

Background

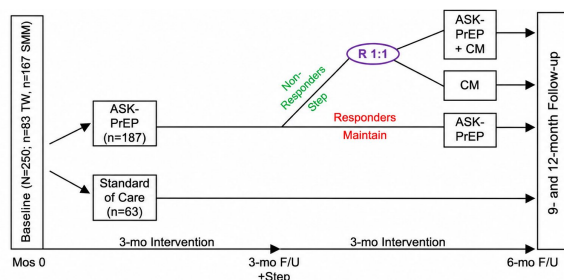
- HIV pre-exposure prophylaxis (PrEP) is a highly effective medication for preventing HIV infection when taken as prescribed.
- PrEP initiation and adherence remain suboptimal among transgender women (TW) and men who have sex with men (MSM) with substance use disorders (SUD), who experience reduced PrEP engagement, increased HIV risk, and greater healthcare utilization.
- A.S.K.-PrEP is a client-centered PrEP navigation intervention with SMS support designed to reduce barriers to PrEP engagement.

Research Aims

- Aim 1:** Describe baseline characteristics of the overall study cohort and by initial treatment assignment (A.S.K.-PrEP vs. SOC).
- Aim 2:** Evaluate the association between initial treatment assignment (A.S.K.-PrEP vs. SOC), PrEP initiation at 3 months, and healthcare costs.
- Aim 3:** Evaluate the association between second-stage treatment assignment amongst initial non-responders (A.S.K.-PrEP + contingency management [CM] vs. CM alone), PrEP adherence at 6, 9, and 12 months, and healthcare costs.

Methods

Study Design



- Randomized controlled trial evaluating a Stepped Care A.S.K.-PrEP intervention versus standard of care (SOC).
- Assessments at baseline and 3, 6, 9, and 12 months.

Statistical Analysis

- Chi-squared and Wilcoxon rank-sum tests.
- Logistic regression for PrEP outcomes.
- Two-part models for healthcare costs.

Outcome Measures

- PrEP initiation (3 months)
- PrEP adherence (6, 9, and 12 months)
- Total healthcare costs

Table 1. Baseline Characteristics

Characteristic	Overall N = 152	ASK PrEP N = 113	SOC N = 39
Gender			
Male (Cisgender)	119 (78%)	88 (78%)	31 (79%)
Trans Man/Transmasculine	5 (3.3%)	3 (2.7%)	2 (5.1%)
Trans Woman/Transfeminine	26 (17%)	20 (18%)	6 (15%)
Prefer not to answer	2 (1.3%)	2 (1.8%)	0 (0%)
Sex Assigned at Birth			
Female	4 (2.6%)	2 (1.8%)	2 (5.1%)
Male	146 (96%)	110 (97%)	36 (92%)
Prefer not to answer	2 (1.3%)	1 (0.9%)	1 (2.6%)
Sexual Identity			
Bisexual	47 (31%)	35 (31%)	12 (31%)
Gay	63 (41%)	48 (42%)	15 (38%)
Heterosexual/Straight	15 (9.9%)	8 (7.1%)	7 (18%)
Prefer not to Answer	2 (1.3%)	2 (1.8%)	0 (0%)
Other	25 (16%)	20 (18%)	5 (13%)
Age			
44 (12)	44 (12)	45 (11)	
Lifetime Injection Drug Use			
85 (56%)	61 (54%)	24 (62%)	
Living Situation			
Stable Housing	82 (54%)	63 (56%)	19 (49%)
Unhoused	40 (26%)	30 (27%)	10 (26%)
Unstable Housing	30 (20%)	20 (18%)	10 (26%)
Education			
College/Tech Degree	32 (21%)	22 (19%)	10 (26%)
Graduate School/Degree	7 (4.6%)	7 (6.2%)	0 (0%)
High School/GED	47 (31%)	34 (30%)	13 (33%)
Less than High School	20 (13%)	18 (16%)	2 (5.1%)
Some College/Tech	45 (30%)	31 (27%)	14 (36%)
Prefer not to answer	1 (0.7%)	1 (0.9%)	0 (0%)
Race/Ethnicity			
African American/Black	46 (30%)	35 (31%)	11 (28%)
Caucasian/White	32 (21%)	22 (19%)	10 (26%)
Hispanic/Latinx	34 (22%)	26 (23%)	8 (21%)
Other	39 (26%)	29 (26%)	10 (26%)
Prefer not to answer	1 (0.7%)	1 (0.9%)	0 (0%)
Lifetime Needle Sharing			
32 (38%)	22 (37%)	10 (42%)	
Insurance			
Commercial	10 (7.1%)	9 (8.7%)	1 (2.8%)
Public	109 (78%)	82 (79%)	27 (75%)
Other/Uninsured	21 (15%)	13 (13%)	8 (22%)
History of STI			
82 (57%)	59 (56%)	23 (61%)	
Ever Prescribed PrEP			
76 (50%)	56 (50%)	20 (51%)	
Work Status			
Employed	52 (34%)	40 (36%)	12 (31%)
Retired	6 (4.0%)	2 (1.8%)	4 (10%)
Student/Training	8 (5.3%)	7 (6.3%)	1 (2.6%)
Unemployed	85 (56%)	63 (56%)	22 (56%)
Income			
<\$12,500	94 (63%)	70 (63%)	24 (63%)
\$12,500–\$30,000	33 (22%)	23 (21%)	10 (26%)
\$30,001+	23 (15%)	19 (17%)	4 (11%)

