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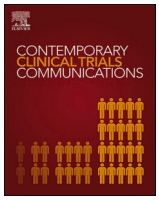

Pilot testing the effectiveness of whether a survey-driven tablet-based intervention increased willingness of Black women to attend to an initial PrEP clinic visit: The protocol for the pilot randomized controlled trial design and methods

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1. Introduction

Pre-exposure prophylaxis (PrEP) is an anti-HIV medication taken to help prevent HIV transmission to people who are HIV negative [1]. PrEP is currently approved through two routes of transmission, a daily oral pill or a bimonthly intramuscular injection [2,3]. By taking PrEP once daily, it can decrease the risk of HIV transmission, even if exposed to the virus. PrEP is approved for open label use, meaning healthcare providers and the patients are aware of the treatment as prevention option and are making an informed decision to engage in its use [4]. The CDC guidelines for identifying substantial risk for acquiring HIV as eligible for daily oral PrEP use among sexually active adults and adolescents are: 1) anal or vaginal sex in the past six months AND any of the following: 1) HIV-positive sexual partners (especially if partner has an unknown or detectable viral load), 2) a bacterial sexually transmitted infection in the past 6 months, and/or 3) a history of inconsistent or no condom use with sexual partner(s) [5,6].

PrEP effectively prevents HIV transmission by more than 90% when taken as recommended [1]. Yet, Houston, TX ranks 11th in the nation for HIV incidence rates, of which 36% were cisgender women, and 71% of those were Black women [7]. Behaviors that place individuals at high risk for acquiring HIV are common: 88% of Black women become HIV positive through condomless heterosexual sex [8], and substance use-related transmission rates are 13.4% for injection drug use and 32.1% for non-injection drug use [9]. Targeted interventions are needed to unlink the HIV risk of heterosexual sex and substance use among cisgender Black women. Meaningful progress towards ending the HIV epidemic plan include strategies that can extend health equity to cisgender Black women.

Most publications substantiating the need for open-label PrEP reference participants who identify as men who have sex with men (MSM) [10–16]. Focus is also needed on promoting PrEP uptake among cisgender Black women. Injectable PrEP was recently approved, expanding opportunities to motivate PrEP uptake for cisgender women with more flexibility (one injection every two months) without a daily adherence requirement in order to achieve maximum efficacy [17].

Absence of published findings on effective interventions that show an increase in PrEP uptake among cisgender Black women indicates a significant literary gap. The HIV Preventions Trial Network study team (HPTN 073) developed a baseline instrument for Black MSM to assess structural and mental health factors predicting PrEP uptake and adherence [18,19]. They used the Client Centered Care Coordination (C4) intervention to promote PrEP use and supported clients through referrals to related services with counseling, resulting in a 79% PrEP

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acceptance rate [18].

A new and innovative intervention, 'Increasing PrEP uptake' (iPrEP) was developed in 2015 to promote PrEP uptake among PrEP-eligible Black women seeking care during an emergency department (ED) visit. The primary outcome was to increase willingness for PrEP uptake. iPrEP's pilot study demonstrated that 69% of Black women enrolled reported willingness to take PrEP.

This single-arm pilot study showed feasibility of iPrEP as a brief intervention that could be integrated during wait times of an ED visit and indicates its ability to evaluate the willingness of Black women to take PrEP [20]. Study findings warranted the development and implementation of the first randomized controlled trial (RCT) to test whether the iPrEP intervention plus referral (experimental group) vs. usual care plus referral (control condition) would increase PrEP uptake among enrolled Black women. The iPrEP intervention is likely ideal over other PrEP uptake protocols because it has potential to facilitate movement towards a specific behavior, PrEP uptake, through building knowledge, PrEP readiness, and PrEP willingness using an innovative, yet usual source for gathering and sharing information – a survey. The study design and procedures, including recruitment, intervention, and assessment procedures, comprise the primary focus of this manuscript.

