PrEPmate

Evidence-Based for Retention in PrEP Care
Evidence-Based for PrEP Medication Adherence/Persistence

INTERVENTION DESCRIPTION

Goals of Intervention
- Improve retention in PrEP care
- Improve PrEP medication adherence/persistence

Target Population
- HIV-negative young men who have sex with men (YMSM) at risk for HIV acquisition

Brief Description

PrEPmate is a multicomponent mobile health (mHealth) intervention that consists of short-message service (SMS) and youth-tailored interactive online content to enhance PrEP adherence among HIV-negative, at-risk YMSM. The SMS-based adherence support component includes weekly "check in" messages asking participants how they are doing with PrEP. Participants also receive daily pill-taking reminder messages sent at a customized time for two weeks after initiating PrEP, with the option to continue reminders throughout the study. Study staff reach out to participants who indicate they need assistance via text or phone call and provide tailored support. Additionally, the platform (i.e., texts, phone calls) supports two-way communication between participants and the project director during the study, which includes reminders for upcoming PrEP clinic visits. Online components include a password-protected website providing access to key information about PrEP, videos and testimonials of peers taking PrEP, and an online support forum moderated by study staff to provide a confidential space to discuss PrEP-related issues with other participants. Both intervention and comparison participants were shown a video explaining how PrEP works in the body.

Theoretical Basis
- Information Motivation and Behavioral (IMB) Theory of Behavior Change

Intervention Duration
- 36 weeks

Intervention Setting
- Clinic
- Online/text messages

Deliverer
- Healthcare worker (e.g., clinician)
- Health educator
- Project director
- Study staff

Delivery Methods
- Counseling (PrEP adherence, risk reduction)
- Online videos
- Interactive text messages
- Phone calls

Structural Components
- None reported

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Albert Y. Liu**, HIV San Francisco Department of Public Health, 25 Van Ness Avenue, Suite 100, San Francisco, CA 94102.

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EVALUATION STUDY AND RESULTS

Study Location Information
The original evaluation study was conducted in Chicago, Illinois between April 2015 and November 2016.

Key Intervention Effects
- Improved retention in PrEP care
- Improved PrEP medication adherence/persistence

Study Sample
The baseline study sample of 121 MSM is characterized by the following:

PrEPmate (n = 81)
- *41% Hispanic/Latino, 27% black or African American, 24% white, 4% Asian, 5% other*
- *96% male; 4% transgender/genderqueer*
- *Mean age of 24.2 years, standard deviation (SD) = 3.0*
- *78% has health insurance*
- *45% has primary care provider*

Standard of Care (n = 40)
- *28% Hispanic/Latino, 30% black or African American, 28% white, 13% Asian, 3% other*
- *93% male; 8% transgender/genderqueer*
- *Mean age of 24.4 years, standard deviation (SD) = 3.3*
- *80% has health insurance*
- *52% has primary care provider*

Recruitment Settings
Public health clinic focused on HIV prevention, online advertisements, and provider referrals

Eligibility Criteria
English-speaking MSM aged 18–29 years who were HIV-negative, as determined within 7 days of enrollment by a non-reactive, laboratory-based, third generation antibody test, and interested in and medically eligible to take PrEP (creatinine clearance >60 mL/minute by the Cockcroft-Gault equation, hepatitis B surface antigen negative, and no other contraindications to PrEP use). Participants had to report having anal sex with a man

and one of the following behavioral risk criteria in the past 6 months: (1) condomless anal sex, (2) ≥3 anal sex partners, (3) self-reported new sexually transmitted infection (STI), or (4) known HIV-infected partner. Participants were also required to have regular availability of a computer and/or smartphone to access the Internet and the ability to send and receive text messages. Participants were excluded if they reported PrEP use within the past year, prior participation in the active arm of an HIV vaccine trial, evidence of acute HIV infection at enrollment, or history of nontraumatic pathological bone fracture.

