Title: Parrying the Pitfalls of PrEP: Preventing Premature PrEP Discontinuation and STIs Among MSM

Date: 11/21/2024

NCT# NCT05072093

PROTOCOL TITLE: Element 2 (Project PEACH)

PRINCIPAL INVESTIGATOR:

Name: Patrick Sullivan, DVM, PhD
Department: Epidemiology
Telephone Number: [redacted]
Email Address: [redacted]

EXTERNAL (NON-EMORY) COLLABORATORS

Rob Stephenson, PhD, Professor, Biologic and Behavioral Health, University of Michigan. Institution's IRB will not review. Rob will oversee the development of the motivational interviewing (MI) intervention which will be used to avert PrEP discontinuation through early identification of risk factors for stopping. He will train study staff on implementing MI and will also be responsible for related quality assurance activities. Rob will also contribute to the fidelity evaluation.

Ellen Caniglia, Assistant Professor, Population Health, New York University. Institution's IRB will not review. Ellie will lead the analysis of uncontrolled studies with historical controls and the target trial emulation which aim to estimate the causal effect of the intervention components on the incidence of PrEP discontinuations.

VERSION: 12.0

FUNDING SOURCE: National Institutes of Health

REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	3-25-21	Edits include a section on provisions to monitor the data for safety monitoring, testing of nasal swabs with S. aureus for doxycycline resistance among STI PEP users, delineation of primary and exploratory outcomes, clarifications on the mobile app requested by IRB.
2	5/14/21	Edited main study consent process to be in-person with participant signature. Clarified some terms in the main study consent. Uploaded BAA with Survey Gizmo
3	8/6/21	Edited screening and main consent and some study procedures including visit structure, nasal swab addition, removal of separate consent for second rectal sample, updated incentive amounts, sharing of PII with laboratories,

		pharmacies, and treatment providers; asking for consent to save screening and contact info for future studies.
4	9/3/21	Edited Main Study Consent to provide option for participants to have their contact information saved for future studies, changed number of blood tubes to be collected for laboratory testing from 2 to 3 tubes, changed timeline for incentive payments from first week of the following month to the second week of the following month. Additional mock ad attached.
5	9/22/2021	Changed amount of blood sample to be collected for laboratory testing to 2 tablespoons. Added Cisgender Male to the inclusion criteria.
6	5/11/2022	Added introduction of new FDA approved long-acting injectable PrEP (cabotegravir extended-release injectable suspension, Apretude), two new arms of study (Injectable PrEP and Injectable PrEP & STI PEP), linkage to Injectable PrEP providers. Changed incentive amounts for Baseline, 12mo, and 24mo visits to $125, $100, $100 respectively. Offering $20 Gift Cards to participants to share our IRB approved ad on their social media. Offering $5 incentive at in-person recruitment events to take study screener. Additional mock ads attached. Expanded eligibility criteria to MSM: ages 18-45, all races, all ethnicity, those currently on PrEP.
7	7/26/2022	Changed incentive amount for the CASI Surveys at Month 4, 7, and 19. Changed it from $20 to $40 to improve retention.
8	9/8/2022	Based on participant feedback, changed frequency of follow up for Motivational Interviewing (MI) to address monthly triggers for Daily PrEP users. Participants expressed frequent follow up for MI was not necessary for some triggers because they felt the trigger was not affecting their PrEP use.
9	10/21/2022	After communication with NIH, changed enrollment target to 240 participants (enrolled prospectively).
10	12/12/2022	Changed incentive amount for second sample collection to conduct GC Resistance Testing to $100. It takes participants a few hours to coordinate their trip to PRISM clinic for second sample collection and then to an outside clinic for treatment. Additionally, as inflation rates continue to increase, providing a higher incentive for participants' time is necessary.
11	5/10/2023	Stopping collection of second sample for GC Resistance Testing due to low yield in isolating *N. gonorrhoeae* culture.

12	11/21/2024	Study funding ends 3/31/2025 before all participants complete their 24 Month Visit. As a result, we will Study Stop some participants early (by 1/31/2025) in order to have adequate time for study close-out procedures.

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1. Study Summary

Study Title	Parrying the Pitfalls of PrEP: Preventing Premature PrEP Discontinuation and STIs among MSM
Study Design	Prospective cohort with counterfactual comparison group serving as control
Primary Objective	Using historical data on reasons for PrEP discontinuation, identify men at elevated risk for discontinuing PrEP before they discontinue and, for those with reported risk for discontinuation, use an early motivational interviewing (MI) approach and consultation with PrEP clinicians to support PrEP persistence.
Secondary Objective(s)	Offer on-demand PrEP for men who do not accept daily oral PrEP or who plan to stop PrEP because of infrequent risk or other reasons. Offer long-acting injectable PrEP through referral to outside providers for men who are not interested in daily oral PrEP or on-demand PrEP. Offer STI post-exposure prophylaxis (STI PEP) to all MSM in the cohort as a strategy for decreasing bacterial STI infections.
Research Intervention(s)/Interactions	In-person and virtual study visits with survey and lab testing; online surveys; mobile app for PrEP/STI PEP use brief surveys, scheduling study visits, providing lab results, and engaging with peer navigator for motivational interviewing.
Study Population	MSM ages 18-45 in Atlanta
Sample Size	240
Study Duration for individual participants	2 years
Study Specific Abbreviations/ Definitions	PrEP: Pre-exposure prophylaxis PEP: Post-exposure prophylaxis STI: Sexually transmitted infection MSM: Men who have sex with men MI: Motivational interviewing
Funding Source (if any)	National Institutes of Health

2. Objectives

AIM 1: Use historical data on reasons for PrEP discontinuation to identify men at elevated risk for discontinuing PrEP before they discontinue and, for those with reported risk for discontinuation, use an early motivational interviewing (MI) approach and consultation with PrEP clinicians to support PrEP persistence.

AIM 2: Offer on-demand PrEP for men who do not accept daily oral PrEP or who plan to stop PrEP because of infrequent risk.

AIM 3*:* Offer long-acting injectable PrEP through referral to outside providers for men who are not interested in daily oral PrEP or on-demand PrEP.

AIM 4: Offer STI post-exposure prophylaxis (STI PEP) to all MSM in the cohort as a strategy for decreasing bacterial STI infections.

Our scientific premise is that we can increase PrEP uptake and persistence and reduce STI incidence in MSM through novel offerings of prevention tools to this population.

3. Background

The US HIV epidemic continues to disproportionately impact men who have sex with men (MSM), who comprise 2% of the US population but account for about two thirds of all new HIV diagnoses in the United States.[1] Epidemic modeling studies[2-4] and our National HIV/AIDS Prevention Strategy[5] emphasize the critical role of pre-exposure prophylaxis (PrEP) in the national HIV prevention response. PrEP use is rising among men, but current estimates of coverage of PrEP among PrEP-eligible MSM (in 2016, about 13% of PrEP-eligible men reported ever using PrEP in their lifetime; in 2017 in Atlanta, less than 11% of PrEP-eligible MSM took PrEP) falls well short of the *sustained* 30%-50% coverage of PrEP among MSM[2, 3] that would be required to produce substantial decreases in new HIV infections. Increasing rates of sexually transmitted infection (STI) diagnoses independent of and concurrent with higher PrEP use[6] lead to concerns that men using PrEP may abandon condom use, contributing to greater increases in STIs in both PrEP-using MSM and other MSM.

The impact of PrEP is currently limited by three important issues: the need to help more men benefit from PrEP protection; challenges with PrEP persistence for men who initiate PrEP; and high rates of sexually transmitted infections (STIs) in both PrEP-using men and in other MSM. Finding novel ways to address these concerns is critical to realizing the full potential of PrEP for HIV prevention. Multiple epidemic models have reached a consistent conclusion that PrEP uptake by 30-50% of PrEP-eligible MSM is predicted to decrease HIV incidence among MSM by 25%.[3, 4, 9] Although PrEP usage has increased dramatically through 2017[10], less than one in 6 PrEP-eligible MSM report ever using PrEP[11], and uptake among Black MSM has not kept pace with the epidemic burden of this highly impacted group.[12, 13] Further, rates of PrEP discontinuation are high: in two samples of MSM who had used PrEP, 28%[14] and 33%[15] had discontinued PrEP, with 4 in 5 men who discontinued PrEP not speaking with their PrEP provider before stopping.[15] We recently concluded an observational cohort of young (18-29) year old HIV-negative Black MSM (EleMENt) in which we studied relationships of substance use to risk behaviors and HIV incidence (R01DA038196). Data from our study supports these other studies' findings: we experienced 52 men at risk for HIV permanently discontinuing PrEP (40%

of the 131 who started PrEP), many of whom discontinued PrEP without talking to our PrEP clinicians. Half of men who discontinued PrEP reported having infrequent risk behavior or not wanting to take a medication daily.

On-demand PrEP, prescribed to be taken the day of sex and for the following two days, reduced HIV incidence by 86% in French MSM, and could be most useful for MSM at infrequent sexual risk or who dislike daily dosing. On-demand PrEP is used in practice in some European countries and is endorsed by IAS-USA with an evidence rating of A1a[16], but has not yet been recommended by CDC in the United States.[17] In a sample of US MSM, on-demand PrEP was ranked as the most preferred mode of PrEP among 9 possible routes of PrEP administration, and men reported statistically significantly higher intention to use on-demand oral PrEP than to use daily oral PrEP.[18] On-demand PrEP has both pros and cons: it offers the potential to provide PrEP protection to men who have less frequent or episodic sexual risks, but is limited in that men need to use upcoming sex as a cue for pre-sex dosing (rather than habituating to daily pill taking), and men do not always know in advance when sex will occur.[19] Given the heterogeneity of sex frequency, risks and preferences, choice in PrEP is important.

STIs in the United States have been persistently increasing since PrEP was licensed as an indication for TDF/FTC in the United States.[20] Against a backdrop of rising STI diagnoses from 2012-2017 (especially syphilis, with a 76% increase), the burden of STIs in the United States is not evenly distributed.[21-23] STI rates are higher among MSM compared to both MSW and women.[24] Syphilis diagnosis rates for MSM rose 151% from 2010-2015.[25] There is geographic disparity in STI incidence, with the South accounting for the highest burden of infections. Georgia ranks 5th, 3rd, and 4th highest for incidence of chlamydia, gonorrhea, and syphilis among all US states. STIs are detrimental to health in multiple ways; one salient concern for MSM is that rectal STIs increase the risk of acquiring HIV through rectal mucosal inflammation, accounting for up to 15% of new HIV infections in MSM.[26, 27] However, there are also exciting new approaches to STI prevention for MSM; in the IPERGAY trial of on-demand HIV PrEP, a subset of participants were offered the chance to use post-exposure prophylaxis for STIs (STI PEP). A regimen of STI PEP, 200 mg of doxycycline taken after sex, was associated with a reduced hazard of acquiring chlamydia and syphilis (70% and 73% reductions).[8] More data on side effects, usage patterns and acceptability are needed, and no data on STI PEP have been published from US MSM.

