

PrEP COUNSELING CENTER

Evidence-Informed for PrEP Initiation/Uptake

INTERVENTION DESCRIPTION

Goal of Intervention

- Increase PrEP initiation/uptake

Target Population

- High-risk HIV-negative young black men who have sex with men (YBMSM)

Brief Description

PrEP Counseling Center is an individual-level intervention for HIV-negative, high-risk, young black men who have sex with men (YBMSM) living in Washington, D.C. This culturally tailored counseling intervention consists of one personalized comprehensive PrEP counseling session with a staff member who identifies as a black MSM and has extensive outreach and counseling experience related to HIV prevention and PrEP needs. In addition, intervention participants receive the following PrEP information from a physician assistant using a standardized script that is also provided to control participants: PrEP education (including how PrEP works, indications for starting PrEP, the use, dosing, efficacy, side effects, and compliance of PrEP), acute seroconversion signs and symptoms, list of local PrEP providers, Truvada copay assistant cards, pill case keychains, condoms with lubricant, and sexual risk-reduction counseling. In addition to the above, intervention participants receive help with assessing and addressing perceived barriers to PrEP initiation (e.g., medical concerns, access difficulties, health care insurance navigation, relationship/family problems, bullying/violence prevention, mental health needs, alcohol/substance abuse, housing, clothing and legal needs), as needed. With assistance, participants make an appointment with a PrEP provider, access other community resources as per their needs, and receive appointment reminders. Participants were encouraged to call or text their PrEP counselor for follow-up questions and for support or new referral needs over the study period. Participants also met with a PrEP counselor for a second session to discuss progress toward achieving PrEP-related or other goals that were set at their initial counseling appointment.

Theoretical Basis

- Client-centered care coordination (C4) approach that is based on the Self-Determination Theory of human motivation

Intervention Duration

- Initial counseling session lasting 20 to 45 minutes; second session held three months after first, duration variable

Intervention Setting

- Clinic
- Phone

Deliverer

- Healthcare provider (physician assistant)
- PrEP counselor

Delivery Methods

- Counseling
- Goal setting
- Printed education PrEP materials and list of PrEP providers
- Risk reduction supplies (e.g., condoms with lubricant)
- PrEP-related supplies (e.g., Truvada copay assistance card, pill case keychain)
- Referrals to resources based on needs assessment

Structural Components

- None reported

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Marc Siegel**, 2150 Pennsylvania Avenue, NW, Suite 8-436, Washington, DC, 20037.

Email: msiegel@mfa.gwu.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in metropolitan Washington, D.C. between August 2016 and February 2017.

Key Intervention Effects

- Improved PrEP initiation/uptake

Study Sample

The baseline study sample of 50 YBMSM is characterized by the following:

- *100% black or African American*
- *100% male*
- *Mean age of 21.7 years*

Intervention participants (n = 25) are characterized by the following:

- *72% has health insurance*
- *72% has seen a medical provider in the last year*
- *28% has ever talked to a medical provider about PrEP*
- *52% indicated plans to take PrEP in the next 3 months*
- *38% had condomless anal sex with a male partner of HIV positive or unknown status in the last 3 months*

Control participants (n = 25) are characterized by the following:

- 96% has health insurance
- 100% has seen a medical provider in the last year
- 24% has ever talked to a medical provider about PrEP
- 24% indicated plans to take PrEP in the next 3 months
- 26% had condomless anal sex with a male partner of HIV positive or unknown status in the last 3 months

Recruitment Settings

Social networking smartphone applications (i.e., Jack'd, Grindr, Tinder, and Adam4Adam). Filters were used to target study recruitment language to the desired age, race, and gender of the study participants.

Eligibility Criteria

Young black men who have sex with men were eligible if they were born male, self-identified as male, between the ages of 16 and 25 years old, self-identified as black or African American, reported more than one episode of anal intercourse within his lifetime, tested HIV-negative at screening, and reported no prior PrEP use.

Assignment Method

YBMSM participants (n = 50) were randomized (1:1) to either the PrEP counseling center/intervention group (n = 25) or the PrEP control group (n = 25), following the baseline survey and HIV/STI testing.

