Statistical Analysis Plan (SAP)

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Title	**Relative Effectiveness of Social Media, Dating Apps, and Information Search Sites in Promoting HIV Self-testing: Observational Cohort Study**
CRU/Department/Division/Center	**Clinical Trials Network (CTN)**
IRB Number	**#18-001580**
Investigators:	
Primary Investigator	**Jeffrey D. Klausner, M.D.**
Collaborative Lead	
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Analysis Biostatistician(s)	
Biostatistics Supervisor	
Lead Biostatistician	
Subject Matter Expert	
Original Creation Date	
Version Date	
Project Folder Location	
Project Goal(s): The project goal is to compare the relative effectiveness of different social media and information sites to promote HIV self-testing.	.
Submission Deadline(s): 1/20/26	

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 paper had done a third wave of promotion and enrolling users for Twitter, Yahoo, and Honest. However, because of the Covid-19 pandemic, no participants enrolled and there were no HIV self-testing kits that were ordered. Therefore, the paper excluded Wave 3 from the analysis.* *Also, the Appendix A states that because Wave 1 recruited at a lower rate, there were some modifications. Specifically, the statistical analysis that is based on pooling rates across waves won't be done since Wave 1 and 2 had a differing recruiting rate. Further, the comparison of the platform rates will be done within the waves, not comparing pooled column rates.*
Acronyms	*PrEP* — *Pre-exposure prophylaxis* *MSM* — *Men Who Have Sex With Men* *HIV* — *Human Immunodeficiency Virus*

1 Study Overview

Background/Introduction: It's important to spread awareness about HIV self-testing because individuals that are sexually active should know whether they have HIV or not. And in the 21st century, it's important to use the internet to spread news. Social media, such as dating apps or search sites have been used in the past to reach people at high risk for HIV infection. But it's not clear which platform is the best and most efficient at promoting home HIV self-testing because the users of each of the platforms have different characteristics that may impact their willingness for HIV testing.

1.1 Study Aims

This study aims to compare the relative effectiveness of social media, dating apps, and search sites for promoting HIV self-testing in minority men who have sex with men at increased risk of an HIV infection. There is one primary aim, six secondary aims, and one exploratory aim.

Primary Aim: The primary aim is to evaluate which platform is the most effective for getting higher number of HIV self-testing kits ordered per day during their respective waves.

Secondary Aims: The secondary aim evaluates these six things below with HIV self-test kit ordering.
1. Substance Use
2. Stage of change for HIV testing that is based on transtheoretical model
3. Attitudes towards HIV testing and treatment
4. HIV-related stigma
5. Medical Mistrust
6. Opinions about PrEP measures

Exploratory Aim: The paper recorded the advertisement metrics for each of their campaigns in order to evaluate the differences in the reach and the cost.

1.2 Study Hypotheses

The primary question was to evaluate the statistical difference in the HIV self-testing kit rates by platform type by utilizing a Poisson regression model.

For the hypotheses below, specifically, pairwise contrasts between platforms for each wave will be done to evaluate whether there is a statistically significant difference across the different platforms.

1.2.1 Primary Hypotheses

Null Hypothesis: There is no difference in effectiveness between platforms for orders of HIV self-testing kit rates.
Alternative Hypothesis: There is a difference in effectiveness between platforms for orders of HIV self-testing kit rates.

1.2.2 Secondary Hypotheses

Null Hypothesis: There is no association of HIV testing kit orders and factors that could possibly affect the ordering of a test kit.
Alternative Hypothesis: There is an association of HIV testing kit orders and factors that could possibly affect the ordering of a test kit.

The hypotheses will be done 6 times with each of these factors.
1. Substance Use
2. Stage of change for HIV testing that is based on transtheoretical model
3. Attitudes towards HIV testing and treatment
4. HIV-related stigma
5. Medical Mistrust
6. Opinions about PrEP measures

2 Study Population

2.1 Inclusion Criteria

- Have clicked on one of the study-specific advertisements posted on the platforms/ websites described in this protocol
- Have been biologically born male (cis-gender man), per participant self-report
- 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 (per participant self-report)
- Have not tested for HIV in the last 3 months prior to the date of the screening questionnaire (per participant self-report)
- 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.
- If they tested for HIV in the last 90 days
- If they were taking PrEP in the present or any time during the last 6 months before enrolling

2.3 Data Acquisition

Fill in all relevant information:

Study design	This paper is a longitudinal observational cohort study
Data source/how the data were collected	
Contact information for team member responsible for data collection/acquisition	
Date or version (if downloaded, provide date)	
Data transfer method and date	
Where dataset is stored	

Notes: No other notes to talk about

Description:
The dataset includes information on the participant's basic demographic information, HIV self-testing order outcomes, and other related variables from the survey on the online sites

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
Number of HIV self-test kits ordered per day	Whether a participant ordered a	ora_redeemed	Yes; No; Over 60 days

through each platform	self-testing HIV kit after finding this survey on a platform		

3.2 Secondary Outcome(s)

Outcome	Description	Variables and Source	Specifications
Association of reported substance use, stage of change for HIV testing based on a transtheoretical model, attitudes toward HIV testing and treatment	Evaluating whether these other characteristics are related to ordering the kits	Q13_1-Q13-22	1=Yes;2=No
Stage of Health Behavior Change	It's the participants thoughts for when they should be getting HIV testing	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.
Attitudes toward human immunodeficiency virus (HIV) testing	It's how the participants view the social aspects of getting HIV testing	Q15_3-Q15_7	1=Agree; 2=Disagree
Attitudes toward human immunodeficiency virus (HIV) treatment	It's how the participants feel about getting HIV treatment	Q94_1-Q94_13	Continuous scale from 1 (strongly disagree) to 7 (strongly agree)
Human immunodeficiency virus (HIV)-related stigma among study participants	It's how participants feel about people that have HIV	Q14_2-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	It's how participants feel about health care	Q16_1-Q16_7	For Q16_2-Q16_7: 1=Strongly agree; 2=Agree; 6=Disagree; 7=Strongly disagree Specifically for Q16-1 though: 28=Strongly agree; 30=Agree; 33=Disagree; 34=Strongly disagree

3.3 Additional Variables of Interest

Variable	**Description**	**Variables and Source**	**Specifications**
site	Which platform they learned about this study on	site	Facebook; Google; Instagram; Jack'd; Grindr; Bing; Yahoo; Hornet; Twitter
Age	The age of the person	Q3_1	Number
Race	Do you self-identify as…	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
Prior HIV testing history	Have you tested for HIV in the past 90 days?	Q6_4	33= Yes; 34= No
Condomless receptive anal sex	Have you had condomless receptive anal sex in the past 90 days?	Q11_4	1=Yes;2=No
HIV status	What is your HIV status?	Q6_1	1=Negative; 2=Positive; 4=I don't know; 5= Refuse to answer
Hispanic/Latino	Are you Hispanic and/or Latino?	Q5_1	1=Yes; 2=No
Sex	What sex were you assigned at birth, on your original birth certificate?	Q4_1	1=Male; 2=Female

4 Statistical Analysis Plan

The statistical analysis plan here is to evaluate the relationship between platforms and HIV self-testing kit orders. The analysis will be done by utilizing Poisson regression models to obtain the ordering rates. This will be the primary analysis or Aim 1 in this case. And the secondary analysis or Aim 2 will be to evaluate the association between behavioral factors and the HIV self-testing kit orders.

4.1 Demographic and Clinical Characteristics ("Table 1")

The list of demographic and clinical characteristics that will go into Table 1 is as follows:

1. Age in years
2. Ethnicity, Hispanic/Latinx
3. Race: American Indian or Alaskan Native, Black or African American, White, Other, Multiracial
4. History of PrEP uptake: never taken PrEP, Taken in the past 6 months
5. Number of male sex partners in the past 90 days
6. Condom use: Never, Sometimes, About half the time, Always
7. Condomless receptive anal sex in the past 90 days
8. Ever tested for HIV during lifetime
9. If tested for HIV, months since last HIV test
10. If not tested for HIV
11. Main reasons cited by the 63 participants for not getting tested: Unlikely to be exposed to HIV, Afraid of testing HIV-positive, Did not want to think about HIV/HIV-positive, Worried about names being reported if positive, Dislike of needles, Unable to trust that the results will be confidential, Unaware of where to get tested, Other reasons

4.2 Analyses Plan for Aim 1

The primary model for Aim 1 uses a Poisson regression model that uses time as an offset.
$\log(o_{ij})=\log(t_i) +\alpha+\beta_i+\gamma_j+\beta\gamma_{ij}$ where:

1. o_{ij} is the number of kits ordered by the site in Wave i, platform type j
2. t_i is the time that the Wave platforms were recruiting
3. β_i is the main effect of wave
4. γ_j is the main effect of platform type
5. $\beta\gamma_{ij}$ is the interaction term.

