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Authors

Biello, Katie

Chan, Philip

Holcomb, Richard

et al.

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PrEPare for Work: A Pilot Randomized Controlled Trial of an Intervention to Optimize HIV PrEP Outcomes Among Male Sex Workers

Katie B. Biello[1,2,3,4,14], **Philip A. Chan**[1,5,6,7], **Richard Holcomb**[8], **Colleen Daley Ndoye**[8], **Pablo K. Valente**[1,9], **Michaela Maynard**[5,6], **Monica Gandhi**[10], **Kenneth H. Mayer**[4], **Matthew J. Mimiaga**[4,11,12,13]

[1]Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence, RI, USA

[2]Department of Epidemiology, Brown University School of Public Health, Providence, RI, USA

[3]Center for Health Promotion and Health Equity, Brown University School of Public Health, Providence, RI, USA

[4]The Fenway Institute, Fenway Health, Boston, MA, USA

[5]Department of Medicine, Brown University, Providence, RI, USA

[6]Open Door Health, Rhode Island Public Health Institute, Providence, RI, USA

[7]Rhode Island Department of Health, Providence, RI, USA

[8]Project Weber/RENEW, Providence, RI, USA

[9]Department of Allied Health Sciences, University of Connecticut, Waterbury, CT, USA

[10]Division of HIV, Infectious Diseases, and Global Medicine, Department of Medicine, University of California, San Francisco (UCSF), CA, USA

[11]Department of Epidemiology, Fielding School of Public Health, University of California, Los Angeles, CA, USA

[12]Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, University of California, Los Angeles, CA, USA

[13]UCLA Center for LGBTQ Advocacy, Research, and Health (C-LARAH), Los Angeles, CA, USA

✉Katie B. Biello, katie_biello@brown.edu.

Authors' Contributions RH, CDN and MM performed the research. KBB, PAC, MJM and KHM designed the research study. KBB, PKV, MG analyzed the data. KBB and PKV drafted the initial paper. All authors gave substantive input on and approved the final manuscript.

Code Availability Code may be made available upon request to the corresponding author.

Conflict of Interest KBB received unrestricted research grants from Merck. KHM received unrestricted research grants from Gilead, Merck; on the Scientific Advisory Board: Gilead, Merck,. The authors report no other conflict of interests.

Ethical approval The study procedures were reviewed and approved by the Lifespan Hospital (IRB) as a single IRB-of-Record. IRB authorization agreements with all participating research entities were enacted.

Consent to participate All participants completed an informed consent process and provided documentation of informed consent.

Registration Clinicaltrials.gov NCT03086057.

[14]121 South Main Street, Providence, RI 02912, USA

Abstract

HIV pre-exposure prophylaxis (PrEP) use is limited among male sex workers, who are at exceptionally high-risk for HIV infection. We developed a theory-informed, two-pronged intervention ("PrEPare-for-Work") to optimize PrEP initiation and adherence among male sex workers, which was preliminarily evaluated in a two-stage pilot randomized controlled trial of 110 male sex workers in the US Northeast. Individuals randomized to the Stage 1 PrEPare-for-Work Case Management arm were three times as likely as those in the standard of care (SOC) arm to initiate PrEP (RR = 2.95, 95% CI = 1.57–5.57). Participants who initiated PrEP and were randomized to the Stage 2 PrEPare-for-Work Adherence Counseling arm had higher rates of prevention-effective adherence (measured via tenofovir in hair) compared to those in the SOC arm (RR = 1.7, 95% CI 0.64–4.77; 55.6% vs. 28.6%, respectively); though not statistically significant. Given the need and the promise of this pilot RCT, further efficacy testing is warranted and should be prioritized.

Resumen

El uso de la profilaxis prexposición (PrEP) para prevenir la adquisición del VIH es limitado entre trabajadores sexuales masculinos, que están en muy alto riesgo de contraerlo. Desarrollamos una intervención de dos partes basada en la teoría para optimizar el inicio y la observancia del tratamiento de la PrEP entre trabajadores sexuales masculinos, que se evaluó preliminarmente en un ensayo piloto controlado y aleatorizado (ECA) de dos fases de 110 trabajadores sexuales masculinos en el noreste de Estados Unidos. Las personas aleatorizadas al grupo de intervención (la primera fase de nuestro programa "PrEPare for Work" – la atención individualizada) eran tres veces más probable que las aleatorizadas al grupo control (la norma de atención) a iniciar la PrEP (RR = 2.95, 95% IC = 1.57–5.57). Los participantes que iniciaron la PrEP y se aleatorizaron al grupo de intervención (la segunda fase de "PrEPare for Work" – la terapia para aumentar la adherencia al tratamiento) tenían tasas más altas de adherencia al tratamiento (medido por tenofovir en el cabello) que los aleatorizados al grupo control (RR = 1.7, 95% IC 0.64–4.77; 55.6% vs. 28.6%, respectivamente); aunque la diferencia no fue estadísticamente significativa. En vista de la necesidad y el potencial de este ECA piloto, más pruebas de eficacia son necesarias y deben ser priorizadas.