Since the debut of PrEP, concerns have been raised regarding the potential for risk compensation and the possibility of subsequent increases in STIs among PrEP users.[28] A systematic review and meta-analysis of PrEP demonstration projects and cohort studies showed an overall increase in the odds of an STI after starting PrEP (pooled odds ratio 1.25, 95% confidence interval 0.99-1.54).[29] The magnitude of association between PrEP use and increased STI incidence was stronger when restricted to more recent studies. The 2017 update to the CDC PrEP guidelines suggest an increase in STI testing to every three months.[30] Although it is too early to evaluate if this increased testing frequency will lead to less STI transmission, there is evidence that laboratory testing in real-world PrEP users is suboptimal.[31]

Black MSM, especially young Black MSM, are a heavily impacted group for whom PrEP is essential. In our InvolveMENt cohort of HIV-negative Black and white MSM in Atlanta, the youngest (18-24 year-old) Black MSM experienced the highest race-specific HIV incidence: 10.9%/year, compared to 0.9%/year for their white counterparts. Black men ages 18-29 years old (matching our proposed study age range) experienced an 8.9%/year incidence in the cohort. Despite this excess risk of infections, there is limited uptake of PrEP among Black MSM.[13, 32] Using data from our InvolveMENt cohort, we developed a PrEP continuum model, and tested its components for HIV-negative Black and white MSM in Atlanta.[12] We found that although awareness and willingness to take PrEP were similar for Black and white MSM, access to healthcare and current PrEP eligibility criteria meant that Black MSM may be a third *less likely* to achieve PrEP protection than white MSM[12], even though the HIV infection risk of Black MSM was *three times greater* than that for white MSM.[33] Further, the CDC criteria for PrEP eligibility in MSM are less sensitive for predicting HIV infection risk in Black than white MSM.[34,35] In addition, young Black MSM in both cohorts experienced high rates of STIs: in the InvolveMENt cohort, incidence of rectal CT (10.8%/year) and rectal GC (9.4%/year) among Black MSM were 2-3 times higher than rates for white participants.[26] In our EleMENt cohort of young Black MSM, the rate of new STI diagnosis was 30.2%/year (men on PrEP: 52%; men not on PrEP: 27%, p=0.008).

For our EleMENt cohort, because we had observed alarmingly high rates of new HIV infections among Black MSM in our InvolveMENt cohort, we felt it appropriate to offer all participants in the EleMENt, regardless of self-reported behavioral risks, the opportunity to start PrEP. Notably, this was not a PrEP demonstration project – men were enrolled without regard to their interest in PrEP initiation. PrEP information and opportunities to start PrEP were provided in our clinic at baseline, and at 3, 6, 12, 18 and 24 months. Over time, the clinic supported 131 of the 300 cohort members to start PrEP (defined as taking the first dose). However, there were significant lags between PrEP interest and PrEP start; the median time from expressing interest to PrEP start was about 4 months.[36] The delays in starting and drop-off between PrEP interest and PrEP initiation was mostly attributed to structural barriers (e.g. health insurance, transportation to appointments).[36] Achieving >40% PrEP uptake in our cohort has been associated with a reduction in HIV incidence among 18-29 year old Black MSM from 8.9% in InvolveMENt to 6.2% in EleMENt – a 30% reduction in incidence compared to the historical controls. This difference is not likely attributable to increases in viral suppression among MSM living with HIV over the period, because viral suppression has not declined significantly among PLWH in Georgia over this period.[37, 38] However, 6.2% incidence of HIV among this group of vulnerable men is still unacceptable, and we must take further steps to realize the full benefits of PrEP.

Of the 131 young Black MSM who took a first dose of PrEP in the EleMENt study, 91 stopped PrEP at least once, and 52 permanently discontinued PrEP. The reasons for PrEP discontinuation vary, and some are appropriate. For example, 18 of the 52 permanent PrEP "stoppers" decided to hold or stop PrEP based on the recommendation of their study PrEP provider. Reasons included adverse events or having a positive HIV test result while prescribed PrEP. However, the other reasons for discontinuation were less clearly appropriate. Among the 34 men who initiated discontinuation on their own, half felt that they were no longer at risk or were at infrequent risk, a quarter cited concerns about side effects, and another quarter were unwilling to take a pill daily

or were talked out of taking PrEP by a partner or parent. In a multivariable analysis of factors associated with PrEP discontinuation, discontinuation was more likely among men who were younger, less educated, without insurance, had used cannabis, or had an STI diagnosis (aHR 1.75, CI: 1.04-2.93). Some men on PrEP reported that when they received an STI diagnosis, they decided to stop PrEP in favor of 100% condom use. PrEP discontinuations sometimes result in new HIV infections: we observed 23 new HIV infections among men offered participation in the PrEP program. Six of those seroconversions were among men who had started PrEP in the EleMENt PrEP program and had subsequently discontinued PrEP, only to go on to acquire HIV in the months after stopping PrEP.[39]

Improving PrEP impact for Black MSM is an implementation problem, and we need to identify effective strategies to support these men at the right time with the right supports. Achieving high levels of PrEP protection for young Black MSM is a critical priority. We have demonstrated through our EleMENt PrEP program that we can support substantial uptake of PrEP in this critical group; integrated client-centered care coordination has also shown models for achieving PrEP uptake for Black MSM.[40] However, maximizing PrEP impact will require that Black MSM at risk for acquiring HIV are linked to PrEP care, start PrEP, persist in PrEP care for the duration of their vulnerability, and avoid increased STIs.

Developing approaches to prevent PrEP discontinuations and avert STI diagnoses is critical. However, there has understandably been more substantial early programmatic focus on recruiting eligible MSM to PrEP care and on developing adherence approaches[41] than on developing systems to mitigate PrEP discontinuations and prevent STI infections for MSM on PrEP. There is a need for implementation-focused studies on how to *holistically* prevent premature PrEP discontinuations and avert STIs. The holistic focus relates importantly to implementation because of our understanding that the barriers to persisting on PrEP are both structural (e.g., distance to provider for follow-up visits, health insurance, reimbursement mechanisms) and socio-relational (e.g., attitudes of friends and family, relationship status, perception of vulnerability to HIV). The barriers to starting PrEP (e.g., lack of awareness of PrEP, barriers to care entry, stigma, doubts about the efficacy or safety of PrEP) are not the same as the barriers to PrEP persistence (e.g., lapse of insurance or assistance program, difficulties with long-term adherence, changing sexual partners, frequency or networks, negative influence of friends or family, concerns about new STIs).

Questions about substance use and HIV risks and prevention are interwoven in questions about PrEP uptake and persistence. The prevalence of substance use in the EleMENt cohort was also high (marijuana: 68%; cocaine: 14%; non-prescribed opioids: 8%; stimulants: 18%; risk alcohol use: 30%). HIV risk behaviors have been long associated with substance use.[43-45]. Yet, in our previous cohort, marijuana use was associated with lower likelihood of starting PrEP and higher risk of discontinuing PrEP once initiated. Further, “chemsex”, or using sex while concurrently using drugs, is associated with high levels of risk behaviors.[46, 47] On-demand PrEP might be especially relevant to men who use drugs during sexual encounters. Because we also propose to measure both self-reported and laboratory-confirmed substance use and to measure co-occurrence of drug use and sex, we will also be able to characterize how substance use relates to choices about mode of PrEP (on-demand versus daily oral) and persistence.

Our study is guided by the Andersen Model of Healthcare Utilization.[48] The theory addresses factors that influence the appropriate uptake of healthcare services (in this study, PrEP uptake and persistence, choice of PrEP options and utilization of STI PrEP). The use of these services relies on decisions of our participants to seek the sustained use of appropriate services including medical services, pharmacy services, adherence support services, and prophylactic medications that, in their utilization, positively influence the prospects for sexual health and reduce risks of HIV and STI infection. Andersen further identifies three broad areas of factors that might influence the use of health services as: *Predisposing* factors (e.g., stigma, race, sexual orientation, marginalization, lower economic opportunity), *Enabling* factors (having to do with the logistical aspects of obtaining healthcare, like proximity of services, travel systems, regular source of care, waiting times, lower pill burden, and access to providers), and *Need* factors (having to do with perceived or evaluated needs for services, like sexual risks, mental health concerns, or STI diagnoses).[48] The Andersen model has been applied to retention in antiretroviral therapy for persons living with HIV, and may be used to guide PrEP care retention.[42]

Table 1. Interventions, eligible populations, approaches, outcomes, and Andersen factors addressed

Intervention	Eligible Population	Intervention Approach	Primary Outcome	Exploratory Outcome	Andersen Factors
Averting PrEP discontinuation through early identification and Motivational Interviewing (MI)	MSM not currently taking daily oral PrEP	Monthly screener surveys delivered through study app to assess for PrEP side effects; PrEP stop intentions; change in relationship status; change in perceived risk for HIV infection; change in insurance status or concerns about upcoming change; negative feedback from friends or family about PrEP; adherence concerns; MI from peer navigator and clinician consultation	Rate of PrEP discontinuation		*Predisposing:* Stigma *Enabling*: travel systems, PrEP care provider, regular source of care, access to adherence tools, insurance navigation *Need:* clarification of ongoing risks
On-demand PrEP	MSM who decline daily PrEP	TDF/FTC fixed dose combination, directions to take 2 doses 2-24 hrs before sex and single dose 24 and 48 hours after first dose	Uptake of on-demand PrEP	Usage patterns of on-demand PrEP	*Enabling*: proximity of care resources, streamlining pill burden[42] *Need*: Clarification of ongoing risks
Injectable PrEP	MSM who decline daily oral PrEP and on-demand PrEP	Apretude (Cabotegravir injection) every two months (to be obtained outside study)	Uptake of injectable PrEP	Usage patterns of injectable PrEP	*Enabling*: proximity of care resources, minimizing pill burden *Need:* Clarification of ongoing risks

					Need: Clarification of insurance coverage issues
STI PEP	All men in cohort	Doxycycline 100 mg, directions to take 2 capsules within 24 (no more than 72) hours after sexual risk	STI diagnoses at 12 and 24 months	Prevalence of doxycycline resistance among all STI PEP users and STI PEP participants diagnosed with NG	*Enabling*: proximity of care resources, minimizing pill burden *Need:* Clarification of ongoing risks

Andersen describes different facilitators of utilization as being variably malleable.[48] We use the model (Table 1) to emphasize intervention on those aspects of utilization which are amenable to intervention (e.g., malleable Andersen enabling factors[48]). For example, we focus on mitigating barriers to care/promoting *enabling* factors by offering commute-free options for discussing PrEP discontinuation decisions with a PrEP counselor before stopping PrEP. Some factors, such as PrEP-related stigma or negative messages about PrEP from friends or family might be a classical Andersen *predisposing* factor. However, ready access to our motivational interviewing (MI)-based counseling (a study-provided enabling factor) may help men put experiences of stigma in perspective. Thus, the MI counseling intervention might mitigate the effects of stigma or peer pressure to stop PrEP. For STI PEP, pre-dispensing doxycycline promotes the *enabling* factor of ready access to medication when it is needed. For all groups, offering multiple means of obtaining support (telephone call, video counseling, or clinic visit with app-based request for transportation assistance) promote *enabling* factors of minimizing time needed for visits and adequate transportation systems.

Our study is innovative in several ways. First, we use empirical data from a past cohort of young Black MSM in Atlanta to proactively identify men at high risk of discontinuing PrEP before they discontinue and intervene promptly. Second, we offer on-demand PrEP as an option to increase the proportion of YBMSM using PrEP and to mitigate PrEP discontinuations in the substantial group of men whose primary reason for stopping is the requirement to take pills daily or that they perceive their risks to be infrequent. Third, with the FDA approval of Apretude (cabotegravir extended-release injectable suspension) on 12/20/2021, we offer injectable PrEP as an alternative to daily oral PrEP or on-demand PrEP. Participants who elect injectable PrEP will be referred to local providers to access the medication; as part of our study, we will monitor their use through monthly surveys. Participants will have the option to switch prevention options at any point during the study by indicating their interest during monthly surveys or contacting study staff directly. Study clinicians will develop transition plan based on clinical indications. Fourth, we are offering STI PEP in the same service setting as we are offering HIV PrEP, which decreases STI infections including rectal Chlamydia -- thereby averting the increased biological susceptibility of rectal mucosa to HIV infection[49] and concerns about MSM on PrEP about STI risk. Fourth, we have developed a design that is responsive to our understanding that we need to learn about the best ways to increase utilization of efficacious services. Randomized clinical trials have shown on-demand PrEP and STI PEP to be efficacious.[8, 50] Therefore, rather than randomizing young Black MSM at risk for HIV to no intervention, we have specified a target trial for emulation[51] and we will use a just-completed study of young Black MSM in Atlanta as a counterfactual comparison group to understand the impact of our intervention on PrEP discontinuations and STI incidence, using methods already used for trial emulation by our

team[52]. Lastly, we will offer participants the opportunity to engage in study visits remotely through the use of telehealth and home testing methods to provide flexibility and ease concerns related to COVID-19.