2. Methods and procedures

The trial takes place at the University of Texas Health Science Center at Houston (UTHealth), McGovern Medical School in partnership with two community clinics, Legacy Community Health and AIDS Foundation Houston. The institutional review board at UTHealth, The Center for Protection of Human Subjects, approved the study protocol (HSC-MS-16-0892). Study materials include the screening REDCap database, informed consent, recruitment, intervention, and English-only electronic assessment forms developed using Qualtrics software. Trained research staff explain the study and reviews the consent form with the participants who then provide written consent. The trial is registered at Clinicaltrials.gov (NCT03930654).

2.1. Study design

The major objective of this 6-month RCT is to evaluate whether the iPrEP intervention coupled with a referral to a local PrEP clinic, relative to usual care, can increase willingness for PrEP uptake enough to prompt behavior change, specifically attendance to an initial PrEP clinic visit among cisgender Black women. Baseline and post intervention data are collected during a single ED visit, with follow-up at 1-, 3-, and 6 months. The primary endpoints, to increase willingness for PrEP uptake and/or stimulate a PrEP clinic visit, are collected at the 6-month time point.

2.2. Study location and participants

The study is recruiting participants during wait times of an ED visit at two participating hospitals, Lyndon B. Johnson Hospital (LBJ) and Memorial Hermann Health System (MHH). Both hospitals are located in Houston, Texas. LBJ is a public hospital and is the state's busiest level 3 trauma center with more than 80,000 unique ED visits annually [21]. MHH is a private, not-for-profit, tertiary care center and has an annual ED census of approximately 75,000 patients per year.

The following study eligibility criteria are used to enroll Black women (N = 40) seeking care in the two EDs: a. current HIV negative status (based on the HIV test outcome in the ED and/or self-report); b) acknowledges condomless sex in the last 3 months; c) acknowledges substance use in the last 3 months; d) does not decline an HIV test during the ED visit; e) age 18–55 years; d) has a low-acuity health condition; e) has a working mobile device with them, and f) able to read and understand English sufficiently to provide informed consent and participate in all study procedures. *Exclusion criteria* include: a) ineligible for PrEP (based on established CDC criteria [22,23]); b) assigned male at birth; c) self-report or evidence of an HIV positive status in the electronic medical record (EMR); d) currently taking medication with known contraindications for PrEP (brand name: Truvada); or e) currently on PrEP. We followed CDC-guidelines to confirm PrEP-eligibility [22,23]. Patient eligibility is confirmed through the EMR and in-person screening by trained researchers. Individuals who are not offered an HIV test during an ED visit, but were of negative status from a previous test, were enrolled. PrEP eligibility requires an HIV negative status.

2.3. Study participant recruitment methods

Using a conservative estimate of recruiting two participants a week, Monday - Friday, the recruitment aspect of this study is estimated to last approximately five months. We established the feasibility of obtaining a sufficient sample of cisgender Black women with this recruitment approach from the ED [24–28] in prior studies; we achieved 100% of our planned accrual of cisgender women at both EDs. Thus, we estimate that recruitment of 40 cisgender Black women over a 12-month recruitment period is feasible.

Study participation in behavioral research is an established part of the ED visit during wait times at both hospitals, which are often over 1 h at private hospitals and exceed 3 h at public hospitals [29–31]. Study activities take place between assessments by healthcare providers in order to prevent interruption of care. During recruitment, we enter the patient's room and verify their name, then explain to them why we are there, describe the study, and ask if they would like to learn more about research participation. When individuals decline, we inquire about the reason for the decision and record it on our screening log. When individuals agree to learn more, we explain the informed consent document while prompting them to ask questions as needed. We explain study objectives and procedures. Once we have reviewed the consent document, we ask if they are willing to take part in the study. When a verbal yes is provided, we sign the consent form as the researcher and then share it with the participant to sign. Enrolled participants are then assigned a unique three-digit study identification (ID) number. The study number will be the only information linking the participant to study data. The research process begins after a study ID is assigned.

