3T: TUNE IN! TURN ON! TURN UP!

PROTOCOL WITH IMPACT ANALYSIS PLAN

Purpose (Brief description)
The purpose of this protocol and analysis plan template is to document the research questions, study design, study methods, and programmatic information along with the planned impact and supplemental analyses. All sections in this analysis plan are intended to elicit text that can be directly copied into final evaluation reports or journal articles. Deviations from these plans are to be discussed and documented for transparency.
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3T Clinical Trials Registration #: NCT04135443

Public Health Narrative (Excerpt from Phase II Proposal)

Black men who have sex with men (BMSM) have been disproportionately affected by HIV/AIDS epidemic. Nearly half of the 1.2 million individuals living with HIV in the United States are African American, even though African Americans represent only 12% of the U.S. population. In 2009, Black MSM represented 73% of new HIV infections among Black men, and more new HIV infections occurred among young Black MSM (aged 13-24) than any other age and racial group of MSM, with an increase of 87% from 2005-2014. Young Black MSM (between the ages of 13 and 24) are more than twice as likely to be infected with HIV than young MSM of any other ethnic group. Yet there is a lack of school-based sexual education for this group of young people and few HIV interventions designed specifically to meet the needs of young BMSM. This project will develop a mobile app based multimedia interactive HIV/STI and sexual health intervention developed for use by YBMSM ages 14- 19 that delivers the intervention as a series of interactive activities tailored to the user and employs a theory based approach to address essential knowledge, perceptions of risk, peer norms, attitudes and skill with two primary goals: (1) To reduce HIV/STIs, it emphasizes partner reduction, avoidance of concurrent partners, condom use and HIV/STI tests; and (2) To improve sexual health, it helps participants to become clearer about what they do/don't want to do sexually, to communicate their choices, and to learn ways to enhance sexual experience without increasing HIV/STI risk.

1) Research Questions That Address Program Effectiveness on Behavioral Outcomes

These are consistent with outcomes listed on the www.ClinicalTrials.gov website.

a. **Primary research question(s):**

i. What is the impact of the 3T app relative to the 3T control website on the number of times engaged in condomless receptive or insertive anal intercourse or condomless vaginal intercourse in the last 3 months at follow-up, approximately 3 months post baseline.

b. **Secondary research question(s):**

Assessed at the 3-month follow-up (note: had to drop 6-month follow-up due to impact of COVID on study progress and timeline)

i. What is the impact of the 3T app relative to the 3T control website on the **number of times participants reported having been tested for STI, including HIV in the last 3 months**?

ii. What is the impact of the 3T app relative to the 3T control website on **communication with a partner about sexual desires/behavior**? (Dyadic Communication Scale)

iii. What is the impact of the 3T app relative to the 3T control website on **condom attitudes**? (Condom Attitude Scale for Adolescents)

iv. What is the impact of the 3T app relative to the 3T control website on condom use self-efficacy? (Sexual Risk Behavior Beliefs and Self-Efficacy Scale)

v. What is the impact of the 3T app relative to the 3T control website on attitudes toward lube?

c. **Dropped outcomes:**

The following secondary outcome was dropped before the study launch and was not asked on the survey in a way that allowed this calculation:

i. What is the impact of the 3T app relative to the 3T control website on the **number of partners with whom had anal or vaginal sex without using condoms in the last 3 months**?

