Statistical Analysis Plan (SAP)

The creation of this template for the Duke BERD Methods Core was made possible by Grant Number UL1TR002553 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.

Title	Relative Effectiveness of Social Media, Dating Apps, and Information Search Sites in Promoting HIV Self-testing: Observational Cohort Study
CRU/Department/Division/Center	
IRB Number:	18-001580
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)	
Biostatistics Supervisor	
Lead Biostatistician	
Subject Matter Expert	
Original Creation Date	
Version Date	The SAP is created on Jan 18, 2026 for the STA 540 homework 1; The first version was completed on Jan 21, 2026; The final version was completed on Jan 28, 2026
Project Folder Location	
Project Goal(s)	Publication
Submission Deadline(s)	Jan 28, 2026
Effort Estimate (optional)	

Investigator Agreement ☐ 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).

	☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses. ☐ 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. ☐I have reviewed the SAP and understand that any changes must be documented. *Acknowledged by:* Click or tap here to enter text. *Date:* Click or tap to enter a date.
Activity Log	• The comparison of HIV self test kit order rate between the three platform types was changed to the comparison of specific platforms within the same wave because of the significant platform-by-wave interactions. • The third promotion wave conducted on Twitter, Yahoo, and Hornet between April 6, 2020, and May 6, 2020. Since no participants were enrolled and no test kit were ordered, the Wave 3 was excluded from the analysis.

Acronyms	MSM	men who have sex with men
	PrEP	pre-exposure prophylaxis
	HIV	human immunodeficiency virus

1 Study Overview

Background/Introduction:
Minority men who have sex with men (MSM) in the United States continue to face a high risk of HIV infection, yet many are not tested regularly. Early HIV testing is important and HIV self-testing has become an important tool.
Digital platforms are now used to deliver health messages and prevention programs to individuals at high risk for HIV infection, but they may respond differently to the same HIV testing message. Therefore, it is important to understand which types of platforms are most effective at encouraging people to request and use HIV self-tests.

1.1 Study Aims

- This study's primary aim is to compare effectiveness of social media platforms (Facebook, Instagram, Twitter), dating apps (Grindr, Hornet, Jack'd), and information search sites (Google, Bing, Yahoo) in encouraging HIV self-testing among MSM. The main measure of effectiveness is test kit order rates.
- Secondary aim 1: Compare the differences in stage of health behavior change between participants who ordered a test kit and those who did not.
- Secondary aim 2: Compare the differences in attitudes toward HIV testing between participants who ordered a test kit and those who did not.
- Secondary aim 3: Compare the differences in HIV related stigma between participants who ordered a test kit and those who did not.

- Secondary aim 4: Compare the differences in medical mistrust between participants who ordered a test kit and those who did not.
- Secondary aim 5: Compare the differences in attitudes toward HIV treatment between participants who ordered a test kit and those who did not.
- Secondary aim 6: Compare the differences in tobacco, alcohol, prescription medications, and other substance use between participants who ordered a test kit and those who did not.

1.2 Study Hypotheses

- This study is primarily exploratory and comparative rather than driven by strong theory-based hypotheses.
- The primary hypothesis is that promotion effectiveness, which is measured by HIV self-test kit order rates, differs across social media platforms, dating apps, and information search sites.
- The hypothesis for primary analysis:

  H0: In the same wave, advertising platforms have the same order rate

  H1: In the same wave, at least one platform has different order rate compared to others
- Pairwise comparison:

  H0: order rate for platform A = order rate for platform B

  H1: order rate for platform A ≠ order rate for platform B
- Secondary analysis hypothesis:

  H0: Participants who ordered a test kit and those who did not have the same distributions of interested characteristics.

  H1: Participants who ordered a test kit and those who did not differ in the distribution of at least one of these characteristics.

2 Study Population

2.1 Inclusion Criteria

- MSM aged 18-30 years who identified as Latinx or Black/African American people (including multiracial and multiethnic individuals of these groups);
- People report having condomless anal sex in the past 90 days or having more than 1 male sex partner in the past 90 days.

2.2 Exclusion Criteria

- Participants who are HIV-positive
- Participants who are tested for HIV infection in the past 90 days
- Participants who are taking PrEP currently or at any time during the past 6 months before enrollment.