4. Study Endpoints

Primary endpoints include: Rate of PrEP discontinuations, uptake and usage patterns of on-demand PrEP, STI diagnoses

Secondary endpoints include: HIV diagnoses

Primary safety endpoints include: PrEP adverse reaction; doxycycline adverse reaction

Secondary safety endpoints include: Doxycycline resistance among STI PEP users and participants diagnosed with GC (exploratory)

5. Study Intervention/Investigational Agent

The three study interventions include the following: (1) offering MI and PrEP clinical consults to reduce PrEP discontinuations; (2) offering on-demand PrEP to increase PrEP uptake and persistence; (3) offering long-acting injectable PrEP through referral to outside providers; and, (4) offering STI PEP to decrease STI incidence.

PrEP discontinuation intervention- Men taking daily oral PrEP (Truvada) will receive a monthly screener through the mobile app. If answers to screener questions indicate a participant is at risk for PrEP discontinuation, then a peer navigator will deliver a motivational interviewing intervention and a clinician will consult with the participant if needed. These efforts are intended to avert PrEP discontinuation. Participants will receive Truvada through local pharmacies.

Offering of on-demand PrEP- For men who are not interested in daily PrEP or plan to discontinue daily PrEP, we will offer on-demand PrEP (Truvada) which will allow them to take it immediately before/after a sexual encounter. It is hoped that this will serve as an alternative to daily PrEP use that is desirable for some people. Participants will receive Truvada through local pharmacies.

Offering of injectable PrEP- For men who are interested in injectable PrEP, they will be referred to local providers to access the medication and for clinical monitoring. In the study, their use of the medication will be monitored through monthly surveys during which they have the option to indicate interest in switching to oral PrEP.

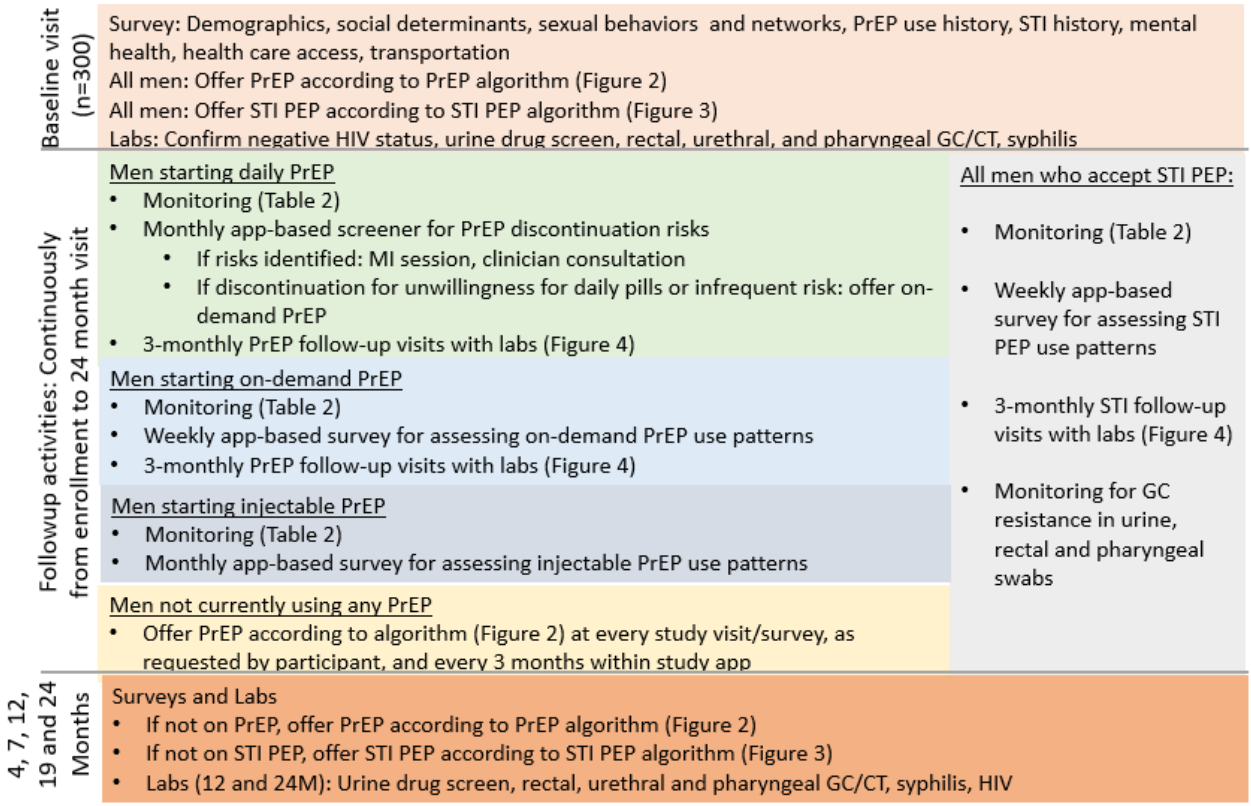
Offering of STI PEP- All men in the cohort will be offered STI PEP (doxycycline) to use after condomless sex with the goal of averting STI diagnoses. We plan to partner with the Emory Investigational Drug Service (IDS) to dispense doxycycline to consenting participants at a dosage of 200 mg to be taken in a single dose ideally within 24 hours of possible exposure (e.g. condomless anal sex) and no later than 72 hours after exposure. Participants will be dispensed enough pills to allow for up to 3 weekly doses of 200mg doxycycline (i.e. 6 pills/week) for 3 months (the interval between STI testing visits). Clinical study staff will write a prescription for

doxycycline and fax to the IDS along with a Fed Ex air bill for shipment of the drug directly to the participant. We obtained an IND waiver for investigational use of doxycycline, through the Emory Investigational Drug Service, to prevent STI infections.

6. Procedures Involved

Design: The study will be a prospective cohort of MSM who are followed prospectively for 2 years either in-person at our PRISM Health Research Clinic and/or virtually with remote study visits. Follow-up visits will occur as frequently as every 3 months, or as appropriate to clinical needs of HIV PrEP or STI PEP (Figure 1). We will enroll men who are not on PrEP at study initiation and who may decide to start or stop PrEP, change from daily oral PrEP to on-demand PrEP or from on-demand PrEP to daily PrEP, and/or start or stop STI PEP at any point in the study period (Figures 1,4). If we have trouble enrolling men who are not currently on PrEP we will expand our enrollment criteria to include men currently on PrEP. All men will be provided with the study's mobile smart phone app to support early identification of risks for PrEP discontinuation, to provide information about STI PEP and document usage patterns of on-demand PrEP and STI PEP, and to support easy linkage to support services for PrEP counseling and addressing concerns or questions about STI PEP. With the advent of newly FDA approved Apretude (cabotegravir extended-release injectable suspension), participants will now have the option of starting long-acting injectable PrEP through a local provider. Participants will be given a list of local providers to initiate the medication on their own. If participants elect both Injectable PrEP and STI PEP, STI clinical follow-up will be done through the study and administration of the injection will be done through a local provider. The local provider will also be responsible for all applicable clinical monitoring of the injection. If participants elect only Injectable PrEP, all clinical follow-up will be done by the local provider who administers the medication; we will monitor participant use of the medication through monthly surveys. The monthly surveys will provide an option to indicate interest in switching to oral PrEP; if indicated, participants will be able to access oral PrEP through the study.

Figure 1: Study Procedures



Eligibility: Eligible participants will: be male at birth, self-identify as cisgender male, ages 18-45 years, have had ≥1 male anal sex partner in the 12 months before the baseline interview, able to complete the survey instruments in English, live in the Atlanta MSA and not planning to move from it over the next 2 years, provide ≥ 2 means of contact, own a cell phone with data service, willing to download and use a health-related study app on cell phone, not be currently enrolled in another HIV prevention clinical trial, and have a confirmed HIV-negative status at the baseline visit.

Recruitment: Our goal is to enroll 240 MSM using the most efficient methods, while minimizing opportunities for bias. We will use two recruitment methods that draw on the study team's strengths. We will recruit MSM who are not known to be living with HIV from 2 sources. The venue-based method is a modified venue-day-time screening approach implemented by CDC for behavioral surveillance under PI Sullivan's leadership.[131] We have tracked the recruitment data for each recruitment venue and day from past studies, and will use those historical data to oversample venues that historically had high numbers of MSM who were HIV-negative. We will also offer $5 incentive to take the study screener at in-person recruitment events. The second method is recruitment via dating apps and social media. This involves targeting advertisements to adult men in Atlanta who are using Grindr or other dating apps, who use social media channels such as Instagram and Snapchat, or whose Facebook profiles connote an interest in men. We will also offer $20 gift cards to current participants to share our IRB approved study ads on their social media. The goal is for participants to simply share this information with their social networks on a voluntary basis. Their participation in the study will

not be affected in any way should they volunteer to share study information. They will not be referring individuals, rather simply share information that has been approved by IRB. Considering the current social climate, our target demographic gets most of their information online. As a result, social media advertising is the most effective way to get information out to intended audiences. Men who click on the online ads are referred to a brief introduction script and a self-administered online screening form. Analyses of our InvolveMENt data show few differences exist in behaviors, HIV/STI infection, and retention between MSM recruited by VDT and subset recruited via Facebook.[61]

Eligibility Screening: Men who click on ads or who are approached in-person will be given the opportunity to complete a screening consent and then an eligibility screening survey.

Enrollment and baseline procedures: Building on successful protocols from InvolveMENt, EngageMENt and EleMENt studies, our staff will contact screening respondents who were initially eligible and will schedule an enrollment (baseline) visit at our PRISM Health Research Clinic, which is in a central location in Decatur and 1.5 blocks from a major MARTA rail station. To minimize selection bias for study enrollment, we will offer Uber rides to the clinic or to a convenient MARTA station for men who have limited transportation options or long commutes (*minimizing bias*). The enrollment visit will consist of informed consent, a computer-assisted self-interview (CASI) behavioral survey, HIV and STI testing, training on using the study app, and a counseling session to include pre- and post-test HIV prevention information and a discussion about PrEP and STI PEP options (see figures 2 and 3) with participants given the option to initiate either or both of these following the baseline visit. The 1-hour CASI survey will assess demographics, HIV and STI testing history, sex and drug use behaviors, anxiety and depression, stigma, and questions about past PrEP use and experience. Men who have a new HIV diagnosis either at baseline or during the study will be helped with accessing HIV care and treatment services and will not proceed to the prospective study or their study participation will terminate upon HIV diagnosis. All men will be referred to other indicated services (e.g., sexual or mental health, housing assistance) based on needs identified during post-test counseling. Respondents who complete an enrollment visit will be compensated $125, whether or not they participate in the prospective study.

