

# Comparison of Home-Based Oral Fluid Rapid HIV Self-Testing Versus Mail-in Blood Sample Collection or Medical/Community HIV Testing By Young Adult Black, Hispanic, and White MSM: Results from a Randomized Trial

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**Abstract** We aimed to determine in a randomized trial if young adult black, Hispanic, and white men-who-have-sex-with-men (YMSM) are more likely to complete home-based oral fluid rapid HIV self-testing than either mail-in blood sample collection or medical facility/community organization-based HIV testing. Stratified by race/ethnicity, participants were randomly assigned to use a free oral fluid rapid HIV self-test ( $n = 142$ ), a free mail-in blood sample collection HIV test ( $n = 142$ ), or be tested at a medical facility/community organization of their choice ( $n = 141$ ). Of the 425 participants, completion of assigned test (66% oral fluid vs. 40% mail-in blood sample vs. 56% medical facility/community), willingness to refer (36% oral fluid vs. 20% mail-in blood sample vs. 26% medical facility/community), and legitimate referrals (58% oral

fluid vs. 43% mail-in blood sample vs. 43% medical facility/community) were greater in the oral fluid rapid HIV self-test than the mail-in blood sample collection HIV test arm, but not the medical facility/community testing arm. There were no differences in assigned test completion by race/ethnicity. Although free home-based oral fluid rapid HIV self-testing showed moderate promise in facilitating HIV testing among black, Hispanic, and white YMSM, it did not lead to greater testing than directing these YMSM to medical facility/community HIV testing venues. ClinicalTrials.gov Identifier: NCT02369627.

**Resumen** El objetivo de este ensayo aleatorio fue determinar si hombres jóvenes negros, hispanos, y blancos que tienen sexo con otros hombres (siglas en inglés YMSM) son más probables de completar una prueba rápida casera de autoexamen para el VIH con fluidos orales que una prueba del VIH en que se envíe una muestra de sangre por correo o una prueba de VIH que se hace en un centro médico/organización comunitaria. Estratificados por raza/etnicidad, los participantes fueron asignados aleatoriamente a usar una prueba oral rápida casera de autoexamen

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gratuita para el VIH ( $n = 142$ ), una prueba gratuita del VIH en que se envíe una muestra de sangre por correo ( $n = 142$ ), o hacerse la prueba del VIH en un centro médico/organización comunitaria de su preferencia ( $n = 141$ ). De los 425 participantes, la realización de la prueba asignada (66% con fluidos orales vs. 40% muestra de sangre enviada por correo vs. 56% hecha en un centro médico/comunitario), disposición a referir (36% con fluidos orales vs. 20% muestra de sangre enviada por correo vs. 25% hecha en un centro médico/comunitario), y referencias legítimas (58% con fluidos orales vs. 43% muestra de sangre enviada por correo vs. 43% hecha en un centro médico/comunitario) fue mayor en el grupo de la prueba rápida de autoexamen para el VIH con fluidos orales que en el grupo de la prueba del VIH en que se envíe una muestra de sangre por correo, pero no mayor que en el grupo que fue a un centro médico/comunitario. No hubo diferencias en la realización de la prueba asignada por raza/etnicidad. A pesar de que la prueba casera con fluidos orales demostró ser moderadamente promisoria en facilitar pruebas del VIH entre negros, hispanos y blancos YMSM, no condujo a más realización de pruebas que dirigiendo a estos YMSM a un centro médico/comunitario donde se hacen pruebas del VIH.

**Keywords** HIV testing · Men-who-have-sex-with-men · Young adult · Clinical trial

## Introduction

In 2012, the US Food and Drug Administration approved the OraQuick<sup>®</sup> In-home rapid HIV test (OraSure Technologies, Bethlehem, PA) for oral fluid HIV self-testing [1.] The test's positive attributes (e.g., convenience and flexibility of testing, oral swab instead of blood sample collection, privacy, rapid provision of results, ready access via stores or the internet, and self-testing) have been hoped to encourage people at higher risk of an HIV infection to be tested, especially those with reduced access to traditional medical/community testing facilities. Although prior studies of US men-who-have-sex-with-men (MSM) indicate that as many as 80% [2, 3] expressed interest in, or willingness to use the test, utilization of this test is believed to be low.