Keywords

Male sex work; HIV; PrEP; Randomized controlled trial

Introduction

Male sex workers, or cisgender men who exchange sex with other men for money, goods, drugs, or other items of value, are at exceptionally high risk for HIV infection, with nearly 25 times the risk of HIV compared to men in the general population in the United States (U.S.) [1]. Compared to men who have sex with men (MSM) who do not engage in sex work, male sex workers have been shown to have both increased HIV prevalence [1] and

incidence [2, 3]; a meta-analysis found a staggering HIV prevalence of 20% among men who have ever engaged in transactional sex in the U.S. [1] Research shows that male sex workers engage in frequent condomless sex with both paying male clients and non-paying male and female partners [4, 5]. Notably, male sex workers have a high burden of contextual challenges, such as previous incarceration, and psychosocial concerns, including substance addiction, depression, victimization, and discrimination, affecting their ability to secure housing, employment, social services and healthcare [6–11]—all of which potentiate sexual and intravenous drug use HIV risk [8, 9, 11, 12].

Sex work, or transactional sex, among men is common. In national studies of MSM, the prevalence of recent transactional sex is approximately 15–20% [13, 14]. However, despite the frequency of sex work and the documented elevation in HIV risk, to the best of our knowledge, there are no tailored HIV PrEP interventions for male sex workers [15]. Male sex workers represent a diverse population—while some identify as gay, many male sex workers identify as heterosexual or bisexual, and despite primarily exchanging sex with other men, may also have female partners [6, 7, 11, 16]. Moreover, compared to cisgender and transgender women sex workers, male sex workers are less likely to self-identify as “sex workers” [16, 17]. This places male sex workers in a unique position, since traditional HIV prevention programs rarely reach them, and when they are reached, many male sex workers may not be comfortable participating due to heightened medical mistrust and overlapping stigmas [17–19]. Hence, interventions addressing the unique circumstances and needs of this population are required to curb HIV spread.

Pre-exposure prophylaxis (PrEP) is an effective strategy for HIV prevention [20–29], and modeling studies have demonstrated that focused expansion of PrEP use among male sex workers will be an efficient and cost-effective strategy for reducing HIV incidence in the broader population of cisgender MSM [30]. However, PrEP use remains limited, particularly among marginalized and stigmatized populations [31–36]. Many of the same factors that put male sex workers at increased risk of HIV also act as barriers to PrEP use, including lack of perceived HIV risk, low awareness and knowledge about PrEP, medical mistrust, complex health systems, inconsistent routines, homelessness, substance use patterns, fluctuating periods of sexual risk, and HIV-related stigma from their sex work clients [19, 37–40]. Increasing PrEP use among male sex workers will require interventions that address these structural, interpersonal and individual level challenges [30, 40–42].

The current paper describes the feasibility and preliminary efficacy of an initial pilot randomized controlled trial of a PrEP uptake and adherence intervention for male sex workers in the U.S.

Methods

Design

This study was a two-stage, two-arm, pilot randomized controlled trial conducted in Providence, Rhode Island—a major center of male sex work in the United States. Participants were enrolled between May 2017 and July 2019, with final follow-up in January 2020. In Stage 1, enrolled participants were equally randomized to either 1a) PrEPare for

Work for initiation—a Strengths-based Case Management intervention with a lay-level case manager or 1b) a standard of care (SOC) condition. In Stage 2, those who initiated PrEP in Stage 1 (regardless of treatment arm) were randomized to either 2a) PrEPare for Work for adherence—a SCT-informed technology and adherence counseling intervention with a Masters level social worker or 2b) a SOC condition. See Fig. 1 for the study design.

Recruitment

In partnership with a community agency that provides harm reduction services to male sex workers, participants were recruited in physical (e.g., community-based organizations, streets, bars, and other venues where male sex workers solicit clients) and virtual (e.g., Craigslist, male escort websites) venues.

Inclusion/Exclusion Criteria

Eligible participants were cisgender men, 18 years of age or older, self-reported being HIV-negative, exchanged sex for money or drugs with another man in Rhode Island in the past 3 months, reported at least one episode of condomless sex with a HIV-positive or status unknown partner in the past 3 months, were not taking PrEP at enrollment, and expressed interest in learning about PrEP as an HIV prevention tool. Participants also had to be able to understand study procedures and provide informed consent and to understand and speak English. Participants were excluded if they could not provide informed consent due to psychiatric or cognitive concerns.

