

Enhancing Pre-Exposure Prophylaxis (PrEP) Adherence in Men Who Have Sex with Men: Determining Optimal Content for a PrEP Adherence Package



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What We Know...

- ❑ **The iPrEx Study:** Adherence to PrEP was associated with greatly increased protection from HIV infection.
- ❑ **The FEM-PrEP Study:** Along with other variables, inadequate adherence may have contributed to the 33 HIV-infections before study was discontinued.
- ❑ **Partners PrEP Study:** Drug levels/adherence correlated with protective effect.
- ❑ **Cognitive Behavioral Therapy (CBT)-based** adherence interventions have been associated with improved adherence to ART.



Project PrEPare

Purpose: To determine the optimal content for a PrEP adherence intervention for MSM who are at high risk for HIV acquisition and to test its feasibility in a RCT.

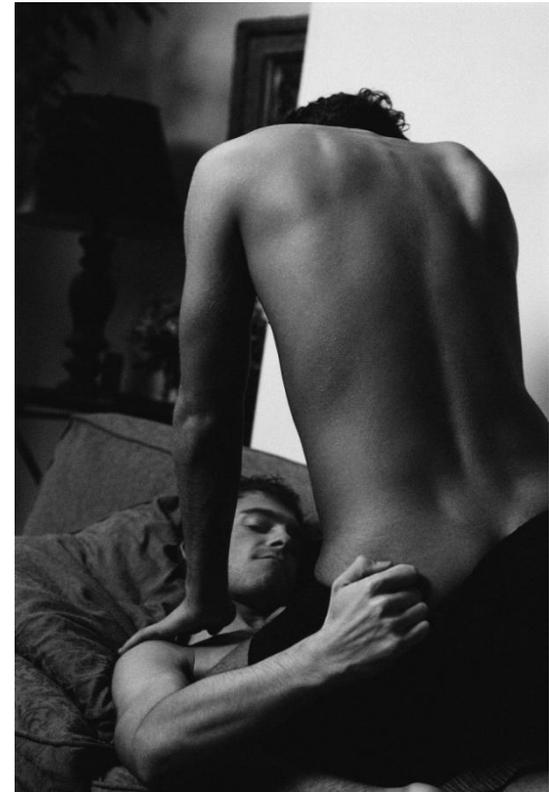
Stage 1: Formative Exploration

☐ Focus groups

- Two groups of former participants in one of two PrEP trials conducted at Fenway Health
- Two groups of naïve participants

Stage 2: Open Pilot (N=10)

Stage 3: Feasibility RCT (N=50)



Focus Group Procedures

Focus Group Entry Criteria

PrEP Experienced	PrEP Naïve
MSM	MSM
HIV-uninfected	HIV-uninfected
UAI in past 3 months	UAI in past 3 months
Participated in iPrEX or CDC PrEP studies	PrEP Naïve

- 4 groups <12 participants per group (total N=39)
- Duration: ~2 hours
- Facilitated discussion
- Semi-structured interview guide
- M.D. in attendance to field specialized medical questions

Setting: Fenway Health

- ❑ Founded 1971: Primary care neighborhood health center
- ❑ Diverse populations, specializing in care for sexual and gender minorities
- ❑ Largest primary care center for LGBT patients in New England
- ❑ >20,000 primary care patients
- ❑ >1700 HIV+ patients in care