[†] n (%); Mean (SD)

Results

Figure 1. Adjusted Odds Ratios for PrEP Initiation at 3 Months

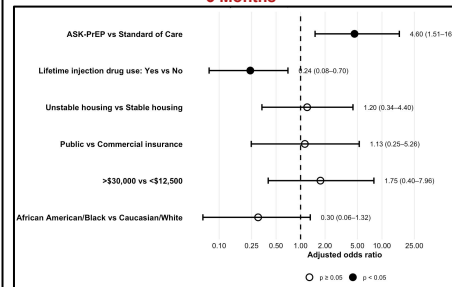


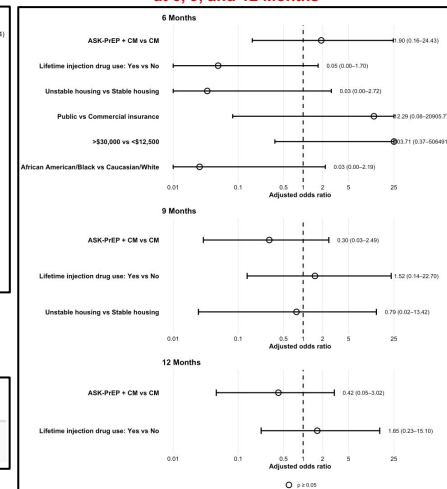
Table 2. Adjusted Cost Difference (3 Months)

Variable	Marginal difference in cost	P-value
ASK PrEP - SOC	-1256.73 (-6513.53, 4000.07)	0.6394

Table 3. Adjusted Cost Difference (6, 9, & 12 Months)

Variable	Marginal difference in cost	P-value
ASK PrEP + CM - CM alone	-5598.62 (-14220.28, 3023.04)	0.2031
ASK PrEP + CM - CM alone	-1972.54 (-5165.23, 1220.15)	0.2259
ASK PrEP + CM - CM alone	-12850.66 (-32285.36, 6584.05)	0.1950

Figure 2. Adjusted Odds Ratios for PrEP Adherence at 6, 9, and 12 Months



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Key Findings

Aim 1:

- Baseline characteristics were comparable across treatment groups, supporting balanced treatment comparisons.
- Participants represented a population with a high burden of socioeconomic and HIV-related risk factors.

Aim 2:

- ASK-PrEP significantly improved PrEP initiation at 3 months compared with Standard of Care.
- Despite improved initiation, healthcare costs did not differ significantly between treatment groups.

Aim 3:

- ASK-PrEP + CM did not significantly improve PrEP maintenance compared with CM alone at 6, 9, or 12 months.
- Healthcare costs remained comparable between second-stage treatment groups throughout follow-up.