Procedures

Participants completed a pre-screening questionnaire either online or in person. Potentially eligible individuals were invited to take part in a screening visit where eligibility was ultimately determined, and informed consent was conducted. All enrolled participants then completed a baseline assessment. Prior to Stage 1 randomization, all participants received SOC (see below). Participants were then equally randomized to either the Stage 1 “PrEPare for Work” strengths-based case management intervention, or to the SOC condition. In brief, for Stage 1, the PrEPare for Work intervention consisted of one structured visit with flexible and as-needed case management support over the course of the following two months (or until PrEP was initiated). All participants were tracked, using medical record release, for PrEP initiation. A follow-up visit was completed at one- and two-month post-baseline, or at PrEP initiation (whichever occurred first). Those who did not initiate PrEP were discontinued from the study. Those who initiated PrEP, in either Stage 1 condition, were then equally randomized to either the Stage 2 “PrEPare for Work” adherence counseling intervention or to the SOC condition. Participants randomized to the “PrEPare for Work” adherence counseling intervention were scheduled for three weekly counseling sessions. All participants had follow-up assessments at three and six months after Stage 2 randomization. Small samples of hair were collected at each follow-up visit for the measurement of tenofovir levels using validated methods in the Hair Analytical Laboratory at the University of California, San Francisco (UCSF) [43]. Further details are described below.

Participants were compensated for their time according to the following schedule: $30 at each survey visit; $15 for one Stage 1 PrEPare for Work Strengths-based Case Management

session; $15 for each of the Stage 2 PrEPare for Work Adherence Counseling intervention sessions attended.

The study procedures were reviewed and approved by IRB at the academic medical center, Lifespan. IRB authorization agreements with all participating research entities were enacted. The PrEPare for Work protocol is registered at ClinicalTrials.gov (NCT03086057).

Randomization

Randomization at both stages was done by the project director with a 1:1 allocation and was assigned in order of enrollment. Given that this was a behavioral intervention, the participants were not blinded to the intervention assignment.

Interventions

The intervention was informed by extensive formative research, and addresses both PrEP uptake and adherence.

Stage 1: PrEP Linkage and Uptake

Standard of Care Condition: For Stage 1, the SOC condition consisted of provision of a pamphlet about PrEP (what it is, how it works, its efficacy), a local resource list (e.g., mental health, substance use, housing), and a referral card to a local PrEP clinic. Given that PrEP was not provided as part of the study, regardless of study condition, participants were prescribed PrEP following the protocols and recommendations of the prescribing clinicians. This was done to increase the real-world applicability of the study and promote sustainability of PrEP services after the study.

"PrEPare for Work" Strengths-Based Case Management Condition: Participants randomized into the strengths-based case management intervention arm were provided a highly trained bachelors-level, non-clinician study case manager to motivate, support, facilitate, and assist in linkage to a local PrEP clinic and to facilitate initiation and obtaining of PrEP medications. The case manager used motivational interviewing (MI) techniques (e.g., focusing on values, strengths and change efforts, asking open-ended questions, making reflective and empathetic statements) and provided culturally appropriate facilitated case management services to improve PrEP linkage and uptake. These services included: (1) providing information about PrEP and how to obtain PrEP, (2) assessing and helping to overcome barriers to PrEP (e.g., e.g., healthcare avoidance due to stigma, psychosocial barriers, insurance barriers, costly co-pays), (3) assisting participants in obtaining health insurance and/or overcoming barriers to co-pay, (4) assisting with making an appointment at the PrEP clinic, (5) accompanying participants to the PrEP clinic, and (6) follow up with participants to ensure that appointments were kept and prescriptions were filled.

Stage 2: PrEP Adherence

Standard of Care: For Stage 2, the SOC condition included all care and services provided to all patients in the context of standard clinical care where they received PrEP. At the local PrEP clinic where nearly all participants received their PrEP care, routine clinical services included visits with medical providers, bloodwork through the local laboratory

system, appointments made by reception staff, and financial assistance through institutional programs and administrative staff for individuals who qualified (i.e., uninsured with documentation of income). There was no patient or peer navigation, and PrEP clinical services represented those at a "typical" outpatient ambulatory care center. Individuals were referred for other services as needed (i.e., mental health or substance use treatment, or other services as indicated) by local providers.

"PrEPare for Work" Adherence Counseling Condition: Informed by Social Cognitive Theory (SCT) [44], participants who initiated PrEP and who were randomized to the experimental adherence counseling condition received daily SMS text messaging of personalized reminders to take PrEP as prescribed for up to three months. Messages were sent at pre-selected times each day and were personalized by the participants. Examples of messages included: "Don't forget!" "You love your family!" "Your health comes 1st." Text message reminders served not only as reminder to take PrEP as prescribed, but also as cues regarding behavioral skills gained as a result of in-person adherence counseling sessions.

In addition to the daily text messages, intervention participants attended three one-on-one adherence training and counseling intervention sessions (once per week for 3 weeks) with a Master's level social worker. Each session lasted approximately 45–60 min. Session content was flexible, allowing the sessions to be tailored to each participant's adherence support needs.

