

Pilot Assessment of a Strengths-Based Patient Navigation Program to Increase Access to Pre-Exposure Prophylaxis

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Background

Pre-exposure prophylaxis (PrEP) with daily oral TDF/FTC can reduce HIV acquisition rates by more than 90% among those at sexual risk for HIV infection. Increased PrEP uptake among individuals at risk for HIV infection can decrease community transmission and impact infection rates. South Florida is the area of the U.S. with the highest rate of new HIV infections. Access to PrEP in South Florida has been limited, with numerous structural, logistical, and personal barriers presenting obstacles to care. Strengths based case management (SBCM) is an evidence-based strategy for improving linkage to care for people living with HIV. We hypothesized that SBCM could be used to mitigate these obstacles and to facilitate PrEP access.

Study Aims

- Implement, evaluate and compare the effectiveness of a brief, theoretically based patient navigation intervention for linkage to PrEP providers to an information-only referral within a target population of individuals with increased risk for HIV and interest in receiving PrEP.
- Determine to what extent initial linkage results in receipt of PrEP prescription, obtaining PrEP medication, and early adherence as measured by tenofovir diphosphate (TFV-DP) levels.
- Identify barriers and facilitators associated with real-world access to PrEP

Methods

- Adults (>18 years) interested in PrEP and meeting CDC suggested criteria for PrEP consideration were recruited through local clinics not directly offering PrEP and through online advertising.
- Participants (n=61) were randomized to receive either passive referral with information regarding PrEP, (control group) or active strengths-based case management with a patient navigator (treatment group).
- All control condition participants were provided with a package of information on HIV prevention strategies including a list of PrEP providers in the area.
- All participants had one in-person session with the patient navigator which lasted 45-60 minutes, 20 minute in-person or phone visits at 6 and 12 weeks, and brief phone call check-ins at 4 and 8 weeks.
- Intervention participants had the option of attending additional follow-up or phone/text session.
- Surveys administered assessed success in obtaining a provider appointment to discuss PrEP and in obtaining PrEP medication at 4, 6, 8 and 12-weeks post-randomization.
- Dried blood spot (DBS) for TFV-DP was obtained 6 weeks after PrEP start for those who initiated PrEP
- Logistic regression analysis was conducted to address the primary study hypothesis.
- Kaplan-Meier and log-rank analysis was performed to determine differences in time-to-provider and time-to-PrEP between the study groups.

Results

Table 1. Baseline characteristics of study groups

		Control N=31		Treatment N=30	
		Count	Column N %	Count	Column N %
Age (Mean, SE)		40.6	2.28	40.2	2.29
Race/Ethnicity	Hispanic	16	51.6%	10	33.3%
	Black / AA	10	32.3%	11	36.7%
	White / Non-Hispan	4	12.9%	3	10.0%
	Other / Multiple	1	3.2%	6	20.0%
Gender (self-described)	Male	26	83.9%	25	83.3%
	Female	5	16.1%	4	13.3%
	Transgender MTF	0	0.0%	1	3.3%
Educational level completed	< High school	2	6.5%	7	23.3%
	HS graduate	9	29.0%	7	23.3%
	Some college	12	38.7%	7	23.3%
	College graduate	8	25.8%	7	23.3%
	Post-graduate	0	0.0%	2	6.7%
Sexual Orientation	Gay or Queer	13	41.9%	13	43.3%
	Bisexual	3	9.7%	4	13.3%
	Straight	13	41.9%	12	40.0%
	Other	2	6.5%	1	3.3%
Previously Heard of PrEP		21	67.7%	18	60.0%
Income	\$0-10,980	9	29.0%	13	43.3%
	\$10,981-19,999	8	25.8%	6	20.0%
	\$20,000-39,999	10	32.3%	3	10.0%
	\$40,000-59,000	3	9.7%	3	10.0%
	\$60,000-99,999	0	0.0%	5	16.7%
\$100,000 or more	0	0.0%	0	0.0%	
Insurance Coverage		15	48.4%	19	63.3%
Alcohol use (90 days)	Daily	1	3.2%	2	6.7%
	5-6 times / week	1	3.2%	0	0.0%
	3-4 times / week	2	6.5%	4	13.3%
	1-2 times / week	10	32.3%	6	20.0%
	2-3 times / month	4	12.9%	3	10.0%
	Once a month	6	19.4%	3	10.0%
None	7	22.6%	12	40.0%	
Injection drug use (90 days)		1	3.2%	1	3.3%

Table 2. Study outcomes by group

	Control (n=31)	Intervention (n=30)	p-value
Made appointment with provider by 12 weeks	8 (25.8%)	16 (53.3%)	0.026*
Initiated PrEP by 12 weeks	9 (29.0%)	12 (40.0%)	0.367
Weeks to get PrEP (mean, SD)	13.4, 0.81	12.8, 0.79	0.362
TFV-DP concentration (mean, SD)	DBS n=5 823.18, 476.7	DBS n=10 702.43, 258.6	0.529
Protective TFV-DP levels (>700 fmol/punch)	3 (60.0%)	6 (60.0%)	1.00

