

Utilizing a Stepped Care Approach to Address Substance Use and Increase PrEP Initiation and Adherence among Trans Women and Sexual Minority Men



Cathy J. Reback^{1,2,3}

Michael Li^{2,3}

Raymond P. Mata¹

Danielle Ryan⁴

Ali Jalali^{4,5}

Raphael J. Landovitz^{3,6}

David Benkeser⁷

Philip J. Jeng⁴

Sean M. Murphy^{4,5}

¹Friends Research Institute

²University of California, Los Angeles, Department of Family Medicine, David Geffen School of Medicine

³University of California, Los Angeles, Center for HIV Identification, Prevention and Treatment Services (CHIPTS)

⁴Weill Cornell Medical College

⁵Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV (CHERISH)

⁶University of California, Los Angeles, Division of Infectious Diseases

⁷Emory University



**Weill Cornell
Medicine**

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Background

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- Although PrEP is a highly effective biomedical HIV prevention strategy, PrEP initiation, adherence, and persistence are exclusively behavioral outcomes that are abrogated by substance use.
- In the US most (~70%) annual new HIV infections are among substance-using trans women and sexual minority men (SMM; CDC, 2016).
- A majority of trans women who initiate PrEP do not achieve protective adherence level, (Deutsch et al., 2015) and similar outcomes are observed among high-risk SMM (Hosek et al., 2017, Molina et al., 2015).
- Substance use, especially stimulant use, interferes with PrEP initiation among SMM, (Biello et al., 2017) and has repeatedly been shown to reduce rates of PrEP adherence and/or persistence among both trans women and SMM (Hoenigl et al., 2018, Goodman-Meza et al., 2019).
- Substance use disorder (SUD) is also associated with reduced quality-of-life, and increased overdose deaths, utilization of high-cost healthcare services, engagement in a street economy, and cycles of incarceration (Stotzer, 2014, Anderson-Carpenter et al., 2017).

To improve public health, researchers must identify scalable and cost-effective behavioral interventions to promote PrEP initiation, adherence, and persistence among trans women and SMM with a SUD.

Study Aims

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Evaluate a Stepped Care approach promoting advancement along the PrEP Care Continuum (initiation, adherence, persistence), *and* reductions in substance use among trans women and SMM with a SUD.

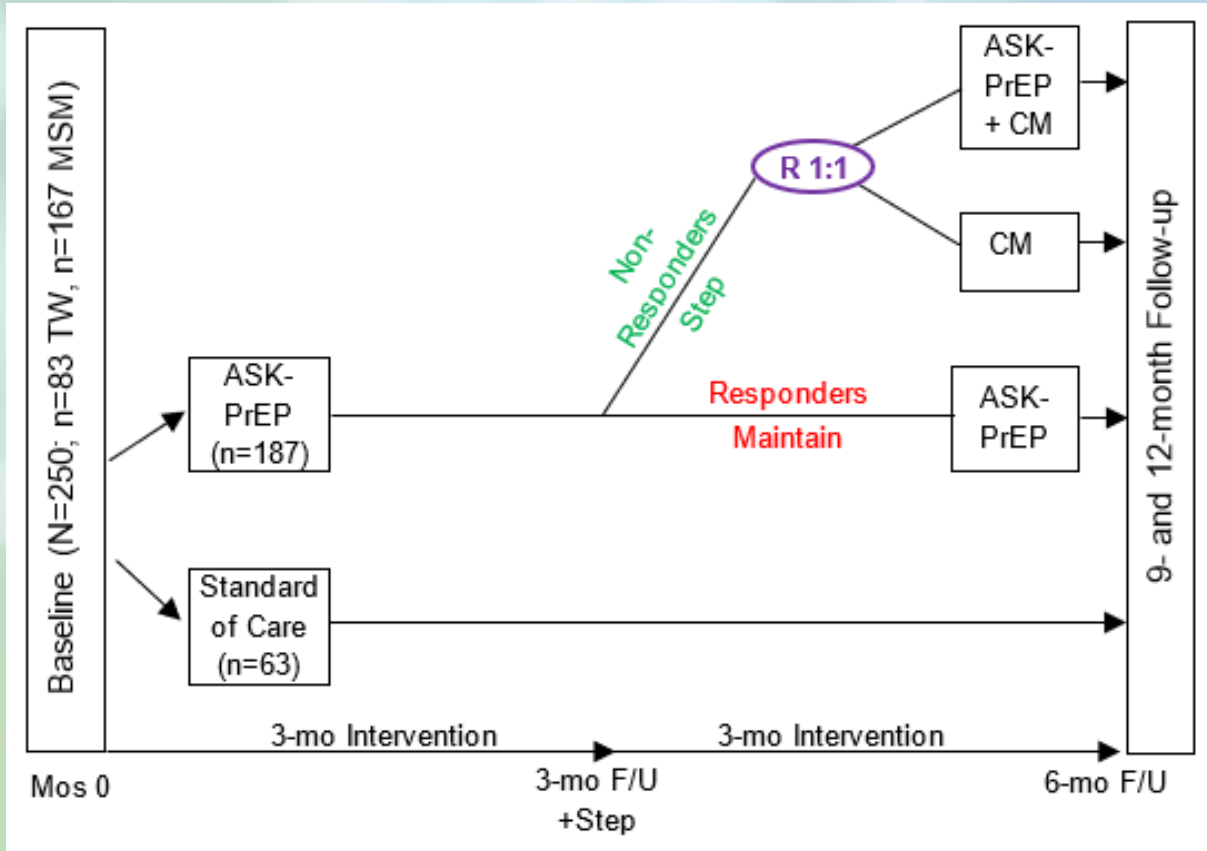
Determine the individual effects of specific substances (e.g., methamphetamine vs. opioids), routes of administration (injection vs. non-injection), severity of SUD (mild, moderate, severe), social and structural determinants of health (e.g., poverty, housing insecurity, food scarcity, educational attainment, lack of insurance), and differing individual-level characteristics (e.g., sexual/gender identity, racial/ethnic identity, age) as moderators of outcomes among trans women and SMM with a SUD.

