

Statistical Analysis Plan (SAP)

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CRU/Department/Division/Center	National Institute on Drug Abuse
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Investigators:	
Primary Investigator	Jeffrey D. Klausner
Collaborative Lead	
Co-authors (if known)	Chrysovalantis Stafylis, Gabriella Vavala, Qiao Wang, Bethany McLeman, Shea M Lemley, Sean D Young, Haiyi Xie, Abigail G Matthews, Neal Oden, Leslie Revoredo, Dikla Shmueli-Blumberg, Emily G Hichborn, Erin McKelle, Landhing M Moran, Petra Jacobs, Lisa A Marsch
Analysis Biostatistician(s)	Haiyi Xie
Biostatistics Supervisor	
Lead Biostatistician	
Subject Matter Expert	Jeffrey D. Klausner
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| Investigator Agreement | <input type="checkbox"/> All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
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- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
 - ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
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Activity Log

This SAP reflects a change to the original primary analysis. The initial plan specified a Poisson regression model to compare self-test kit ordering rates by platform type (social media, information search site, and dating app). During analysis, significant platform-by-wave interactions and differences in ordering rates across sites within the same platform were observed, making pooling across platform types inappropriate. Thus, the analysis approach was revised to compare ordering rates between specific sites within the same wave. Pairwise comparisons across all six sites from the two waves were conducted with multiple testing adjustment using the Hochberg method.

Acronyms

MSM	Men who have sex with men
CDC	Centers for Disease Control and Prevention
PrEP	Pre-Exposure Prophylaxis
TAPS	Tobacco, Alcohol, Prescription medication, and other Substance
SD	Standard deviation
IQR	Interquartile range
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
NIDA	National Institute on Drug Abuse

1 Study Overview

Background/Introduction: This study is a longitudinal observational study designed to evaluate the effectiveness of different web platforms in promoting HIV self-test kit ordering among young Black and Latinx MSM at increased risk for HIV infection. Participants were recruited through advertisements placed on social media sites, dating apps, and web browsers during two recruitment waves, with each wave simultaneously including one site from each platform type. The primary outcome was the number of HIV self-test kits ordered per day from each platform. Ordering rates were analyzed using Poisson regression models with log-time offsets to account for varying recruitment durations.

1.1 Study Aims

Primary aim:

- Compare the effectiveness of social media sites, informational search sites, and dating apps in promoting HIV self-testing, as measured by the number and timing of HIV kit orders during the recruitment period

Secondary aims:

- Compare PrEP uptake across participants recruited from social media sites, informational search sites, and dating applications
- Evaluate whether baseline substance use modifies HIV self-test kit ordering and PrEP uptake
- Assess how participants' readiness for HIV testing varies by recruitment platform and influences HIV test ordering and PrEP usage
- Determine the relative efficiency of web platforms for promoting HIV self-testing and PrEP uptake using platform-specific analytics and conversion metrics
- Evaluate associations between participant perceptions (like attitudes toward HIV testing and PrEP, HIV stigma, and medical mistrust) and HIV kit ordering
- Examine relationship between sexual delay discounting, HIV risk behaviors, and HIV testing outcomes

Exploratory aim:

- Compare advertisement reach, engagement, and cost metrics across web-based platforms used to promote HIV self-testing

1.2 Study Hypotheses

1.2.1 Primary Hypothesis

- H0: The rate of HIV self-test kit ordering does not differ across social media sites, informational search sites, and dating applications vs. H1: The rate of HIV self-test kit ordering differs across at least one of these platforms