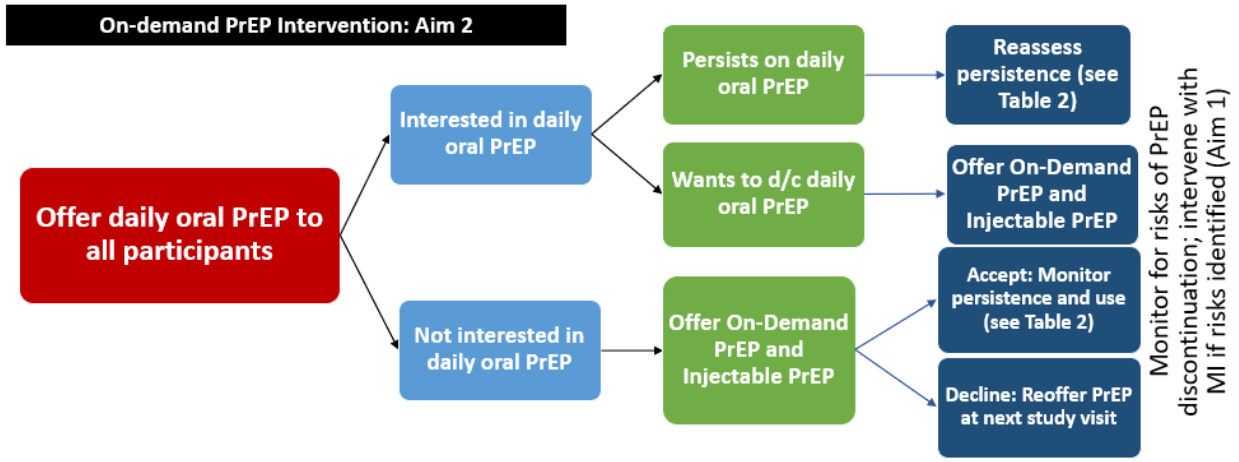
Daily PrEP offering: All participants will be offered daily PrEP (Figure 2) at baseline and at the 12-month follow-up visit. Men who are not taking daily PrEP will also have the opportunity to indicate interest in it with each of the CASI surveys at months 4, 7, 12, and 19 and also with the 3-monthly clinical monitoring for STI PEP and/or on-demand PrEP. Men can also request an ad-hoc PrEP or STI PEP initiation visit at any time in the study app. Using the protocol established in our EleMENt cohort for PrEP offering and insurance navigation, we will show participants a short informational video about daily oral PrEP. Men who are interested in starting PrEP can talk to a counselor at the visit; if they are interested in starting daily PrEP, we will perform a commercial 4th generation HIV test as well as test for Hepatitis B surface antigen and creatinine (liver function) level in addition to the HIV and STI testing already being conducted for all study participants. Participants will either be prescribed Truvada as a fixed-dose combination of 300 mg TDF/200 mg FTC or Descovy as a fixed-dose combination of 25 mg TAF/200 mg FTC. Decisions about which PrEP medication will be prescribed will be made by the study clinicians. We will help with navigating insurance concerns or applying for patient assistance programs to

help cover the costs of PrEP. Daily PrEP users will be sent an at-home specimen collection kit every 3 months to clinically monitor them for HIV and STIs. Preliminary data on PrEP offering: In EleMENt, we offered PrEP to 300 young Black MSM, of whom 125 initiated daily oral PrEP using similar processes and materials proposed for this study[36]. Participants will receive Daily PrEP through local pharmacies.

On-Demand PrEP Offering: If men are interested in PrEP but do not accept daily oral PrEP, we will offer on-demand PrEP (see Figure 2) which will also be described in the video participants watch about the prevention options. Men who initiate on-demand PrEP will receive the same laboratory testing as men who initiate daily oral PrEP (e.g., HIV 4th gen Ag/ Ab testing, Hepatitis B surface antigen, creatinine). Men who choose on-demand PrEP will be prescribed Truvada as a fixed-dose combination of 300 mg TDF/200 mg FTC or Descovy as a fixed-dose combination of 25 mg TAF/200 mg FTC Participants will be directed to take two pills 2-24 hours before sex, and to take an additional pill 24 hours after the first pill and a final dose 24 hours after that ("2-1-1").[50] To support appropriate dosing, the mobile app will allow participants to record their first (pre-sex) dose, and receive non-specific reminders ("remember to take your pill!", or a participant-chosen message[92,135]) 24 and 48 hours later. On-demand PrEP users will be sent an at-home specimen collection kit every 3 months to clinically monitor them for HIV and STIs. Participants will receive On-Demand PrEP through local pharmacies.

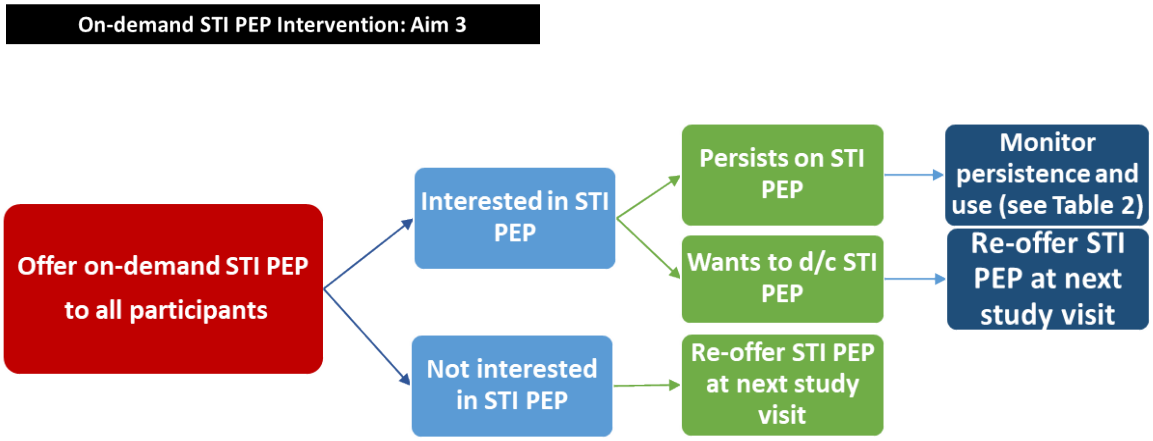
Injectable PrEP Offering: If men are interested in injectable PrEP, we will provide referrals to local providers. They will be given a list of local providers to initiate the medication on their own. Men who initiate injectable PrEP and STI PEP will receive the same laboratory testing as men who initiate only STI PEP, which includes HIV/STI screening. Clinical monitoring of injectable PrEP will be done by the local provider who administers the injection. If they elect only injectable PrEP, all clinical follow-up will be conducted by the provider who administers the injection; we will only monitor their use of the medication and HIV testing status through monthly and periodic surveys. Men will also have the option of changing prevention options at any point during the study by indicating their interest during their monthly surveys or simply contacting us directly through the study phone, text or email.

Figure 2: PrEP Offering Algorithm



STI PEP Offering: All men in the cohort will be offered STI PEP (Figure 3) per the published IPERGAY protocol.[8] We will use the same model to introduce STI PEP as we have used to introduce HIV PrEP in our current cohort: participants will be shown a short video introduction to STI PEP, instructed on use and possible side effects, and will be offered initiation on STI PEP on the day of the baseline visit or at all subsequent study interactions. Men will also be offered the option to initiate STI PEP on each of their CASI surveys at months 4, 7, 12, and 19 as well as at a potential 3-monthly visit for PrEP users. Men may also schedule an appointment between regular study visits to initiate STI PEP. A licensed clinician, overseen by Dr. Kelley, will prescribe all STI PEP, using doxycycline at a dosage of 200 mg to be taken in a single dose ideally within 24 hours of possible exposure (e.g. condomless anal sex) and no later than 72 hours after exposure. Participants will be dispensed enough pills to allow for up to 3 weekly doses of 200mg doxycycline (i.e. 6 pills/week) for 3 months (the interval between STI clinical monitoring testing). Doxycycline will be provided by the Emory Investigational Drug Service Pharmacy that will mail out initial and renewal prescriptions. The weekly STI PEP monitoring surveys will assess how a participant's STI PEP use has gone, ask about STI symptoms, side effects or concerns, and confirm whether the participant wants to continue using STI PEP and needs a refill. Additionally, STI PEP users will be sent an at-home specimen collection kit every 3 months to clinically monitor them for HIV and STIs. If a participant ever has side effects or questions about STI PEP, they will be able to contact the provider through the HIPPA-compliant messaging system, by phone, or by telehealth video chat. GI side effects were common in IPERGAY. We will pay special attention to educating participants and eliciting GI side effects.

Figure 3: STI PEP Offering Algorithm



Prospective follow-up:

Prospectively-enrolled participants will be followed for two years (Figure 4). Depending on what services are used, some participants will receive additional app-based assessments to document risks for PrEP discontinuation and use of on-demand PrEP, injectable PrEP or STI PEP (Table 2). Oral PrEP initiators and STI PEP initiators will receive brief weekly surveys ($5 incentive for each) for the first 2 weeks after they start their new regimen to identify side effects or other barriers to use as early as possible. After this period, all daily PrEP users will receive monthly short surveys for risk factors for PrEP discontinuation administered through the study app ($10 incentive for each). Injectable PrEP users will receive monthly short surveys ($10 incentive for each) to measure PrEP use and assess risks for discontinuation. Participants who start on-demand PrEP or STI PEP will continue weekly short surveys ($5 incentive for each) to measure PrEP and/or STI PEP use and assess risks for PrEP discontinuation (on-demand PrEP); the frequent follow-up intervals will reduce recall bias (*minimizing bias*). Participants will be compensated for all weekly and monthly assessments during the second week of the following month. All participants will complete CASI surveys at months 4, 7, 12, 19 and 24 months, attend in-person follow-up visits at 12 and 24 months ($40/4,7,19 months; $100/12 month survey and study visit; $100/24 month survey and study visit) and additional telehealth or in-clinic visits if risk for PrEP discontinuation is identified by surveys. Daily or on-demand PrEP users will have 3-monthly HIV/STI home-testing for clinical monitoring of their PrEP use [36, 132], and STI PEP users will have the same home testing to clinically monitor their STI PEP use (Figure 4). For injectable PrEP users, all clinical monitoring will be done outside the study by a local provider of the participants' choosing.

Participants will be study stopped early when funding ends. The budget for this study will end on 3/31/2025. Participants will complete all study activities by 1/31/2025 to provide adequate time for study close-out procedures. At this point, some participants will have completed their 24 Month Visits. Others will be study stopped, before they complete their 24 Month Visit. All participants will be provided refills for medications, when applicable, and linkage resources to continue their health journey.

Table 2. Schedule of Added Interim Surveys for Men on PrEP/STI PEP

Regimen	Initial Check-in Frequency	Maintenance check-in frequency
Daily PrEP	Weekly for first 2 weeks	Monthly
On-Demand PrEP		Weekly
STI PEP		Weekly
Injectable PrEP	None	Monthly

Mobile app to support participant management, on-demand PrEP, injectable PrEP and STI PEP usage, and weekly/monthly screeners: We will build on our extensive experience in designing and evaluating mobile apps for MSM[76, 92, 98, 133], and the SMaRT (Study Management and Retention) system developed by the Emory CFAR. The SMaRT system is a study management platform that allows for participant management (reminders, scheduling, survey administration, and communication by email and text messaging). It includes a companion mobile app that study participants install on their smart phones that supports several key functions of study participation: notifications of surveys/screeners available, administration of surveys, messaging center, appointment scheduling for in-person or telehealth visits, HIPPA-compliant uploading of documents and return of laboratory results, and HIPPA-compliant telehealth video meetings.

We will modify the SMaRT system and participant app to deliver weekly/monthly surveys assessing risk factors for PrEP discontinuation and on-demand PrEP/injectable PrEP/STI PEP use, scheduling for assessment visits and other prevention services, telehealth meetings with trained peer navigators, and messaging systems to request transportation assistance (e.g., Uber ride to clinic or nearest MARTA station). Given the robust SMaRT platform, we estimate that initial production of the tailored version will take 6 weeks. *Preliminary data for mobile app platform*: We have developed several mobile apps for HIV prevention for MSM and documented our process of piloting and getting feedback from communities and end-users.[92, 98, 134, 135] The SMaRT system is currently used for 14 NIH-supported HIV prevention studies[41, 98, 99, 136-141] (all supported by Emory staff) and is available as a CFAR service from the Emory CFAR Prevention Sciences Core.