The first session included PrEP education and the rationale behind adherence to PrEP, and served as the basis for motivating the participant to taking PrEP consistently. It also included a discussion of the participant's sexual behavior patterns, client relationships, social capital and social roles, particularly in the context of sex work. The session ended with introducing a list ("steps") of potential barriers to PrEP adherence, and identifying which issue may present difficulties for the participant with regards to adherence. These barriers included, but are not limited to: transportation, cost of and obtaining medications, communicating with providers and handling provider stigma, storing and transporting medications, complex and unstable schedules, side effects, substance use and competing health demands, mental health, role of family, friends, partners and clients in PrEP use, and concerns regarding stigma and disclosure.

Sessions 2 and 3 both began with adherence check-ins, re-visiting of the "steps" and engaging in problem solving to address any barriers to adherence experienced in the past week. In addition, the counselor introduced common coping and destressing techniques, and helped participants to create and implement reminder strategies for PrEP, such as programming a reminder on a cell phone alarm or tying PrEP-taking with another daily activity (e.g., breakfast, tooth-brushing). Finally, the counselor discussed future PrEP adherence goals and helped the participant plan for continued PrEP use upon intervention completion.

Assessments—As previously described, assessments were done at Stage 1 baseline (pre-randomization) and at 1- and 2- months post-randomization. For participants who initiated PrEP, a Stage 2 baseline was completed in lieu of the Stage 1 follow-up (immediately

following PrEP initiation), and prior to Stage 2 randomization. Two additional follow-up assessments were then conducted at 3- and 6-month post-randomization. The assessments were interviewer-administered, with the exception of sensitive questions (e.g., substance use, sexual behaviors), which were self-administered to reduce social desirability bias.

Sample Characteristics: During the baseline visit, participants' age, race/ethnicity, sexual orientation, educational attainment and income were collected. Additionally, participants reported the number of years they had been engaged in sex work and recent sexual behaviors (i.e., number of clients, condomless anal sex). Participants also reported both alcohol and non-alcohol substance abuse or dependence [45].

Stage 1 Primary Outcomes: Linkage to PrEP care was assessed via medical record review and was defined as documented EMR attendance of at least one PrEP appointment. Receipt of a PrEP prescription was also assessed via medical record review and was defined as having been prescribed PrEP by a clinician. PrEP initiation was assessed by visual inspection of a PrEP pill bottle by study staff (only one formulation, and no generics, were available in the U.S. at the time of this study).

Stage 2 Primary Outcome: The primary outcome was prevention-effective adherence, and was based on pharmacologic monitoring in hair samples, which measured past-month tenofovir (TFV) drug levels at the 3- and 6-month follow-up visits. Approximately, 50–100 strands of hair were cut to 1–2 mm length segments, and sent to the UCSF Hair Analytical Laboratory for analysis [46]. Evidence demonstrates that TFV concentration in hair of 0.023 ng/mg is protective (i.e., equivalent to 4 + doses per week), which we then defined as the threshold to adjudicate prevention-effective adherence [46, 47]. Because of missing hair samples (see Results), we conducted sensitivity analyses where we created a composite measure of PrEP adherence that imputed missing hair sample data with self-reported adherence at each visit. Specifically, we asked participants to report the number of missed doses in the past 30 days. For those without a valid hair sample, 0 missed doses were coded as achieving prevention effective adherence and 1 or more missed doses was coded as sub-optimally adherent.

This cut-off was used because of tendency for participants to over-report their adherence due to social desirably bias,[48] and is thus a conservative estimate.

Sample Size

As a pilot study, the primary emphasis was on feasibility and acceptability of the intervention, as well as to examine preliminary efficacy to prepare for a full-scale trial, as such we did not assume that we would have statistical power. However, we did a priori estimate that there would be a 30-percentage point difference in PrEP initiation across the two Stage 1 conditions (e.g., if 20% of the comparison arm and 50% of the intervention arm initiated PrEP) and a 25-percentage point difference in prevention effective adherence across the two Stage 2 conditions (e.g., if 50% of the comparison arm and 75% of the intervention arm had prevention effective adherence). With these estimates we would need approximately 22 participants per arm in Stage 2 to achieve 80% power with a two-sided, 0.05 alpha level.

Statistical Analysis

Medians for continuous variables and frequencies for categorical variables were calculated to describe sample characteristics at baseline for the overall sample and stratified by study condition. Mann Whitney U test for continuous and chi-square tests for nominal variables were used to examine balance by study condition on key variables.

The primary analyses for Stage 1 compared the differences in the proportion of participants who attended an initial PrEP appointment, received a PrEP prescription and initiated PrEP within 2 months of Stage 1 randomization between the study arms. Frequencies and cross-tabulations with chi-square tests were used to examine differences; risk ratios with 95% confidence intervals (CIs) were calculated.