Black, Hispanic, and white young adult (18–24 year-old) men-who-have-sex-with-men (YMSM) in the US appear to be an ideal population for home-based oral fluid rapid HIV self-testing. YMSM typically have lower healthcare access and lower HIV testing rates than other MSM [4–7], yet suffer from increasing HIV incidence rates, high HIV prevalence, and undiagnosed HIV infections. [4, 6, 8–12] Public health groups or researchers have

launched campaigns to facilitate the use of oral fluid rapid HIV self-tests to increase testing among MSM [13.] However, it is not known if YMSM are more likely to use this test compared to other HIV testing methods, if it encourages them to be tested sooner, or if they are more likely to encourage other YMSM to use this test. Comparison to currently available testing options is vital in assessing if expressed interest in and perceived advantages of the oral fluid rapid HIV self-test confer greater test utilization in actual practice. It would be particularly useful to examine these questions among YMSM social media users, since social media could be employed to access this hard-to-reach population quickly and confidentially in future HIV testing campaigns.

The primary objective of this randomized trial was to determine if social media-using black, Hispanic, and white YMSM randomly assigned to free home-based, oral fluid rapid HIV self-testing are more likely to complete HIV testing within a 3-month period, as compared to those randomly assigned to either free home-based mail-in blood sample collection HIV testing or testing at a medical facility/community organization (rapid or conventional) of their choice. We further assessed assigned test completion by race/ethnicity. The secondary objectives were to compare these three study arms by use of any, another, or no HIV test; time to HIV test completion; and willingness to refer and referrals of other black, Hispanic, or white YMSM to use the same test they had been assigned in the trial. We also compared pre-trial preferences about HIV testing to actual HIV test use and elucidated participant reasons for their HIV test use in the trial.

## Patients and Methods

### Study Design

This randomized trial was conducted from April 2015 to April 2016 among a random sample of 18–24-year-old social media-using black, Hispanic, or white MSM who completed an internet-based anonymous pre-trial survey about their demographic characteristics, HIV testing history, sexual risk-taking behaviors, and HIV testing preferences [14.] Our institutional review board approved the study.

### Participant Recruitment

1934 black, Hispanic, and white YMSM solicited via multiple social media platforms completed the pre-trial survey, and 1128 indicated that they would be interested in being contacted by email about participating in a randomized trial (See supplemental material for description of

these platforms). These YMSM signified their consent to participate in the pre-trial survey and randomized trial through the respective survey and trial electronic consent forms. From these pre-trial survey participants, we randomly selected YMSM by race/ethnicity to participate in the trial. Our goal was to enroll 150 black, 150 Hispanic, and 150 white participants. Random selection, email invitations, and subsequent study enrollment continued until the race/ethnicity quotas were filled or no more participants could be recruited. We based our target sample size on the primary objective of determining if completion of oral fluid rapid HIV self-testing was at least a 10% greater than mail-in blood sample collection or medical facility/community organization testing within and across racial/ethnic groups ( $\alpha = 0.05$ , power  $> 0.80$ ). Study eligibility criteria for the pre-trial survey and trial were: age 18–24 years; English- or Spanish-speaking; self-identified black, Hispanic, or white race/ethnicity; living in the US; ever having had anal sex with another man; and not being HIV infected (per self-report).

### Study Protocol

Within each racial/ethnic group, we randomly assigned participants into one of three study arms (1:1:1 randomization) using block sizes of six. Participants in the oral fluid rapid HIV self-test and in the mail-in blood sample collection HIV testing study arms were provided with instructions, an internet-based gift card to purchase the assigned test kit, and weblinks to companies from which to purchase their assigned test via the internet. We selected major national companies that included 2-day shipping in the purchase price and accepted the gift card. We verified the ordering and delivery processes prior to conducting the trial. YMSM in these two study arms ordered the tests themselves and chose where and when their assigned tests would be delivered. YMSM in the community organization/medical facility testing arm were asked to get tested at a community organization or medical facility of their choice (conventional or rapid HIV testing). They were provided with a weblink to the National HIV and STD testing website ([gettested.cdc.gov](http://gettested.cdc.gov)) to locate testing locations, but were not given a gift card to facilitate testing. YMSM in all three study arms were instructed to contact the study staff to answer questions or resolve difficulties in participating; however, study staff did not encourage participants to be tested and did not offer testing advice or assistance.