Identification of risk factors for PrEP discontinuation through monthly surveys: We will "push" a survey notification through the study app monthly to all participants on Daily PrEP. The survey will include several items to identify common concerns that have led to PrEP discontinuation

among previous participants (See Table 1 for sample indicators) and participants can schedule an appointment to discuss PrEP questions or concerns, if they choose to. Appointments may be scheduled through the app for a telephone call, a video call, or an in-person clinic visit. If transportation assistance is needed for an in-clinic visit, it can be requested through the app at the time of scheduling. This brief monthly survey is 7 questions in length and will be completed securely within the HIPPA-compliant app. When a participant endorses ≥1 risk factor for PrEP discontinuation, study staff will be notified by a secure electronic message and the participant will be asked immediately to schedule a motivational interviewing (MI) session with a peer navigator in the mode/location of his choice, and offered available times to schedule through the app. If the participant does not self-schedule within 72 hours, we will communicate with the participant through the secure messaging features in the app to establish a time for a call, in which study staff will explain that we would like the participant to have a telehealth or in-person visit with a PrEP peer navigator. Frequency of follow up on monthly triggers for MI session will vary based on the needs and experience of each participant. After an initial MI session for each indicated trigger, participants will have the opportunity to express which triggers are relevant to their PrEP experience and thus require future follow up when indicated. Based on participant feedback, peer navigators will tailor frequency of follow up for each indicated trigger.

Injectable PrEP users will receive monthly short surveys to measure PrEP use, HIV testing status, and assess risks for discontinuation. They will have the option to indicate interest in switching their prevention option within the survey.

PrEP discontinuation intervention: If answers to the monthly screener questions indicate a participant is at risk for PrEP discontinuation, a peer navigator will deliver a motivational interviewing (MI) intervention and a clinician will consult with the participant if needed. These efforts are intended to avert PrEP discontinuation. When a participant reports any of the risk factors, they will be invited to schedule a discussion with a peer navigator. Triage sessions will be client-centered, using an approach grounded in MI. By focusing on the last time the client was confident about being on PrEP (e.g., think back to when you were taking your medication every day. What was going on in your life? Where were you living? Who were you dating?), the peer navigators will be able to understand the holistic context of the current risk factor – for example, changes in willingness to take a daily medication might arise from changes in housing situation or relationship patterns. Based on this comprehensive understanding of needs and the monthly screening data, trained peer navigators will use MI tools to help participants problem solve based on the needs identified and will work with them to develop a plan to address those concerns while maintaining PrEP, if appropriate. For example, if a participant says they plan to stop PrEP because they have a new partner who they feel committed to, the counselor might talk to the client about HIV and STI testing with the partner before discontinuing PrEP or using Couples HIV Testing and Counseling[145] services to discuss mutual decisions about PrEP, condom use, and other prevention tools. Clinical concerns (e.g., side effects) will be referred to a PrEP clinician for discussion.

Injectable PrEP users will receive monthly short surveys to measure PrEP use and assess risks for discontinuation. They will have the option to indicate interest in switching their prevention option within the survey. However, an MI intervention and clinical consultation will not be provided as part of the study based on their survey answers. Our goal will be to simply monitor

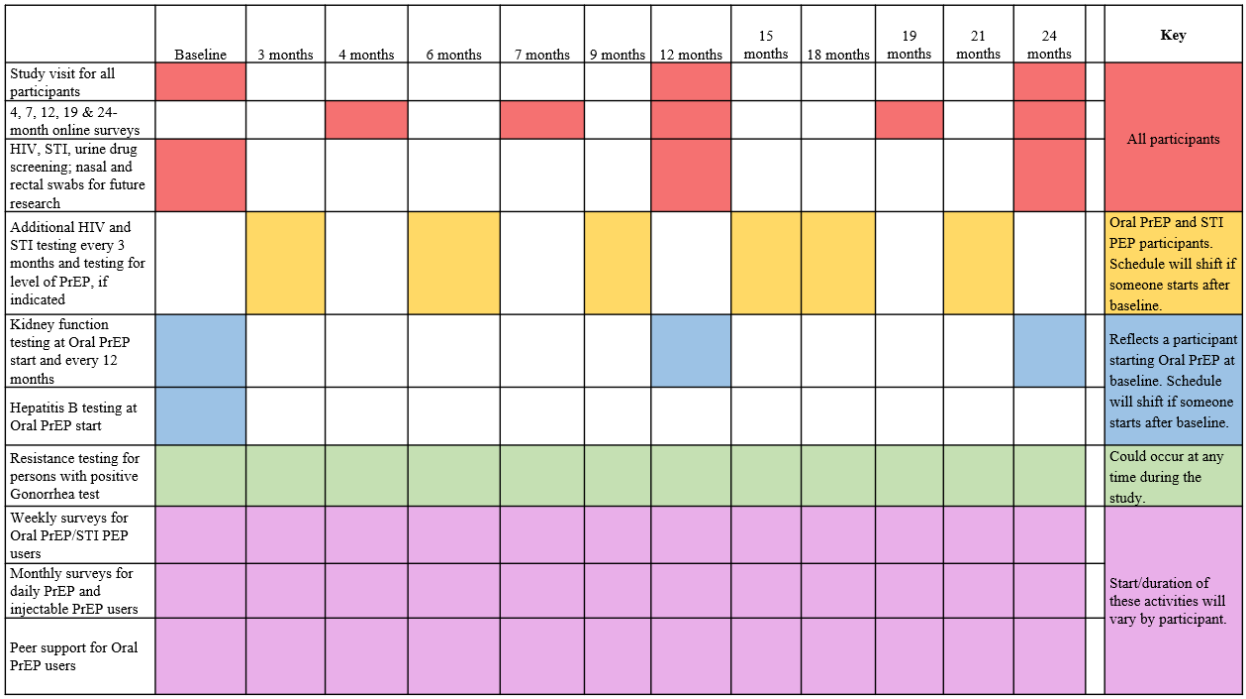
the use of injectable PrEP and HIV testing status among our participants. If they elect to switch to oral PrEP at any point during the study, then the above interventions will apply.

Computer assisted self-interview (CASI): Participants will complete online CASI surveys on a HIPPA-compliant survey platform at baseline, 4, 7, 12, 19 and 24 months (Figure 4). Surveys will either be done remotely or at our research clinic. The CASI will assess updated contact information, recent sex and drug-using behaviors, psychosocial factors, use of PrEP and STI PEP, and HIV and STI testing outside the study and self-reported results since the previous visit. For PrEP and STI PEP users, more frequent (weekly and/or monthly) assessments of daily PrEP, on-demand PrEP, injectable PrEP and STI PEP use will be administered through the study app. *Preliminary data - CASI:* We have employed secure, online CASI with 4,503 follow-up surveys in previous cohorts. Most men (80%) chose to take follow-up surveys from home, using their own computers.

Laboratory testing procedures: Laboratory testing (Figure 4) will be done at the research clinic or remotely by the participant at home using self-collection specimen methods. If specimens are collected at the clinic, we will use INSTI, a CLIA-waived HIV rapid test, to confirm self-reported negative HIV infection status at baseline. INSTI will also be used for HIV testing at the 12 and 24-month study visits. If the rapid test is positive or indeterminate, or if someone is initiating PrEP/STI PEP, we will send a blood sample to Quest for commercial fourth generation testing. If specimens are collected remotely, we will have the participant use a dried blood spot card and have MTL laboratories perform commercial fourth generation HIV testing. Regardless of whether participants attend a remote or in-person study visit, they will self-collect urine, rectal and pharyngeal samples to test for the presence of C. trachomatis (CT) and N. gonorrhea (NG) using the Abbott Real Time CT/NG assay. Serum samples for an FDA-approved syphilis rapid plasma reagin (RPR) test and titers will either be collected in-person at the clinic by a phlebotomist or remotely via participant fingerstick blood sample. STI samples will either be sent to MTL (self-collected) or Quest (in-person) for testing. Oral PrEP candidates will also receive creatinine testing at baseline, 12 and 24 months, Hepatitis B screening at baseline or whenever PrEP is initiated, and periodic testing of tenofivir-diphospate (TFVdp) levels using a dried blood spot card. Blood samples for these tests will either be self-collected and sent to MTL or phlebotomist-collected and sent to Quest with the exception of all TFVdp testing being done by MTL. Injectable PrEP users will receive the same laboratory tests as everyone for baseline, 12 and 24 month visits. They will not have 3-monthly clinical monitoring through the study unless they also elect STI PEP. If they elect STI PEP, they will receive HIV/STI screening every 3 months to monitor STI PEP use. Clinical monitoring of injectable PrEP use will be done by the local provider who administers the medication.

Any positive test results will be provided to participants over the phone by a study staff member who can refer participants to study-paid treatment for STI infections at a local community-based health clinic, or participant-paid treatment through a provider of their choosing. Negative tests will generally be delivered through the HIPPA-compliant study app. To minimize bias in self-report data on substance use, we will conduct urine drug screening (UDS) in our onsite CLIA-waived laboratory at baseline, 12 and 24 months using the Ten Panel Integrated EZ Split Key Cup Drug Test (*minimizing bias*).

Figure 4: Timeline of study visits, activities, and labs



Staphylococcus aureus nares resistance testing: A recent Canadian study of daily doxycycline use to prevent STIs among MSM on PrEP found doxycycline resistance in nasal carriages of S. aureus over the study's duration. Over the course of our study, we will collect a total of 2-4 nasal swabs at in-person study visits from all participants to assess the prevalence of doxycycline resistance among persons taking STI PEP versus those who are not. The swabs will be banked for later analysis by Sarah Satola's Emory Investigational Clinical Microbiology Core lab for testing.

Preliminary data for laboratory: We previously performed HIV rapid testing for 1,668 participants in our cohort studies. In total, we performed STI testing with the same study team and CFAR laboratory colleagues for 3,102 STI measurements in MSM in Atlanta.[122] We have completed 2,913 UDS results in previous studies, and have published data on using UDS to

characterize and adjust for misclassification bias from self-report.[126] Dr. Kelley has extensive experience in studying the rectal microbiota in MSM.[62, 68, 144]

Retention activities: Several activities will be developed to maximize retention, building on the experiences and expertise of the study team. Our past cohort studies and clinical trials have employed a sophisticated participant management database (SMaRT) and successful retention coordination activities that will also be used for this study. An Emory staff person will be allocated exclusively to retention activities. The SMaRT mobile app customized for this study can schedule/reschedule/receive reminders of/cancel study appointments, communicate securely with study staff, and update contact information from within the HIPPA-compliant app. Participants will be prompted every 3 months to review and update their contact information in the SMaRT app. At enrollment, we will ask permission for several means of contacting participants. Retention contacts will be customized based on participants' contact preferences (email, text, call, US mail) and organized by SMaRT. Participants will be reminded about their follow-up visits through the app messaging system or through their preferred means of contact 4 weeks before the scheduled follow-up date. If we lose contact with participants (missed surveys or appointments and non-responsive to contact requests), we will have obtained consent to use for-fee public-use databases (e.g., Lexis-Nexis) to locate participants; this has been used by us in previous studies to relocate participants lost to follow-up. For participants who cannot be contacted, after IRB approval, staff will attempt to link the identities of participants to registries of known decedents using a statewide dataset (vital records) and a nationwide dataset (National Death Index).

Intervention training and quality assurance

Training and QA protocols will be developed and supervised by Consultant Stephenson; management of QA record selection and evaluation will be coordinated by the Study Coordinator. Our team has a wide range of experience training and monitoring intervention staff in behavioral clinical trials. Training: Training will encompass the intervention approach and procedures, PrEP information/education, general health and mental health issues, and research ethics. Specific techniques for adhering to a manualized intervention while allowing for flexibility to address individual participant needs will be taught, role-played and supplemented by instructional readings. QA procedures of intervention delivery across peer navigators and over time during the course of the study have been developed from the team's prior trials[94, 96] and the relevant literature and include: (1) development of detailed manuals for the intervention; (2) intensive training; (3) incorporation of mock training sessions that enable us to ensure all facilitators meet performance criteria for intervention delivery, leading to certification of peer navigators based on common performance standards; (4) digital recording of sessions, with 20% of all files randomly selected among facilitators for QA ratings. QA checklists will be developed and will provide the structure for review; ratings will be contingent upon >80% inter-rater reliability; and (5) QA feedback will be incorporated into routine project supervision. Over the course of the proposed trial, it is therefore anticipated that up to 50 hours of intervention delivery will be monitored for QA purposes, reflecting 20% of sessions. Additional monitoring will continue for staff whose

QA ratings fall below pre-designated thresholds until performance improves or, if necessary, the staff member is replaced.