For Stage 2, the primary analysis compared the proportion of participants that were optimally adherent to PrEP at the 3- and 6-month visits between the study arms. We used generalized estimating equations (GEEs) with robust standard error estimates, and specified a Poisson distribution with log link to estimate relative risks—which is more valid than odds ratios for outcomes that are not rare (e.g., > 10%) [49]. The GEEs allowed for appropriate modeling of covariance structures given the repeated nature of the data (e.g., 3- and 6-month follow-up). All analyses followed intent-to-treat principle. Significance was defined as $p < 0.05$. All analyses were conducted in Stata/SE 17.0.

Results

A total of N = 110 individuals were enrolled and randomized (Fig. 1; Table 1). Among these, 80.1% had a Stage 1 follow-up visit. Of the 35 participants who were randomized in Stage 2, 27 completed 3-month follow-up and 27 completed 6-month follow-up (n = 29, 82.9% with at least one follow-up visit). Reasons for non-completion are described in Fig. 1. Of the 27 who completed the respective assessment visits, an additional 4 and 11 had either missing (i.e., bald, remote visit) or invalid (i.e., insufficient sample provided) hair samples at 3- and 6-month follow-up visits, respectively. Retention rates did not differ significantly by study condition ($p > 0.05$).

Sociodemographics and other behavioral characteristics of the sample are described in Table 2. In brief, the median age of participants was 33 (IQR = 28–39) years. About half were white (55.5%). 44% of participants identified as bisexual, 19.1% as gay and 19.1% as straight. Most participants (59.1%) reported annual income of $6,000 or less. In the past month, participants reported having a median of 5 male playing clients (IQR = 2–10) and having condomless anal sex with male paying clients a median of 2 times (IQR = 0–75). Over two-thirds met criteria for non-alcohol substance abuse or dependence. At baseline, 23.6% felt that they were extremely or very likely to acquire HIV, and 76% were extremely or very likely to initiate PrEP within the next month. These characteristics did not differ by the study conditions.

In Stage 1, of the 55 participants randomized to receive the PrEPare for Work strengths-based case management intervention, 85.5% had at least one visit or phone conversation with the PrEP case manager. In Stage 2, among the 17 participants that were randomized

to the intervention condition, the average overall attendance at the adherence counseling sessions was 74.5%, and 82% attended at least one session. See Table 1 for details.

Stage 1, PrEP Initiation

Based on medical records, as shown in Table 3, participants randomized to PrEPare for Work strengths-based case management were approximately three times as likely as those in the SOC to attend an initial PrEP appointment (RR = 2.23, 95% CI = 1.30–3.82, p = 0.0018), receive a PrEP prescription (RR = 2.50, 95% CI = 1.33–4.70, p = 0.0022), and initiate PrEP (RR = 2.95, 95% CI = 1.57–5.57, p = 0.0002). In sensitivity analysis, if all participants who were lost to follow-up or dropped out were assumed to have not initiated PrEP, the strengths-based case management intervention effect did not change meaningfully and remained significant (RR = 2.89, 95% CI = 1.49–5.59, p = 0.0005).

Stage 2, PrEP Adherence

All 35 participants who initiated PrEP in Stage 1 were re-randomized in Stage 2—and Stage 1 intervention participants were balanced across Stage 2 conditions. As shown in Table 3, using the data from hair samples only, 39% had prevention-effective adherence at 3-month follow-up and 25% at 6-month follow-up. While not statistically significant, adherence in the intervention arm was higher than in the control arm at both 3-month follow-up (55.6% vs. 28.6%, respectively; p = 0.196) and 6-month follow-up (42.9% vs. 11.1%, respectively; p = 0.146). The pattern was similar when examining self-reported adherence in the past 30 days: adherence in the intervention arm was higher than in the control arm at both 3-month follow-up (36.4% vs. 12.5%, respectively; p = 0.143) and 6-month follow-up (36.4% vs. 25.0%, respectively; p = 0.525).

In a repeated-measures GEE model, individuals randomized to receive the PrEPare for Work Adherence Counseling intervention were nearly twice as likely to have prevention-effective adherence (via hair samples) compared to those in the SOC arm (RR = 1.7, 95% CI 0.64–4.77, p = 0.278), though it did not reach statistical significance. In sensitivity analyses, where self-reported adherence (i.e., missing 0 vs. 1 + doses in past 30 days) was used to impute for missing hair sample data, the results were similar (RR = 2.0, 95% CI 0.84–4.67, p = 0.116).

Discussion

Our findings demonstrate the feasibility, acceptability and preliminary efficacy of an intervention to improve PrEP outcomes among male sex workers. Male sex workers, or men who have sex with other men in exchange for money or other resources, an understudied population with diverse sexual practices and patterns. Our prior work has demonstrated that broader use of PrEP among male sex workers would be beneficial at the individual level (i.e., protect male sex workers themselves) and population level (i.e., reduce population incidence via their sexual network partners) [30]. We have also shown that PrEP awareness, knowledge and use among male sex workers is extremely limited [42], but interest is high when they are informed about its existence [40]. However, qualitative research with male sex workers as well as prior experience in other populations acknowledges multiple, complex

barriers to PrEP initiation and ongoing adherence [7, 19, 40, 50]. As a result, we developed the PrEPare for Work intervention to optimize PrEP initiation and adherence among male sex workers which works to address structural, interpersonal and individual level challenges to PrEP use.

