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	
IRB Number	
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Original Creation Date	Sept 23, 2022
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. *Acknowledged by:* Click or tap here to enter text. *Date:* Click or tap to enter a date.
Activity Log	Wave 3 was canceled because of no enrollment due to COVID-19 pandemic.

Acronyms	MSM	Men who have sex with men
	PrEP	Pre-Exposure Prophylaxis
	HIV	Human Immunodeficiency Virus

1 Study Overview

Background/Introduction: Different internet mediums have been used to reach individuals at high risk for HIV, but we want to find what platform is more efficient in increasing testing rates (test orders/day).

1.1 Study Aims

The goal of this study is to compare the relative effect of social media, dating apps, and information search sites in promoting HIV self-testing.

1.2 Study Hypotheses

1.2.1 Primary Hypotheses

There is a comparative difference between dating apps and the other social media platforms in its effectiveness in promoting HIV self-testing in the number of tests ordered per day.

1.2.2 Secondary Hypotheses

Different views about HIV and HIV testing will correlate with whether an individual orders a test or not.

2 Study Population

2.1 Inclusion Criteria

- Men who have sex with men
- 18-30 years old
- Black or Latino
- Condomless anal sex in past 90 days or more than one sex partner in past 90 days

2.2 Exclusion Criteria

- HIV positive

- Tested for HIV in past 90 days
- Taking PrEP currently or in the last six months

2.3 Data Acquisition

Fill in all relevant information:

Study design	Two waves of ads on different internet platforms where participants could enroll to take a survey and get a free HIV test in a longitudinal observational study
Data source/how the data were collected	Via an initial survey and follow up 14 and 60 days after enrollment
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:

Description:
Ads were placed in two waves with an ad on one dating app, one social media platform, and one information search in each wave. Participants who clicked on the ad got a survey to determine enrollment and then they chose to order a test or not. If they did they were followed up with questions about the result, and based on the result whether they saw a doctor or started PrEP.

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
Order Test Rate	Tests/day for each medium		ora_within_60_yesno

3.2 Secondary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
Substance Use	Use/desire for using harmful substances in the last 3 months		Q13_1 to Q13_24
Stage of HIV Testing	Time between survey and last HIV test		Last_hiv_test_interval
Attitudes Towards HIV Testing and Treatment			Q15_1 to Q15_7
HIV-Related Stigma	Attitudes towards people with HIV		Q14_2 to Q14_5

Medical Mistrust	Integrity/capabilities of medical institutions		Q16_1 to Q16_7

3.3 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Do you self-identify as…	Race		Q5_3
Have you ever taken PrEP?			Q6_2
How often do you use condoms?			Q11_3

4 Statistical Analysis Plan

[insert]

4.1 Demographic and Clinical Characteristics ("Table 1")

Record ethnicity, race, history of PrEP uptake, condom use, HIV testing history, and main reasons for not getting tested for HIV.

4.2 Analyses Plan for Aim 1

Use a Poisson regression to evaluate the order rates (tests/day) through each type of platform (search engine, social media, dating app) within each wave to see if platforms differed significantly in orders per day.

4.3 Analyses Plan for Aim 2

Evaluate the association between substance use, stage of change for HIV testing based on the transtheoretical model, attitudes towards HIV testing and treatment, stigma around HIV, medical mistrust, and opinions about PrEP and the probability that someone would order a test kit.

5 Limitations

Study only conducted in 9 areas with high HIV incidence. Low enrollment in different waves could affect results and results are only relevant for the specific platforms (Facebook, Grindr, etc.).

6 Addendum for Additional Analyses

[insert if applicable]

7 Appendix

8 References

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.

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	2a	Listing of principal investigators, clinical leads, and co-authors (if known)	
responsibility	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	
Signatures	6	Signatures of SAP author, senior statistician, and principal investigator(s)	
Activity Log			
SAP revisions	7a	SAP revision history with dates	
	7b	Justification for each SAP revision	
	7c*	Timing of SAP revision in relation to any interim analyses or submissions	

[1]Turner L, Shamseer L, Altman DG, et al. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. *Cochrane Database Syst Rev*. 2012;11:MR000030. Published 2012 Nov 14. doi:10.1002/14651858.MR000030.pub2

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	