Study Medications

The study medications include Truvada or Descovy for daily and on-demand PrEP and doxycycline for STI PEP. All three medications are FDA approved. The study qualifies for an IND waiver for the investigational use of doxycycline to prevent STI infections. Side effects of PrEP include nausea/vomiting, diarrhea, abdominal pain, high creatinine level, bone fracture, proteinuria, glycosuria, elevated alanine aminotransferase. Side effects of doxycycline include nausea/vomiting, diarrhea, abdominal pain, high creatinine level, proteinuria, glycosuria, elevated ALT concentrations. Participants can access Apretude (cabotegravir extended-release injectable suspension) through a local provider of their choosing, this medication will not be provided through the study. Side effects of injectable PrEP include: pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, discoloration, diarrhea, headache, fever, tiredness, sleep problems, nausea, dizziness, passing gas, stomach pain, vomiting, muscle pain, rash, loss of appetite, drowsiness, back pain, or upper respiratory infection.

Safety and Risk Minimization

Throughout the study, we will minimize risks to participants and monitor their safety by engaging with them frequently through study visits, surveys, and telehealth appointments and assessing side effects and other clinical and/or behavioral issues that need addressing. Clinical staff, as well as the peer navigator, will intervene when issues are identified to minimize potential harm to the participant and ensure safe use of study medications.

7. Data and Specimen Banking

Additional data analyses besides those described in this protocol will be performed. Data will be stored in accordance with the description outlined in section 17.0 “Data Analysis, Management and Confidentiality.” Participants will be asked during the consent process if they consent to release certain data to Emory for use in the study. No data will be collected after all research procedures are completed.

A second set of rectal samples collected at in-person study visits will be stored for possible future analyses to examine perturbations in the microbiota associated with daily or on-demand PrEP and/or STI PEP. Specimens will be stored in a freezer at The Hope Clinic of Emory University for no longer than 20 years for use in future microbiome research. Nasal swab samples collected at in-person study visits will also be frozen and banked for no longer than 20 years for future analyses of doxycycline resistance to staph aureus in nasal carriages.

Data associated with banked specimens will include participant ID, date of collection, test results and date, and PrEP/STI PEP use at time of specimen collection.

The data and specimen release process will include completion of a data request form, review and approval by a subset of study investigators, and monitoring for appropriate use and dissemination.

8. Sharing of Results with Participants

Results from all diagnostic and routine monitoring tests will be shared with participants either in person (i.e., rapid HIV test done at in-person study visits), over the phone or through the HIPPA-compliant study app. Any positive non-rapid test results will be provided to participants over the phone by a study staff member who can refer them to treatment. Negative tests will generally be delivered through the HIPPA-compliant study app.

9. Study Timelines

Individual participants will be in the study for 2 years. Full study enrollment is anticipated to take one year. Primary analyses are estimated to be completed by the end of year 5 (April 2025).

10. Inclusion and Exclusion Criteria

Inclusion Criteria

- Male at birth
- Self-identify as Cisgender Male
- Ages 18-45 years
- ≥1 male anal sex partner in the 12 months before the baseline interview
- Live in the Atlanta MSA
- Owns cell phone with data service
- Willing to download a health-related app to their cell phone as part of the research study
- Able to provide ≥ 2 means of contact
- Not currently enrolled in another HIV prevention clinical trial
- Confirmed HIV-negative at baseline visit

Exclusion Criteria:

- Female at birth
- Do not self-identify as Cisgender Male
- Individuals < 18 years of age or > 45 years of age
- HIV positive status
- No male anal sex partner in the 12 months before the baseline interview
- Does not own mobile phone with data service
- Not willing to download a health-related app to their cell phone as part of the research study

- Live outside the metro Atlanta MSA and/or planning to move from Atlanta area in the next 2 years
- Currently enrolled in an HIV prevention or treatment clinical trial

We will also exclude all of the following:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

Data informing new eligibility/inclusion criteria: There is a substantial literature about risks and PrEP use and intentions to use during the COVID pandemic. Many MSM who were using PrEP stopped using it, in the US South (154, 155) and globally (156, 157). Visits for PrEP initiation were lower in US practice settings (158), and increases in chlamydia and syphilis diagnoses during the pandemic (159) suggest lower levels of risk behaviors were occurring. As a result, while maintaining our original scientific aims, we are expanding our eligibility criteria.

Surveillance data and data from our own research in Atlanta show that MSM, especially MSM in the South, face substantial risk of HIV infection through their 40s. We originally enrolled exclusively young MSM because HIV risk is even higher in that group; we will now broaden our criteria to include MSM through age 45.

We also will broaden our eligibility criteria to include men other than Black MSM. HIV risk and PrEP indications are high for all MSM in the US South. We originally focused on Black MSM based on a relatively higher risk for HIV compared to other groups; however, the COVID pandemic especially impacted Black Americans and Black Atlantans face more substantial challenges to traveling to HIV prevention and care (160-162). We will address this challenge for participants by expanding support for transportation and increasing study incentives. We will also enroll other MSM to meet the scientific objectives of understanding the patterns of PrEP usage as more PrEP modalities are available. Though some of our background information cites previous outcomes among Black MSM, we are expanding our eligibility criteria to include all races and ethnicities based on similar risk factors for HIV as well as indicated changes in PrEP use and risk behaviors as a result of COVID.

Our group has a long history of research with minority communities. The design of this study is based on prior research by our group, including qualitative data, aimed to increase PrEP persistence in people at increased risk of HIV acquisition. We will be using self-reported race during the study. Race and/or ethnicity may be used for descriptive statistics or in explanatory model. Differences in HIV acquisition, PrEP use, and PrEP persistence are known to occur across demographic factors. While these demographic factors are a surrogate for other social determinants of health (e.g. poverty, lack of access to healthcare, structural racism), they remain a standard of measurement in epidemiologic studies and in CDC reporting of HIV incidence and PrEP use. Race will be used as a proxy for social determinants of health.

Up until May 2022, we have enrolled MSM who were not currently taking PrEP, to observe initial choices. Given our scientific objectives to avert PrEP discontinuations by making more PrEP choices available, we will include men already taking PrEP, and offering them monitoring for risks for PrEP discontinuation, the same range of PrEP options, and STI PEP.

We have also analyzed the PrEP choices of our participants to date, to inform our consideration of whether we might be able to accomplish our scientific objectives with a lower total sample size. We found a more even distribution of initial PrEP choices than we had anticipated. When we proposed this project, we had essentially no prior data about what initial PrEP choices might be, and our sample size was proposed based on confidence intervals around changing PrEP modalities. We proposed a higher sample size to be able to have some reasonable estimates of use, even for modalities that might have lower uptake. However, our experience with our first 114 participants suggests that we have a broad variety of PrEP modalities being chosen. Further, we powered our STI PEP aim based on an anticipation of 25% uptake of STI PEP, and we have observed nearly 73% uptake to date. We had anticipated that up to a third of participants might not choose to start PrEP immediately, but only 11% have chosen not to start PrEP. Based on these data, we will reduce our total sample size to 240. With the observed distribution of STI PEP uptake and assuming 30/100 PY rate of diagnosis of STIs, we would have 85% power to detect a 70% reduction in STI diagnoses (compared to 80% power to detect a 70% reduction in the original design.

Individuals will be screened for eligibility through a self-administered online screener that will either be done in-person on a tablet device during a recruitment event or online after clicking on a link in a recruitment ad. Those men found eligible will then be invited to an enrollment (baseline) visit. At the enrollment visit they will be re-screened for eligibility by a study staff and will be tested for HIV to confirm the required HIV negative status for prospective study enrollment.

Results from the study will be shared with participants and the broader community they represent through study newsletters, publication announcements, and community meetings. Additionally, a peer navigator, who will be part of the study staff, will represent the community of MSM in Atlanta and be involved in the study design and implementation.

11. Vulnerable Populations

N/A

12. Local Number of Participants

We plan to enroll 240 study participants for the prospective study. It is expected that a small number of men (<20) will be deemed ineligible at the baseline appointment due to a positive HIV status and/or not meeting other eligibility criteria.

13. Recruitment Methods

Our goal is to enroll 240 MSM using the most efficient methods, while minimizing opportunities for bias. We will use two recruitment methods that draw on the study team's strengths. We will recruit MSM who are not known to be living with HIV from 2 sources. The venue-based method is a modified venue-day-time (VDT) screening approach implemented by CDC for behavioral surveillance under PI Sullivan's leadership.[131] We have tracked the recruitment data for each recruitment venue and day from past studies, and will use those historical data to oversample venues that historically had high numbers of MSM who were HIV-negative. Venues includes bars, nightclubs, gyms, parks, gay pride events, etc. We will also offer $5 incentive to take the study screener at these in-person recruitment events. The second method is recruitment via dating apps and social media. This involves targeting advertisements to adult men in Atlanta who are using dating sites such as Grindr and Adam4Adam, and who use social media channels such as Instagram and Snapchat, or whose Facebook profiles connote an interest in men. We will also offer $20 gift cards to current participants to share our IRB approved study ads on their social media. The goal is for participants to simply share this information with their social networks on a voluntary basis. Their participation in the study will not be affected in any way should they volunteer to share study information. They will not be referring individuals, rather simply share information that has been approved by IRB. Considering the current social climate, our target demographic gets most of their information online. As a result, social media advertising is the most effective way to get information out to intended audiences.

Men recruited through venues or online will read a brief introduction of the study, sign the screening consent (if interested in participating), complete an online eligibility screener, and leave their first name, phone number and email for follow-up, if eligible for study participation. Staff will in turn reach out to eligible men to schedule them for a baseline visit. Analyses of our InvolveMENt data show few differences exist in behaviors, HIV/STI infection, and retention between MSM recruited by VDT and subset recruited via Facebook.[61]

Respondents who complete an enrollment visit will be compensated $125, whether or not they participate in the prospective study. Participants who complete the in-person survey and study visit at 12 months will receive $100 and those completing the 24-month survey and study visit will also be compensated $100. Daily PrEP users, on-demand PrEP users and STI PEP users will be paid $5 for each weekly survey they complete, as appropriate. After the first two weeks of initiating PrEP, daily PrEP users will receive monthly short assessments for risk factors for PrEP discontinuation administered through the study app and will be paid $10 for each survey. All participants will take online surveys at months 4, 7, and 19 and these will be compensated at $40 each. If a participant needs to return to the clinic for a blood draw or other specimen collection outside of their study visit schedule, they will be paid $20.

Participants will be offered transportation assistance such as an Uber ride to the research clinic or to the nearest Marta station for all in-person visits including the enrollment one.

14. Withdrawal of Participants

Study investigators may withdraw participants from the study in order to protect participant or staff safety. Investigators have a right to stop their participation in the study without their consent if:

- They believe it is in their best interest;
- They were to object to any future changes that may be made to study procedures;
- Other factors related to their eligibility change during the study;
- Or for any other reason.

It is anticipated that some participants will voluntarily withdraw from the study and, when this occurs, we will document on a study withdrawal form the circumstances necessitating the action. If they withdraw, the study information they provided will remain with Emory University and will be used in analyses.

15. Risks to Participants

Following are anticipated risks to participation, and procedures to reduce risk.

- Persons may learn they have HIV or an STI, and this may be upsetting. To minimize this risk, we will have counselors who have attended a HIV counseling and testing training course and a passed a proficiency panel assessment.

- Persons may be uncomfortable with some survey questions. To minimize this risk, we will offer participants the option in the survey to not answer any question that makes them uncomfortable. Participants who find the questionnaire to be generally uncomfortable can choose to discontinue participation in the study.

- Persons may have bruising or a local infection at the site of venipuncture. This is a typical risk of having blood drawn in any setting. We will employ experienced phlebotomists who have a certificate of training from a program that meets the core national standards for training, and who have at least 40 hours of experience as a phlebotomist. We will also provide schematics for participants self-collecting their specimens at home to help minimize the risk of bruising and infection.