However, like stated in the Activity Log, since Wave 1 was recruiting at a lower rate than expected, there were some changes to the plan. The analysis based on the pooling rates won't be done because Wave 1 and Wave 2 had differing recruiting rate. Further, the comparing of the platform rates will be done within the waves as opposed to comparing the pooled column rates.

There are also some secondary analyses that will be done for the primary outcome measure.

The original plan was to analyze the comparison of rates within a given column and also the pairwise comparison of the pooled rates between columns (Columns refers to the different platforms here). However, the new plan is to get pairwise comparisons of column rates within Wave 1 and 2. For example, they will analyze whether the rates of column 1 and 2 are equal in Wave 1 and Wave 2. Then they will do the say for columns 1 and 3 and columns 2 and 3. This will be done using SAS contrast and estimate statements in the primary model.

4.3 Analyses Plan for Aim 2

The plan here is to evaluate the association between the behavioral and social factors and the HIV self-testing kit orders. To evaluate the differences between people that ordered and didn't order a HIV

self-testing kit, the paper used a Student t test for continuous variables, Fisher exact test for categorical, and Wilcoxon rank sum test for Likert responses. This was also done in SAS.

4.4 Analyses Plan for Exploratory Analysis

The paper says that they will monitor the performance of the advertisements by using:

Impressions: the number of times the ad is shown on a screen
Clicks: the number of times the ad was clicked on
Click-through rate: clicks divided by impressions
Funds spent

5 Limitations

Some limitations are that the study was only conducted in 9 areas with high HIV incidence, so the conclusion probably is not generalizable to the whole country. Also, there was low participation in certain waves that affected the ability to make broader comparison between platforms and between sites. Also, the most popular apps and sites were grouped into "platforms" with similar characteristics, and the goal was to find the differences between platforms. So, the findings are specific to sites included in the campaigns.

6 Addendum for Additional Analyses

Three sensitivity analyses were conducted for the primary outcome.

1. The first primary sensitivity analyses included any kits ordered at any time during the study and by any participants in the participant population. The primary one only counted orders within 60 days, but this sensitivity analysis allows more participants to count since it can be ordered anytime.
2. The second one tries to address that Wave 1 occurred in two phases because Grindr stopped all advertising. This analysis only evaluated participants enrolled during the second phase of Wave 1 because that's when most of the Wave 1 recruitment time occurred.
3. The final sensitivity analysis evaluated the impact of Covid-19 on the study. Only the data from participants enrolled before the beginning of the pandemic were analyzed for this sensitivity analysis.

7 Appendix

There are multiple links on the website to other word docs for the appendix.

8 References

Appendix A of Manuscript
Appendix B of Manuscript
Appendix C of Manuscript
Data Dictionary
https://datashare.nida.nih.gov/study/nida-ctn-0083
https://datashare.nida.nih.gov/sites/default/files/studydocs/add/CTN0083-Protocol-Social-Media-PrEP.pdf
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.

Statistical Analysis Plan Checklist

Below you will find a checklist of recommended items to include in a statistical analysis plan. Some of these are specific to clinical trials (based on this JAMA paper) and some are other are specific to observational studies (based on STROBE/RECORD guidelines), so every item will not be necessary for every project. The biostatistician should start with the SAP template above and add in necessary information from the checklist. Item numbers that are starred (*) are not explicitly included in the SAP template and should be added by the author if relevant to the project. This checklist was developed using the CONSORT 2010 Checklist.

I'm not sure if this is part of the assignment but most of them are no because we don't know the actual process from the paper.

Section/Topic	Item #	Description	Included (Yes/No/NA)
Administrative Information			
Study Information	1a	Descriptive title that matches the protocol, with SAP either as a forerunner or subtitle	
	1b	Trial registration number, protocol version number, and/or IRB number.	
	1c	CRU/Department/Division/Center/other collaborative unit that the study falls under	
Roles and responsibility	2a	Listing of principal investigators, clinical leads, and co-authors (if known)	
	2b	Name and affiliation of SAP author(s)	
	2c	Names, affiliations, and roles of other SAP contributors (e.g. senior statistician)	
SAP Information	3	SAP version number, with date of current version and original creation date	
Project Information	4a	Project folder location	
	4b	Project goals (e.g. manuscript, abstract, presentation, etc.)	
	4c	Project deadlines (of listed goals)	
	4d	Effort estimate	
Investigator Agreement			
Investigator Agreement	5	Confirmation that BERD Method Core's collaborative process has been reviewed, that all statistical analyses included in an abstract or manuscript should reflect the SAP, no changes should be made to the SAP without discussing with the SAP author, all biostatisticians on the SAP are co-authors on the manuscript, and that publications resulting from the SAP must cite grant number UL1TR002553 and be submitted to PubMed Central	No
Signatures	6	Signatures of SAP author, senior statistician, and principal investigator(s)	No
Activity Log			
SAP revisions	7a	SAP revision history with dates	No
	7b	Justification for each SAP revision	No
	7c*	Timing of SAP revision in relation to any interim analyses or submissions	No