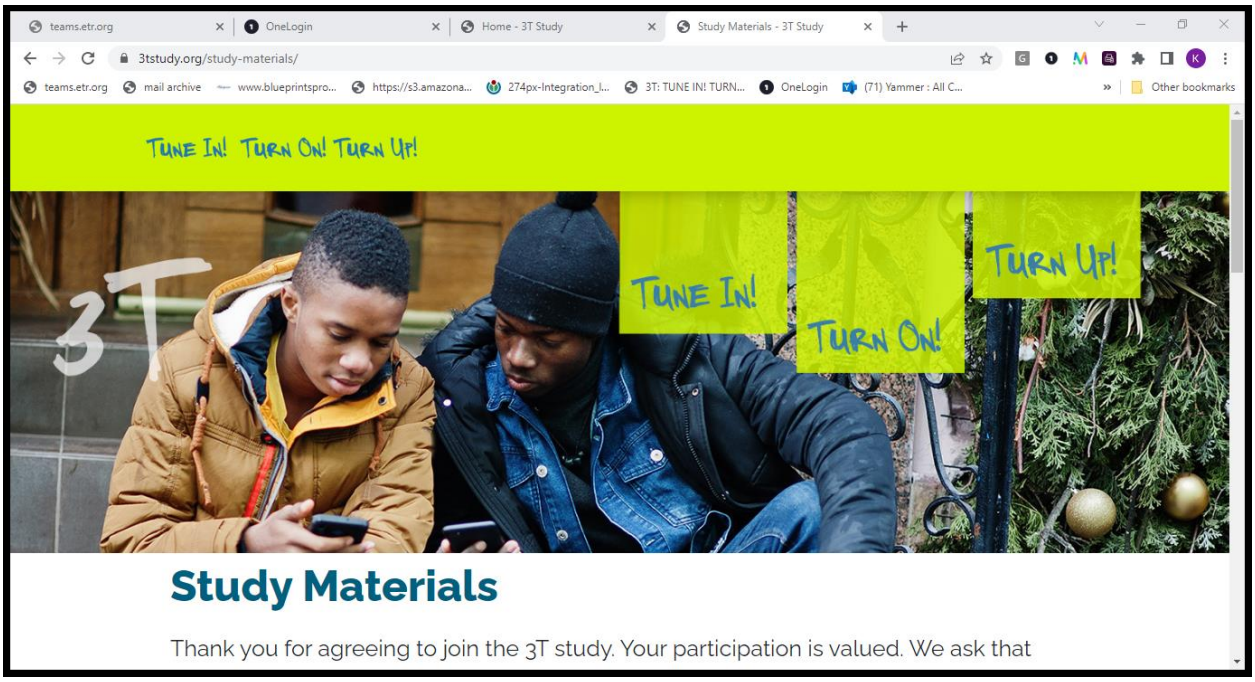
2) Description of the Intended Intervention and the Attention Control Conditions

Intervention condition: The intervention is a mobile app delivered sexual health promotion program designed specifically for young black men who have sex with men or

who are attracted to men. The mobile app includes 36 interactive activities including resource maps, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) content, and an asynchronous communication forum. The app helps participants to become clearer about what they do/don't want to do sexually, to communicate their choices. It also focuses on ways to increase healthy relationships, enhance sexual experience if having sex while reducing HIV/STI risk.

Attention control condition: The control intervention featured a website containing seven health promotion materials in online pamphlet or post formats focusing on mental health (2 pamphlets), nutrition (2 pamphlets), relationships (2 pamphlets) and COVID (1 poster). Young people were asked to select 4 materials to review as part of their participation.

- Mental Health
    - 5 Ways to Stop Stress
    - Suicide Talk, What To Do If You Hear It
- Nutrition
    - Eating Well With No Time & No Money
    - What's a Serving? Choose healthy serving sizes to stay at a healthy weight.
- Relationships
    - Yes Means Yes, What is Affirmative Consent?
    - Relationship Check, Healthy or Un?
- COVID
    - Actions to Protect Yourself and Others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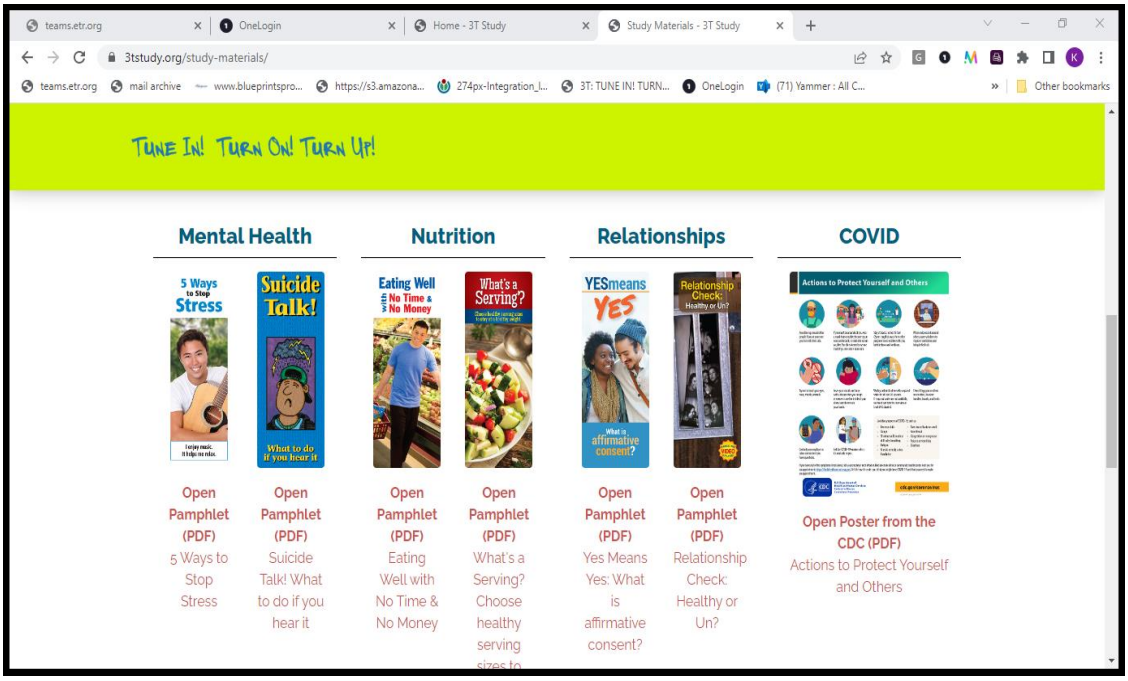
Study Materials
Thank you for agreeing to join the 3T study. Your participation is valued. We ask that