1.2.2 Secondary Hypotheses

- H0: The probability of PrEP uptake does not differ by recruitment platform vs. H1: The probability of PrEP uptake differs by recruitment platform
- H0: Baseline substance use is not associated with HIV self-test kit ordering or PrEP uptake vs. H1: Baseline substance use is associated with HIV self-test kit ordering and/or PrEP uptake
- H0: Readiness for HIV testing is not associated with recruitment platform, HIV self-test kit ordering, or PrEP uptake vs. H1: Psychological readiness for HIV testing is associated with recruitment platform and with HIV self-test kit ordering and/or PrEP uptake
- H0: Advertisement efficiency metrics (conversion rates, cost per kit ordered, etc.) do not differ across recruitment platforms vs. H1: Advertisement efficiency metrics differ across recruitment platforms
- H0: Participant perceptions related to HIV testing and PrEP, HIV-related stigma, and medical mistrust are not associated with HIV self-test kit ordering vs. H1: Participant perceptions related to HIV testing and PrEP, HIV-related stigma, and medical mistrust are associated with HIV self-test kit ordering
- H0: Sexual delay discounting is not associated with HIV risk behaviors or HIV testing at follow-up vs. H1: Sexual delay discounting is associated with HIV risk behaviors and HIV testing at follow-up

2 Study Population

2.1 Inclusion Criteria

- Have clicked on one of the study-specific advertisements posted on the study platforms/websites
- Have been biologically born male (cis-gender man)
- Report condomless anal intercourse and more than one male sex partner in the 90 days prior to the date of the screening questionnaire
- Be between the ages of 18-30 years old, inclusive
- Self-identify as Latino and/or Black/African American
- Not currently on PrEP and haven't taken PrEP in the last six months prior to the date of the screening questionnaire
- Have not tested for HIV in the last 3 months prior to the date of the screening questionnaire
- Have a Facebook account (for identity validation to reduce duplicate attempts at enrollment)

- Be willing to provide contact information (phone number, email) to the study team

2.2 Exclusion Criteria

- Are unwilling or unable to provide informed consent
- Are unwilling to provide contact information (phone number, email address)
- Report having a preliminary positive or positive HIV result in a test completed less than 30 days prior to the date of screening or report being currently under treatment for HIV infection.

2.3 Data Acquisition

Fill in all relevant information:

Study design	Longitudinal observational cohort study
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Notes: Participants enrolled from Google and Facebook during periods when Grindr was inactive were excluded from analysis to ensure comparability across the different platforms. The two advertisement periods of Wave 1 were combined prior to analysis. Wave 3 data were excluded entirely due to zero enrollment during the COVID-19 emergency, making statistical models inestimable.

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	Description	Variables and Source	Specifications
HIV self-test kit ordering	Whether a participant ordered an HIV self-test kit	Variable: ora_redeemed Source: Orasure redemption records	Categorical variable indicating HIV kit ordering status: <ul style="list-style-type: none"> • Yes = participant ordered an HIV kit • No = participant did not redeem voucher • Over 60 days = voucher redeemed outside analytic window

3.2 Secondary Outcome(s)

Outcome	Description	Variables and Source	Specifications
Substance use	Participant-reported substance use at baseline	Variables: Q12_2, Q12_3, Q12_4 (past 12 months frequency); Q13_1–Q13_23 (past 3 months yes/no); Q13_24 (“other drug”) Source: Baseline questionnaire	Q12_2–Q12_4: categorical frequency with levels like 1=Daily or almost daily; 4=Weekly; 5=Monthly; ... Q13_1–Q13_23: 1=Yes; 2=No. Q13_24: text
Stage of change for HIV testing	Participant readiness for HIV testing at baseline	Q15_1	Ordinal categorical (precontemplation → action/determination)
Attitudes toward HIV testing	Participant attitudes and beliefs regarding HIV testing and HIV treatment	Variables: HIV testing attitudes: Q15_3, Q15_4, Q15_5, Q15_6, Q15_7	Q15_3–Q15_7: 1=Agree; 2=Disagree. Q94_*: numeric responses

