Linkage to care in the Partner Services Pre-exposure Prophylaxis (PS-PrEP) study: a pilot randomized control trial

#0954

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Objective

Examine the feasibility, acceptability and preliminary efficacy of an intervention in linking high-risk seronegative Black men who have sex with men (MSM) to Pre-Exposure Prophylaxis (PrEP) care as part of partner notification services (PNS) and network testing services (NTS).

Background

PrEP with Truvada prevents HIV infection among men who have sex with men (MSM).[1]

Black MSM in the US experience disproportionate rate of HIV,[2] but demonstration of PrEP implementation in the US may not be applicable to Black MSM.[3] Accordingly, Black MSM are less likely to take PrEP or be aware of PrEP.[4-6] Black MSM have been under-represented in PrEP studies, and barriers and facilitators to effective PrEP uptake in this population are not fully known.

PNS are coordinated through departments of public health to notify sexual partners of people with recently diagnosed sexually transmitted infections, who are likely eligible for PrEP and at increased risk for HIV infection. NTS is a social network approach to identify and refer individuals at high-risk for HIV infection, and likely eligible for PrEP, for HIV testing.

Methods

Study design

- 2 phase unblinded randomized control trial
  - Phase 1: Modified protocol to address identified gaps, developed interventionist manual and refined questionnaires.
  - Phase 2: Pilot testing
- Participants were interviewed at 3, 6 and 12 months to assess attitudes towards PrEP, HIV, and risk perception and behaviors. Compensation for each interview was $25.

Inclusion criteria:

- HIV seronegative
- Black MSM
- 18-40 years of age
- Eligible for PrEP[1]
- English speaking
- Living in the Chicago metropolitan area ≥ 6 months of the year
- Agreeable to text/phone communication
- Own a cell phone not shared by other persons
- Completed post-test counseling

Exclusion criteria:

- Taken PrEP in the previous 12 months
- Unable to provide consent
- Plan to move out of the area permanently within the next 12 months
- Not willing to attend intervention sessions or return for assessments

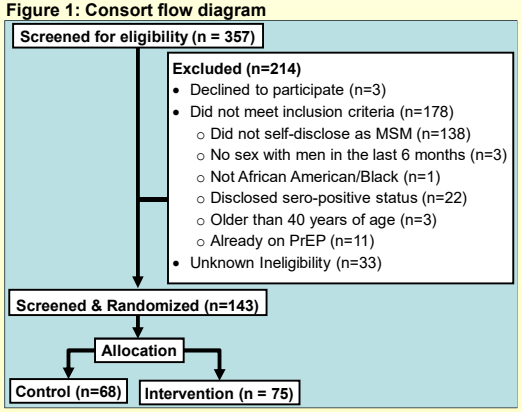
Setting

- Screening through Chicago Department of Public Health (CDPH) PNS and University of Chicago (U of C) NTS.
- PrEP care provided at Howard Brown Health clinics.

Methods

- **Intervention group:**
  - 65 minute face-to-face session with an interventionist to develop individualized Linkage Roadmap[7] and review PrEP information and linkage to care process. Included motivational interviewing to reduce HIV risk. Occurred within 1 week of enrollment.
  - Mini-booster sessions via phone to answer questions, problem solve, and review Linkage Roadmap.[7] Up to 4 sessions until linked to PrEP care or 3 months after enrollment.
- **Control group:** Care as usual, which may include CDPH PrEP referrals.[8] CPDH staff contacted PrEP eligible and interested clients within 72 hours of CDPH STI clinic visit to make a PrEP appointment.
- Both the control and intervention groups were offered transportation vouchers.
- **Allocation**: Block randomization.
- **Primary outcome:** Linkage to PrEP care was defined as at least 1 PrEP visit within 3 months of enrollment. A PrEP visit is defined as a clinic visit during which PrEP is initiated, continued, or during which PrEP counseling occurred.
- **Analysis**: Baseline interview and clinic visits 3 months after enrollment were analyzed. Statistical significance for categorical variables was evaluated using the chi-square test and Fisher's exact test where n < 5 in at least one category, and t-test for continuous variables. Unadjusted logistic regression was used to quantify the association between the intervention and the primary outcome. Data analyzed in R Statistical Software (R version 3.5.2)