Retention rates for both assessments and intervention sessions in our study were acceptable and comparable to or higher than other studies with participants who have high rates of substance use, unstable housing and criminal justice involvement [51, 52]. That said, maintaining contact with participants over six months was challenging and there is room for improvement. We learned a number of lessons that can be applied to future studies. First, in this current study, the research team consisted of academic researchers, clinicians and community outreach workers. This collaborative relationship was essential to our success. Second, it was essential to obtain a broad array of contact information for participants, including organizations/centers that they frequent (e.g., shelters, treatment centers) and at which they would be willing to be contacted or approached for follow-up. Third, when requested we provided low-cost cellphones to enhance retention—future studies should consider budgeting for this for all participants. Relatedly, while participants found provision of hair samples for PrEP adherence testing acceptable—no participant refused to provide a sample—the proportion of useable samples was suboptimal (~ 60% at 6-month follow-up) for a number of reasons, including very short or no head hair and invalid samples due to collection errors. Although testing of PrEP through hair samples reduces bias given that pharmacologic metrics are objective (compared to self-report) and assesses a longer period (compared to dried blood spots, for example),[47] future studies should consider ancillary measures of adherence, including collecting dried blood spots or urine, when hair cannot be validly collected.

Overall, rates of PrEP initiation were high, with nearly 60% of the individuals randomized to receive the Strength-based Case Management-informed PrEPare for Work intervention who initiating PrEP within 2 months—a rate three-fold greater than in the SOC arm. If these results are reproduced in a future fully-powered efficacy trial and the intervention is subsequently scaled up, the PrEPare for Work intervention has the potential to make a meaningful impact on HIV incidence among male sex workers. Moreover, while more resource-intensive than SOC (which was quite limited), the intervention was implemented by nonclinicians with minimal experience in case management; therefore is likely scalable and sustainable even with limited resources and within the community (i.e., outside of clinical settings). Future studies should assess the cost-effectiveness of this intervention, potentially using mathematical modeling to assess the cost per HIV infections averted [53].

The unique two-stage study design that we employed allowed us to simultaneously but distinctly assess the efficacy of a counseling intervention on PrEP adherence as well. Among those who initiated PrEP in Stage 1, we found that participants randomized to the PrEPare for Work counseling intervention had 70% higher adherence over 6-months of follow-up compared to those in SOC—though the effect size did not reach statistical significance. Given that this was a pilot study with a small sample size in Stage 2, we were not powered to test the efficacy. Nevertheless, this effect size is at least comparable to the evidence-based and evidence-informed PrEP interventions currently included in the CDC's Compendium of

Evidence-Based Interventions and Best Practices for HIV Prevention [54]—all of which are among MSM more generally. Given that this was a pilot study, future fully powered trials are needed to determine if these effect sizes are replicable. Future studies should consider ways to further enhance adherence in this population, such as increasing engagement with male sex workers over follow-up or bundling PrEP services with substance use treatment or housing services. Additionally, while re-randomization in Stage 2 resulted in a balance of participants from Stage 1 experimental condition, bias in Stage 2 may have remained given the small sample size. Finally, while the effect size was maintained, or even increased, over follow-up, we only followed participants for 6 months, and as a result, longer term PrEP persistence could not be evaluated. Future studies should aim to follow a cohort of male sex workers for longer to further assess patterns of PrEP usage and adherence over an extended period of time.

Despite the limitations, this is the first study, to our knowledge, to test and demonstrate feasibility and preliminary efficacy of a PrEP uptake and adherence intervention developed specifically to address the needs of male sex workers in the United States. This promising approach will be studied further in a larger trial, with objective adherence metrics used to provide a more robust metric of this outcome. Male sex workers are at exceptionally and disproportionately high risk for HIV infection, and transactional sex among men is common. While PrEP is highly effective and has been available for no or low cost for over a decade, PrEP uptake remains low among male sex workers. Ensuring male sex workers can access PrEP and then have the support to initiate and adhere to it will not only benefit male sex workers but also could reduce HIV incidence in the broader population of MSM. Given the need, the gap and the promise of this initial pilot RCT, further efficacy testing is warranted and should be prioritized.

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Data Availability

De-identified data may be made available upon request to the corresponding author.