Study Overview			
Background and introduction	8	Synopsis of scientific background and rationale for the study	
Aims and Hypotheses	9a	List of all scientific aims/objectives of the study, with specifications of primary, secondary, etc.	
	9b	List of all statistical hypotheses (corresponding to the scientific aims), with specifications of primary, secondary, etc.	
Variables of Interest	10a	List of all outcome/endpoint variables, with a description of their coding/units, timing, and source, corresponding to the statistical hypotheses. If any variables are defined using ICD or CPT codes, list them out.	
	10b	List of all exposure variables, with a description of their coding/units, timing, and source, corresponding to the statistical hypotheses. If any variables are defined using ICD or CPT codes, list them out.	
	10c	List of any additional variables of interest (e.g. covariates, potential confounders, effect modifiers, etc.) in the analysis	
	10d*	Location of data dictionary (or provided as an appendix)	
	10e*	Report category boundaries if continuous variables are collapsed into categories, and describe any other relevant data transformations	
Causal Graph	11*	May be helpful to include a DAG or other graph/diagram that describes the way the variables of interest are presumed to relate to each other	
Study Methods			
Study Plan and Design	12a	Description of the study design (e.g. parallel group randomized trial, case-control study, cohort study, etc.)	
	12b*	Study setting, location, and relevant dates (e.g. periods of enrolment, exposure, follow-up, and collection)	
	12c*	Description of intervention or exposure groups, with allocation ratios, and details of any matching criteria	
	12d*	Details on randomization (e.g. stratification factors) and blinding procedures	
	12e	List of eligibility and/or inclusion/exclusion criteria	
	12f*	Description of screening/enrolment/recruitment processes	
	12g*	Description of patient flow (e.g. CONSORT diagram)	
	12h*	Description of analysis population (e.g. intention to treat, per protocol, etc.)	
	12i*	Definitions of adherence/compliance, protocol deviations, loss-to-follow-up, adverse events, etc.	
	12j*	Time points at which outcomes are measured	
	12k*	Timing of final analyses (are all outcomes analysed collectively, or will short-term outcomes be analysed separately from long-term outcomes, etc.)	

Sample Size	13a*	Sample size calculation or justification (either provided in full or summarized, with link to original source)	
	13b*	Description of pre-planned subgroup analyses, power for these analyses, and planned multiple comparison adjustment procedures	
Interim Analyses	14a*	Description of what interim analyses will be conducted at which time points, and what methods used to adjust significance levels due to the interim analysis	
	14b*	Details of any guidelines (e.g. safety, futility) for stopping the study early	
	14c*	Details of any changes to trial design due to interim analyses (e.g. enrolling more patients)	
Data	15a	Description of data collection/acquisition process, with contact information for team member responsible	
	15b	Description of data flow/transfer from primary data collection through to creation of final analysis dataset	
	15c	Data transfer method and date	
	15d	Folder location where datasets are stored	
	15e*	Description of any additional data management, quality control, or processing undertaken	
	15f*	If any data are extracted from a database, a description of the database and the query used for the extraction, and whether/how it was merged with any data from outside that database. If the study involved linkage of databases, consider use of a flow diagram to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	
	15f*	Description of any other data sources incorporated in the analysis	
Missing Data	16a*	Description of sources and magnitudes of missing data	
	16b*	Description of how missing data patterns will be presented/summarized (may be helpful to have a table shell or draft CONSORT-style diagram)	
	16c*	Description of contingency plans for handling missing data in analysis	
Simulations	17a*	If conducting a simulation, a description of the purpose of the simulation and its design (e.g. fully factorial, partially factorial, grid search, etc.)	
	17b*	Define the fixed and variable factors or parameters in the simulation, the estimands/targets of the simulation, and the performance measures to be estimated (with justifications of their relevance to the estimands/targets)	
	17c*	Description of the tabular and graphical presentations of simulation results and their interpretation	
Statistical Analysis Plan			
Statistical Significance	18a*	Hypothesis testing framework (e.g. superiority, equivalence, non-inferiority), or description of alternative analytic framework (e.g. evaluation of a posterior in a Bayesian analysis, etc.)	
	18b*	Level of significance for primary hypotheses, including a description and rationale for any multiple comparisons adjustment or Type I error control procedures	

