Statistical Analysis Plan (SAP)

Please complete all relevant sections. Instructions are in red and should be deleted when completing the SAP. The purpose of this template is to provide a general layout, but sections can be reformatted as you wish.

Title

CRU/Department/Division/Center

IRB Number

Investigators:

    Primary Investigator

    Collaborative Lead

    Co-authors (if known)

Analysis Biostatistician(s)

Biostatistics Supervisor

Lead Biostatistician

Subject Matter Expert

Original Creation Date

Version Date

Project Folder Location

Project Goal(s)

Submission Deadline(s)

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.

Activity Log

Acronyms

1 Study Overview

Background/Introduction:

HIV incidence remains high among minority men who have sex with men (MSM), particularly Black and Latinx individuals aged 18–30 years. Although home-based HIV self-testing is an effective and FDA-approved strategy to increase testing uptake, optimal methods for promoting self-testing remain unclear.

Digital platforms such as social media and dating apps are commonly used for HIV prevention outreach, while informational search sites are frequently used to seek HIV- and PrEP-related information. However, the relative effectiveness of these platform types in promoting HIV self-testing has not been directly compared.

This longitudinal observational cohort study evaluates the relative effectiveness of three types of internet-based platforms—social media sites, dating apps, and informational search sites—in promoting HIV self-test kit ordering among high-risk minority MSM. HIV self-test kit ordering rate is used as a proxy for promotional effectiveness. Associations between individual-level characteristics and test kit ordering are also explored.

1.1 Study Aims

- **Primary Aim:**
To compare the effectiveness of social media sites, dating apps, and informational search sites in promoting HIV self-test kit ordering among high-risk minority MSM.

- **Secondary Aim:**
To evaluate whether individual-level behavioral and attitudinal factors are associated with HIV self-test kit ordering.

1.2 Study Hypotheses

This analysis is inferential.

1.2.1 Primary Hypotheses

- **H₀:** Within a given recruitment wave, HIV self-test kit ordering rates are equal across platform types.

- **H₁:** Within a given recruitment wave, HIV self-test kit ordering rates differ across platform types.

1.2.2 Secondary Hypotheses

- Based on the exploratory analyses in Multimedia Appendix 3, the following associations with HIV self-test kit ordering were examined:

  - Substance use: HIV self-test kit ordering is not associated with tobacco, alcohol, prescription medication, or other substance use (assessed using TAPS tool scores).
  - Stage of health behavior change: HIV self-test kit ordering is not associated with psychological readiness for HIV testing (assessed using Transtheoretical Model stages: Precontemplation, Contemplation, Determination, Action, Maintenance).
  - HIV-related stigma: HIV self-test kit ordering is not associated with HIV-related stigma, including fear of people living with HIV/AIDS and willingness to befriend HIV-positive individuals.
  - Medical mistrust: HIV self-test kit ordering is not associated with medical mistrust toward health care organizations.
  - Attitudes toward HIV testing and treatment: HIV self-test kit ordering is not associated with attitudes toward HIV testing (e.g., perceived social consequences of HIV-positive status) or beliefs about HIV treatment efficacy.

2 Study Population

2.1 Inclusion Criteria

- Men who have sex with men (MSM)

- Age 18–30 years

- Self-identified as Black/African American or Latinx (including multiracial or multiethnic individuals)

- Reported condomless anal sex or more than one male sexual partner within the past 90 days

- Residing in one of the study recruitment locations during the enrollment period

2.2 Exclusion Criteria

- Self-reported HIV-positive status at baseline

- HIV testing within the past 90 days prior to enrollment

- Current or recent use of pre-exposure prophylaxis (PrEP) within the past 6 months prior to enrollment

- Enrollment during recruitment periods when not all platform types were simultaneously active (per primary analysis plan)

2.3 Data Acquisition

Fill in all relevant information:

Study design	Longitudinal observational cohort study.
Data source/how the data were collected	Data were collected through an internet-based recruitment and enrollment process. Participants were recruited via advertisements placed on social media sites, dating apps, and informational search sites. Eligible participants completed an online baseline survey and follow-up assessments at 14 and 60 days post-enrollment. HIV self-test kit ordering data were collected through automated reports from the test kit distribution vendor, and advertisement performance metrics were obtained directly from platform analytics tools.
Contact information for team member responsible for data collection/acquisition	Data were obtained from the National Institute on Drug Abuse (NIDA) Data Share repository.
Date or version (if downloaded, provide date)	NIDA-CTN-0083
Data transfer method and date	
Where dataset is stored	

Notes:

Description:
The analytic dataset includes participant-level baseline and follow-up survey data, HIV self-test kit ordering information, recruitment platform identifiers, recruitment wave indicators, and advertisement campaign metrics. Data from Wave 3, conducted during the early COVID-19 pandemic with no participant enrollment, are excluded from all analyses. Only data from recruitment periods during which all three platform types were concurrently active are included in the primary analysis.