TUNE IN! TURN ON! TURN UP!
Mental Health
Nutrition
Relationships
COVID
Open Pamphlet (PDF)
5 Ways to Stop Stress
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Suicide Talk! What to do if you hear it
Open Pamphlet (PDF)
Eating Well with No Time & No Money
Open Pamphlet (PDF)
What's a Serving? Choose healthy serving sizes to
Open Pamphlet (PDF)
Yes Means Yes: What is affirmative consent?
Open Pamphlet (PDF)
Relationship Check: Healthy or Un?
Open Poster from the CDC (PDF)
Actions to Protect Yourself and Others

Study Design

a. Sample

The study was open to participants who self-identify as male, Black, African American, or biracial Black/African American; report being ages 14-19 at baseline; self-identify as cisgender male; report sexual attraction to men; and reside in any state in the United States. The age range was expanded to include young people ages 18-19 in May 2022 after facing significant COVID-related challenges in recruiting young people in the 14–17-year age range.

b. Recruitment approaches

The study went through four distinct recruitment phases to accrue the sample (Table 2). Recruitment was impacted severely by the COVID pandemic, requiring multiple pivots in recruitment plans over a two-year period spanning August 2020 to July 2022. After facing COVID-related and other challenges in our proposed recruitment approaches, the study sample was secured through paid advertising on social networking sites.

Table 2. 3T Recruitment Phases

Phase	Dates	Recruitment Focus	Results
Phase 1: CBO recruitment partners	August-November 2020	We engaged selected CBOs to do direct recruitment for the study through their networks and social media, referring interested youth to the 3T recruitment website directly. We had signed MOUs with the following CBOs: AIDS Alabama; the LGBTQ Center, Long Beach; Michigan Organization on Adolescent Health; Nashville Cares; and Triangle Empowerment Center.	We established MOUs with five agencies; agencies were enthusiastic about study but ultimately not successful in engaging youth due to challenges of COVID and its impact on youth engagement with agency services. No youth were recruited during this phase, and we pivoted to general social media strategies.
Phase 2: Broad social media and micro influencers	May 2021	We worked with Commando, a company specializing in social media study recruitment and ad placement for LGBTQ populations to use social media (Instagram) to promote the study nationally. At the same time, we identified a small number of micro influencers (2) who were paid to promote the study using IRB approved recruitment messages through their social media channels. We also tried TikTok and Snapchat but those platforms would not allow us to promote the study due to their restrictions on promoting studies (Snapchat) and promoting	Over 800 individuals completed the screener over the launch weekend in May 2021. Nearly all appeared to be out of country and age range but were claiming to be in age range and within the US. We closed recruitment and rejected all surveys coming in during this period because the sample was not our desired population. We also stopped general social media recruitment and moved toward a new phase of more targeted recruitment to avoid international and