Assignment Method

Study participants (n = 121) were randomized (2:1) to either PrEPmate (n = 81) or Standard of Care (n = 40).

Comparison Group

Standard of Care (n = 40) included a risk assessment, PrEP education, and brief adherence and risk-reduction counseling conducted by a health educator; clinical evaluation, medical management, and PrEP dispensation by a study clinician; and access to a pager to reach a clinician whenever needed. Participants received reminders for clinic visits via phone calls per the local clinic protocol. Additionally, all participants (including the intervention group) were shown a video explaining how PrEP works in the body.

Relevant Outcomes Measured and Follow-up Time

- Retention in PrEP medical care was measured by having a PrEP study visit completed at 4, 12, 24, and 36 weeks.
- PrEP adherence was measured by having a visit completed and blood test showing TFV-DP ≥700 femtomole (fmol)/punch (consistent with ≥ 4 doses/week). This has been associated with high levels of protection among MSM in the iPrEx Open Label Extension. PrEP adherence was measured at 4, 12, 24, and 36 weeks.

Participant Retention

- PrEPmate intervention arm:
  - 96% retained at 4 weeks follow-up
  - 86% retained at 12 weeks follow-up
  - 81% retained at 24 weeks follow-up
  - 80% retained at 36 weeks follow-up

  Average proportion of retention rate: 86%
- Standard of Care control arm:
  - 88% retained at 4 weeks follow-up
  - 75% retained at 12 weeks follow-up
  - 65% retained at 24 weeks follow-up
  - 57% retained at 36 weeks follow-up

  Average proportion of retention rate: 71%

Significant Findings on Relevant Outcomes

- A significantly larger proportion of visits were completed by PrEPmate participants compared to Standard of Care participants (86% vs. 71% among all visits; odds ratio (OR) = 2.62; 95% CI: 1.24 - 5.54; p = 0.01). This finding remained significant after adjusting for baseline differences in depression (adjusted OR = 2.73, 95% CI: 1.30 – 5.74, p = 0.008).
- A significantly larger proportion of visits had protective TFV-DP levels ≥ 700 fmol/punch among PrEPmate participants compared to Standard of Care participants (72% vs 57% of all visits; OR= 2.05, 95% CI: 1.06 - 3.94; p = 0.03). This finding remained significant after adjustment for baseline differences in depression (adjusted OR = 2.06, 95% CI: 1.07 - 3.99, p = 0.03).

Note: All analyses were conducted on an intention-to-treat basis.

Additional Study Strengths

- Focused on young MSM
- No disparities in study outcomes (see Considerations)

Considerations

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

- PrEPmate efficacy for both retention and adherence did not differ significantly by age, race/ethnicity, education, or insurance (all p value > 0.05 for interaction) (See Additional Study Strengths)

Negative findings

- None reported

Other related findings

- No HIV seroconversions occurred over 74.3 person-years of follow-up, with an incidence rate 0.0 per 100 person years (95% CI: 0.0 - 5.0) for both arms.
- Mean number of anal sex partners, proportion reporting condomless anal sex, and proportion with a diagnosed STI all declined from baseline during follow-up (all $p < 0.05$) for both arms.

Implementation research-related findings

- None reported

Process/study execution-related findings

- 88% of participants in the PrEPmate arm reported the intervention was very/somewhat helpful; 83% wanted to continue using PrEPmate after the study, and 92% would recommend it to others at week 36.
- No social harms (e.g., experiencing stigma or rejection) were reported related to PrEPmate, and few were worried others would see PrEPmate (3%) or had trouble sending and receiving messages (7%).
- The daily and weekly text message components had the largest proportion of participants reporting they were very helpful and were the most frequently used components. The authors suggest the daily and weekly text messages were the most “active ingredients” of PrEPmate.

Adverse events

- There was a report of one serious adverse event of depression and suicidal ideation in the Standard of Care arm that was assessed as not related to the study product; PrEP was stopped per the recommendation of the patient’s provider.

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REFERENCES AND CONTACT INFORMATION

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