and treatment		HIV treatment perceptions/optimism: Q94_1, Q94_5, Q94_6, Q94_7, Q94_8, Q94_9, Q94_10, Q94_12, Q94_13 Source: Baseline questionnaire	
HIV-related stigma	Participant-perceived HIV stigma	Variables: Q14_2, Q14_3, Q14_4, Q14_5 Source: Baseline questionnaire	Likert-type categorical responses 1=Strongly agree; 2=Agree; 3=Somewhat agree; 4=Disagree; 5=Strongly disagree
Medical mistrust	Participant mistrust of medical organizations/providers	Variables: Q16_1–Q16_7 Source: Baseline questionnaire	Likert-type categorical responses. Most items: 1=Strongly agree; 2=Agree; 6=Disagree; 7=Strongly disagree
Opinions about PrEP	Participant opinions, barriers, and facilitators related to PrEP use	Variables: Q7_5_fu1, Q7_8_fu1, Q7_9_fu1, Q7_10_fu1, Q7_16_fu1, Q8_1_6_fu1, Q8_1_12_fu1, Q8_1_13_fu1 Source: Follow-up questionnaires	Q7_*_fu1: Likert 1=Strongly agree ... 5=Strongly disagree) Q8_1_*_fu1: 1=Not at all important; 2=Slightly important; 3=Moderately important; 4=Very important; 5=Extremely important

3.3 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Age	Participant age at enrollment	Q3_1	Continuous (years)
Sex at birth	Sex assigned at birth	Q4_1	1 = Male, 2 = Female
Ethnicity	Hispanic/Latinx identity	Q5_1	1 = Yes, 2 = No
Race	Self-identified race	Q5_3, Q5_3_28_TEXT	Categorical; multiple race categories; free-text for "Other"
PrEP history	Prior PrEP use	Q6_2	Categorical (includes "never" vs recent use)
Sexual risk behavior	Number of male sex partners (90 days); condom use frequency;	Q11_2, Q11_3, Q11_4	Q11_2: numeric; Q11_3: ordinal (Never → Always); Q11_4: 1 = Yes, 2 = No

	condomless receptive anal sex (90 days)		
HIV testing history	Ever tested for HIV and time since last test	Q11_5, Q11_6, Last_hiv_test_months, Last_hiv_test_interval	Binary for ever tested; date field; derived interval categories
Reason for not testing	Main reason participant had not tested for HIV	Q11_7	Categorical (multi-level; includes other-specify)
Substance use	Baseline substance use across multiple substances	Q13_1–Q13_23, Q13_24	Q13_1–Q13_23: 1 = Yes, 2 = No; Q13_24: free text
Stage of change for HIV testing	Readiness for HIV testing	Q15_1	Ordinal categorical (precontemplation → action/determination)
Attitudes toward HIV testing and treatment	Attitudes and perceptions regarding HIV testing and treatment	Q94_1, Q94_5–Q94_13	Continuous / slider-type responses (no fixed labels in dictionary)
HIV-related stigma	Perceived HIV stigma	Q14_2, Q14_3, Q14_4, Q14_5	Likert-type categorical (agree → disagree)
Medical mistrust	Mistrust of medical providers and organizations	Q16_1–Q16_7	Likert-type categorical
Opinions about PrEP	Perceived barriers, facilitators, and importance of PrEP	Q7_10_fu1, Q7_12_fu1–Q7_19_fu1, Q8_1_3_fu1–Q8_1_13_fu1	Agreement Likert items and importance scale (Not at all → Extremely important)
Recruitment platform	Platform type and specific site of recruitment	Platform, site	Categorical (Social media, Dating app, Informational site; site-level categories)
Recruitment wave	Study recruitment wave	wave	Categorical (1, 2, 3, 4)
Geographic location	Participant state of residence	state	Categorical (US states)

4 Statistical Analysis Plan

4.1 Demographic and Clinical Characteristics (“Table 1”)

Table 1 summarizes demographic and behavioral characteristics of participants included in the sample. Participant age is summarized using the median and interquartile range. Race and ethnicity are presented as frequencies and percentages, including Hispanic/Latinx ethnicity and race categories. Behavioral characteristics include history of PrEP uptake, number of male sex partners in the past 90 days, condom use frequency, and engagement in condomless receptive anal sex during the past 90 days. HIV testing history is summarized by lifetime HIV testing status and time since last HIV

test for those who have been tested before. For participants who reported never having been tested for HIV, the primary reasons for not testing are summarized using frequencies and percentages.