2.4. Study participant screening methods

The EMR at LBJ and MHH are used by trained researchers to identify patients with potential for eligibility. A screening database using REDCap software [32,33] was built with the inclusion criteria. Research team members log into the EMR using credentialed view only access to screen for potential participants in the ED. When patients meet the eligibility criteria based on race, level of acuity, age, and social history, the patient's location is identified and researchers on-site approach the patient and recruit them.

Upon arrival, researchers verify the identity of patients with their name. Once verified, researchers introduce and describe the UT HIV Education, Awareness, Referral and Treatment for Substance Use Disorders (UT-HEARTS) program, a social service program that provides HIV prevention and substance use disorders treatment to ethnic minority individuals who acknowledge current substance use and are also at-risk for HIV through condomless sex. Researchers offer the patient a referral. Questions within the referral survey in Qualtrics software provides eligibility information for the iPrEP study through inquiries about sexual activity and substance use, which helps to discern study eligibility.

If deemed ineligible, the encounter ends. If deemed potentially eligible, the referral is made and researchers share a summary about the study, and asks for permission to complete an in-person eligibility screening. The eligibility screening database is accessed on a tablet device using REDCap software [32,33].

2.5. Process of assigning participants to a study arm

Once deemed eligible, the consent process, takes place followed by randomization into a study arm. Randomized assignments increase chances of obtaining groups that are comparable on salient baseline variables, even with a relatively small sample size. The randomize button, linked to a pre-loaded randomization schema prepared by the statistician, is selected. While there is only one intervention session for participants randomized to the experimental arm, all other study procedures (Table 1) are uniform across both study arms over the 6-month period. Once randomized, study procedures begin. Enrolled participants complete a pre-test (see Table 1) on a tablet device.

2.6. Conceptual overview of the study intervention

The experimental intervention, iPrEP, is based on an adaptation of the HPTN 073 study (described in section 1) [20]. The theoretical framework of the adapted intervention was rooted in the Theory of Gender and Power and the Sexual Script Theory with efforts to create connection to the content and produce a culturally-competent and tailored intervention for cisgender Black women.

The team adapted the content and format of the HPTN 073 baseline instrument by integrating both an innovative intervention approach and a novel delivery platform using a tablet device. Intervention elements targeted increased awareness of sexual and substance use behaviors that places individuals at risk for acquiring HIV and promoted enrollment in PrEP programs among cisgender Black women seeking care in the ED [20]. iPrEP integrates brief, informational messages within a traditional survey to indirectly raise awareness of sexual risk behaviors and increase willingness for PrEP uptake. iPrEP increases knowledge through standard educational information about PrEP protocols, benefits, and side effects. This intervention aims to increase willingness for PrEP uptake among Black women seeking healthcare in an ED. iPrEP is grounded in behavioral willingness [34–36], a potentially stronger predictor of behavior than intentions or implicit attitudes [37]. Increasing willingness of cisgender Black women to take PrEP would theoretically increase the chances of follow-up at a PrEP clinic after referral.

The primary focus of the iPrEP intervention is to increase willingness for PrEP and stimulate a PrEP clinic visit. As part of the intervention, participants learn about PrEP through standard educational information about PrEP protocols, benefits, and side effects. When we pair a referral to a PrEP clinic visit following the iPrEP intervention, an intervention that is theoretically rooted in behavioral willingness, we tangibly link the feeling of willingness with an action (i.e. PrEP clinic visit), supported by resources designed to address traditional barriers (i.e. transportation, communication with agencies) to mobilize that action.

Table 1
Detailed Description of Procedures in the RCT comparing iPrEP to Usual Care.

Procedures	Details
UT-HEARTS referral	• Prior to enrollment, individuals are screened in-person and are offered a referral to the UT-HEARTS program. Questions assessing eligibility for the study are imbedded within the screening form. • Women who accepted the referral were contacted by a UT-HEARTS coordinator following the initial study visit.