2.3 Data Acquisition

Fill in all relevant information:

Study design	Longitudinal observational cohort study using two recruitment waves of web-based advertisements on social media (Facebook, Instagram), dating apps (Grindr, Hornet), and information search sites (Google, Bing) to enroll minority MSM. Advertisements promoting free HIV self-testing were run on these platforms during the same time period with the same advertising budget. Participants who enrolled completed a baseline survey and were followed up at 14 and 60 days after

	enrollment with additional survey questions. HIV self-test kit ordering was recorded and used to evaluate the relative effectiveness of HIV self-test promotion across platform types.
Data source/how the data were collected	Participants were recruited via paid digital advertisements on Facebook, Instagram, Grindr, Hornet, Google, Bing, and Jack'd. Their order data was collected from Orasure.com (Bethlehem, PA).
Contact information for team member responsible for data collection/acquisition	https://datashare.nida.nih.gov/study/nida-ctn-0083
Date or version (if downloaded, provide date)	Data downloaded on Jan 18, 2026.
Data transfer method and date	The data is downloaded from NIDA Data Share
Where dataset is stored	In Excel (xlsx file)

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
HIV self-test kit order rate (kits/day) by recruitment platform	The number of HIV self-test kits ordered per day on average through each type of platforms	• ORA_WITHIN60_YESNO • Advertising time for each wave • Source: Orasure.com for the order history; paper for the advertising time	• Yes; No; Missing (note: Missing refers to those who did not redeem the code) • order rate = number of orders / number of advertising days during each wave
Advertising wave	The specific wave number	• WAVE	• 1=wave 1; 2=wave 2; 3=wave 3; 4=wave 4 • Wave 3 was removed in the analysis; Wave 4 was the second phase of wave 1
Recruitment platforms	Information for the platforms conducting the study	• SITE • SITE_TYPE	• Facebook; Google; Instagram; Jack'd; Grindr; Bing; Yahoo; Hornet; Twitter • Social media; Info sites; Dating apps
Primary analysis indicator	Indicator of whether the participant is involved in the primary analysis	• po_flag	• Include; Do not include

3.2 Secondary Outcome(s)

Outcome	Description	Variables and Source	Specifications
Stage of Health Behavior Change	Which of these statements is most true for you?	This is from the survey question: • Q15_1	1=I don't see any need to regularly test for HIV; 2=I think I should get tested for HIV regularly, but I am not sure; 3= I'm ready to start getting regularly tested for HIV; 4=I'm trying to get tested regularly for HIV; 5=I've been getting testing for HIV regularly over the past few years.
People's attitudes toward HIV testing	• Getting tested for HIV helps people feel better. • Getting tested for HIV helps people from getting HIV. • People in my life would leave if I had HIV. • People who tested positive for HIV should hide it from others. • I would rather not know if I have HIV.	This is from the survey question: • Q15_3 • Q15_4 • Q15_5 • Q15_6 • Q15_7	• 1=Agree; 2=Disagree for all five questions.
Attitudes toward HIV testing	• I am less threatened by the idea of being HIV positive than I used to be. • I am less worried about HIV infection than I used to be. • I think HIV/AIDS is less of a problem than it used to be. • I think HIV/AIDS is a less serious threat than it used to be because of new HIV/AIDS treatments. • I am much less concerned about becoming HIV positive myself because of new HIV/AIDS treatments. • I think that condom use during sex is less necessary now	• Q94_1 • Q94_5 • Q94_6 • Q94_7 • Q94_8 • Q94_9 • Q94_10 • Q94_11 • Q94_12 • Q94_13	• Numeric • continuous scale from 1 [strongly disagree] to 7 [strongly agree]

	that new HIV/AIDS treatments are available. • I think that someone who is HIV positive now needs to care less about condom us. • I think that the need for condom use is less than it used to be, because you can always start new treatments. • I think that someone who is HIV positive and uses new HIV/AIDS treatments can be cured. • I think that new HIV/AIDS treatments can eradicate the virus from your body.		
HIV-related stigma among study participants	• I feel afraid of people living with HIV/AIDS. • I could not be friends with someone who has HIV/AIDS. • People who get HIV/AIDS through sex or drug use got what they deserve. • I feel anger toward people with HIV/AIDS.	• Q14_2 • Q14_3 • Q14_4 • Q14_5	• 1=Strongly agree; 2=Agree; 3=Somewhat agree; 4=Neither agree nor disagree; 5=Somewhat disagree; 6=Disagree; 7=Strongly disagree
Medical mistrust	• You'd better be cautious when dealing with healthcare organizations. • Patients have sometimes been deceived or misled by health care organizations. • When health care organizations make mistakes they usually cover it up. • Health care organizations have sometimes done harmful experiments on	• Q16_1 • Q16_2 • Q16_3 • Q16_4 • Q16_5 • Q16_6 • Q16_7	• Q16_1: 28=Strongly agree; 30=Agree; 33=Disagree; 34=Strongly disagree • All other questions: 1=Strongly agree; 2=Agree; 6=Disagree; 7=Strongly disagree

	patients without their knowledge. • Health care organizations don't always keep your information totally private. • Sometimes I wonder if health care organizations really know what they are doing. • Mistakes are common in health care organizations.		