- Persons who take Truvada or Descovy for PrEP may have adverse reactions to the drugs. These adverse reactions are uncommon and include gastrointestinal symptoms, allergic reactions, and kidney and liver problems. The safety of Truvada and Descvoy has been established through multiple clinical trials and are FDA approved and indicated for HIV prevention. The study will provide all required clinical monitoring to ensure that the medications are being used as safely as possible and the study physician will discontinue or modify the participant's use to ensure safety. Side effects that will be monitored for include: nausea, vomiting, diarrhea, abdominal pain, headache, weight loss, abnormal blood tests (creatinine, glycosuria, proteinuria, elevated ALT concentration).

- Persons who take Apretude (cabotegravir extended-release injectable suspension) may have adverse reactions to the drug. These adverse reactions are uncommon and include allergic reactions, liver problems, and depression or mood changes. The safety of Apretude has been established through multiple clinical trials and is FDA approved and indicated for HIV-1 prevention. Clinical monitoring to ensure medication is being used safely will be done by the local provider where the participant initiates injection. The local provider will discontinue or modify use of Apretude to ensure safety. The local provider will also monitor all common side-effects such as: pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, discoloration, diarrhea, headache, fever, tiredness, sleep problems, nausea, dizziness, passing gas, stomach pain, vomiting, muscle pain, rash, loss of appetite, drowsiness, back pain, or upper respiratory infection.

- Persons may have their study information compromised. We describe procedures for data security below. All study staff will have training in confidentiality policies, and will sign a confidentiality agreement annually. We use SSL encryption for transfers of information online, and SurveyGizmo has a business partner HIPAA agreement with Emory. SurveyGizmo's servers are HIPAA compliant.

- Additional protections for children (aged 16-21): According to 46 CFR subpart D, children are defined for the purpose of that section as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

  We will not be enrolling men ages 16-17. In Georgia, persons aged 13-21 have attained the legal age of consent for HIV/STI services, including HIV testing, care and treatment. However, we are aware that the consequences of disclosure of one's HIV status, or of having male sex partners, may be particularly difficult for younger men (ages 18-21) in our cohort. For all participants, we will specifically ask when contact information is requested if there are any special instructions or considerations for contact, for example if the participants live with parents or other family who should not be made aware of the participant's enrollment in the health study.

  There are unique privacy-related concerns for youth ages 18-21 given their likelihood of residing with and/or being dependent on parents, guardians, and others. Special considerations will be taken to discreetly schedule and remind participants of study appointments to ensure privacy is maintained. This will include asking participants for their preferred method of study reminder communication, such as personal mobile phone texts or private email, avoiding the use of mailings to home addresses or landline phones.

16. Potential Benefits to Participants

Participants will learn their HIV and STI status and, as needed, be linked to care and treatment for HIV, STIs, mental health and substance abuse treatment services. Free

treatment for STIs at a community clinic will be offered to all participants during their study duration. Additionally, participants will be supported by study staff in getting free, or minimal cost, Truvada or Descovy (PrEP), and free STI PEP (doxycycline) through the Emory Investigational Drug Service. Participants who take PrEP may significantly lower their chances of acquiring HIV and participants taking STI PEP may lower their chances of acquiring a bacterial STI.

17. Data Management and Confidentiality

Data Analysis

Aim 1

The primary analytic goal of Aim 1 will be to estimate the causal effect of the intervention components on the incidence of PrEP discontinuations. To rigorously specify the analysis, we articulate a target trial design as described by Hernan et al.[51] Target trial emulation recreates a randomized control trial (RCT) using a secondary data source (in this case our prior cohort) when a contemporary control condition is not available.

We recognize that the target trial is subject to selection bias, because some men will not initiate PrEP during the trial and will be excluded from the analysis. To account for possible differences in the composition of the cohorts by factors related to risk of PrEP discontinuation, we will use inverse probability weights to create a synthetic for which the baseline covariates are independent of treatment assignment.[148] We will include items related to PrEP attitudes and intentions (e.g., how confident are you that PrEP will provide protection from HIV infection) asked in the historical cohort and asked in the new cohort, as a way of adjusting for the effects of potential secular trends in PrEP attitudes on discontinuation. We will construct adjusted Kaplan Meier estimates for survival until PrEP discontinuation[149] and truncate weights to avoid instability[150]. The results will indicate marginal, rather than conditional probabilities, which is appropriate to our analytic question.[151] Power: Based on an estimated rate of PrEP discontinuations of 31/100 person-years (based on preliminary data) and 50% PrEP uptake overall, we would have 80% power to detect a 30% reduction in PrEP discontinuation in the intervention cohort (rigor; calculations in PS software152 using α=0.05, power=0.80, n=150 PrEP users, m1=220, A=365, F=730, m=1¬).

Secondary analyses: In this implementation-focused study, we will characterize rate of identification of risk factors for PrEP discontinuation (source: monthly screening survey data); the prevalence of discontinuation at the time of identification of risk factors (source: CRFs from peer navigator sessions); and the utilization of different modes of accessing support (telephone call, video call, clinic visit) for men at risk for PrEP discontinuation. Confidence intervals for these proportional outcomes are as follows: initially selected mode of PrEP: ± 5%; rate of risk factors: ± 0.7%; prevalence of stops at risk factor identification: ± 11%; utilization of mode of access: ± 9% (rigor).

Aim 2

The primary analytic goal of Aim 2 will be to estimate the proportion of men who choose to start intermittent PrEP after declining daily oral PrEP, the proportion of men with risks

for discontinuing daily oral PrEP who switch to on-demand PrEP, and the patterns of usage of on-demand PrEP among those who choose it. Analyses will be descriptive, reporting proportions of outcomes of interest for starting on-demand PrEP (data source: visit records and PrEP counseling CRFs). We will also depict the patterns of use of on-demand PrEP by visualizing the dates of self-reported use and by calculating the rate of self-reported use. Data for these analyses will come from the study mobile app, which will ask men on intermittent PrEP to report at least weekly to document use and to minimize recall bias (minimizing bias). Power: Given our sample size, the proportions of men starting or changing to on-demand PrEP will be estimated as proportions +/- 5%, given 30% uptake (rigor).

Aim 3

The primary analytic goal of Aim 3 will be to estimate the proportion of men who choose to start injectable PrEP after declining oral PrEP, the proportion of men with risks for discontinuing daily or on-demand PrEP who switch to injectable PrEP, and the patterns of usage of injectable PrEP among those who choose it. Analyses will be descriptive, we will depict the patterns of use of injectable PrEP by visualizing the dates of self-reported use and by calculating the rate of self-reported use. Data for these analyses will come from the study mobile app, which will ask men on injectable PrEP to report their use of injectable PrEP on a monthly basis. Power: Given our sample size, the proportions of men starting or changing to injectable PrEP will be estimated as proportions +/- 5%, given 30% uptake (rigor).

Aim 4

The primary analytic goal of Aim 3 will be to estimate the causal effect of the intervention components on STI incidence. Participants in the proposed study (i.e., 'intervention group') will be compared to an historical control group derived from an existing cohort of age-matched, HIV-negative MSM in Atlanta. The primary outcome of interest will be diagnoses of any STI (rectal, urethral or pharyngeal gonorrhea or chlamydia, syphilis) at the 12- to 24-month study visits with STI testing. To assess the effect of the intervention, we will calculate the standardized incidence ratio (SIR) for STIs between the current cohort and historical cohort. The expected number of STI diagnoses will be determined based on the risk of diagnoses at 12- and 24-month visits from the historical cohort. To account for possible differences in the composition of the cohorts by factors related to risk of STI, we will adjust for factors that are found to be associated with STI (if any) in the historical cohort, to be analyzed after the historical cohort ends in 2019. Secondary analyses: We will calculate a secondary incidence comparison based on the STIs for which doxycycline is expected to be efficacious (chlamydia and syphilis). In this implementation-focused study, we will characterize the rate of interest in discussing STI PEP (source: weekly screening survey data); the proportion of men who accept STI PEP (source: CRFs from STI PEP counselors); and the self-reported patterns of STI PEP use (source: mobile app weekly brief surveys). Power: Based on an estimated rate of STIs (30/100 p-y) and 25% STI PEP uptake overall, we would have 80% power to detect a 70% reduction in STI diagnoses (as observed by Molina for syphilis and gonorrhea8; rigor).

Data Security:

Data will be stored on a SQL server in the "trusted zone" (HIPPA compliant) of the Rollins School of Public Health computing service. Daily backups of the entire dataset will be performed. All participants will be assigned a unique identification number for the study. A master list linking these numbers and identifying data will be stored on the SQL server, and access to these confidential files will be managed by the Study Director and Principal Investigators. Documents with identifying information (name, contact information) such as study forms, consents, prescription logs, etc. will be stored in a separate SQL database from all other de-identified data. Access to the identifying information will be on a role-based system: access to identifying information will be restricted to those who need access to perform their work function. Thus, access to identifying information will be restricted to the Principal Investigators, the Retention Coordinator, who must contact participants to schedule visits; the Study Director and Coordinator who may assist with notification of test results or as a backup for visit scheduling; counselors and peer navigators providing support to participants; and, 2-3 graduate research assistants who will enter the identifying information into the data system. Access will be controlled by business rules on the SQL server based on the login ID. Paper forms will be stored in a locked cabinet in a locked room in PRISM's research clinic. The locks for the room and cabinet require different keys/codes. Access to the room and cabinet will be limited to the PIs, Study Director, Data Manager; Graduate Research Assistants who perform data entry, and other study staff responsible for filing forms in study binders. Once all study data are collected, all identifiers will be removed from study data.

The main sources of possible data entry errors will lie with any manual entering of study data however we expect this to be minimal as most data collections systems will be automated. For app- and survey-based data, the participant identifiers are associated with the electronic record automatically, so the chance of problems with attribution of responses to the incorrect participant is very small.

We will follow regulations for mandatory reporting of breaches in confidentiality or adverse events. There is a statement in the consent form notifying participants of this possibility. All study personnel will have completed CITI training and attended a confidentiality training and signed an associated agreement. Any additional personnel who join the study after initial launch will have to complete this training before they handle any subject data. Issues regarding confidentiality will be reinforced prior to each data collection with study personnel.

All study staff will be trained to recognize, document, and report any unusual events or circumstances that occur during data collection immediately to the PIs and to Emory IRB. If an adverse event appears to be research-related, it will be reported to the OHRP and the funding institution project officer, along with summaries of discussions concerning the event. The funding institution project officer will be informed of any IRB action taken concerning any adverse event. The Principal Investigators and Study Director will monitor staff closely. Staff deficient in any aspect of performance will be re-trained, closely monitored for proficiency, and if not adhering to established protocols and procedures, will be terminated.

SurveyGizmo: When data are collected via Survey Gizmo, they are automatically encrypted, with the coded access only available to the Data Manager, Study Director and the PIs. This procedure increases the security of the data, as commercial survey providers (e.g., SurveyMonkey, SurveyGizmo, etc.) store the data in their own servers. Furthermore, all web survey data will be secured using an SSL 256-bit encryption. SSL encryption is the standard for all web-based transactions that include any identifiable information, including names, addresses, and credit card numbers.

Once data are downloaded from the server, we will expunge them from the server. Survey and intervention data files will be identified using numeric study participant ID numbers, assigned by study staff, which will be unrelated to the participant's name or email address. All online survey data will be collected using SurveyGizmo, a secure, encrypted electronic platform with which the Emory site team has established a business associate agreement to ensure HIPAA-compliance. Study data stored by Survey Gizmo are maintained on a dedicated secure server, with no co-mingling of study data with other SurveyGizmo customer data, or between Emory projects administered by Survey Gizmo.