Pre-test	• The pre-test assesses:
	  • Socio-demographics (age, education level, sexual orientation, income level, and employment status)
	  • Behaviors (sexual activity and substance use) – based on the risk assessment battery (RAB)
	  • Predictive data (risk perception and willingness for PrEP uptake)
	• Study data includes phone numbers, physical and email addresses for follow-up

RCT assignment	Intervention Group:
	• Women will receive the iPrEP intervention on a tablet device
	• iPrEP uses qualitative themes
	• iPrEP is divided into sections addressing factors with historical success at increasing PrEP adherence [42]
	• Scales chosen to measure themes and sections are retained from the original HPTN 073 instrument
	• Scales are modified (in some cases) for cultural competency and tailoring to women
	Control Group:
	• Women will receive usual care
	  • An assessment visit with an ED-assigned social worker who specializes in substance use
	  • Social worker will offer a list of substance abuse treatment referral agencies, but no intervention
	  • Study procedures will not interfere with the protocol for social workers

Post-test	• Women who are randomized will complete a post-test after the RCT. • The post-test will assess predictive data in two areas risk perception and willingness for PrEP uptake.
Outcomes	Primary: • Increased willingness for PrEP uptake post intervention and at follow-up assessments (1, 3, and 6 months). • Stimulate an initial PrEP clinic visit within a 6-month period. Secondary: • Decrease high risk sex 6-months post intervention measured by TLFB [38,39], RAB [35–37] • Decrease in substance use [43–47] measured by TLFB, and self-report • STI outcome, confirmed via EMR and/or self-report [48,49] • HIV seroconversion within 6 months, confirmed via self-report • Perception of whether the intervention informed decision making (Yes/No format)

2.7. Intervention fidelity and quality assurance

Intervention fidelity and quality assurance in both study arms are maintained through monthly trainings, weekly monitoring for protocol deviations, and a daily checklist at enrollment to provide continuity with RCT delivery. We engage in weekly staff meetings to review progress, and consult with our institutional review board as needed and on an annual basis with continuing reviews. As enrollments take place in real-time across two sites, we engage in a text-message based software using a healthcare collaboration platform (TigerConnect) to ensure chronology of study ID number assignments and real-time communication among staff members.

2.8. Study participant retention methods

Study retention methods include the "warm hand-off" from the ED to: 1) the UT-HEARTS program, 2) our partners at local PrEP clinics, and 3) follow-up appointments to keep participants engaged in the research and offer multiple opportunities for linkage to local PrEP clinics.

Upon completion of the post-test, study participants are referred to a partnering local PrEP clinic. To maximize chances of a secure linkage, each participant receives a referral card including their assigned PrEP clinic's names, addresses, and phone numbers, along with a de-identified, 8-digit referral code. Research staff make the appointment to the PrEP clinic during the ED visit. Each participant is offered roundtrip transportation via an established vendor who transports them from the ED or their personal location to the PrEP clinic within 72 h of the ED visit or hospital discharge. Information during the ED visit are tracked electronically on the tablet device next to the study ID within a Microsoft Excel database housed securely on the university's server.

Our final retention strategy during the ED visit is to require that enrolled participants take a picture of the card with their mobile device. This step serves as a safety net in case the physical referral card is misplaced. While enrolled participants are using their phone to take the picture, the research team member calls their mobile device, in real-time, to confirm it as a reliable communication source.

2.9. Study assessment tools

We measure one of the intervention's primary outcomes by assessing whether the iPrEP intervention increases willingness to take PrEP more than usual care. We use a validated instrument, the Davie's willingness scale [38], which has been used to assess willingness for alcohol use in young adults [38], and tailored it to evaluate willingness to use PrEP at baseline, immediately post-treatment, and at follow-up visits. The Davies' willingness scales used Likert scale-based willingness questions from 1 (unlikely) to 7 (highly likely) [39]. To calculate a total willingness score, the response to two hypothetical scenarios (e.g. *Scenario*: A 25 year old woman willingly engages in condomless sex with her boyfriend of 7 years. One week later, she heard rumors from reliable community members that her boyfriend had sex with a woman who her reliable community member suspects is HIV positive. *Question*: If you were this woman, how likely would you be willing to take PrEP?), and all items are summed such that higher scores indicate greater willingness to take PrEP [39].