		sexually related content (Tik Tok). We also planned to use a snowball sampling approach during this phase, which allowed young people to refer up to three others from their networks and receive a stipend if the individual met eligibility criteria.	national scam attacks. Further, we added an online video screening requirement for age and country verification for those who did screen as eligible. Further, we dropped use of social media influencers as their promotion also contributed to scam attacks. Finally, we also dropped snowball sampling to reduce scam attacks and because it was not yielding expected results in a different study. After this phase, we considered and explored other avenues (e.g., schools and school clubs such as GSAs) but COVID continued to impact schools' and agencies' ability to reach youth and engage with us.
Phase 3: Change in study design to conduct study directly at CBOs	November 2021-March 2022	We shifted our study design to work with direct service CBOs who serve the study population. The design involved training staff to recruit for the study and then invite young people to the site where study staff would have participants engage with their assigned app or website and complete the intervention while at the agencies. We aimed to recruit 1-2 sites near each of two project advocate staff members (1-2 in Atlanta or MS and 1-2 in TX) to minimize travel expenses and maximize the number of times we might be able to host young people at the sites.	Up to 4 agencies expressed interest and then could not move forward because they were not seeing/serving enough young people who met the inclusion criteria at their agencies. This alternate design was then dropped. We discussed and decided to return to using paid advertising and shifted our age of eligibility to include 18- and 19-year-olds, seeking IRB approval to recruit via Grindr, Jack'd and Scruff.
Phase 4: Paid advertising via social networking sites (Grindr, Jack'd/Scruff)	Grindr inbox ad: May 24, 2022 (12 states) Jack'd/Scruff ads: May 2022 and July 2022 (National)	We re-engaged with Commando, an agency specializing in paid advertising for studies centering LBBTQ populations with the new study age criteria. They prepared ads and placed them during the designated time frames.	Screened 2,047. Enrolled 178 eligible participants who completed baseline (see final flow diagram for specifics).

c. **Screening criteria and process**

Participants were invited to complete a screening survey (via Qualtrics) that assessed eligibility for the study. Those who did not meet eligibility criteria received an immediate message thanking them for this interest in the study and informing them that they were not eligible for participation. Those who met eligibility criteria were forwarded to the study consent form and asked to read and complete the form to indicate their interest in taking part. (Note: As noted below: The IRB approved a waiver of parental consent for those ages 14-17).

d. **Consent process**

Participants who screened into the study were directed to an online assent (14-17) or consent (18-19) form that explained the study expectations along with risks and benefits. The IRB approved a waiver of parental consent for participants ages 14-17). Participants were asked to provide their consent if interested in taking part by clicking "yes" on the consent form and providing basic contact information (mobile number for texting and email as well as a question on which was their preferred method of contact). Those who provided affirmative consent went through a further confirmation protocol to reduce the risk for bots, scams, or those out of the country to enroll. The protocol included review of metrics from Qualtrics' internal fraud detection system, ReCAPTCHA and Scamalytics. All prospective participants whose application was flagged as follow were rejected:

Indicator	Reject if
RelevantIDDuplicate	True/1
RelevantIDDuplicateScore	>75
RecaptchaScore	<.5
RelevantIDFraudScore	>30
BallotBoxStuffing	True/1

Young people also were given a chance to indicate they needed more information before making a study decision. Those who marked that option were asked to provide contact information so a study ambassador could follow-up to address any unanswered questions. Once participants' eligibility, consent, and geographic location (US) were confirmed, participants received a link to the baseline survey.

e. **Random assignment process**

The 2-arm randomized controlled trial involves randomizing individual participants using an equal allocation (allocation ratio 1:1) to receive the 3T app or access to the attention control website. Participants were randomized after completing their baseline surveys using the randomizer feature of Qualtrics.

f. **Baseline and follow-up data collection**

The primary source of data for the outcome analyses is the self-report survey. The survey was administered two times: Baseline and 3-months post-baseline. The original study design included a 6-month follow-up timepoint that had to be dropped because of delays and challenges in getting the study launched during COVID.

Data collection was ongoing due to rolling enrollment. Surveys were primarily distributed by SMS message. Shortly after their screener responses were reviewed and approved, prospective participants received a text message containing an explanatory message and a link that would be them to the baseline survey on the Qualtrics platform. Follow-up surveys were sent out in a similar fashion approximately 1 month and 3 months post baseline. Participants who had not yet completed a survey automatically received up to 5 reminders for survey completion in addition to their initial invitation. In cases where the Qualtrics system indicated an SMS message bounced, email invitations to take the survey were attempted.

3) Analysis

Table 3. Behavioral outcomes used for primary impact analyses research questions.