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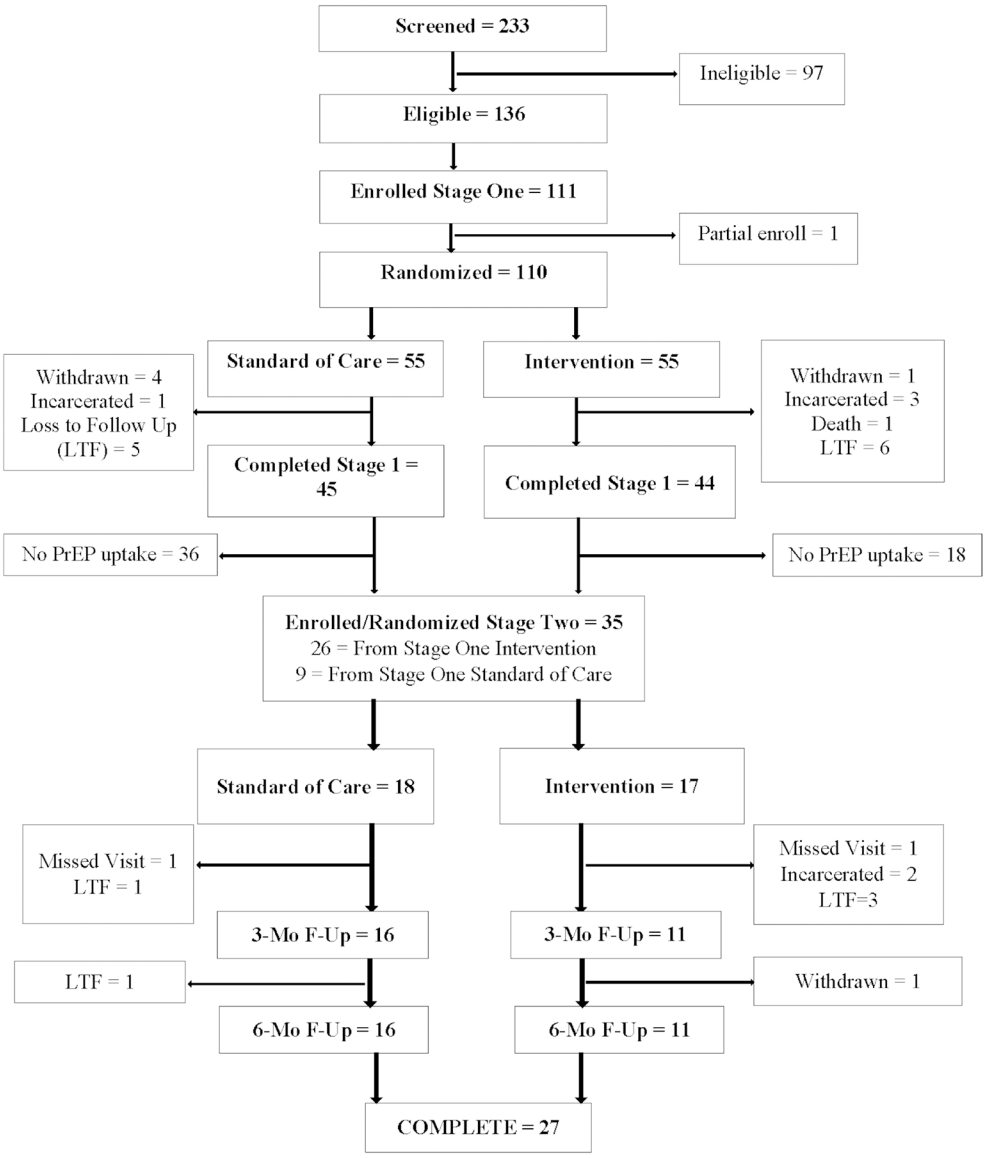

Fig. 1.
CONSORT diagram for a pilot RCT of the PrEPare for Work intervention

Table 1

Retention of Participants for Assessments and Intervention Sessions in a pilot RCT of the PrEPare for Work intervention

	Stage 1			**Stage 2**					
	Follow-up			**3-month follow-up**			**6-month follow-up**		
	Total N = 110	**Intervention n = 55**	**SOC n = 55**	**Total N = 35**	**Intervention n = 17**	**SOC n = 18**	**Total N = 35**	**Intervention n = 17**	**SOC n = 18**
Assessment, N (%)	89 (80.9)	44 (80.0)	45 (81.8)	27 (77.1)	11 (64.7)	16 (88.9)	27 (77.1)	11 (64.7)	16 (88.9)
Hair Sample, N (%)	-	-	-	23 (65.7)	9 (52.9)	14 (77.8)	16 (45.7)	7 (41.2)	9 (50.0)
Intervention	**Stage 1 Intervention Attendance**			**Stage 2 Intervention Attendance**					
Sessions	**N (%)**			**N (%)**					
0 sessions	8 (14.5)			3 (17.6)					
1 session	47 (85.5)			2 (11.8)					
2 sessions	-			0 (0.0)					
3 sessions	-			12 (70.6)					

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Table 2

Characteristics of a sample of male sex workers in the U.S. Northeast, overall and stratified by randomization condition (N = 110)