Secondary measures are comprised of components used in the Davie's willingness scale [38], a validated instrument. Validated assessment tools to measure secondary study outcomes include *Risk Assessment Battery* (RAB) score [40–42] and *TimeLine Follow-Back* (TLFB) [43,44] to measure the frequency and persistence of high risk sex and substance use. Assessment objectives are to: 1) screen for eligibility and 2) evaluate intervention outcomes.

The RAB is a survey that is often used with substance-using populations and is delivered repeatedly over the study period. This is a brief assessment of risk behaviors associated with HIV, and provides scores for substance use and sexual risk. RAB is scored by adding values to create a total score of combined drug and sex risk that is then divided by 40 (highest possible score). Scores range from 0 to 3 (highest value is 3). The findings of the sub-scales can be combined to yield a measure of total HIV risk. This assessment generally requires 15 min for completion.

In addition to the RAB, we are utilizing the TLFB, the most reliable and valid follow-up method in clinical research for assessing prior substance use [43,45], to quantitatively measure changes in substance use and sexual behaviors over 6-months. TLFB uses a retrospective structured interview with a continuous evaluation of substance use. A revision of TLFB for assessing sexual activity and condom use was tested and refined in several CDC and NIH funded studies to reduce unprotected sex and substance abuse (i.e. Project Choices) [43,45] and is used in this pilot study. This measure is used to retrospectively estimate and quantify substance use between a seven day and two-year period prior to the interview date. For the purpose of this pilot study, we are using TLFB at each follow-up call to measure substance use between baseline and 1-month; 1–3 months, and 3–6 months. This will allow us to measure changes in substance use and sexual behavioral practices throughout the follow-up period at the individual-level and across the study population. The TLFB can also be used as a motivational advice feedback tool to increase the motivation to change among participants. This tool is used in this pilot study to motivate participants to schedule and attend an initial or follow-up visit to the assigned local PrEP clinic [44,46].

2.10. Assessment: primary outcome measures

The primary study outcomes are to increase willingness for PrEP uptake and stimulate a PrEP clinic visit after the intervention and across follow-up assessments. As behavioral willingness [34–36] is a potentially strong predictor of behavior when compared to intentions or implicit attitudes [37], the intervention aims to increase willingness and includes an actionable referral to a local PrEP clinic for an initial visit. For all participants, attendance to a PrEP clinic visit is assessed at one, three, and six months. The 6-month follow-up assessment is used to evaluate potential for long-term sustainability of PrEP use and adherence. We aim to provide further validation or challenge the notion that the iPrEP intervention increases willingness of cisgender Black women, who acknowledge both condomless sex and substance use, to take PrEP [20]. Findings will allow us to assess whether an increase in willingness to take PrEP translates to a PrEP clinic visit and/or PrEP uptake within six months.

2.11. Secondary outcome measures

2.11.1. Changes of behaviors after the iPrEP intervention

Heterosexual sexual behaviors that place individuals at risk for acquiring HIV as a secondary outcome of interest includes reports of condomless sex, transactional sex in exchange for money and/or substances, and sex with multiple partners [40–42]. This secondary outcome was measured using the RAB and TLFB.

2.11.2. Changes in reports of a sexually transmitted infection (STI)

Participants are asked about whether or not they had a recent STI diagnosis at each study visit. Self-reported STI status are verified with the EMR within two local hospital systems for enrolled participants by trained research staff. This information was tracked over time to discern changes. This metric is an indicator of sexual risk and may correlate with the consistency of practicing condomless sex.