Estimate the cost of implementing and sustaining each intervention (Stepped Care with: a) *A.S.K.-PrEP* + CM; b) CM alone) and conduct a cost-effectiveness analysis to determine the value of each intervention relative to SOC, and to each other, from the healthcare-sector, state-policymaker, and societal perspectives.

Evaluate intervention engagement (# *A.S.K.-PrEP* sessions in the initial 3-months) and intervention response (responders vs. non-responders) by chosen PrEP modality (i.e., oral daily [Truvada or Descovy] or long-acting injectable [Cabotegravir]).



Study Design





Stepped Care Criteria

At 3-month follow-up assessment for those initially randomized to the A.S.K.-PrEP arm (step criteria are not mutually exclusive):

Step Criteria Based on PrEP:

- Has **not** initiated PrEP (either Truvada, Descovy or Cabotegravir)
- On oral daily PrEP but self-reports non-adherence (missed 4 or more days in a row) in past 3 months
- On long-acting injectable but has **not** received 2nd dose within +/- 7 day of 28 days (i.e., 35 days) after 1st dose

Step Criteria Based on Substance Use:

- Self-reported drug use of the targeted SUD diagnosed at baseline for 1 (or more) day(s) in the past 14 days
- Positive urine drug screen for targeted SUD diagnosed at baseline

Methods

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- Eligibility
 - Self-identified trans woman or SMM
 - 18 years or older
 - Verified HIV negative
 - Identified as “high risk” based on Los Angeles County criteria:
 - Sex without a condom
 - Methamphetamine use
 - Sex with an HIV-positive partner
 - Injection drug use
 - DSM-5 diagnosed SUD (excluding cannabis and alcohol)
- Enrollment began in May 2023
 - Recruitment span will be approximately 36 months, through May 2026
 - Data collection will be completed in June 2027
- Assessment time points and incentives:
 - Screener = \$15
 - Baseline = \$50
 - 3-month f/u = \$50 with a \$25 bonus for completing with +/- 7 days of exact due date
 - 6- and 9-month f/u = \$75 each
 - 12-month f/u = \$100
- Audio Computer Assisted Self Interview (ACASI) administered through Qualtrics



Recruitment Flyers

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Ready to PrEP?



You've got options – a pill or a shot.



Are you a trans woman, or a gay or bisexual man, or a man who has sex with other men?



Are you 18 years or older? Do you use drugs? Are you HIV-negative?

If so, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 1 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments all at the study site in Hollywood. You may earn up to \$435 or \$1,030 (based on randomization and study participation) in gift cards.



CALL or TEXT 323-493-6824

friendscommunitycenter.org 6800 Santa Monica Blvd, Los Angeles, CA 90038

PrEP Makes Sense



It's like a safety belt for your health.



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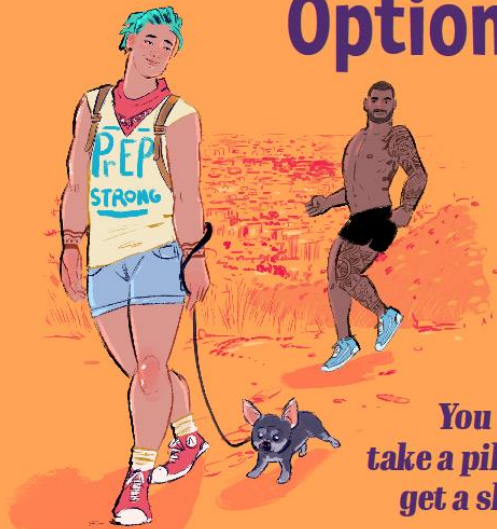


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Interested in PrEP Options?