Participants were asked to notify study staff after completing their assigned test using a provided weblink. At 1-month intervals for up to 3 months post-enrollment, participants who had not notified us that they were tested were emailed and asked if they had been tested for HIV.

The email did not include motivational messages encouraging them to test. After notifying us via the weblink if they were tested, or at the end of the 3-month period, participants completed a brief questionnaire to indicate if, how, and when they were tested for HIV (whether they had done so with their assigned test or another HIV test); to indicate their main reasons for testing or not testing and for using the test they selected; and to answer questions about their testing experience. In addition, participants who used their assigned test were asked if they were willing to refer other YMSM to use the same test. Those who indicated their willingness could refer up to three other 18–24-year-old black, Hispanic, or white YMSM (whether or not concordant with their own racial/ethnic identity) to be invited via email by study staff to undergo the same type of testing they had been assigned. Participants received a \$10 internet-based gift card for completing the follow-up questionnaire (irrespective of whether they tested or not), and up to three \$5 gift cards for providing email addresses of other YMSM to be contacted about the study. Study staff reviewed the email addresses provided, and removed those who were already in the study, duplicate referrals, or potential fraudulent referrals (e.g., email addresses that were the same as the referring participant). Following this process, study staff emailed the legitimate-appearing referees with an invitation to be screened for study eligibility; those who indicated they met the aforementioned study eligibility criteria were invited to be tested using the same HIV testing method as the person who referred them, and completed the same follow-up process, but were not asked to provide their own referrals.

### Data Analysis

Recruitment, enrollment, and retention were summarized, and participants were compared by enrollment and retention status using descriptive statistics. An intention-to-treat analysis was performed without imputation for missing values; those not responding to the follow-up questionnaire were counted as not meeting measured outcomes. The proportions of those tested using their assigned test by study arm and by race/ethnicity were calculated along with corresponding 95% confidence intervals (CIs). The proportions of those using any type of HIV test, a test other than which they were assigned, or not undergoing testing; those willing to refer; and testing completion by referees were compared in a similar manner. Median time to testing (in days) was calculated along with 95% bootstrap percentile CIs. The number of referrals, number of legitimate referrals, and number of successful referees were summarized, and the mean number of referrals was calculated along with corresponding 95% CIs. We also compared participants by study arm according to their responses in

the pre-trial survey about which type of HIV test they would prefer to use for their next HIV test and the HIV test they actually used during the trial. Proportions and corresponding 95% CIs were calculated. Two-sample tests of binomial proportions or Mann–Whitney *U* tests were used for pair-wise study arm comparisons, as appropriate. Stated reasons for completing and for recommending the assigned HIV test to others as well as other qualitative responses were summarized.

## Results

### Participant Characteristics

Study enrollment, assignment, and follow-up results are presented in Fig. 1. Of the 425 YMSM participants, the median age was 22 years (IQR 21–24); 30% were black, 35% Hispanic, and 35% white; and they lived in 46 of the US states and the District of Columbia. The majority reported condomless anal intercourse with another man within the past 6 months (67%), and many reported ever having had two or more casual condomless insertive (42%) or receptive (43%) anal sex partners; few had ever injected drugs (2%). Most (83%) had been previously tested for HIV, not during a blood donation. Among these 353 YMSM ever tested for HIV (not during a blood donation), most had their last HIV test at a community organization or medical facility (85%), or used an oral fluid rapid HIV self-test (12%), or a home-based mail-in blood sample collection HIV test (2%). The supplemental material provides comparisons by study arm of participant demographic characteristics, HIV testing history, and HIV risk sexual histories.

### HIV Testing Completion and Referrals

Of the 425 participants, 59% completed any type of HIV test (54% completed their assigned test, and 5% used a test they were not assigned) and 41% were not tested. Completion of the assigned HIV test was greater in the oral fluid rapid HIV self-test and the community organization/medical facility arms than the mail-in blood sample collection HIV test arm ( $p < 0.01$  for both comparisons) (Table 1), but assigned test completion was not greater in the oral fluid rapid HIV self-test than the community organization/medical facility arm ( $p < 0.08$ ). There were no differences by race/ethnicity in completion of assigned HIV test (Table 2).