2.11.3. Changes in HIV status

A negative HIV status at baseline is compared to a self-reported HIV status at each study visit, confirmed with HIV tests results within EMR within two local hospital systems and at local PrEP clinics among participants who attended the study visit. This metric discerns whether enrolled participants contracted HIV during the study period or whether they maintained a negative HIV status.

2.11.4. Perceived utility of the intervention

Participants are asked whether they perceived the information shared during the intervention assisted them in making a more informed decision about utilizing PrEP. The response format here is a yes/no response. This inquiry gauges whether participants perceive either the iPrEP intervention or usual care as providing useful information as it pertains to their decision-making process regarding PrEP uptake.

2.11.5. PrEP uptake and adherence

Researchers will inquire about whether a PrEP prescription was received or filled with both participating PrEP clinics. Participants are also asked to self-report PrEP uptake. These inquiries are made uniformly, as we are aware that enrolled women could have ascertained PrEP from a healthcare provider outside of the referred PrEP clinic.

2.12. Warm hand-off process

In section 2.8, the details of the warm hand-off are described. The initial warm hand-off from the ED visit to the PrEP clinic is supported by continued motivational interviewing techniques by the trained researcher responsible for leading study visits during the follow-up period, which is integrated in the RAB and TLFB tool, to motivate an initial PrEP clinic visit among PrEP-eligible enrolled participants. This process affords three new opportunities to link enrolled participants to the initial PrEP clinic visit and/or follow-up clinic visits after the initial clinic visit during the 6-month follow-up period that are beyond the baseline visit.

2.13. Data analysis plan

An estimated sample size for two-sample comparison of proportions using a null hypothesis of $p1 = p2$, where p1 is the intervention group and p2 is the usual care group, with an alpha of 0.05, and a power of .80, $n = 20$ in each group will accomplish a PrEP willingness of 65% in the intervention group (based on the acceptance of PrEP in the development study) and 18% among the usual care group [47]. The calculations are

valid to measure PrEP acceptance but are not adjusted for attrition or loss to follow-up.

2.13.1. Bayesian statistical methods

Bayesian statistical inference provides a principled approach [48–50] to assess the two research aims [51–57]. Bayesian analyses estimate the probability of the alternative hypothesis given the observed data, and are accessible even with a small sample size of 40 with 20 in each arm [51–62, 65–66, 68, 71–72, 74]. We propose a data analytic strategy that will use generalized linear modeling for continuous, count, dichotomous and time-to-event (dropout) data (Proc GENMOD and Proc MCMC, SAS 9.4; R v.3.5; and Stan, v.2.17) or proportional hazards regression (Proc PHREG; SAS 9.3). Analyses will evaluate willingness to use PrEP (see measurements in Aim 1) and PrEP uptake as a function of the intervention group. Sensitivity analyses will evaluate robustness of analytic conclusions to missing data. Specification of diffuse, neutral priors will reflect the initial uncertainty regarding effect sizes. For all generalized linear models, priors for coefficients will be specified as $\sim$ Normal ($\mu = 0$, $\sigma^2 = 1 \times 10^6$), level one error variances will be specified as $\sim$ Folded T-Distribution ($df = 3$, $\mu = 0$, $\sigma^2 = 100$). Evaluation of posterior distributions will permit statements regarding the probability that effects of varying magnitudes exist, given the data. We stipulate that an intervention effect that has at least a 75% probability of increasing the odds ratio of attending a PrEP clinic visit by > 1.25 will warrant further investigation in a larger trial.

2.14. Analysis of the primary outcome and secondary outcomes

We will conduct a final evaluation to determine how well the project achieved goals and objectives. We will compare validity of self-reported data to PrEP clinic data. Assessments will measure whether the outcomes obtained aligned with project aims. The study will gather data necessary to determine effect size estimates, and data on intervention acceptability and feasibility for a future efficacy trial.