Methodology

Qualitative Description

- Naturalistic Inquiry
- Low-level interpretation

Content Analysis

- Within-case/across-case review
- Line-by-line coding

Significant Statements

- Emerging themes
- Integration into the literature and/or intervention

Participant Characteristics

Demographics	PrEP Groups (N=19)	Naïve Groups (N=20)
Age (in years)	44.37 (6.98)	44.05 (11.00)
Sexual Orientation	N (%)	N (%)
Heterosexual/straight	1 (5.0)	2 (10.5)
Homosexual/gay	13 (65.0)	11 (57.9)
Bisexual	4 (20.0)	3 (15.8)
Other	1 (5.0)	3 (15.8)
Racial Group	N (%)	N (%)
Black/African American	5 (25.0)	12 (63.2)
White	15 (75.0)	6 (31.0)
American Indian	0 (0)	1 (5.3)
Education	N (%)	N (%)
High School or Less	6 (30.0)	6 (31.6)
Some College	3 (25.0)	4 (21.1)
College Graduate	5 (25.0)	4 (21.1)
Graduate Work	6 (30.0)	5 (36.0)
Alcohol Use (any)	11 (55.0)	15 (79.0)
Substance Use (any)	11 (55.0)	11 (57.9)

5 Emerging Themes

PrEP Education Information

I think there needs to be more education about how it (PrEP) effects our health, because I read an article and it wasn't clear to me. I wasn't convinced that this really can benefit the community.

AA, 48 y/o, Naïve



What if someone's taking this inconsistently, and they do become positive, and they've taken it for a long time, they probably wouldn't be able to take this once they became positive, right?

C, 49 y/o, Naïve

Motivation to Participate

I wanted the protection. And then the idea of contributing to a larger good, that this might become common knowledge that this pill works... But my primary motivation was my behavior was not under control; I want to find out if this pill can protect me.

C, 52 y/o, PrEP

Being part of something that was part of the community -- that's why I got involved. It gave me what I was looking for. There's no doubt about that. Very positive.

C, 50 y/o, PrEP

Potential Barriers to Adherence

Mental Health Burdens: I have problems with anxiety and insomnia. When it was at its worst, it was when I couldn't take the medication.

C, 44 y/o, PrEP

Perceived Stigma: Truvada is a medication for people who are HIV, right? If somebody finds out you're taking Truvada, they're going to think you're HIV.

AA, 48 y/o, Naïve

Provider Relationship: Some people aren't "out" to their provider, let alone telling them 'I'm engaged in risky sexual behaviors.' I think those conversations don't happen very often.

C, 38 y/o, PrEP

Potential Facilitators of Adherence

I have a double ritual [schedule] , which is at night I take the pill out and I put it by the bed, so in the morning, I take it.

C, 51 y/o, PrEP

I travel with it, so if I was going to work, I'd put it in a bag with vitamins and have a couple extra, because if I forgot it at home, I would take it at work.

C, 38 y/o, PrEP

You could have phone calls, or emails, telling you to take it, just automatically generated on a daily basis.

AA, 45 y/o, Naïve

Sexual Decision Making

The first thing that comes to mind when I hear about a pill such as that would be that I could push the condom aside and I can have this pill, so if something goes wrong this is the contraceptive.

AA, 30 y/o, Naïve



I'm thinking to myself, if I fell in love with somebody who was HIV-positive, and I was a "bottom," that PrEP would be perfect for me. It would allow us to have a little bit less stress around our intimacy. And, I'm not saying we shouldn't still be safe.

C, 30 y/o, Naïve

How Can These Themes Inform a PrEP Adherence Intervention?

Emerging Themes	Putative Intervention Content Areas
PrEP Education	Information Empirically informed curricular content
PrEP Motivations	Identify individualized motivated targets for adherence
Barriers to Adherence	Adherence Problem Solving
Facilitators of Adherence	Novel approaches (e.g., texting, smart phone apps, creative dosing, storage)
Sexual Decision Making	Sexual risk appraisal, sexual risk education, PrEP disclosure

Project PrEPare: Next Steps

❑ Openly pilot CBT-based adherence intervention with up to 10 participants

- Adapt implementation iteratively
- Augment the CBT-based intervention
- Use wise pill delivery/text messaging



❑ Randomized Control Trial: Pilot (N=50)

- To conduct a feasibility RCT trial of a PrEP prescription plus adherence package compared to an active, time-matched control:
 - Experimental group: **Novel CBT-based Adherence Intervention**
 - Comparison/control group: **Health Education and Supportive Counseling**

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