Data collected through the SMaRT app will be stored on a HIPPA-compliant server housed at Emory University; data will be stored within the Emory AWS platform. The SMaRT system and app went through a security review and were approved by Emory LITS in 2020. They were not created specifically for this study. We will not send individual results from this study to the mobile app with the exception of laboratory results that participants will receive through the app. App data will be encrypted at rest. All data will be stored in an Emory AWS RDS database using in-box AWS database encryption. Data in transit will be encrypted with TLS 1.2. The study team will not be able to access participants' mobile device activity, they will only be able to see their completion of some activities in the study app through its admin web portal. They will be required to log in to the application with a username and password as an additional app security measure. All app screens are covered by authorization. Data are stored on the server and not locally in the app. Per HIPAA requirements, sessions expire after several minutes and require users to log back in. When participants finish the study, we will help them remove the app from their mobile device and they will no longer be able to log in to the app.

<u>Describe how data or specimens will be handled study-wide</u>:

- What information will be included in that data or associated with the specimens?

  Specimens will be labeled with the participant's unique study identifier or name depending on the laboratory testing the specimens and their associated requirements to use names and DOB.

- Where and how data or specimens will be stored?

  Specimens from in-person study visits will be stored in a locked laboratory with only limited staff access until they are picked up or delivered to the lab for testing. Laboratory results will be returned electronically and associated files will be stored

on the SQL server reserved for study documents with identifying information and with restricted access by study staff. All data files will have SSL encryption and strong password protection. Participant survey data will be stored by SurveyGizmo.com on a secure, HIPAA-compliant webserver until downloaded by Emory.

Molecular Testing Lab (MTL) will receive the name and address of the participants for the purpose of shipping specimen collection kits to them. Test results will be stored in MTL's HIPPA-compliant database used for clinical laboratory reporting.

The PIs will provide oversight of all study procedures and quality assurance checks. All printed records pertaining to the study will be securely stored in locked file cabinets within locked offices at the PRISM research clinic and will be monitored for access by the PIs and Study Coordinator. Only designated staff will have access to the data. The Principal Investigators and Co-Investigators will be responsible for dissemination of study findings through presentations and publications. The Principal Investigators will also be solely responsible for handling any requests from other investigators to examine the data collected during this study.

- How long the data or specimens will be stored?

  Specimens will only be stored for as long as it takes the labs to process the samples. All personally identifiable information will be destroyed when all study data are collected and the study is complete. Specimens for possible future analyses to examine perturbations in the microbiota associated with daily or on-demand PrEP and/or STI PEP will be stored for no longer than 20 years however no identifying information will be stored with the specimens. Similarly, nasal specimens will also be stored in a freezer at The Hope Clinic of Emory University for up to 20 years for future analyses of doxycycline resistance to staph aureus found in nasal carriages. Data associated with specimens will include participant ID, date of collection, test result and date, and PrEP/STI PEP use at time of specimen collection.

- Who will have access to the data or specimens?

  All electronic files and records will be stored in a firewall-protected, encrypted server at Emory University. Access to printed or electronic data will be on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures. Laboratory staff will be the only study personnel handling the specimens from in-person study visits and ensuring their pick-up/delivery for testing. Participants self-collecting their specimens at home will be responsible for packaging their specimens in a study-provided shipping box and either arranging pick up of the box or dropping it at a USPS drop box.

- Who is responsible for receipt or transmission of the data or specimens?

MTL and Quest Diagnostics will be responsible for the laboratory specimens' receipt, handling and transmission of test results. SurveyGizmo will be responsible for the receipt and transmission of screening questionnaires, consents and survey data to Emory study staff. Emory University will be responsible for the management of data collected through the SMaRT app.

- How data or specimens will be transported?

  Specimens collected in-person will either be transported to Quest Diagnostics by a lab staff or picked up by a Quest courier. Home collected specimens will be transported to MTL via US mail.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

Quality Assurance Data Monitoring
Emory study staff, including the Co-Principal Investigators, will monitor data periodically for data quality and protocol compliance. Twice yearly, study staff will conduct a systematic review of study data using the Emory University-Self-monitoring Tool available at http://www.ctac.emory.edu/clinical_trial_resources/Audit%20Tools.html.

Adverse Events
An Adverse Event (AE) is any untoward medical occurrence in a clinical investigation subject administered a pharmaceutical product regardless of its causal relationship to the study treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal (investigational) product.

Any AE that is reported to either the investigators or their designated research associates by a study subject or by medical staff caring for the subject and which meets the criteria will be documented in the participant's chart. The reporting period for participant AEs begins at enrollment and continues until the subject either completes or withdraws from the study.

All AEs and laboratory abnormalities will be graded according to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table), Version 2.1, July 2017, which can be found on the DAIDS RCC Web site: http://rcc.tech-res.com/tox_tables.htm.

Each AE will be assessed for relatedness to study product. Study investigators will determine AEs to be either definitely related, probably related, possibly related or not related to study product. If the adverse event is, in the investigator's opinion, possibly, probably, or not related to study drug or procedures, then an alternate etiology will be provided by the investigator.

Related AEs ≥ Grade 3 will be included in the summary reports provided to the Medical Monitor of the study. Exceptions to expedited reporting are detailed below.

This study uses FDA approved drugs with known common side effects (please refer to the risk section of the protocol for common side effects). The following side effects will not be reported as an EAE unless it increases in severity or becomes prolonged.

Nausea: Report if severity is a Grade 3 or higher

Vomiting: Report if severity is a grade 3 or higher

Diarrhea: Report if severity is a Grade 3 or higher

Serious Adverse Events

A SAE is an adverse drug experience that results in any of the following outcomes:

1. Death.
2. Life-threatening situation - The subject was at risk of death at the time of the adverse event/experience. It does not refer to the hypothetical risk of death if the AE were more severe or were to progress.
3. Inpatient hospitalization or prolongation of existing hospitalization.
4. Persistent or significant disability/incapacity - Any AE having an outcome that is associated with a substantial disruption of the ability to carry out normal life functions, including the ability to work. This is not intended to include transient interruption of daily activities.
5. Congenital anomaly/birth defects - Any structural abnormality in subject's offspring that occurs after intrauterine exposure to treatment.
6. Important medical events/experiences that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse event/experience when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above, i.e., death, a life-threatening adverse event/experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Examples of such medical events/experiences include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

The reporting period for participant SAEs begins at study enrollment and continues until the subject either completes or withdraws from the study. All SAEs will be reported to the Medical Monitor within 24 hours of site awareness and reported to the IRB per its policies.

It should however be noted that a severe adverse event/experience is not necessarily serious, as the term severe is a measure of intensity while a serious adverse event (SAE) is determined based on the aforementioned regulatory criteria.

Data Safety Monitoring

AEs ≥ Grade 3 or 4 and targeted AEs will be reviewed in real time by study investigators.

Medical Monitor

A medical monitor will be assigned to this study for the purpose of safety oversight. The medical monitor will be notified of all SAEs within 24 hours of site awareness and receive quarterly summary reports of all AEs meeting the previously described criteria.

19. Provisions to Protect the Privacy Interests of Participants

The following procedures will be used to protect the privacy interests of those involved in this research:

Participants' contact information and any pieces of study data containing identifying information will be stored on a HIPPA-compliant server with access controls on the data files. Additionally, all files with identifying information will be password protected. Six months after study completion, participant contact information and all links between study data and contact information will be destroyed. The study will use SSL encryption for transfers of information online and survey data will be stored in the secure, HIPAA-compliant servers of SurveyGizmo. The Emory team maintains a business partner HIPAA agreement with SurveyGizmo. Participants attending a baseline visit who are not eligible will be thanked for their time, and although we will retain screening data, no identifying information will be collected. Individuals will not be informed of why they were ineligible to avoid unintentional disclosure and to protect against fraud.

Only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures and will sign a confidentiality agreement before receiving access to any participant data.

Procedures will be developed to minimize indirect disclosure that a participant is participating in an HIV/STI prevention research study. Contact preferences will be solicited from participants at baseline and at follow-up study visits to ensure that we are reaching out to them in their preferred way for all types of study communication (appointment reminders, test results, etc.). We will never reference HIV/STI in our messaging to protect participants' privacy. The SMaRT app will not reference HIV/STI in its name.

Participants will be reminded before an online survey begins to only take the survey in a private area, where they will not be observed. Participants will also be provided with detailed instructions for how to self-collect specimens at home so that they can plan for what they will need, both materials and privacy-wise.

Study participant data, including limited personally identifiable information (PII), may be shared with the Georgia Department of Public Health, for the purpose of reportable disease notification.

Study participants will interact with staff and clinical providers in person or through telehealth sessions. Data will be collected via paper and online forms, through surveys, and through the SMaRT app. Should participants feel uncomfortable filling out surveys or attending in-person visits, their concerns and questions will be addressed by a member of the study staff with effort made to place the participant at ease.

20. Economic Burden to Participants

The participants will have no foreseen economic costs associated with this study.

21. Consent Process

Consent to be screened for study eligibility will occur online and participants will read a brief introduction to the eligibility screener before checking a box indicating whether or not they consent to be screened. Participants will then consent for the main study at their in-person baseline visit. They will be provided with a paper copy of the consent and will be asked to take their time reading and signing the consent. The consent will incorporate the options to start or stop PrEP and/or STI PEP at any time. Study counselors will be trained to answer any questions individuals have regarding the consent and participants will be given a paper copy of the consent to keep if they choose.

The electronic informed consent for the screening process will be administered through a secure online portal, SurveyGizmo.com, with whom Emory has established secure and HIPAA-compliant business practices.

We will inform participants that they will be given the option of allowing the study to collect and store their current contact information (i.e. name, phone number, email address) in a confidential database for contact about participation in future PRISM Health research studies. The consent will clarify that authorization to store their contact information is completely optional, does not affect their involvement in any other part of the study, and can be withdrawn at any time. Participants will be given the option in the main study consent of selecting yes or no for their contact information to be saved for possible participation in future PRISM Health studies.

Non-English-Speaking Participants: N/A

Participants who are not yet adults (infants, children, teenagers): N/A

Cognitively Impaired Adults N/A

Adults Unable to Consent N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

We are not including persons who do not speak English given the significant cost of having a bilingual staff and all study materials and resources in another language.

22. Setting

The research will be conducted in the Atlanta MSA. Depending on the study visit and participants' optional decision to take PrEP and/or STI PEP, some study visits will take place at the research clinic in downtown Decatur and some at a participant's home. Participants will have the option to meet with clinical and study staff either in-person or virtually through HIPPA-compliant videoconferencing platforms. Laboratory testing will take place either at Quest Diagnostics (for specimens collected at in-person study visits) or at Molecular Testing Lab in Vancouver, Washington (self-collected

specimens). Recruitment will take place via physical venues such as bars and restaurants, and online through social media/dating sites such as Facebook and Jack'd.

We will form a Clinical PrEP Advisory Board (CPAB) to gain provider input on implementation strategies from the outset, and to speed dissemination of implementation lessons learned into practice.

23. Resources Available

- We routinely recruit large cohort samples of people through venue- and web-based recruitment with great success. There is a large population of MSM ages 18-45 who reside in the Atlanta MSA and who are accessible for both in-person and online recruitment methods. We recruited 300 participants from this population for our EleMENt study with few challenges and we expect a similar process for this study.
- We expect to commit multiple full-time and part-time staff, faculty and clinicians to this study with oversight by Drs. Sullivan and Kelly, the Multiple Principal Investigators.
- The research will be conducted in our research clinic located in downtown Decatur as well as virtually over HIPPA compliant videoconferencing platforms. Staff will work remotely from home work stations as well as in the research clinic offices.
- There are minimal risks to this protocol. We will provide the name, phone number and email address for a study staff member in case the participants have questions or concerns. Clinicians will be available to meet in-person or via telehealth to discuss clinical concerns related to PrEP and STI PEP. We will also have a resource directory that can be used to help link participants to medical, mental health, substance abuse treatment, housing and other ancillary services identified as needed.
- We will have extensive training of all staff prior to initiating recruitment including review of standard operating procedures, interventions to be delivered such as Motivational Interviewing, and respective roles and expectations for each study component.

24. Multi-Site Research when Emory is the Lead Site

N/A

25. References

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