

Effectiveness of a culturally-tailored HIV prevention intervention in promoting PrEP among Black women in community supervision programs in New York City: A randomized clinical trial

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Introduction

- Black women in the U.S. are disproportionately impacted by HIV, comprising 54% of new diagnoses among women in 2019 (1,2)
- Pre-exposure prophylaxis (PrEP) is an effective prevention tool. However, there are significant racial and gender disparities in PrEP uptake (2):
 - Black women are four times less likely to have initiated PrEP than their non-Hispanic white female counterparts (3)
- Research has shown this gap may be driven by low PrEP knowledge and awareness, low perceived HIV risk, medical mistrust and poor experiences with healthcare providers, and structural barriers such as insurance or transportation (4,5,6)
- Despite these barriers, there are few PrEP uptake interventions focused on cisgender women, and none have targeted women in community supervision programs (CSPs), which predominately serve Black women

Methodology

We conducted a randomized clinical trial among Black women in CSPs (7,8). Here, we evaluate the effectiveness of the E-WORTH intervention on increasing awareness, intention and use of PrEP:

Participants and recruitment

- We recruited 995 women from CSPs in NYC (probation, parole, alternative-to-incarceration programs) and screened them for eligibility
- Eligibility criteria included: 1) Identifying as African-American/Black; 2) On probation, parole, or ATI in the past 90 days; 3) Any illicit drug use or in drug treatment in the past 90 days; 4) Condomless sex in past 90 days; 5) One additional HIV risk in past year
- 352 participants were eligible and randomized to either E-WORTH (N=172) or an HIV testing control (Treatment as usual, TAU, N=180)
- Participants completed assessments at baseline (prior to randomization), then 3-, 6-, and 12-months post-intervention
- This analysis excludes n=16 participants who were HIV+ at baseline

Intervention

- E-WORTH participants received a 5-session, culturally-tailored, group-based HIV prevention intervention plus HIV testing:
 - General HIV prevention content included: HIV/STI awareness, condom use, sexual negotiation skills, risk reduction goal setting, partner violence screening and safety planning, increasing social support, and linkage to medical, social, and partner violence services
 - PrEP-related content included: awareness and knowledge-raising through a brief overview of PrEP and how it can prevent HIV
- TAU participants received HIV testing alone
- Both conditions were delivered by Black female staff at a large CSP

Measures & Analysis

- Descriptive statistics of participants by study arm are provided in Table 1.
- Primary outcomes include:
 - PrEP use ever and in the past 90 days
 - Awareness of PrEP as a biomedical HIV prevention strategy (Yes/No)
 - Willingness to use PrEP (4-point Likert Scale consisting of 3 items)
- The intervention effect for each outcome was estimated through mixed effects generalized linear models that included a random effect for repeated measures
 - Each model also includes age, high school graduate, employed, marital status, and confirmed STI at the baseline as covariate adjustments.

References: 1) CDC. Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): National HIV Surveillance System data reported through June 2021; and preexposure prophylaxis (PrEP) data reported through March 2021. HIV Surveillance Data Tables 2021;2(No. 4); 2) CDC. Diagnoses of HIV infection in the United States and dependent areas, 2019. HIV Surveillance Report 2021;32; 2) Conley C, Johnson R, Bond K, Brem S, Salas J, Randolph S. US Black cisgender women and pre-exposure prophylaxis for human immunodeficiency virus prevention: A scoping review. *Womens Health(Lond)*. 2022;18:17455057221103098; 3) Bush S, Magnuson D, Rawlings MK, Hawkins T, McCallister S, Mera Giler R. Racial Characteristics of PrEP/TDF for Pre-exposure Prophylaxis (PrEP) Users in the US. presented at: ASM Microbe; 2016; Boston, MA. 4) Nydegger LA, Dickson-Gomez J, Ko Ko TA. Longitudinal Qualitative exploration of perceived HIV risk, healthcare experiences, and social support as facilitators and barriers to PrEP adoption among black women. *AIDS Behav*. 2021; 5) Nydegger LA, Dickson-Gomez J, Ko TK. Structural and systemic barriers to PrEP adoption among Black women at high risk for HIV: a qualitative exploration. *Cult Health Sex*. 2021; 6) Hirschhorn LR, Brown RN, Friedman EE, Greene GJ, Bender A, Christeller C, ... & Ridgway JP (2020). Black Cisgender Women's PrEP Knowledge, Attitudes, Preferences, and Experience in Chicago. *Journal of acquired immune deficiency syndromes* (1999), 84(5), 497-507. 7) Johnson K, Gilbert L, Hunt T, et al. The effectiveness of a group-based computerized HIV/STI prevention intervention for black women who use drugs in the criminal justice system: study protocol for E-WORTH (Empowering African-American Women on the Road to Health), a Hybrid Type 1 randomized controlled trial. *Trials*. 2018;19(1):486; 8) Gilbert L, Goddard-Eckrich D, Chang M, et al. Effectiveness of a Culturally Tailored HIV and Sexually Transmitted Infection Prevention Intervention for Black Women in Community Supervision Programs: A Randomized Clinical Trial. *JAMA Netw Open*. 2021;4(4):e215226.

Results

A total of 336 participants women tested HIV negative at baseline and were therefore considered PrEP-eligible and included in this sample.