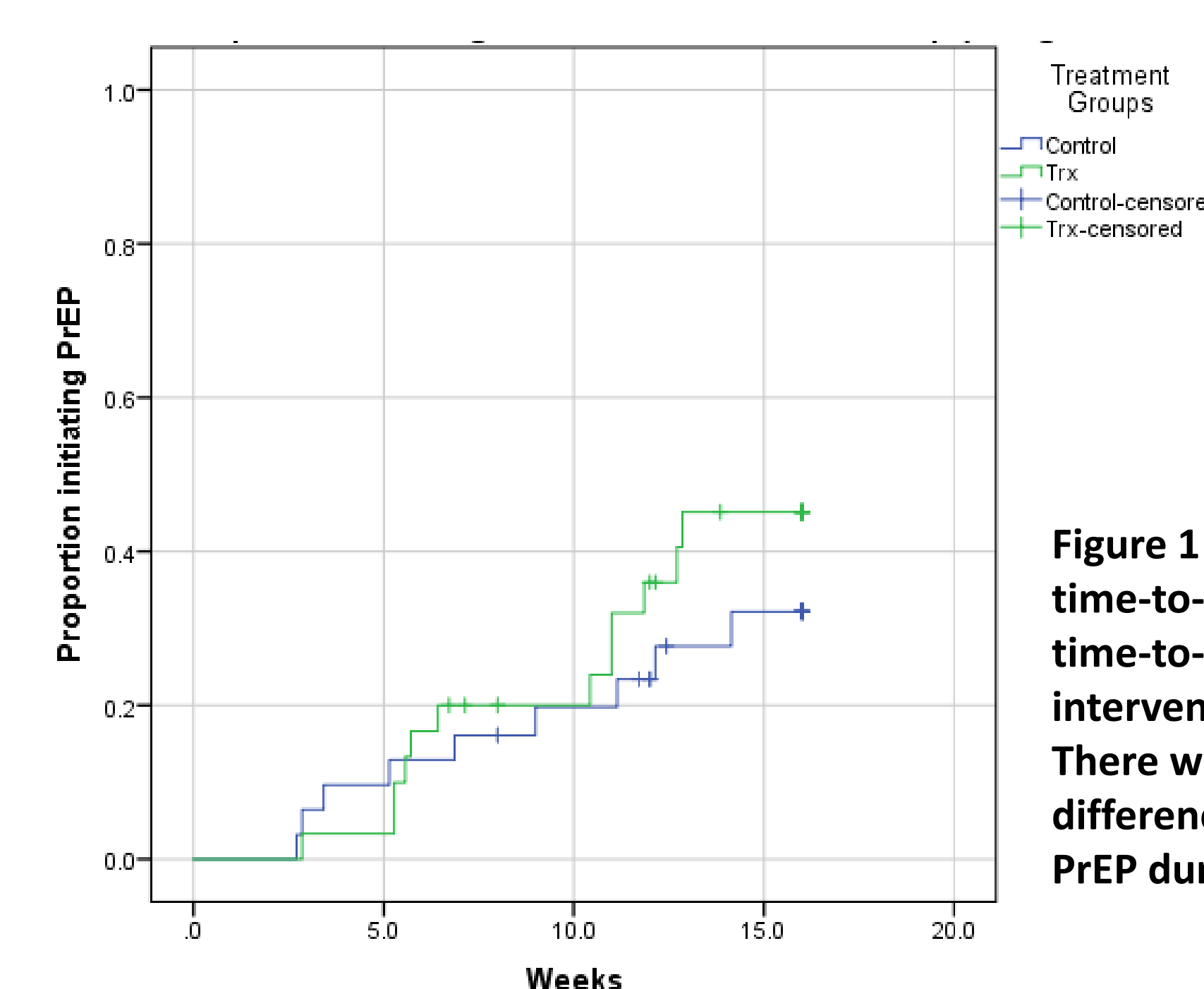


Figure 1 (left). Kaplan-Meier time-to-event analysis describing time-to-obtaining-PrEP in the intervention and control groups. There was no significant difference in time to obtaining PrEP during the observed period

