

LIFE-STEPS for PrEP

Evidence-Informed for PrEP Medication Adherence/Persistence

INTERVENTION DESCRIPTION

Goal of Intervention

- Increase PrEP adherence/persistence

Target Population

- Men who have sex with men (MSM) who are HIV-uninfected and at high risk for HIV acquisition

Brief Description

Life-Steps for PrEP is a nurse-delivered, individual-level, cognitive-behavioral intervention that focuses on PrEP adherence, sexual behavior, and barriers to adherence. *Life-Steps for PrEP* is adapted from *Life-Steps*, a brief intervention to increase ART adherence for persons with HIV. The intervention consists of four counseling sessions and two booster sessions, and participants are provided with a six-month supply of PrEP* over the course of the study. At the initial session, participants are given a 30-day supply of PrEP and are introduced to the program. The first session includes rapport building, discussing the psychosocial context in which PrEP use would occur, a brief motivational interviewing exercise, and exploring the establishment of a regular dosing schedule. The second session focuses on understanding participants' experiences taking PrEP and engaging in a problem-solving activity to address any reported barriers to adherence. The third session introduces sexual risk behavior education, identifies high-risk activities, and factors that could increase and decrease personal risk for HIV as well as other sexually transmitted infections. The session also involves a discussion about biological factors associated with HIV transmission (e.g., partners' level of infectiousness, measured by plasma HIV RNA) and discusses ways to reduce their risk in the context of taking PrEP. The final session involves setting PrEP adherence goals and discussing prior session content, as well as the participant's plans for continued PrEP use upon intervention completion. The session context is designed to be flexible, allowing participants to identify their adherence support needs; optional modules provide a framework to help interventionists work with participants who are experiencing substance abuse or mental health concerns that are adversely impacting PrEP adherence. The two booster sessions include electronic real-time adherence monitoring.

Theoretical Basis

- Cognitive-Behavioral therapy
- Problem-solving therapy

Intervention Duration

- Four weekly 50-minute delivered over one month plus two booster sessions at two and three months

Intervention Setting

- Primary care clinic for sexual and gender minority patients

Deliverer

- Trained nurse-counselor

Delivery Methods

- Counseling
- Discussion
- Goal setting/plan
- Risk reduction supplies
- Skills building

Structural Components

- None reported

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Steven Safren**, University of Miami, Mental Health and the Health Promotion and Care Research Program, Coral Gables, Florida 33124.

Email: ssafren@miami.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in Boston, Massachusetts between November 2012 and June 2014.

Key Intervention Effects

- Increased PrEP adherence/persistence

Study Sample

The baseline total study sample of 50 men is characterized by the following:

- 86% white, 8% Hispanic/Latino, 4% other, 2% black or African American
- 100% male
- Mean age of 38 years, standard deviation (SD) = 12.6
- 62% used alcohol/ binge drank (5 or more drinks) during the past month
- 64% used recreational drugs during the past month

Recruitment Settings

Clinic providing primary care for sexual and gender minority patients.

Eligibility Criteria

Men (assigned male at birth), 18 years or older who were HIV-uninfected and at high risk for HIV acquisition, defined by having condomless anal sex (insertive or receptive) with an HIV-infected partner at least once in

the prior three months, or condomless anal sex (insertive or receptive) at least three times in the last three months with at least two partners during the same time period, were eligible if they were medically cleared to take PrEP.

Comparison Group

The comparison group (Information and Supportive Counseling) was a time- and session-matched comparison condition. Participants randomized to this condition were also provided with PrEP*, but the sessions did not focus on problem solving PrEP adherence challenges or include other cognitive behavioral interventions. Each session started with education on a specific health concern such as sexual health, diet, or exercise. After this discussion, the nurse counselor spent the remainder of the session providing supportive counseling on a topic dictated by the participant. If mental health concerns were presented, they were referred to appropriate care at the clinic where the study took place.

Relevant Outcomes Measured and Follow-up Time

- PrEP drug levels (plasma tenofovir) were measured at 3- and 6-month follow-up assessments. Plasma tenofovir (TFV) was isolated via protein precipitation and quantified via liquid chromatography-tandem mass spectrometry.
- PrEP medication adherence/persistence was measured via Wisepill™, an electronic pill storage device that allows for real-time adherence monitoring) at 3- and 6-month follow-up assessments.

Participant Retention

- Life-Steps for PrEP (intervention):
 - 84% retained at 3 months
 - 76% retained at 6 months
- Information and Supportive Counseling (comparison):
 - 80% retained at 3 months
 - 80% retained at 6 months

Significant Findings on Relevant Outcomes

- Intervention participants had significantly higher mean plasma tenofovir levels than comparison participants at 6 months post-intervention (157.8 ng/ml, SD = 131.6 vs. 101.0 ng/ml, SD = 84.1, $p = 0.037$).
- Eighty-four percent of intervention participants had drug levels consistent with daily tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) compared to 63% of comparison participants at 6 months ($p = 0.03$).

Note: These findings were based on using mean substitution for imputing missing data and intent-to-treat analyses.

Additional Study Strengths

- Focused on MSM

Considerations

Due to sample sizes per arm are < 40 but ≥ 25 , this intervention is considered as an Evidence Informed Intervention (EI), not an Evidence-Based Intervention (EBI).

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

- There were no significant intervention effects at three months on PrEP drug levels (plasma tenofovir)
- There were no significant intervention effects at three or six months on PrEP medication adherence/persistence (Wisepill™ adherence monitoring)

Negative findings

- None reported

Other related findings

- There were no significant differences in the proportion engaged in condomless anal sex between the intervention and comparison groups assessed as weeks with less than 100% condom use measured by daily text messages (61% vs. 58%, odds ratio (OR) = 0.9, CI = 0.6 – 1.2, p = 0.47).

Implementation research-related findings

- None reported

Process/study execution-related findings

- Training for the intervention trainers was conducted over two half-day sessions. Training content focused on the fundamentals of using cognitive-behavioral therapy and problem-solving therapy to support health related behavior change, as well as the intervention protocol. In addition, role plays to illustrate key concepts were used.

Adverse events

- Three serious adverse events (SAEs) were identified. These SAEs occurred in the comparison condition and included hospitalizations for the following reasons: appendicitis, bowel obstruction, and panic attack that were not related to PrEP use.
- Two participants developed changes in renal function which resolved after product discontinuation and several participants reported mild and transient gastrointestinal symptoms, primarily flatulence or diarrhea, but only one participant discontinued product use because of symptoms.
- There were no social harms that emerged due to participation in the trial; however, one participant discontinued PrEP because of personal concerns of others' perceptions regarding his PrEP use.

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*Gilead Sciences provided an unrestricted supply of study medication

REFERENCES AND CONTACT INFORMATION

Reference for trial

Mayer, K. H., Safren, S. A., Elsesser, S. A., Psaros, C., Tinsley, J. P., Marzinke, M., Clarke, W., Hendrix, C., Wade Taylor, S., Haberer, J., & Mimiaga, M. J. (2017). [Optimizing pre-exposure antiretroviral prophylaxis adherence in men who have sex with men: Results of a pilot randomized controlled trial of “Life-Steps for PrEP.”](#) *AIDS and Behavior*, 21, 1350-1360.

Reference for intervention manual

Psaros, C., Mayer, K. H., Mimiaga, M. J., Puccinelli, M. J., Taylor, S. W., Elsesser, S. A., & Safren, S. A. (2020). *Life-Steps for PrEP*. Unpublished intervention manual. [Available from author, Steven A. Safren]

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