Table 1: Participant Sociodemographics

	Control (n=173)	E-WORTH (n=163)	Total (N=336)
Age	31.6 (10.7)	32.1 (10.7)	31.8 (10.7)
Born in US	164 (95.3%)	155 (95.1%)	319 (95.2%)
Latinx ethnicity (All identified as Black during screening)	42 (24.4%)	34 (20.9%)	76 (22.7%)
High school graduate/GED	96 (55.8%)	91 (55.8%)	187 (55.8%)
Marital status			
married, including common-law marriage	25 (14.5%)	33 (20.2%)	58 (17.3%)
Single, including never married, widowed, separated and divorced	66 (38.4%)	74 (45.4%)	139 (41.5%)
Sexual orientation			
Heterosexual	114 (66.3%)	105 (64.4%)	219 (65.4%)
Bisexual	51 (29.7%)	54 (33.1%)	105 (31.3%)
Other	7 (4.1%)	4 (2.5%)	11 (3.3%)
Employed	55 (32.0%)	45 (27.6%)	100 (29.9%)
Homeless in the past 90 days	27 (15.7%)	36 (22.1%)	63 (18.8%)
Not enough money for food in the past 90 days	104 (60.5%)	108 (66.3%)	212 (63.3%)
Criminal Justice Involvement			
In jail or prison in the past 90 days	36 (20.9%)	43 (26.4%)	79 (23.6%)
On parole in the past 90 days	27 (15.7%)	28 (17.2%)	55 (16.4%)
In an Alternative to Incarceration program in the past 90 days	27 (15.7%)	32 (19.6%)	59 (17.6%)
On probation in the past 90 days	124 (72.1%)	117 (71.8%)	241 (71.9%)
Substance Use			
Ever binge drinking	122 (70.9%)	110 (67.5%)	232 (69.3%)
Binge drinking in the past 30 days	75 (43.6%)	71 (43.6%)	146 (43.6%)
Ever used any illicit drug	138 (80.2%)	141 (86.5%)	279 (83.3%)
Used any illicit drug in the past 30days	102 (59.3%)	96 (58.9%)	198 (59.1%)
Ever injected drugs	5 (2.9%)	9 (5.5%)	14 (4.2%)
Injected drugs in the past 90 days	3 (1.7%)	3 (1.8%)	6 (1.8%)

Table 2: Comparison of PrEP Outcomes by Study Arm Over Time

	Arm	Baseline	3-month	6-month	12-month
PrEP Use					
Have you ever taken Truvada or another antiretroviral medication to reduce your likelihood of getting HIV? (Yes/No)	TAU	3 (2.0%)	3 (2.2%)	4 (2.7%)	5 (3.4%)
	E-WORTH	3 (2.0%)	8 (6.6%)	6 (4.4%)	7 (5.1%)
Have you taken Truvada or another antiretroviral medication to reduce your likelihood of getting HIV in the PAST 90 days? (Yes/No)	TAU	1 (0.7%)	2 (1.5%)	2 (1.4%)	4 (2.7%)
	E-WORTH	0 (0%)	0 (0%)	2 (1.5%)	3 (2.2%)
PrEP Awareness					
In the past 90 days, have you heard of PrEP as an antiretroviral medication that you can take to reduce your risk of getting HIV from HIV positive partners? (Yes/No)	TAU	43 (25.0%)	39** (27.7%)	48** (32.4%)	78** (53.1%)
	E-WORTH	49 (30.1%)	73** (55.7%)	72** (52.6%)	98** (71.5%)
PrEP Willingness					
1. If PrEP is available to you, how likely would you be willing to use PrEP as an HIV prevention method? (Range: 1-4)	TAU	2.52 (1.16)	2.39* (1.15)	2.45 (1.08)	2.28 (1.14)
	E-WORTH	2.58 (1.19)	2.70* (1.14)	2.47 (1.24)	2.50 (1.18)
2. If PrEP is available to you how likely would you be willing to tell your partner that you are taking PrEP? (Range: 1-4)	TAU	2.70 (1.20)	2.52 (1.21)	2.70 (1.16)	2.54 (1.21)
	E-WORTH	2.85 (1.23)	2.82 (1.27)	2.61 (1.27)	2.72 (1.21)
3. If PrEP is available to you and you decided to take this medication, how likely would you use condoms while you are taking PrEP? (Range: 1-4)	TAU	2.78 (1.11)	2.74 (1.23)	2.68 (1.19)	2.55* (1.23)
	E-WORTH	2.84 (1.20)	2.91 (1.25)	2.64 (1.21)	2.88* (1.20)
Total PrEP willingness score (sum of above three items; Range: 3-12)	TAU	7.99 (2.96)	7.64* (3.11)	7.82 (2.94)	7.37* (3.00)
	E-WORTH	8.28 (2.99)	8.43* (3.11)	7.73 (3.42)	8.10* (3.06)

Key findings:

- Compared to control participants, E-WORTH participants had significantly greater odds of being aware of PrEP as a biomedical HIV prevention strategy (AOR=3.25, 95% CI=2.01- 5.25, p<.001)
- Compared to control participants, E-WORTH participants had significantly greater willingness to use PrEP (b= 0.19, 95% CI=0.001-0.38, p=.049)
- No significant difference between conditions was found with respect to PrEP use, which was low in both conditions

Conclusion

- These findings suggest the effectiveness of a culturally-tailored intervention for Black women in CSP settings in increasing awareness, willingness, and intention to initiate PrEP
- The low uptake of PrEP in both arms may be due to lack of access, but also may highlight the need for providing more robust PrEP-on-demand strategies (e.g., PrEP telemedicine) during the intervention rather than linkage to a PrEP provider
- Advancing an effective PrEP intervention for Black women in CSPs holds great promise for reducing inequities in PrEP uptake and increasing HIV prevention among this vulnerable group

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