Outcome name	Description of the outcome, including how it is operationalized (e.g. "The outcome is a yes/no response taken directly from the survey" or "the risk outcome is calculated as the average of the five risk indicator variables").	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)
i. Number of times engaged in condomless receptive or insertive anal intercourse or condomless vaginal intercourse in the last 3 months at follow-up, approximately 3 months[a]	Count of condomless receptive anal, insertive anal, and/or vaginal sex acts with main partners and casual partners. Note: Participants who report they have never had sex or did not have sex in past 3 months (anal or vaginal) are assigned a 0. Constructed from the following variables (both T1 and T3 were used but only T3 is listed): T3_Q69_1 and T3_Q95_1 (insertive anal, no condom); T3_Q69_3 and T3_Q95_3 (receptive anal, no condom); T3_Q69_5 and T3_Q95_7 (insertive vaginal, no condom); T3_Q29 (EVER had vaginal/anal sex); T3_Q30 (had vaginal/anal sex in last 3 months).	Outcome survey	3 months following baseline

[a] This outcome was assigned a value of 0 if a respondent reported they have never had that type of sex or didn't have that type of sex in the past 3 months. This allows for the full sample to be included in analytic models. This outcome will be dichotomized if the distribution is highly skewed.

Table 4. Behavioral and attitudinal outcomes used for secondary impact analyses research questions.

Outcome name	Description of the outcome, including how it is operationalized (e.g. "The outcome is a yes/no response taken directly from the survey" or "the risk outcome is calculated as the average of the five risk indicator variables").	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)
i. Number of times participants reported having been tested for HIV in the last 3 months[a]	Count of number of times reported being tested for HIV in the last 3 months. Constructed from T1_Q55/T3_Q55 (how many times tested for HIV in last 3 months).	Outcome survey	3 months post baseline
ii. Number of times participants reported having been tested for STIs (excluding HIV) in the last 3 months[a]	Count of number of times reported being tested for STIs other than HIV in the last 3 months. Constructed from T3_Q58 (how many times tested for an STI/STDs in last 3 months).	Outcome survey	3 months post baseline
iii. Sexual Communication Self-Efficacy scale	Average of 20 items on a 4-point scale (1 to 4), with a range of 4 - 80, with a higher score indicating better outcomes. Calculate the average if at least 50% of items were answered (10 of 20). Items embedded in and drawn from questions Q46, Q94, Q47, Q48 and Q49.	Outcome survey	3 months post baseline
iv. Condom Attitudes Scale for Adolescents	Average of 21 items on a 4-point scale (1 to 4) with a range from 21 to 84 with higher scores indicating better outcomes. (Two items were omitted from the original 23-item scale.) Ten questions are reverse coded. Items embedded in and drawn from questions Q40 and Q93.	Outcome measure	3 months post baseline
v. Condom use self-efficacy	Average of 4 items adapted from the Sexual Risk Behavior Beliefs and Self-Efficacy Scale scored on a 4-point scale (1 to 4) with a range from 4 to 16 with higher scores indicating better outcomes. Items embedded in and drawn from question Q42.	Outcome measure	3 months post baseline
i. Attitudes towards lube	Average of 3 items on openness to using sexual lubricant on a scale from 1 to 4 with higher scores indicating more positive views towards		

	lube (better outcome). The third item is reverse coded. Items embedded in and drawn from question Q41.

[a] If an outcome assessing the number of times has a very skewed distribution, it may be collapsed into a dichotomous variable (e.g., 0 times, 1 or more times) based on the final distribution.

a. **Analytic sample**

We will use complete case analysis as the benchmark sample for this study. The analytic samples for both primary and secondary outcomes will include all individuals who respond to the questions making up the outcomes at baseline and follow-up and have complete data on the covariates included in each model.

b. **Data cleaning**

Missing data. We will examine missingness of potential covariates and use data from the follow-up survey to fill in missing values from baseline on covariates that are hypothesized not to change between the two survey timepoints. The primary and secondary outcomes will be analyzed using complete cases.

Inconsistencies. Because of forced skip patterns pre-programmed into the electronic data collection devices, we expect the sexual behavior outcome data to be relatively clean within time points. *Within time* consistencies will be checked on questions asking about the type of sex had in the last 3 months and the number of times respondents had the type of sex across all partners. For respondents with inconsistencies, we will assess patterns across all variables and discuss decision rules. *Across time* inconsistency will be checked on questions asking whether respondents have ever had vaginal or anal sex. With only two data points, we will analyze the data with and without inconsistent cases.