**You can
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It's Time for PrEP



Taking care of yourself comes first.

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Are you 18 years or older? Do you use drugs? Are you HIV-negative?

If so, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 1 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments all at the study site in Hollywood. You may earn up to \$435 or \$1,030 (based on randomization and study participation) in gift cards.

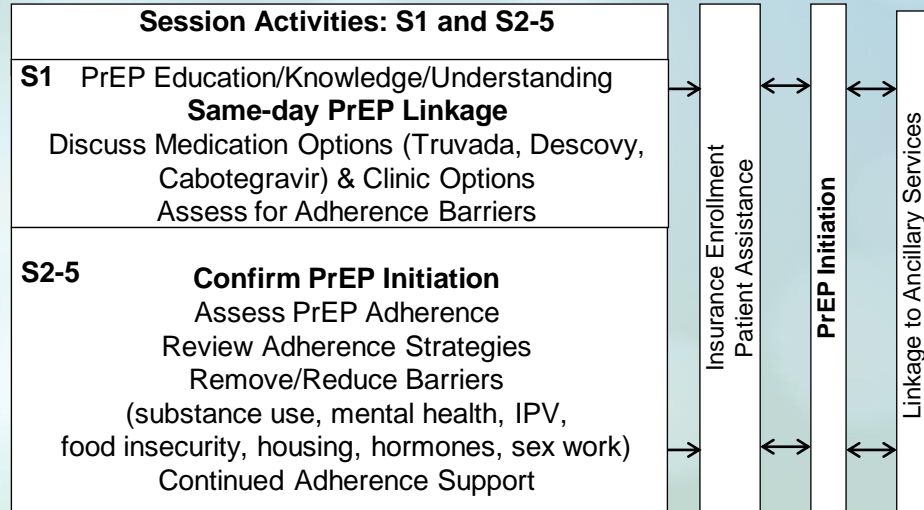


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A.S.K.-PrEP Intervention Delivery System



Support Text Messages

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Trans Text Messages

SST	Your trans beautiful body is worth protecting, stay on PrEP
HBM	Take PrEP to stay healthy and beautiful. If you don't want to take a PrEP pill, you can get a PrEP shot
SCT	Hormones are safe to take with PrEP! PrEP is safe to take with hormones! You can do both!
SST	Be good to yourself and stay on PrEP, because you are priceless!
HBM	Getting frisky doesn't have to be risky, if you are on PrEP
SCT	Hey gurl, you can prioritize PrEP, even if you're high
SST	Live a trans healthy life, take your PrEP
HBM	Don't be a statistic. We need every trans woman on PrEP
SCT	Doing drugs? You can take your PrEP, too
SST	Protect your trans beautiful health by taking PrEP
HBM	Don't skip PrEP, gurl, the consequences can be harmful
SCT	You can take care of yourself and your trans community by taking PrEP

SMM Text Messages

SST	Take your health seriously by taking PrEP seriously
HBM	Take PrEP to stay healthy. If you don't want to take a PrEP pill, you can get a PrEP shot
SCT	If you can see your friends, you can get your PrEP
SST	Be good to yourself and stay on PrEP, because you are worth it
HBM	Getting frisky doesn't have to be risky, if you are on PrEP
SCT	You can prioritize PrEP, even if you're high
SST	Stay on PrEP to maintain your negative status
HBM	Don't be a statistic, don't forget about PrEP
SCT	Doing drugs? You can take your PrEP, too
SST	Take PrEP before you PnP
HBM	Don't skip PrEP, the consequences can be harmful
SCT	Take care of yourself, take care of your sex partners, take PrEP

SST = Social Support Theory
 HBM = Health Belief Model
 SCT = Social Cognitive Theory

Contingency Management Payout Schedule

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Week #	Mon	Wed	Fri	Bonus	Weekly Totals	Total Earned
Week 1	\$2.50	\$3.00	\$3.50	\$7.50	\$16.50	\$16.50
Week 2	\$4.00	\$4.50	\$5.00	\$7.50	\$21.00	\$37.50
Week 3	\$5.50	\$6.00	\$6.50	\$7.50	\$25.50	\$63.00
Week 4	\$7.00	\$7.50	\$8.00	\$7.50	\$30.00	\$93.00
Week 5	\$8.50	\$9.00	\$9.50	\$7.50	\$34.50	\$127.50
Week 6	\$10.00	\$10.50	\$11.00	\$7.50	\$39.00	\$166.50
Week 7	\$11.50	\$12.00	\$12.50	\$7.50	\$43.50	\$210.00
Week 8	\$13.00	\$13.50	\$14.00	\$7.50	\$48.00	\$258.00
Week 9	\$14.50	\$15.00	\$15.50	\$7.50	\$52.50	\$310.50
Week 10	\$16.00	\$16.50	\$17.00	\$7.50	\$57.00	\$367.50
Week 11	\$17.50	\$18.00	\$18.50	\$7.50	\$61.50	\$429.00
Week 12	\$19.00	\$19.50	\$20.00	\$7.50	\$66.00	\$495.00
Maximum CM Payout:						\$495.00

