encouraged future testing (i.e., the eTEST condition) provided limited additional benefit in encouraging repeat testing over simply providing HST kits at regular intervals.

FIG. 3. Rates of referral and follow-up with other prevention services by study condition across the study period. * $p<0.05$.

FIG. 4. Average number of condomless anal sex (CAS) acts (left panel) and CAS acts with new and unknown status partners (right panel) per month by study condition and testing interval.

Finally, 60.2% of participants in the HST conditions (55% in standard and 67% in eTEST conditions) reported having also received clinic-based testing at least once, even in this relatively narrow 7-month time frame, compared with 72.7% in the control condition. This suggests that despite the concerns of some,³⁰ home delivery of HST kits may not lead MSM to rely solely on self-tests and to forego clinic-based testing. Overall, these findings provide strong support for the use of HST to increase testing among MSM who are at high risk and encourage them to do so regularly.

Although findings show that delivering HST kits is an effective way to increase testing compared with outreach efforts encouraging clinic-based testing, the control condition in this study was clearly not inert. Over 70% of control participants reported testing for HIV at least once during the study period and almost 40% reported testing twice over 6 months based only on receiving a mailed letter with information on free HIV testing clinics. This testing rate was unexpected, particularly given the low level of contact these participants had with research staff, and might suggest that either many participants lacked basic access to information about available HIV testing sites or that their participation in a research study increased testing rates.

Study results also show that offering real-time follow-up counseling and referral calls to participants after they used HSTs may be more effective to connect MSM with counseling (to reduce HIV risk behavior) and safe sex supplies (e.g., condoms and lube) than standard HST kits alone. Similarly, conducting follow-up calls after HST was also more effective in connecting MSM with information and referrals for PrEP than HST alone or clinic-based testing. Importantly, eTEST phone counselors provided this information only during phone calls in which participants inquired about PrEP, suggesting that connecting MSM with counselors who are knowledgeable about PrEP may result in more receptiveness. However, these referrals did not appear to result in a higher number of PrEP prescriptions, regardless of study condition. This could suggest either that more dedicated efforts may be needed to ensure that participants who are referred for PrEP actually follow through or that the follow-up period was not long enough to capture participants who started PrEP after the 7-month study period.

Rates of testing for other STIs did not differ across study conditions, suggesting that neither providing HST nor post-

HST follow-up counseling had any effect on STI testing. However, efforts to provide self-testing for other STIs are currently being studied and show promising results.^{49,50} These services could be useful for similarly boosting STI testing rates among high-risk MSM.

It is important to highlight that no participants in the current study received reactive results from HST or tested positive through a clinic-based test. As such, it is not yet known whether those using HST would delay seeking follow-up testing and care if they received a reactive result using this test. This scenario is critical to understand since delays in linking these individuals with follow-up care could lead to onward infections and poorer health outcomes as a result of delayed treatment initiation.³⁰ Further research in high HIV incidence areas is needed to more thoroughly understand the impact of HST on linkage to care outcomes.

Regarding the eTEST system, the 73.4% overall rate of success in detecting the HST kit warrants improvement. Although failure to detect kit use could be caused by a number of technical issues, such as smartphone service, disruptions in connectivity, and device malfunctions, the substantially lower rates of detection at later study intervals suggest that this was most likely due to participants manually deleting the eTEST app from their smartphones or switching to a new device during the study period. App data further support this conclusion, showing that 29% of eTEST participants had deleted the app from their smartphones at some point during the study period and that the average duration of continuously having the app installed was 3 months. This underlines the importance of developing new solutions for this problem before using the eTEST system in future research or prevention programs. Newer versions of popular smartphone operating systems (iOS/Android) afford app developers expanded access to functionality that could help improve test use detection in future app versions.

Limitations

Although the results of this study add important knowledge to the existing literature on HST, several limitations are important to note. First, while this research represents one of the first longitudinal studies of HST in high-risk MSM, the sample size was small ($N=65$), limiting interpretation of the

findings. Second, this study focused exclusively on MSM due to their high risk for HIV, so these results may not generalize to other populations.

Third, online assessments used brief self-report measures and thus are vulnerable to reporting bias. Finally, while we hoped to adopt a limited interaction approach in this study so as to understand HST effects in conditions as close to the real world as possible, the prototype nature of the eTEST smartphone app meant that it was not publicly available for remote download through either app store (e.g., Apple App Store or Google Play) and therefore required that research staff first meet with participants in-person to assist them in downloading and installing the app. This meeting may have inadvertently influenced outcomes across all conditions, improving them beyond what might normally be expected if MSM had no contact with staff or other professionals before receiving HST kits or testing reminders. Future research should explore whether onboarding high-risk MSM into a similar system entirely remotely produces different results.

In summary, this study found that mailing HST kits directly to high-risk MSM with a history of infrequent HIV testing improved their rates of testing sufficiently enough to align with CDC-recommended intervals. Offering follow-up counseling and referral over the phone within 24 h of HST kit use also helped connect more MSM with HIV risk reduction counseling, safe sex supplies, and referrals for PrEP than standard HST kits and clinic testing referrals alone. However, phone-based post-HST counseling was not associated with higher rates of testing for other STIs or actually beginning a PrEP regimen. Future research should examine the potential these approaches have for improving HIV-related outcomes in a larger sample of MSM and other high-risk groups.

Acknowledgments

This study was supported by R21MH109374 and R01MH114891 from the National Institute of Mental Health and L30AA023336 from the National Institute on Alcohol Abuse and Alcoholism. P.A.C. is supported by the National Institute of Mental Health (R01MH114657). D.O. is supported by the National Institute on Alcohol Abuse and Alcoholism (U24AA022000).

Author Disclosure Statement

The authors have no conflicts of interest to report.

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