Time to completing assigned or any HIV test was similar across study arms. Willingness to refer ( $p < 0.01$ ), making at least one referral ( $p < 0.03$ ), and average number of legitimate referrals ( $p < 0.04$ ) were greater in the

oral fluid rapid HIV self-test than the mail-in blood sample collection HIV test arm. Participation by referees was similar across study arms (21% for oral fluid rapid HIV self-test, 25% for mail-in blood sample collection, and 14% for the community organization/medical facility arm ( $p < 0.46$ ). Other referral outcomes did not differ among the three study arms. Most referees completed their assigned test.

In terms of HIV testing process measures, 18 participants in the oral fluid rapid HIV self-test arm underwent testing with another person present, and two received assistance from another person for testing. Eight in the mail-in blood sample collection arm underwent testing with another person present, seven reported problems with testing (confusing directions, difficulty obtaining the blood sample, trouble with shipping), and three called the company's help line for assistance. One person in the oral fluid rapid HIV self-test and one in the community organization/medical facility arm reported having a positive HIV test result.

### HIV Testing in Trial Versus Pre-trial Preferences and Reasons for Testing and Referral

When asked in the pre-trial survey which test they would prefer for their next HIV test, 68% of the 425 YMSM selected HIV testing at a community organization/medical facility, 25% the oral fluid rapid HIV self-test, and 4% the mail-in blood sample collection HIV test. Table 3 displays a comparison of HIV testing use during the trial and pre-trial HIV testing preferences vs. HIV testing assignment in the trial. For the oral fluid rapid HIV self-test arm, test completion despite not being assigned to a preferred test was high; however, over one-quarter of participants assigned to this test and for whom it was not their preferred test did not undergo testing. For the mail-in blood sample collection HIV test arm, over 40% deferred testing when this was not their preferred test. For the oral fluid rapid HIV self-test arm (Table 4), compliance with the trial requirements was reported most often as the reason for completing the assigned test. Testing simplicity, privacy, convenience and availability of rapid results were cited as reasons for recommending this test to others.

## Discussion

This randomized trial provides insight into the yield of a free home-based oral fluid rapid HIV self-testing campaign that could be directed towards social media-using black, Hispanic, and white YMSM in the US. In a similar approach as our investigation, researchers and public health