Comparison Group

Participants randomized to the PrEP control group (n = 25) received a 10- to 15-minute visit via a standardized script with a health care provider (physician assistant) who provided PrEP education on how PrEP works; indications for starting PrEP; the use, dosing, efficacy, side effects, and compliance of PrEP; HIV risk-reduction counseling; acute seroconversion signs and symptoms; list of local PrEP providers; Truvada copay assistant cards; pill case keychains; and condoms with lubricant. Participants were then asked to make an appointment with a provider to access PrEP. Intervention participants also received these services.

Relevant Outcomes Measured and Follow-up Time

- PrEP initiation/uptake was measured as the number (proportion) of study participants who self-reported taking PrEP within the last three months at the 3-month follow-up visit.

Participant Retention

- PrEP intervention group
 - 100% retained at 3-month follow-up
- PrEP control group
 - 92% retained at 3-month follow-up

Significant Findings on Relevant Outcomes

- A greater proportion of intervention participants reported initiating PrEP in the last 3 months compared to control (6 [24%] vs. 0 [0%]; p = 0.023).

Additional Study Strengths

- PrEP initiation/uptake was assessed within 3 months of starting the intervention.
- Focus on young black or African American MSM

Considerations

Due to sample sizes per arm are < 40 but ≥ 25 , this intervention is considered as an Evidence-Informed Intervention (EI), not an Evidence-Based Intervention (EBI).

Additional significant positive findings on non-relevant outcomes

- A greater proportion of intervention participants talked to a medical provider about PrEP in the last 3 months compared to control participants (11 [85%] vs. 5 [42%]; $p = 0.023$).

Non-significant findings on relevant outcomes

- At the 3-month follow-up, the proportion of participants reporting current PrEP use was greater among intervention participants compared to control participants, but this difference was not significant (4 [16%] vs. 0 [0%]; $p = 0.11$).

Negative findings

- None reported

Other related findings

- Among the intervention participants, the most common need addressed was how to access PrEP, which was discussed with 21 participants, of whom 19 participants had a goal to access and initiate PrEP. Seventeen participants had a referral to a PrEP provider as a result.
- At the time the study started enrolling participants, daily emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) was only approved for those 18 years and older, although the FDA subsequently approved PrEP for adolescents in May 2018. The study authors decided to include persons who were aged 16 and 17 based on 2013 CDC data which revealed that adolescents aged 15-24 in Washington, D.C. had among the highest incidence of sexually transmitted infections (STIs) nationally. Moreover, Washington, D.C. public health law allows minors aged 12-17 to access sexual health services without parental approval and the Washington, D.C. Department of Health was already providing PrEP to adolescents at the time this study was conducted.
- Two participants, one from each study group, tested HIV positive at the 3-month visit. Neither participant was taking PrEP nor recalled any symptoms indicative of an acute retroviral syndrome. Both were referred to care, but it is unknown if they were linked to care.
- Twenty-two participants (44%) were diagnosed with at least one STI over the course of the study; 13 were diagnosed with 17 STIs at their baseline visit and 13 were diagnosed with 19 incident STIs at their 3-month follow up visit. There was no difference in the incidence of new STIs between the two study groups. Across all participants, 15 (30%) were diagnosed with chlamydia, 11 (22%) with gonorrhea, and 3 (6%) with syphilis.
- A greater proportion of control participants reported having health insurance than intervention participants (23 [96%] vs. 18 [72%]; $p = 0.049$).
- A greater proportion of control participants reported seeing a medical provider in the past year than intervention participants (25 [100%] vs 18 [72%]; $p = 0.010$).
- Both participants who stopped taking PrEP stated that the main reason for stopping was not being sexually active at the current time.
- Of the participants who declined to initiate PrEP, the most commonly cited reasons were not considering themselves at high risk for HIV, not having health insurance, and not being able to see a medical practitioner.

Implementation research-related findings

- None reported

Process/study execution-related findings

- None reported

Adverse events

- None reported

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REFERENCES AND CONTACT INFORMATION

Desrosiers, A., Levy, M., Dright, A., Zumer, M., Jallah, N., Kuo, I., Magnus, M., & Siegel, M. (2019). [A randomized controlled pilot study of a culturally tailored counseling intervention to increase uptake of HIV pre-exposure prophylaxis among young black men who have sex with men in Washington, DC.](#) *AIDS and Behavior*, 23, 105–115.

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