Baseline Sociodemographics as of 5/15/24 (n=94)

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Variable	Category	n (%) or Mean (SD)
Sex/Gender	Male (cisgender)	82 (87.2%)
	Trans female/feminine	12 (12.8%)
Age		45 (13.2)
Race/Ethnicity*	Latinx	30 (26.6%)
	White	21 (18.6%)
	African American/Black	38 (33.6%)
	Other/Multi	24 (21.2%)
Sexual Identity	Gay	43 (43.8%)
	Bisexual	32 (33.3%)
	Heterosexual/Straight	9 (9.4%)
	Other	10 (12.5%)
Unstable Housing	Yes	39 (40.6%)
Education Attainment	Less than High School	11 (11.5%)
	High School Diploma/GED	26 (27.1%)
	Some College	36 (28.1%)
	College Graduate/Postgraduate	21 (21.8%)

*not mutually exclusive

Substance Use Disorder at Baseline as of 5/15/24 (n=94)

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	Mild	Moderate	Severe
Methamphetamine	6	4	48
Amphetamine	2	1	4
Cocaine	2	1	12
Hallucinogens	0	0	3
Inhalants	0	2	4
Opiates	0	0	4
PCP	0	0	0
Sedative/Benzo	0	1	0
TOTAL	10	9	75

PrEP Initiation as of 5/15/24

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- Slightly over one-third, n=94 (38%), of the total # of participants have enrolled in the study; 70 have been randomized into the *A.S.K.-PrEP* arm and 24 into the Standard of Care (SOC) arm
- 58/70 (83%) of those randomized to *A.S.K.-PrEP* have been linked to a PrEP provider
- As of 5/15/24, 52 participants completed their 3-month follow-up assessment

At the 3-month follow-up assessment,

23/35 (57%) of those randomized to

A.S.K.-PrEP initiated PrEP

- 21 initiated oral-daily PrEP
- 2 initiated long-acting injectable PrEP

At the 3-month follow-up assessment,

4/17 (24%) of those randomized to **SOC**

initiated PrEP

- 2 initiated oral-daily PrEP
- 2 initiated long-acting injectable PrEP

Stepped Care Status as of 5/15/24

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- **At the 3-month follow-up assessment**, 27/35 (77%) have been identified as non-responders based on the following criteria (not mutually exclusive):
 - Did not initiated PrEP = 15
 - On oral daily but non-adherent = 3
 - On LAI but no 2nd dose = 0
 - Self-reported drug use of targeted SUD = 14
 - Positive urine drug screen for targeted SUD = 11
- 14/27 (52%) of non-responders were re-randomized to **A.S.K.-PrEP + CM**
- 13/27 (48%) of non-responders were re-randomized to **CM alone**
- Out of a possible 948 CM visits, 337 were attended (36%)
 - 293/337 (87%) had a nonreactive urine sample for their targeted SUD
- Among those randomized to **A.S.K.-PrEP + CM**, out of a possible 496 CM visits, 163 were attended (33%)
 - 128/163 (79%) had a nonreactive urine sample for their targeted SUD
- Among those randomized to **CM alone**, out of a possible 452 CM visits, 174 were attended (38%)
 - 165/174 (95%) had a nonreactive urine sample for their targeted SUD

Conclusions

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There is an urgent need for effective, scalable behavioral interventions that can encourage PrEP initiation and advancement along the PrEP Care Continuum.

Sociodemographics & SUD

To date, most participants have identified as gay/bisexual SMM and BIPOC.

Mean age: 45 years (13.2).

41% reported unstable housing, and 39% earned a high school diploma or less.

Most participants (62%) were diagnosed with a Methamphetamine Use Disorder; 51% severe.

PrEP Linkage & Initiation

PrEP linkage has been strong with 83% in the *A.S.K.-PrEP* arm linked to a PrEP provider.

PrEP initiation has been greater among those in the *A.S.K.-PrEP* arm than those in SOC (57% vs. 24%).

Stepped Care

At 3-mo f/u, 27/35 (77%) were identified as a non-responder, primarily due to non-PrEP initiation (56%) and/or substance use (52%) and stepped up to a CM intervention.

Contingency Management

Thus far, adding PrEP navigation (*A.S.K.-PrEP*) to CM has not increase attendance at CM visit, nor increased nonreactive urine samples for targeted SUD.

Recruitment and enrollment will continue through May 2026.

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Thank You!

Cathy Reback
reback@friendsresearch.org