Statistical Analysis Plan (SAP)

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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

There was an adjustment to wave 1, which was extended up to 63 days. In addition, they did not pool sites across the same platform in their Poisson regression due to significant interaction effects.

Acronyms

AE	**Adverse Event**
AHF	**AIDS Healthcare Foundation**
AIDS	**Acquired Immunodeficiency Syndrome**
CAPA	**Corrective and Preventative Action**
CCC	**Clinical Coordinating Center**
CCTN	**Center for the Clinical Trials Network**
CDC	**Centers for Disease Control and Prevention**
CoC	**Certificate of Confidentiality**
CRF	**Case Report Form**
CTN	**Clinical Trials Network**
DSC	**Data and Statistics Center**
DSMB	**Data and Safety Monitoring Board**
eICF	**Electronic Informed Consent Form**
ETR	**Education, Training and Research**
FDA	**Food and Drug Administration**
GBMMS	**Group-Based Medical Mistrust Scale**
GCP	**Good Clinical Practice**
HAART	**Highly Active Antiretroviral Therapy**
HHS	**Department of Health and Human Services**
HIPAA	**Health Insurance Portability and Accountability Act**
HIV	**Human Immunodeficiency Virus**
HOPE	**Harnessing Online Peer Education**
IRB	**Institutional Review Board**
LN	**Lead Node**
MOP	**Manual of Operating Procedures**
MSM	**Men who have sex with men**
NIH	**National Institutes of Health**
NIDA	**National Institute on Drug Abuse**
OHRP	**Office for Human Research Protections**
PI	**Principal Investigator**
PRB	**Protocol Review Board**
PrEP	**Pre-Exposure Prophylaxis**
QA	**Quality Assurance**

RHBA	**Rapid HIV Behavioral Assessment**
SAE	**Serious Adverse Event**
SAMHSA	**Substance Abuse and Mental Health Services Administration**
SOP	**Standard Operating Procedure**
SSO	**Single Sign On**
STD	**Sexually Transmitted Disease**
STI	**Sexually Transmitted Infection**
TAPS	**Tobacco, Alcohol, Prescription medication, and other Substance use**
TTM	**Transtheoretical Model**
TDF–FTC	**Emtricitabine - tenofovir disoproxil fumarate**
UCLA	**University of California, Los Angeles**
WHO	**World Health Organization**
YTH	**Youth Technology and Health**

1 Study Overview

Background/Introduction: Social media sites, dating apps, and information search sites have been used to reach individuals at high risk for HIV infection. However, it is not clear which platform is the most efficient in promoting home HIV self-testing, given that the users of various platforms may have different characteristics that impact their readiness for HIV testing.

1.1 Study Aims

The primary objective of this study is to compare the relative effectiveness of three web-based platforms: social media sites (e.g., Facebook), dating applications [apps] (e.g., Grindr/alternative), and informational sites (e.g., Google) to promote self-testing of Human Immunodeficiency Virus (HIV) infection among men who have sex with men (MSM) who are at increased risk of HIV exposure and/ or infection. The secondary aims focus on reported substance use, stage of change for HIV testing based on the transtheoretical model, attitudes toward HIV testing and treatment, HIV-related stigma, medical mistrust, and opinions about PrEP measures and self-test kit ordering. One exploratory aim was the advertisement metrics of each campaign to measure differences in the reach and cost.

1.2 Study Hypotheses

1.2.1 Primary Hypotheses

H0: The null hypothesis is that all sites have the same ordering rate

H1: The alternative hypothesis is that one or more sites have different order rates.

The hypothesis will be tested by pairwise comparison using the Hochberg correction and the contrasts for each platform are the combinations of the two sites in that platform.

2 Study Population

2.1 Inclusion Criteria

Individuals must meet all of the inclusion criteria in order to be eligible to participate in the study. Individuals participating in the study must:

1. Have clicked on one of the study-specific advertisements posted on the platforms/ websites described in this protocol;

2. Have been biologically born male (cis-gender man), per participant self-report;

3. Report condomless anal intercourse and more than one male sex partner in the 90 days prior to the date of the screening questionnaire;

4. Be between the ages of 18-30 years old, inclusive;

5. Self-identify as Latino and/or Black/African American;

6. 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);

7. Have not tested for HIV in the last 3 months prior to the date of the screening questionnaire (per participant self-report);

8. Have a Facebook account (for identity validation to reduce duplicate attempts at enrollment); and

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

Exclusion Criteria

All individuals meeting any of the exclusion criteria at baseline will be excluded from study participation. Participants will be excluded if they:

1. Are unwilling or unable to provide informed consent.

2. Are unwilling to provide contact information (phone number, email address).

3. 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.