	18c*	Description of any decision-making rules based on confidence intervals, credible intervals, prediction intervals, Bayes' factors, or other alternative inferential methods	
	18d*	Description of how the results of any hypothesis tests (or alternative inferential methods) will be interpreted with respect to both the statistical hypotheses and scientific aims/objectives of the study	
Descriptive Statistics	19a*	List of characteristics (e.g. demographic, clinical) to be summarized descriptively (e.g. "Table 1")	
	19b*	Description of how these characteristics will be summarized descriptively (e.g. means/medians vs. N (%), tabular displays, graphical displays, etc.)	
	19c*	Summarize follow-up time (e.g. average and total amount) and number of events	
Analysis Methods	20a	For each aim/hypothesis (see items 9a/9b), a description of what analysis method will be used and how the results from this method will be reported and interpreted	
	20b*	Description of any transformations, standardizations, covariate or confounder adjustments, weighting, or stratification methods to be used and why.	
	20c*	For each analytic method proposed, a description of the assumptions of that method and what processes will be used to evaluate whether or not those assumptions hold	
	20d*	Details of contingency plans/alternative methods to be used if the assumptions are found not to hold	
	20e*	In the case of non-standard test statistics, formulas provided for the test statistic with a description of the mathematical null hypothesis, how significance is determined, and how the test statistic is interpreted	
	20f*	In the case of regression models, formulas provided for the full model with a description of which parameters are to be used, how they will be interpreted, how confidence intervals will be constructed, etc.	
	20g*	In the case of survey, hierarchical/nested, or clustered data, a description of what methods will be used to adjust for the data structure and why (e.g. if using a GEE, describing which correlation structure and why it was chosen, etc.)	
	20h*	For non-continuous outcomes, clearly explain the effect used (e.g. risk difference, risk ratio, odds ratio, etc.), whether it is relative or absolute, and justify why that was chosen as the effect measure of interest	
	20i*	Documentation of any non-standard methods used (e.g. using alternative degree of freedom calculation methods, using a non-canonical link function, etc.)	
	20j*	Description of any limitations, sources of bias, internal/external validity, and other relevant discussions concerning the interpretation and generalizability of the design or methods used	
Additional Analysis Methods	21a*	Description of any pre-planned sensitivity analyses and how they will be interpreted	
	21b*	Description of pre-planned subgroup analyses, power for these analyses, and planned multiple comparison adjustment procedures	
	21c*	Description of any additional post-hoc calculations or analyses (e.g. evaluating interaction/modification effects, calculating mediation or local average treatment effects, evaluation of AUROC curves, etc.)	
	21d*	If conducting any bootstrap analyses, a description of the sampling algorithm and number of iterations used	

	21e*	If conducting any cross-validation procedures, a description of how the cross-validation is conducted (e.g. leave-one-out, train/validation/test, etc.)	
Exploratory Analyses	22a*	Description and justification for any pre-planned exploratory analyses and what methods will be used to conduct them	
	22b*	Framework for conducting any unplanned exploratory analyses and how they will be integrated into the planned analysis	
Software	23*	List of statistical software (along with version numbers) to be used for each phase of the analysis; in the case of R or Stata, additionally list any requisite installed packages and their version numbers	
Other	24*	Description of any additional planned analyses of the data (e.g. a safety analysis looking at adverse event rates for a Data Safety Monitoring Board, etc.)	
Tables and Figures			
Table Shells	25*	Example tables related to any of the conducted analyses; if possible including any available preliminary data	
Example Figures	26*	Example figures related to any of the conducted analyses; if possible including any available preliminary data.	
References			
References	27a	References for any non-standard statistical methods used	
	27b	References (and locations) for any relevant protocols, standard operating procedures, or other documents cited in the SAP	
Additional Information			
Appendices	28*	If necessary, appendices may be included (e.g. a full data dictionary, a copy of a Case Report Form, etc.)	
Addendums	29*	Any additional analyses conducted that were not included in the SAP should be documented in an addendum, describing the purpose of the additional analysis, when it was conducted, and by whom	