3. Results

Participant study enrollment started on November 13, 2019. A total of 40 participants were enrolled in the trial (iPrEP intervention arm: N = 20; usual care arm: N = 20). To date, study participants range in age from 18 years to 54 years (Mean age [SD] = 33.7 [8.8] years, and 100% are cisgender women. Education levels varied evenly between some high school education and graduate education. Most participants were single (n = 25) or married (n = 7). Twenty-two participants were employed full-time. The highest enrollment yield (48.9%) came from the private hospital and the majority of the enrolled participants were handed-off to the AIDS Foundation Houston PrEP clinic (55.6%).

4. Discussion

To our knowledge, the iPrEP trial is the first RCT of a behavioral intervention aiming to increase PrEP uptake with cisgender Black women who use substances. This pilot trial presents the HIV prevention field with an opportunity to expand the impact of individual-level interventions and better integrate preventive care in sexual health within the clinical care cascade of healthcare systems that traditionally offer treatment and care only. Engaging PrEP-eligible cisgender Black women who are seeking primary care services in the ED, into prevention care cascades that offer efficacious services to preserve their sexual and reproductive health is necessary. Mobilizing novel intervention approaches to extend PrEP access and promote PrEP uptake within clinical settings that do not routinely offer sexual health opportunities is an engagement strategy with potential to actualize a meaningful decrease in new HIV cases at the population level. The teachable moment of an ED visit can go beyond the fear of life preservation; it can positively shift perspectives to sustain and maintain a good and healthy quality of life that includes sexual and reproductive health. In order to make meaningful strides towards ending the HIV epidemic and permeate populations that experience the highest new HIV cases, interventionists must: 1) identify pathways to connect with HIV-vulnerable populations in a way that doesn't further stigmatize or marginalize them, 2) approach conversations about sexual health and PrEP with privacy and discretion, and 3) mobilize effective strategies at moving individuals along the spectrum of decision making towards behavior change. The iPrEP intervention considers all three and has potential to move cisgender Black women towards readiness and willingness for PrEP and serve as a bridge to community resources whether they can take action (i.e. PrEP uptake) through a warm hand-off protocol. The warm hand-off process highlights a pathway to broaden the scope of referrals for treatment and care to include referrals to treatment as prevention. Future research can assess the cost of this strategy versus the cost of treatment and care when preventable conditions are diagnosed versus when prevention options are not provided prior to a diagnosis.

5. Conclusion

The ED is the only clinical setting that serves as a health care safety-net to this population [58]. The iPrEP trial amplifies the health impact of an ED visit for cisgender Black women by including an HIV prevention intervention with a link to an effective HIV prevention service. During each ED visit, there is an opportunity to: a) engage this at-risk population in HIV prevention interventions, and b) offer a pre-HIV intervention and referrals to HIV prevention services. Leveraging the ED as an access point to HIV prevention, specifically PrEP, is key to reach a transient population of Black women with significant HIV risks who otherwise would not receive HIV prevention services.

Authors' contributions

MH: Developed the study investigation and design, obtained funding to support the research, provided general study oversight, including study methods development and implementation, contributed to analysis and interpretation of results, and took the lead in writing the manuscript. **AH**: Contributed to study methods development and implementation, data management and interpretation of results, edited the manuscript and approved the final version of the manuscript, **CG**: Developed the statistical design, randomizations schema, and data analysis plan; data management, statistical analysis and interpretation, and approved the final manuscript.**RS**: Data management, statistical analysis and interpretation, and approved the final manuscript.**AS**: Contributed to study methods development and implementation, data management and interpretation of results, edited the manuscript and approved the final version of the manuscript.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: This investigation is supported by Gilead Sciences, Inc. (IN-US-276-5464, PI: Hill) from an Investigator Sponsored Research award awarded to Dr. Hill. The above funding source had no involvement in the described research, including research development, execution, analysis, interpretation of results, and write-up and submission of this paper's content and results

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