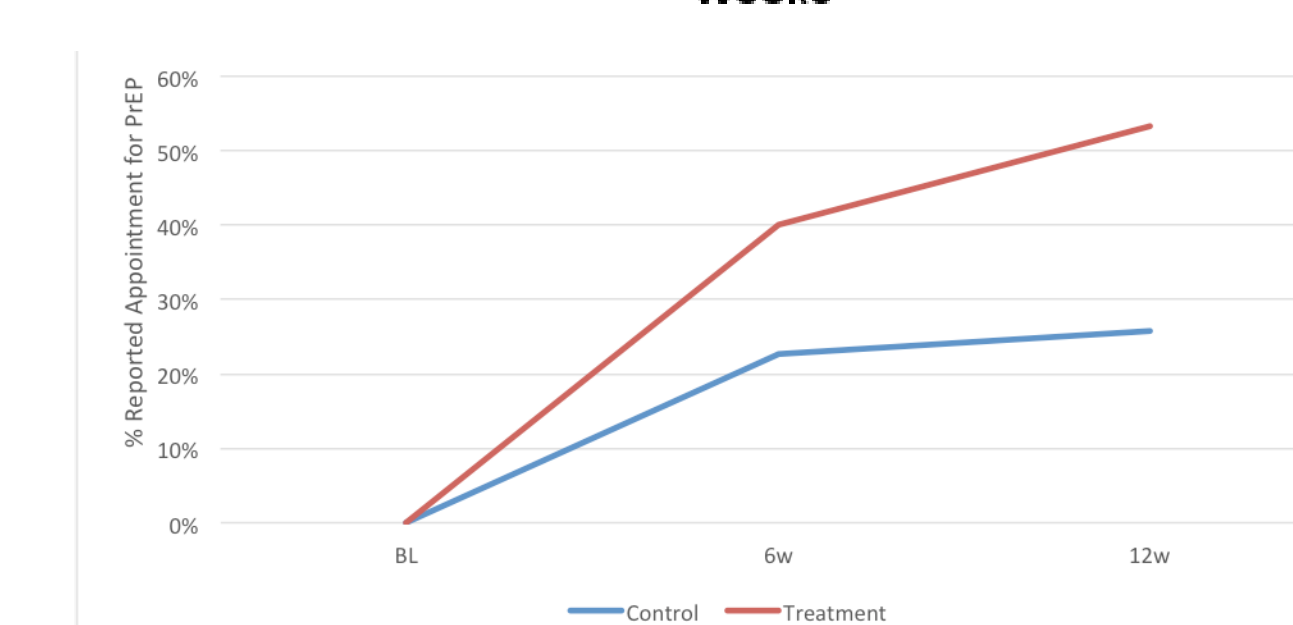


Figure 2 (left). Percentage of participants obtaining a provider visit to discuss PrEP by 6 and 12 weeks. Difference between intervention and control groups is significant at 12 weeks (p=0.026).

Conclusions

- In our heterogeneous group of largely racial/ethnic minority PrEP-seekers, a SBCM-based patient navigation strategy resulted in a significantly larger proportion of participants obtaining a visit with a medical provider to discuss PrEP by 12 weeks.
- Time to obtain PrEP was longer than expected in both the SBCM intervention and the control group (> 12 weeks).
- Delays in obtaining PrEP were most often due to wait for a provider visit.
- The SBCM intervention resulted in an 11% absolute increase in the proportion of PrEP initiations during the study period, a non-statistically significant difference. The increase may have been limited due to the long period needed to obtain a provider visit.
- For those who initiated PrEP and had DBS obtained for drug levels, mean levels and percentage with protective levels did not differ by group, but sample size was small.
- Our pilot data suggest that SBCM-based patient navigation is a promising strategy for assisting PrEP-seekers in obtaining a medical provider visit. Our previous data suggest that this step is the most critical in eventually obtaining PrEP.
- Strategies to combine community patient navigation with direct scheduling of a provider visit may be needed to overcome administrative delays that compromise PrEP access in South Florida and may result in frustration and abandonment of the process.
- Addressing structural-level barriers to care is essential to successful PrEP implementation in South Florida.

References

- Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas. [Accessed February 17, 2017];2011 <http://www.cdc.gov/hiv/surveillance/resources/reports/2011report/index.htm>.
- Doblecki-Lewis, S., Liu, A., Feaster, D., Cohen, S. E., Cardenas, G., Bacon, O., ... & Kolber, M. A. (2017). Healthcare Access and PrEP Continuation in San Francisco and Miami Following the US PrEP Demo Project. JAIDS Journal of Acquired Immune Deficiency Syndromes.
- Anderson, P.L., et al., Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. Sci Transl Med, 2012. 4(151): p. 151ra125
- Gardner, L. I., Marks, G., Strathdee, S. A., Loughlin, A. M., del Rio, C., Kerndt, P., ... & Metsch, L. R. (2016). Faster entry into HIV care among HIV-infected drug users who had been in drug-use treatment programs. Drug and alcohol dependence, 165, 15-21.
- Centers for Disease Control and Prevention, Pre-Exposure Prophylaxis for the Prevention of HIV in the United States - 2014 Clinical Practice Guideline. 2014.