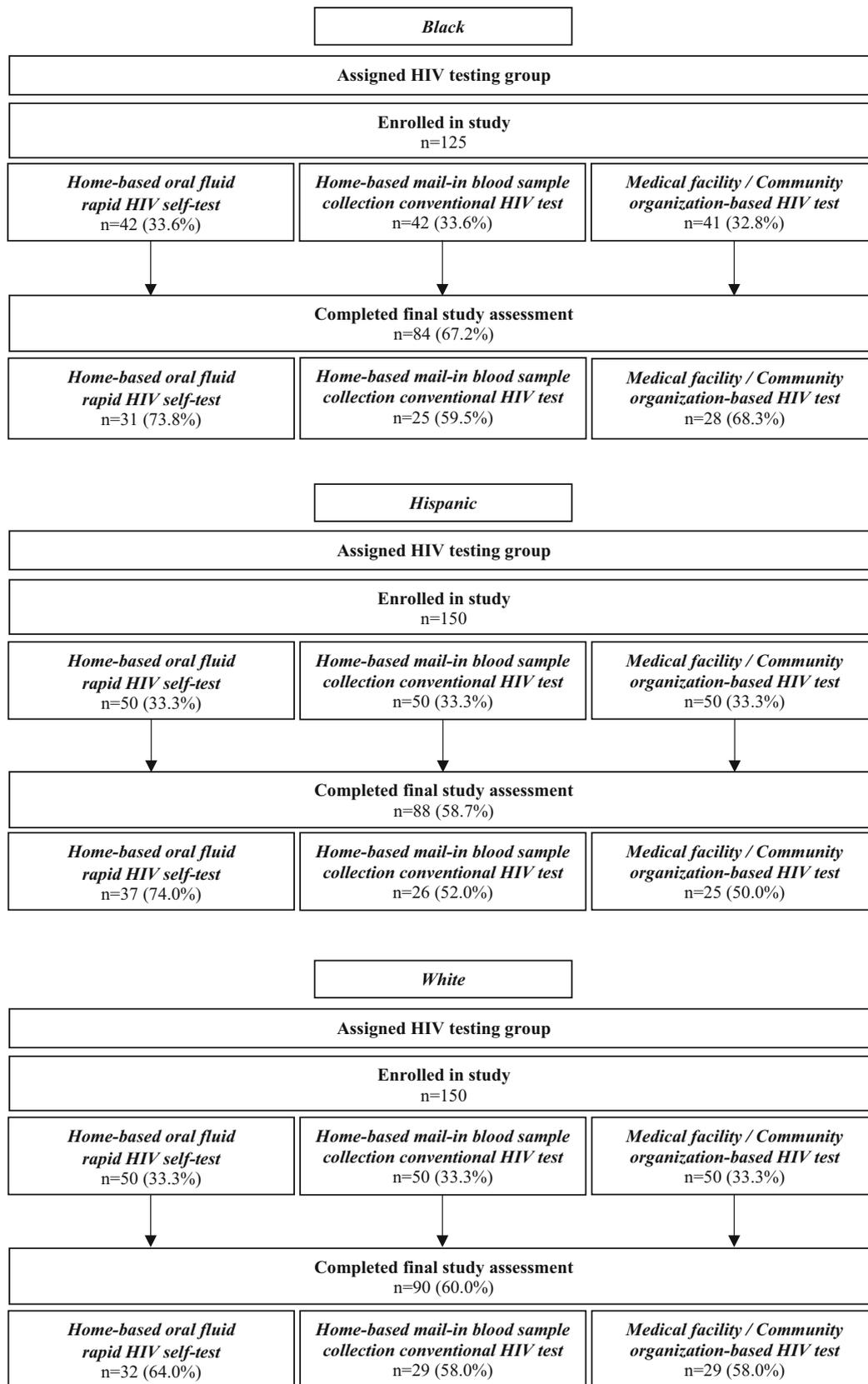


Fig. 1 Participant enrollment and follow-up

**Table 1** HIV test completion, time to HIV testing, HIV testing referrals, and referee completion by assigned HIV testing group

	Assigned HIV testing group		
	Home-based oral fluid rapid HIV self-test <i>n</i> = 42	Home-based mail-in blood sample collection conventional HIV test <i>n</i> = 142	Medical facility/community organization-based HIV test <i>n</i> = 141
<b>HIV testing results</b>			
Completed assigned HIV test, % (95% CI)	66.2 (58.4, 74.0)	40.1 (32.1, 48.2)	56.0 (47.8, 64.2)
Completed testing other than assigned HIV test, % (95% CI)	2.8 (0.1, 5.5)	11.3 (6.1, 16.5)	1.4 (0.0, 3.4)
Completed any HIV test, % (95% CI)	69.0 (61.4, 76.6)	51.4 (43.2, 59.6)	57.4 (49.3, 65.6)
Did not complete any HIV test, % (95% CI)	31.0 (23.4, 38.6)	48.6 (40.4, 56.8)	42.6 (34.4, 50.7)
<b>Time to HIV testing<sup>a</sup></b>			
Days to complete assigned HIV test, median (95% CI) <sup>b</sup>	14.0 (11.0, 17.0)	17.0 (15.0, 22.0)	17.0 (11.0, 26.0)
Days to complete test other than assigned HIV test, median (95% CI) <sup>b</sup>	59.0 (52.0, 72.0)	12.0 (3.0, 38.0)	31.0 (3.0, 59.0)
Days to complete any HIV test, median (95% CI) <sup>b</sup>	14.0 (11.0, 18.0)	17.0 (13.0, 21.0)	17.0 (11.0, 26.0)
<b>Referral results</b>			
Agreed to refer, % (95% CI)	35.9 (28.0, 43.8)	19.7 (13.2, 26.3)	26.2 (19.0, 33.5)
Made at least one referral, % (95% CI)	33.8 (26.0, 41.6)	19.7 (13.2, 26.3)	24.1 (17.1, 31.2)
Made at least one legitimate referral <sup>c</sup> , % (95% CI)	28.9 (21.4, 36.3)	18.3 (11.9, 24.7)	22.0 (15.1, 28.8)
<b>Referral numbers</b>			
Number of referrals	105	61	79
Average number of referrals, mean (95% CI)	0.7 (0.5, 0.9)	0.4 (0.3, 0.6)	0.6 (0.4, 0.7)
Number of legitimate referrals <sup>c</sup>	82	57	71
Average number of legitimate referrals <sup>c</sup> , mean (95% CI)	0.6 (0.4, 0.7)	0.4 (0.2, 0.6)	0.5 (0.3, 0.7)
	<i>n</i> = 17 referees	<i>n</i> = 14 referees	<i>n</i> = 10 referees
<b>Responses by legitimate referees<sup>c</sup></b>			
Completed referred HIV test, % (95% CI)	70.6 (48.9, 92.2)	57.1 (31.2, 83.1)	70.0 (41.6, 98.4)
Completed any HIV test, % (95% CI)	82.4 (64.2, 100.0)	57.1 (31.2, 83.1)	70.0 (41.6, 98.4)