3.3 Additional Variables of Interest

Demographic Information	• Age • Gender assigned as birth • Are you Hispanic and/or Latino? • Self-identified race	• Q3_1 • Q4_1 • Q5_1 • Q5_3	• Q3_1: Numeric • Q4_1: 1=Male; 2=Female • Q5_1: 1=Yes; 2=No • Q5_3: 25= American Indian or Alaska Native; 26= Asian; 24= Black or African American; 27= Native Hawaiian or Pacific Islander; 23= White; 28= Other, please specify
HIV test related information	• Have you ever taken PrEP? • Have you ever been tested for HIV in your lifetime? • If you have not been tested for HIV, which one of the following would you say is the MAIN reason why you have not been tested?	• Q6_2 • Q11_5 • Q11_7	• 1=Yes; 2=No • Q11_7: 1= It's unlikely you've been exposed to HIV; 2 = You are afraid to find out if you are HIV positive; 3 = You didn't want to think about HIV or about being HIV positive; 4 = You were worried your name would be reported to the government if you tested positive; 5 = You don't like needles; 6 = You don't trust the results to be confidential; 7 = You didn't know where to get tested; 8= Some other reason. Please specify.

4 Statistical Analysis Plan

4.1 Demographic and Clinical Characteristics ("Table 1")

We will summarize baseline sociodemographic and behavioral characteristics for the overall study population. Values and percentages for factors including age, race/ethnicity, history of PrEP uptaken, condom use, HIV testing history (reported as median, IQR), and reasons for not testing will be reported.

4.2 Analyses Plan for Aim 1

For Aim 1, we will compare HIV self-test kit order rates across recruitment platforms. Participants enrolled from Google and Facebook during periods when Grindr was inactive will be excluded so that all platform types have equal opportunity to recruit participants. Participants who do not order a test kit within 60 days after receiving a test code will be classified as not having ordered a kit.

Before modeling, we will summarize the number of test kits ordered, recruitment days, and calculate daily order rates for each site and platform type. To evaluate differences in order rates among different websites, we will use Poisson regression models. Because order rates differ substantially across sites and waves, comparisons will be conducted between specific sites within the same wave rather than pooling across platform types. Pairwise comparisons will be performed with adjustment for multiple testing using the Hochberg method.

4.3 Analyses Plan for Aim 2

We want to compare baseline characteristic differences between participants who ordered and did not order an HIV self-test kit. Fisher's exact test and Wilcoxon rank-sum test will be used to calculate p-values for group comparisons. For each characteristic, the null hypothesis is that there is no difference between the ordered and not ordered groups, and the alternative hypothesis is that a difference exists.

5 Limitations

- The study was conducted in nine areas with high HIV incidence, so results may not generalize to the whole country.
- Conclusions maybe limited to the specific sites included in the campaigns rather than all possible platforms.

6 Addendum for Additional Analyses

In addition to the primary analysis, three sensitivity analyses will be conducted using Poisson regression with post hoc contrasts to assess the robustness of conclusions. These include:
(1) allowing kit orders at any time during follow-up.
(2) addressing the fact that Wave 1 occurred in two phases due to one promotional platform (Grindr) stopping all advertising.
(3) evaluating potential impacts of the COVID-19 pandemic.

7 Reference

Stafylis C, Vavala G, Wang Q, McLeman B, Lemley SM, Young SD, Xie H, Matthews AG, Oden N, Revoredo L, Shmueli-Blumberg D, Hichborn EG, McKelle E, Moran LM, Jacobs P, Marsch LA, Klausner JD. Relative Effectiveness of Social Media, Dating Apps, and Information Search Sites in Promoting HIV

Self-testing: Observational Cohort Study. JMIR Form Res. 2022 Sep 23;6(9):e35648. doi: 10.2196/35648. PMID: 36149729; PMCID: PMC9591705.

National Institute on Drug Abuse. (2025, April 9). NIDA-CTN-0083: Using Social Media to Deliver HIV Self-Testing Kits and Link to Online PrEP Services (Social Media PrEP). NIDA Data Share. https://datashare.nida.nih.gov/study/nida-ctn-0083

Lenth R (2025). *emmeans: Estimated Marginal Means, aka Least-Squares Means*. R package version 1.11.2-8, https://CRAN.R-project.org/package=emmeans.