2.2 *Data Acquisition*

Fill in all relevant information:

Study design	This is an observational, non-randomized longitudinal study. Study procedures will take place online on the participant's mobile device or computer. After following the link on the advertisement, users will land on the study informational page, where they will receive information on the study and can choose to proceed with the eligibility screening process.
Data source/how the data were collected	All participant data will be collected from survey responses and stored in a secure database. The performance metrics for each

	platform is collected weekly from each service. The HIV test kit provider will provide reports on ordering.
Contact information for team member responsible for data collection/acquisition	UCLA is responsible for collecting and managing the data. The Northeast Node is responsible for all study quality assurance monitoring.
Date or version (if downloaded, provide date)	5.0
Data transfer method and date	Data will be transferred among study collaborators for analyses and data quality monitoring.
Where dataset is stored	UCLA secure servers

Description:
[insert]

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
# of HIV home self-test kits ordered per day by platform	A calculated value of the number of test kits ordered divided by the duration	ORA_REDEEMED/duration Self-report survey hosted on UCLA servers	#HIV kits / wave duration. Numerical value

3.2 Secondary Outcome(s)

Outcome	**Variables and Source**	**Variables and Source**
Tobacco, Alcohol, Prescription Medications, and Other Substance Use	Q13_1 – Q13-22, Self-report survey hosted on UCLA servers	Binary (Yes/No)
Stage of Health Behavior Change	Q15_1 Self-report survey hosted on UCLA servers	5 Categorical Levels 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	Q15_3 – Q15_7 Self-report survey hosted on UCLA servers	Agree/Disagree Binary
Attitudes toward human immunodeficiency virus (HIV) treatment	Q94_1 – Q94_13 Self-report survey hosted on UCLA servers	Continuous Scale from 1-7 Strongly Disagree to Strongly Agree
Human immunodeficiency virus (HIV)-related stigma among study participants	Q14_2 – Q14_5 Self-report survey hosted on UCLA servers	Discrete Categories from 1-7 Strongly Disagree to Strongly Agree
Medical Mistrust	Q16_1 – Q16_7 Self-report survey hosted on UCLA servers	Categories with 4 levels Strongly Disagree to Strongly Agree

3.3 Additional Variables of Interest

Age	Q3_1 Self-report survey hosted on UCLA servers	Whole number Numeric
Race (If not Hispanic)	Q5_3 Self-report survey hosted on UCLA servers	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 Character
Race (if Hispanic)	Q5_1 Self-report survey hosted on UCLA servers	1=Yes; 2=No Binary

See the data dictionary here: CTN0083-Data-Dictionary.xlsx

4 Statistical Analysis Plan

This is an observational study where participants will be recruited from three types of promotional platforms (social media sites, informational sites, and dating apps) to evaluate the effectiveness of the platforms in promoting HIV self-testing

4.1 Demographic and Clinical Characteristics ("Table 1")

This table includes information about demographic characteristics of the participant: age, ethnicity, race, history of PrEP uptake, # of MSM partners in past 90 days, condom use, condomless receptive anal sex in past 90 days, testing for HIV, and reasons not to get tested for HIV.

4.2 Analyses Plan for Aim 1

The primary analysis model will thus be a Poisson regression model using time as an offset, in which:

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

where:

- o_{ij} is the number of kits ordered by the site in row ii (i.e. time period ii), column jj
- t_i is the time that the Wave platforms were recruiting (i.e., ~133 participants recruited)
- β_i is the main row (wave) effect
- γ_j is the main column (promotional site series) effect
- $\beta\gamma_{ij}$ is the row-column interaction term

The main effects for each promotional site can be interpreted against each other as long as the interaction effects are not significant. The study will have the following waves:

	A	B	C
Wave 1	Google	Facebook	Grindr/alternative
Wave 2	Bing	Instagram	Jack'd
Wave 3	Yahoo	Twitter	Hornet

The study will also look at the pooled rates by combined all the platforms in each group. On the theory that lumping when you should split is worse than splitting when you should lump, multiplicity adjustments are undesirable, since increasing skepticism about p-values leads to lumping.

The protocol assumes an independent Poisson process, and the model will have to be tested for over/underdispersion.
Secondary and exploratory analyses will be conducted using univariate tests and descriptive statistics such as counts, percentages, and 95% confidence intervals. The order rate, defined as kits ordered per day by platform will be compared against each other.
There will be no missing data or dropouts for the primary outcome since only participants who meet eligibility criteria and order HIV home self-testing kits will be included in the analysis.

4.3 Analyses Plan for Aim 2

Survey responses were divided into two groups: ordered test kit and not ordered. These two response groups were compared across a variety of survey questions corresponding to the secondary aims. The p-value for each response group was checked using Fisher's exact test (categorical data) or Wilcoxon Rank test (ordered categorical) depending on the question type.

Descriptive Analysis

The descriptive statistics such as count, standard deviation, percentage, confidence interval will als be used to evaluate the aims in addition to univariate tests.

5 Limitations

The study was conducted in 9 areas with high HIV incidence; thus, the conclusions may not be generalizable to the whole country. Due to low enrolment/participation in certain waves, the study may not be able to make broad comparisons between platforms. Thus, the findings are specific to the sites included in the campaigns.

6 Addendum for Additional Analyses

7 Appendix

Adverse Event Reporting

Site's Role in Eliciting and Reporting Adverse Events This is a minimal risk study and the possibility of adverse events is low. The study team will not specifically elicit AEs from participants over the course of the study. However, if a participant spontaneously reports an adverse event at either a follow-up or when contacting the research team directly by phone or email, the study team will follow UCLA IRB's reporting policies and procedures.

Additional documents:

See link to survey

See link to follow-ups

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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 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	
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	