CI confidence interval

<sup>a</sup> Participants who had negative time to HIV test completion were assigned a time to testing of zero

<sup>b</sup> Confidence intervals were calculated using bootstrap percentiles

<sup>c</sup> Legitimate referrals were determined by comparing referral versus referee email addresses

officials recently reported results of internet-based distribution of oral fluid rapid HIV self-testing programs in the US. [13] Rosengren et al. used the social media site Grindr™ during a 1-month period in 2014 to advertise free oral fluid rapid HIV self-tests in Los Angeles, CA, to adult black or Hispanic MSM [15.] For their feasibility demonstration study, there were 333 test requests, 74% for tests to be mailed to the recipients, 17% for vouchers, and 8% for vending machine codes. Other researchers have described

the feasibility of distributing these tests to MSM or other populations through community organizations, direct outreach, or other non-internet-based means in the US [16, 17] and other countries [18, 19].

In contrast to the promising results of these feasibility studies and outreach campaigns, HIV test completion, time to testing, and referrals of others for oral fluid rapid HIV self-testing was not greater than asking YMSM to undergo HIV testing at community organizations/medical facilities

**Table 2** HIV test completion by assigned HIV testing group and race/ethnicity

Assigned HIV testing group	Race/Ethnicity		
	Black <i>n</i> = 42 % (95% CI)	Hispanic <i>n</i> = 50 % (95% CI)	White <i>n</i> = 50 % (95% CI)
Home-based oral fluid rapid HIV self-test			
Completed assigned HIV test	69.0 (55.1, 83.0)	70.0 (57.3, 82.7)	60.0 (46.4, 73.6)
Home-based mail-in blood sample collection conventional HIV test	<i>n</i> = 42 % (95% CI)	<i>n</i> = 50 % (95% CI)	<i>n</i> = 50 % (95% CI)
Completed assigned HIV test	31.0 (17.0, 44.9)	38.0 (24.5, 51.5)	50.0 (36.1, 63.9)
Medical facility/community organization-based HIV test	<i>n</i> = 41 % (95% CI)	<i>n</i> = 50 % (95% CI)	<i>n</i> = 50 % (95% CI)
Completed assigned HIV test	63.4 (48.7, 78.2)	54.0 (40.2, 67.8)	52.0 (38.2, 65.8)

*CI* confidence interval

**Table 3** Comparisons of HIV testing preferences in pre-trial survey versus HIV testing behavior in trial by assigned HIV testing group