	Total sample (N = 110)	PrEPare for Work Intervention (n = 55)	Standard of Care Control (n = 55)	P-value
Age, Median (IQR) (range = 20–57 years)	33 (28–39)	34 (29–39)	32 (26–42)	0.862
Years in sex work, Median (IQR) (range = 1 month-43 years)	5 (3–13)	6 (3–15)	5 (3–13)	0.320
Number of male paying clients, past month, Median (IQR) (range = 0–150)	5 (2–10)	4 (2–10)	5 (2–14)	0.746
Number of condomless anal sex acts with male playing clients, past month, Median (IQR) (range: 0–197)	2 (0–75)	2 (0–8)	1 (0–6)	0.256
Race/ethnicity, n (%)				0.363
Non-Latinx white	61 (55.5)	26 (47.3)	35 (63.6)	
Latinx	24 (21.8)	15 (27.3)	9 (16.4)	
Non-Latinx Black	16 (14.5)	9 (16.4)	7 (12.7)	
Multiracial/Other	9 (8.2)	5 (9.1)	4 (7.3)	
Sexual identity, n (%)				0.103
Bisexual	48 (43.6)	26 (47.3)	22 (40.0)	
Gay	21 (19.1)	12 (21.8)	9 (16.4)	
Straight	21 (19.1)	12 (21.8)	9 (16.4)	
Don’t know/Other	20 (18.2)	5 (9.1)	15 (27.3)	
Educational attainment, n (%)				0.330
Less than high school	25 (22.7)	15 (27.3)	10 (18.2)	
High school or GED	39 (35.5)	18 (32.7)	21 (38.2)	
Some college	30 (27.3)	12 (21.8)	18 (32.7)	
College degree or higher	16 (14.5)	10 (18.2)	6 (10.9)	
Annual household income, n (%)				0.339
Less than $6,000	65 (59.1)	34 (61.8)	31 (56.4)	
$6, 000 – $11,999	22 (20.0)	8 (14.5)	14 (25.5)	
$12,000 or higher	23 (20.9)	13 (23.6)	10 (18.2)	
Alcohol Use				0.188
Dependence	37 (33.6)	15 (27.3)	22 (40.0)	
Abuse	18 (16.4)	12 (21.8)	6 (10.9)	
Unproblematic use/no use	55 (50.0)	28 (50.9)	27 (49.1)	

	Total sample (N = 110)	PrEPare for Work Intervention (n = 55)	Standard of Care Control (n = 55)	P-value
Non-Alcohol Substance Use				0.812
Dependence	74 (67.3)	38 (69.1)	36 (65.5)	
Abuse	3 (2.7)	1 (1.8)	2 (3.6)	
Unproblematic use/no use	33 (30.0)	16 (29.1)	17 (30.9)	
Injection Drug Use				
Lifetime	58 (52.7)	31 (56.4)	27 (49.1)	0.445
Past three months	38 (34.5)	20 (36.4)	18 (32.7)	0.688
Incarcerated in past 6 months	28 (25.5)	15 (27.3)	13 (23.6)	0.662
Perceived Likelihood of Acquiring HIV				0.403
Extremely/very likely	26 (23.6)	10 (18.2)	16 (29.1)	
Somewhat likely	45 (40.9)	24 (43.6)	21 (38.2)	
Extremely/very unlikely	39 (35.5)	21 (38.2)	18 (32.7)	
Likelihood to Initiate PrEP				0.566
Extremely/very likely	83 (76.1)	40 (74.1)	43 (78.2)	
Somewhat likely	25 (22.9)	13 (24.1)	12 (21.8)	
Extremely/very unlikely	1 (0.9)	1 (1.9)	0 (0)	

Table 3

Uptake of and adherence to PrEP for participants in a pilot RCT of the PrEPare for Work intervention

	Total sample N (%)	PrEPare for Work N (%)	Standard of Care N (%)	RR (95% CI)
Stage 1				
1a. Attended initial PrEP appointment (n = 110)	42 (38.2)	29 (52.7)	13 (23.6)	2.2 (1.3–3.8)
1b. Received a PrEP prescription (n = 110)	34 (31.8)	25 (45.5)	10 (18.2)	2.5 (1.3–4.7)
1c. Initiated PrEP within 2 months (n = 89)	34 (38.2)	26 (59.1)	9 (20.0)	3.0 (1.7–5.0)
Stage 2				
2a. Prevention-effective adherence *at 3 months (n = 23)	9 (39.0)	5 (55.6)	4 (28.6)	1.9 (0.7–5.4)
2b. Prevention-effective adherence at 6 months (n = 16)	4 (25.0)	3 (42.9)	1 (11.1)	3.9 (0.5–29.5)
2c. Prevention-effective adherence, repeated measures	-	-	-	1.7 (0.6–4.8)

* Defined as having TFV concentration in hair of ≥ 0.023 ng/mg