Figure 1: Consort flow diagram

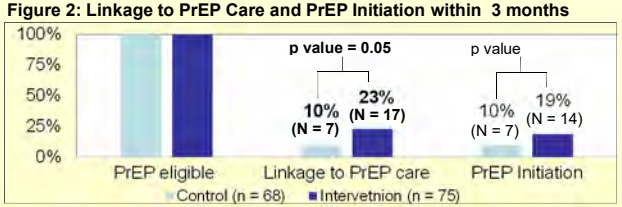


Results

Table 1: Study population characteristics

	Total (n = 143)	Control (n = 68)	Intervention (n = 75)	p value
Recruited from NTS (%)	133 (93)	63 (93)	70 (93)	0.89
Mean age in years (SD)	26 (5)	26 (4)	25 (5)	0.83
Latino ethnicity (%)	8 (6)	5 (7)	3 (4)	0.48
Transgender or queergender identity (%)	12 (8)	6 (9)	6 (8)	1
Sexual orientation (%)				0.08
Straight	2 (1)	1 (1)	1 (1)	
Gay	89 (62)	47 (69)	42 (56)	
Bisexual	47 (33)	20 (29)	27 (36)	
Queer	5 (3)	0 (0)	5 (7)	
Education (%)				0.56
Some high school	13 (9)	6 (9)	7 (9)	
High school	41 (29)	17 (25)	24 (32)	
Some college, associate's or technical school	73 (51)	35 (51)	38 (51)	
Bachelor's or post graduate studies	16 (11)	10 (15)	6 (8)	
Employment (%)				0.16
Full-time	55 (38)	32 (47)	23 (31)	
Part-time	38 (27)	14 (21)	24 (32)	
Unemployed	38 (27)	18 (26)	20 (27)	
Other	12 (8)	4 (6)	8 (11)	
Health Insurance (%)	118 (83)	60 (88)	58 (77)	0.14
Depression (%)	21 (15)	12 (18)	9 (12)	0.34
Binge drink alcohol (%)	34 (24)	17 (25)	17 (23)	0.74
Marijuana use ≥ 4x/week (%)	59 (41)	30 (44)	29 (39)	0.51
Illicit substance use (%)	19 (13)	8 (12)	11 (15)	0.61

Figure 2: Linkage to PrEP Care and PrEP Initiation within 3 months



From August 2014 to May 2017, 357 individuals were screened, of which 157 participants were from CDPH PNS and 200 participants were from U of C NTS.

Participants who were linked to PrEP care (17% [N = 24]) were more likely to be older (26 years v 28 years; p = 0.05), and less likely to report gay sexual orientation (50% v. 65%; p = 0.03).

Participants in the intervention arm were 2.55 (OR CI 95% 1.02-7.02; p = 0.05) times more likely to be linked to PrEP care in comparison to the control arm.

Discussion

Overall, among the PS-PrEP study population, linkage to PrEP care was low (17%). In comparison, a study of the CDPH PrEP referral program found 31% of recipients were linked to PrEP care.[8] This suggests that Black MSM are a hard to reach population, which is consistent with previous studies that have found lower uptake of PrEP among Black MSM compared to other races and risk groups.[4-6]

Participants who received the PS-PrEP intervention were significantly more likely to linked to PrEP care compared to the control group (23% v. 10%, p = 0.05).

Implementation challenges included staffing turnover and barriers to contacting participants.

Conclusions

The PS-PrEP intervention is an effective intervention to increase linkage to PrEP care among Black MSM compared to care as usual.

Integrating a PrEP linkage intervention into PNS and NTS is feasible and effective.

Acknowledgements

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