HIV test preferred in pre-trial survey/ HIV test taken in trial	Assigned HIV testing group		
	Home-based oral fluid rapid HIV self-test <i>n</i> = 142 % (95% CI)	Home-based mail-in blood sample collection conventional HIV test <i>n</i> = 142 % (95% CI)	Medical facility/community organization-based HIV test <i>n</i> = 141 % (95% CI)
Preferred assigned HIV test/tested with assigned HIV test	16.2 (10.1, 22.3)	0.7 (0.0, 2.1)	39.0 (31.0, 47.1)
Did not prefer assigned HIV test/tested with assigned HIV test	48.6 (40.4, 56.8)	39.4 (31.4, 47.5)	16.3 (10.2, 22.4)
Preferred assigned HIV test/did not test with assigned HIV test	7.7 (3.3, 12.1)	3.5 (0.5, 6.6)	29.8 (22.2, 37.3)
	Used mail-in blood sample: 0.0	Used rapid: 0.7	Used rapid: 0.7
	Used community/medical: 0.7	Used community/medical: 0.0	Used mail-in blood sample: 0.0
Did not prefer assigned HIV test/did not test with assigned HIV test	26.1 (18.8, 33.3)	52.8 (44.6, 61.0)	13.5 (7.8, 19.1)
	Used mail-in blood sample: 0.7	Used rapid: 4.9	Used rapid: 0.7
	Used community/medical: 1.4	Used community/medical: 5.6	Used mail-in blood sample: 0.0
	Did not test: 23.9	Did not test: 42.3	Did not test: 12.8

Nine participants did not state their preferred HIV test, and are omitted from the table

*CI* confidence interval

in this study. We were surprised that oral fluid rapid HIV self-testing, despite its perceived advantages, ready availability, and previous research indicating interest in the test, was not embraced more strongly than community organization/medical facility testing. On the other hand, consistent with how infrequently it is used, it was apparent that the mail-in blood sample collection HIV test was not a favored testing methodology by YMSM in this sample.

How can this investigation's results be interpreted in light of the need to increase HIV testing among black, Hispanic, and white YMSM? One interpretation is that perceived barriers of the oral fluid rapid self-test (e.g., concerns about its accuracy and reticence to self-test) make YMSM apprehensive in using it. If true, interventions to build confidence in its accuracy and ease of use as well, such as through testing demonstrations and testimonials on

**Table 4** Stated reasons for HIV testing behavior in trial and HIV testing recommendations

	Assigned home-based oral fluid rapid HIV self-test n=142	Assigned home-based mail-in blood sample collection conventional HIV test n=142	Assigned medical facility / community organization-based HIV test n=141
<b>Main reason for using assigned HIV test</b>	<b>Reason:</b> n Was curious about the test 17 Was part of being in the study 56 Wanted to find out if had HIV 20 Refuse to answer 1	<b>Reason:</b> n Was curious about the test 6 Was part of being in the study 41 Wanted to find out if had HIV 10	<b>Reason:</b> n Was convenient to get tested 15 Was free 19 Was inexpensive 1 Was part of being in the study 26 Wanted to find out if had HIV 18
<b>Main reason for not using assigned HIV test</b>	<b>Reason:</b> n Had difficulty with assigned test 2 Too stressful to test with assigned test 1 Don't know 1	<b>Reason:</b> n Did not want to test self 2 Another test was more convenient 4 Had difficulty with assigned test 2 Too stressful to get with assigned test 1 Did not want to wait for test results 3 Did not want blood sample taken 1 Did not want to prick finger 1 Don't know 2	<b>Reason:</b> n Did not want to wait for test results 2
<b>Main reason would recommend assigned HIV test</b>	<b>Reason:</b> n Test is easy to perform 30 Can be tested in private 23 More convenient testing 17 Can get test results in 20 minutes 12 Find out for yourself if have HIV 4	<b>Reason:</b> n Test is easy to perform 8 Can get results within a few days 4 Can be tested in private 10 More convenient testing 11	<b>Reason:</b> n Experienced person performs test 12 Can get test results quickly 11 Can be tested confidentially 9 Have help if test is positive 22 Test results are accurate 6 Can be tested by someone familiar 9
<b>Main reason would not recommend assigned HIV test</b>	<b>Reason:</b> n Better for someone else to test 3 Test costs too much 1 Too stressful to test self 1	<b>Reason:</b> n Too stressful to get own blood sample 8 Too complicated to perform test 2 Better for someone else to test 4 Test costs too much 4	<b>Reason:</b> n Too stressful to ask for test 3 May need to pay for testing 1 Testing is not private 1