4.2 Analyses Plan for Aim 1

The primary objective is to compare HIV self-test kit ordering rates across individual online recruitment sites within each recruitment wave. Analyses are restricted to periods during which all recruitment sites were simultaneously active. Participants enrolled during early Wave 1 from Google and Facebook while Grindr was inactive are excluded. The two advertisement periods within Wave 1 are combined. Participants who did not order an HIV self-test kit within 60 days of receiving a test code are classified as not having ordered a kit.

For each recruitment site and wave, the number of HIV kits ordered and the number of days the site was active are summarized and observed daily order rates are calculated. Ordering rates are modeled using Poisson regression with a log link function and a log time offset to account for different recruitment durations. Due to differences in ordering rates across sites and significant wave-by-site interactions, sites are not pooled within platform types. Site-specific ordering rates are estimated separately within each wave.

Model-based estimates of site-specific ordering rates are reported as kits ordered per day with 95% confidence intervals. Pairwise comparisons of ordering rates across recruitment sites are conducted within each wave using contrasts. Adjustment for multiple comparisons is performed using the Hochberg method. Model fit and distributional assumptions are analyzed using residual deviance and goodness of fit statistics.

4.3 Analyses Plan for Aim 2

Secondary analyses evaluate the associations between participant-level characteristics and HIV kit ordering. HIV kit ordering is a binary outcome saying whether a participant ordered a HIV self-test kit during the study period. This is intended to identify potential relationships of HIV self-test kit ordering, including substance use, stage of change for HIV testing, sexual risk behaviors, attitudes toward HIV testing and treatment, stigma, medical mistrust, and perceptions of PrEP.

Demographic and behavioral characteristics are compared between participants who ordered a test kit and those who did not. Continuous variables are summarized using measures of central tendency and variability (median, 25th, 75th percentiles) and compared between groups using Student's t tests when approximately normally distributed. Ordinal variables (like Likert-scale variables) are compared using Wilcoxon rank-sum tests. Categorical variables are summarized using frequencies and percentages and compared between groups using Fisher's exact tests.

4.4 Descriptive Analysis

Descriptive analyses are done to summarize study recruitment, participant characteristics, and behavioral and clinical outcomes. Recruitment metrics are summarized using counts, including the number of individuals directed to the study website from advertisements and the number of participants enrolled by platform and geographic location.

Participant demographic characteristics are summarized, including age (mean/standard deviation), race and ethnicity (counts/percentages), and geographic recruitment region. Baseline behavioral characteristics are summarized using descriptive statistics and include sexual risk behaviors, like number of sex partners in the prior 90 days summarized (medians/IQR), condomless anal sex as a binary variable, prior HIV testing history (binary), and time since last HIV test measured in months (median/IQR).

HIV self-test-related outcomes are also summarized, including HIV self-test kit ordering and use, self-reported HIV test results, and linkage to testing and HIV treatment following a positive result

(counts/percentages). Prior PrEP use and looking for PrEP following a negative HIV self-test result are summarized using frequencies and percentages.

4.5 Sensitivity Analysis

Sensitivity analyses are conducted to evaluate the robustness of the findings to alternative analytic assumptions. These include analyses incorporating all test kit orders regardless of timing, alternative handling of phased recruitment during Wave 1 (which has to be stopped due to Grindr shutting down for a short time), and the handling of data collected during periods affected by the COVID-19 pandemic. Sensitivity analyses use the same modeling framework as the primary analysis and are interpreted relative to the main results.

4.6 Missing Data

The analysis of the primary outcome does not include missing data, as HIV self-test kit ordering counts and recruitment duration are received from automated records. For the individual-level survey, participants were permitted to skip questions. Skipped responses are classified as missing and are excluded from the calculation of summary statistics and from analyses involving these variables. No imputation methods are applied in the study.

4.7 Software

Statistical analyses were conducted using Statistical Analysis Software (SAS), version 9.4.