Extreme values. For questions asking about the number of times a behavior occurred we will examine extreme values in the context of other responses and apply a consistent decision rule.

c. **Assessment of baseline equivalence**

In addition to the baseline measures of the outcomes, we also will assess equivalence of the intervention and control groups at baseline on age and having a main partner. To assess equivalence between groups on each of these variables, we used regression analyses with the variable of interest as the dependent variable and the intervention indicator as the independent variable. The groups are considered not equivalent on a given variable if the p-value for the intervention indicator's regression coefficient is < 0.05 using the Wald test.

d. **Condition crossover and contamination**

An intent to treat model will be used in the analysis so that participants will be analyzed as randomized to treatment or control and followed up regardless of whether they interact with participants in the other condition.

e. **Analytic approach for primary research questions**

i. **Model specification:**

SPSS will be used to conduct the descriptive and bivariate analyses as well as the multivariable analyses. Statistical significance levels will be set at $p<.05$ unless otherwise noted.

Separate data analyses will be performed on each outcome variable named above and will progress through the following stages:

First, *descriptive analyses* will be used to explore the data on all model variables at baseline and follow up for distributional assumptions and unanticipated patterns that might affect subsequent analyses. For example, as noted in the outcomes table, some outcomes may need to be dichotomized if the distribution is too skewed towards 0.

Second, *bivariate analyses* will be used (1) to compare the baseline demographic and background characteristics of the intervention and control groups and (2) to test for relationships between the outcome variable and potential covariates (confounders) being measures. A potential covariate will be included in the model if: (1) the variable is associated with the condition indicator at $p<0.15$; and (2) the variable is associated with the outcome at $p<0.15$ in ***individual bivariate analyses***. Our plan for covariate screening is derived from those suggested in Altman (1991) and Hosmer and Lemeshow (1989). In the latter, it is suggested that $p<.25$ as a screening criterion may be more appropriate than $p<.05$ because the latter often fails to identify variables that may be important to control. We have traditionally "split the difference" and selected a $p<.15$ to preserve degrees of freedom of the model. We routinely include the baseline value of the outcome regardless of screening criteria (Pocock et al, 2002). Below, we clarify which covariates will be included regardless of these screening criteria. (4) Bivariate analyses will also be conducted to assess baseline equivalence for the final primary analytic samples.

Third, *multivariable analyses* will be conducted using regression analyses (linear or logistic) to evaluate the research questions as definitively as possible.

Each model will include an indicator variable denoting (1) intervention group, (2) the baseline outcome variable, (3) the number of days between the baseline and follow-up survey (if there is a large range), (4) age at baseline, and (5) a set of *a priori* demographics and outcome-related covariates that screened positively as candidates for inclusion in the bivariate screening step.

Covariates

Covariates to be forced into all models on an *a prior* basis:

1. Baseline value of outcome
2. Actual # of days between baseline and follow-up

3. Age at baseline

Race was not included as it was a study eligibility requirement (black identifying).

A priori covariates to be screened into the models:

1. With whom have had sex (cis men only vs cis men+others)
2. Effect of COVID pandemic on their ability to see a romantic or sexual partner (0=not at all, 1=somewhat, 2=very).
3. Effect of COVID pandemic on ability to get condoms (0=not harder, 1=may or may not be harder, 3=harder).
4. Has a main partner.

NOTE: if there is high correlation (r>.5) between some of these indicators we will not include them all.

ii. **Sample attrition**

Attrition analyses will be conducted to examine the rate of attrition by condition. Results from the attrition analyses will help evaluate the need to temper interpretations of outcome results.

iii. **Sensitivity analyses**

(1) Sensitivity analyses will be conducted examining the sub-group of participants with matching self-reported birthdates at baseline and the 3-month follow-up and within the allowable age range (14-20).

f. **Analytic approach for secondary research questions**

Analyses for secondary research questions will proceed using the same steps as described for the primary research questions.

4) Additional planned analyses

Additional exploratory analyses of the impact evaluation data may include the following.

a. Subgroup analyses based on participants in each condition who used their respective interventions (use evident from log in data vs no use evident) may be completed for the primary and secondary outcome variables.

b. Analyses of the following variables not specified as primary or secondary:

   a. Lube Knowledge (which are safe w/latex condoms)

   b. HIV Knowledge (includes PrEP and PEP awareness)

c. Examination of impact on primary outcome for those reporting casual partners if sample size warrants this level of exploration.