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	Description	Variables and Source	Specifications
HIV self-test kit ordering rate	Number of HIV home self-test kits ordered per day from each recruitment platform within each recruitment wave; used as a proxy for promotional effectiveness	Count of HIV self-test kits ordered (vendor automated reports); recruitment duration in days; platform type and wave (study metadata)	Count outcome modeled using Poisson regression with $\log(\text{time in days})$ as an offset; rates estimated separately for each platform within each wave

3.2 Secondary Outcome(s)

Outcome	Description	Variables and Source	Specifications
HIV self-test kit ordering (individual-level)	Whether an enrolled participant ordered an HIV self-test kit during follow-up	Self-test kit order status (vendor order records)	Binary variable: 1 = ordered a test kit within 60 days of enrollment; 0 = did not order within 60 days
Linkage to PrEP services	Whether participants who tested HIV-negative reported visiting a provider to discuss or initiate PrE	Follow-up survey responses at 14 and 60 days	Binary variable: 1 = reported PrEP consultation or initiation; 0 = no PrEP consultation or initiation

3.3 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Attitudes toward HIV testing	Perceived social consequences of HIV-positive status	Q15_5: "People in my life would leave if I had HIV"	Binary: 1 = Agree; 2 = Disagree
Beliefs about HIV treatment	Misconceptions about HIV treatment efficacy	Q94_13: "I think that new HIV/AIDS treatments can eradicate the virus from your body"	Continuous scale: 1 (Strongly disagree) to 7 (Strongly agree)
HIV-related stigma	Willingness to associate with HIV-positive individuals	Q14_3: "I could not be friends with someone who has HIV/AIDS"	Ordinal scale: 1 (Strongly agree) to 7 (Strongly disagree)
Substance use	Alcohol, cannabis, stimulant, opioid, sedative use	TAPS tool scores calculated from baseline survey	Categorical: None, Problem use (score=1), High-risk use (score≥2)
Stage of health behavior change	Readiness to test for HIV regularly	Single-item Transtheoretical Model question	Categorical: Precontemplation, Contemplation, Determination, Action, Maintenance
Medical mistrust	Trust in health care organizations	7-item medical mistrust scale from baseline survey	Ordinal Likert responses (Strongly agree to Strongly disagree)

4 Statistical Analysis Plan

4.1 Demographic and Clinical Characteristics ("Table 1")

Baseline demographic and behavioral characteristics will be summarized for the per-protocol sample (N=254). The per-protocol sample excludes participants enrolled when not all sites were active (PO_FLAG ≠ "Include") and participants from Wave 3 conducted during the COVID-19 pandemic.

Continuous variables (age, number of male sex partners, months since last HIV test) will be summarized using median and interquartile range (IQR).

Categorical variables (ethnicity, race, PrEP history, condom use, condomless receptive anal sex, ever tested for HIV, reasons for not testing) will be summarized using frequencies and percentages.

4.2 Analyses Plan for Aim 1 (Primary Outcome)

The primary objective is to compare HIV self-test kit ordering rates across three platform types (social media, dating apps, and information search sites) within each recruitment wave. A Poisson regression model will be fitted with the log of the number of days each wave was active as an offset, allowing estimation of daily ordering rates. The model will include main effects for wave and platform type, as well as their interaction term to account for differential platform performance across waves. Within each wave, pairwise contrasts between platforms will be conducted using the Hochberg method for multiple testing adjustment. Statistical significance will be assessed at the alpha equals 0.05 level using two-sided tests.

4.3 Analyses Plan for Aim 2 (Secondary Outcomes)

The secondary objective is to evaluate associations between HIV self-test kit ordering status (ordered versus did not order) and participant characteristics. Fisher's exact test will be used for binary and categorical variables such as attitudes toward HIV testing. Wilcoxon rank-sum test will be used for ordinal Likert-scale responses such as HIV-related stigma and for continuous variables such as beliefs about HIV treatment efficacy. Variables examined include substance use based on TAPS scores for alcohol, cannabis, stimulants, opioids, and sedatives; stage of health behavior change based on the Transtheoretical Model; attitudes toward HIV testing and treatment; HIV-related stigma; and medical mistrust. Statistical significance will be assessed at the alpha equals 0.05 level using two-sided tests, with no adjustment for multiple comparisons given the exploratory nature of these analyses.

5 Limitations

- Generalizability: The study was conducted in 9 geographic areas with high HIV incidence; results may not generalize to other regions.
- Platform-specific findings: Results are specific to the platforms included (Facebook, Instagram, Grindr, Jack'd, Google, Bing) and may not apply to other social media, dating apps, or search engines.
- Wave imbalance: Low enrollment during certain periods (especially Wave 3 during COVID-19) limited the ability to make broader between-wave comparisons.
- Self-reported outcomes: Secondary outcomes rely on self-reported survey responses, which may be subject to recall bias or social desirability bias.
- Missing data: Participants who skipped questions were excluded from the analysis of those specific variables, potentially introducing selection bias.