the internet or at clinical or non-clinical settings, might be helpful. As YMSM consumers become more accustomed to the test, apprehension might decrease. Another interpretation is that community organization/medical facility testing is viewed as the accepted standard for testing by YMSM, perhaps because of the other services offered there, support provided during testing, or its notoriety in the community. If true, perceived concerns about these venues inhibiting HIV testing among this population are not accurate. If this explanation is correct, our investigation also indicates that YMSM can be encouraged via the internet to seek testing in their community with good results and lower costs to them. Interventions instead could be directed at facilitating testing at these locations, perhaps instead of distributing oral fluid rapid HIV self-testing to YMSM. On the other hand, there is no one-size-fits-all approach to HIV testing, and the results of this trial cannot be deemed definitive. Access, availability, confidence, convenience, cost, reputation, and other tangible and

intangible considerations drive testing behavior. In a more optimistic view, the study results might suggest that home-based oral fluid rapid HIV self-testing might be at least as acceptable to YMSM as being asked to test in their local communities. If testing access and inconvenience override ability to seek testing through traditional means, then oral fluid rapid HIV self-testing might be a good alternative. Even though research can indicate how public health efforts and expenditures might be directed optimally, multiple options for testing need to be readily available. In addition, the costs of having testing available in community organizations, given their fixed costs, might be greater than providing for funding for home-based HIV testing. Further larger-scale investigations comparing testing utilization internet-based approaches among this higher HIV risk population are needed to guide public policy.

As part of this study, we also investigated if a chain-referral process could be generated that would enable additional black, Hispanic, or white YMSM to be tested.

Such a chain could capitalize on social media and social networking (online or offline relationships) to reach other YMSM who might not participate in research or public health campaigns. However, only 20% of referees enrolled in the study and some referrals were fraudulent. Fraudulent referrals have been a problem observed in other internet-based HIV studies [20, 21], perhaps due to the financial incentives involved. On a positive note, 66% of referees used their assigned test, which is a similar proportion as those enrolled in the trial, albeit a much smaller sample. Future HIV testing campaigns will need to examine methods to reduce or mitigate fraudulent referrals, particularly if incentives are involved; encourage referrals; and persuade referees to be tested. Future approaches might consider direct referrals by campaign participants, instead of through an intermediary, and developing interventions that promote referrals and referee participation.

This investigation had several limitations. Despite enrolling a diverse sample of black, Hispanic, and white YMSM, we cannot verify that the observed results definitively represent those that would be obtained by studies involving other YMSM in the US. We do believe that using multiple social media platforms to recruit participants across the US and randomly selecting participants for the trial assisted with promoting the validity of the findings. As expected for anonymous internet-based studies, follow-up was not optimal, which could have affected the observed results. Also, larger sample sizes could have identified differences not detected statistically in this investigation. We also relied on self-report of HIV testing completion, which could be inaccurate. However, we would not expect self-reporting of test completion to differ by HIV testing methodology. The study's sample size precluded meaningful sub-analyses by factors such as sexual self-identity, socioeconomic and environmental/community-related influences, reasons for testing, self-perceived or reported risk behaviors—whether or not these potential factors were assessed as part of the study. Future larger studies on this topic should investigate the potential influence of factors on HIV testing behavior because they might further impact the design and implementation of interventions to increase HIV testing among this higher HIV risk population.

In conclusion, free, home-based oral fluid rapid HIV self-testing showed moderate promise in facilitating HIV testing among black, Hispanic, and white YMSM in the US recruited through social media, but was not greater than directing these men to use traditional community organization/medical facility HIV testing venues. Further investigation is needed to determine if additional interventions can be developed to increase HIV testing utilization with any of the existing modalities and how public health campaigns should be directed for this higher HIV risk population.

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#### Compliance with Ethical Standards

**Conflict of interest** Dr. Rosenberger previously was a consultant for Online Buddies, Inc. Dr. Mayer has received unrestricted research grants from Gilead Sciences and ViiV Healthcare. Drs. Bauermeister, Clark, Liu, and Merchant declare no conflicts of interest.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All participants provided consent to be in the study.

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