5 Limitations

Several limitations should be considered when interpreting analyses conducted in this study. The study was conducted in selected geographic areas with high HIV incidence, so findings may not be generalizable to populations outside these regions. Enrollment was varied across recruitment waves, which limited the ability to conduct broad comparisons between platforms and made pooling of data across waves impossible.

In addition, recruitment was conducted on a selected set of commonly used apps and websites, which were grouped into platform categories based on similar characteristics. Analyses are therefore specific to the platforms and sites that were chosen to display the ads and may not extend to other platforms or sites not included in this study.

6 References

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Poisson Regression. Institute for Digital Research and Education, University of California, Los Angeles.
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7 Appendix

Model specification for primary analysis:

$$\log(o_{ij}) = \log(t_i) + \alpha + \beta_i + \gamma_j + \beta\gamma_{ij}$$

where

o_{ij} is the number of kits ordered by the site in Wave i (i.e. time period i), platform type j .

t_i is the time that the Wave platforms were recruiting.

β_i is the main effect of wave.

γ_j is the main effect of platform type.

$\beta\gamma_{ij}$ is the interaction term.

Under this model, the rate for any site ij is given by:

$$rate_{ij} = \exp(\alpha + \beta_i + \gamma_j + \beta\gamma_{ij})$$

Population sociodemographic and behavioral characteristics:

Characteristic	Value
Age in years, median (IQR)	25 (23-27)
Ethnicity, n (%)	
Hispanic/Latinx	66 (26)
Race, n (%)	
American Indian or Alaskan Native	1 (0.4)
Black or African American	196 (78.4)
White	28 (11.2)
Other	14 (5.6)
Multiracial	11 (4.4)
History of PrEP^a uptake, n (%)	
Never taken PrEP	232 (91.3)
In the past 6 months	22 (8.9)
Number of male sex partners in the past 90 days, median (IQR)	4 (3-6)
Condom use, n (%)	
Never	36 (14.2)
Sometimes	108 (42.5)
About half the time	37 (14.5)
Most of the time	68 (26.8)
Always	5 (2)
Condomless receptive anal sex in the past 90 days, n (%)	210 (82.7)
Ever tested for HIV during lifetime, n (%)	191 (75.2)
If tested for HIV, median (IQR)	
Months since last HIV test	11 (6-21)
If not tested for HIV, n (%)	63 (24.8%)
Main reasons cited by the 63 participants for not getting tested, n (%)	
Unlikely to be exposed to HIV	8 (12.7)
Afraid of testing HIV-positive	26 (41.3)
Did not want to think about HIV/HIV-positive	8 (12.7)
Worried about names being reported if positive	3 (4.8)
Dislike for needles	5 (8)
Unable to trust that the results will be confidential	3 (4.8)
Unaware of where to get tested	7 (11.1)
Other reasons	3 (4.8)

Number and rate of HIV home self-test kits ordered through promotional platforms by wave per protocol sample:

Type of platform	Wave	Number of days for each wave	Number of test kits ordered	Order rate (ordered test kits/day)
Social media site				
Facebook	1 ^a	70	13	0.19
Instagram	2	38	13	0.34
Subtotal	N/A	108	26	0.24
Dating app				
Grindr	1 ^a	70	9	0.13
Jack'D	2	38	125	3.29
Subtotal	N/A	108	134	1.24
Information search site				
Google	1 ^a	70	17	0.24
Bing	2	38	0	0.00
Subtotal	N/A	108	17	0.16
Total	N/A	108	177	1.64

Performance of advertisements by platform throughout the advertisement campaign:

Platform	Impressions ^a	Clicks ^b	Click-through rate		Enrolled participants	Total funds spent (US \$)
			(%) ^c	Users screened ^d		
Social media	3,864,778	21,399	0.6	2679	33	16,221.52
Dating apps	1,331,200	53,067	4	4390	202	17,939.40
Information search sites	708,770	10,869	1.5	2562	19	15,978.86