iText

Evidence-Informed for PrEP Medication Adherence/Persistence

INTERVENTION DESCRIPTION

Goal of Intervention
- Improve PrEP adherence

Intended Population
- Men who have sex with men (MSM) who are HIV-negative and current PrEP users

Brief Description

iText is an individual-level, mobile health intervention focusing on improving PrEP adherence. The *iText* platform utilizes weekly bidirectional short message services (SMS) or email messages to check in with study participants and encourage PrEP adherence. Study participants choose their method of communication (SMS or e-mail), which outgoing message to respond to (i.e., "How are you doing?," "Are you okay?," or "How is PrEP going?") and their response to the question (i.e., "Ok" or "not OK", "Fine" or "not fine"). If a participant responds with "not OK" or did not respond to the weekly message, a reminder message is sent within 48 hours and a study staff person contacts them by phone. Following the completion of the study at 12 weeks, which was aligned with the participants' quarterly iPrEx Open Label Extension (OLE) visit, participants completed a follow-up questionnaire and were deactivated from the iText system.

Theoretical Basis
- None reported

Intervention Duration
- Weekly bidirectional support messages over 12 weeks

Intervention Setting
- Mobile phone

Deliverer
- Health Insurance Portability and Accountability Act (HIPAA)-compliant SMS support platform
- Study staff

Delivery Methods
- Bidirectional supportive messaging
- Phone calls

Structural Components

There are no structural components reported for this study.

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Jonathan D. Fuchs**, San Francisco Department of Public Health, 25 Van Ness Avenue, Suite 500, San Francisco, CA 94102.

Email: jonathan.fuchs@sfdph.org for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information
The original evaluation study was conducted in San Francisco, CA, Chicago, IL, and Boston, MA from 2011 to 2012.

Key Intervention Effects
- Increased PrEP adherence

Study Sample
The analytic study sample of 56 MSM is characterized by the following:
- *68% White, 12% Black or African American, 11% Hispanic, Latino, or Latina, 9% other*
- *75% >30 years, 25% ≤ 30 years*
- *87% completed some college*

Recruitment Settings
iPrEX OLE sites in San Francisco, Chicago, and Boston

Eligibility Criteria
MSM were eligible if they had taken tenofovir/emtricitabine (TDF/FTC) for at least 12 weeks, were willing to continue taking TDF/FTC for an additional 12 weeks and had a text-capable phone or active email account to receive and send messages.

Comparison Group
This study used a one-group pre/post design: pre-intervention/baseline data were compared to post-intervention data (first post-iText visit).

Relevant Outcomes Measured and Follow-up Time
- PrEP medication adherence/persistence was measured by pill count, self-report, and medication possession ratio:
    - Pill count: clinic-based pill counts in reporting period
    - Self-report: self-reported missed days in reporting period
    - Medication possession ratio: number of doses dispensed, divided by the number of days in the reporting period

Participant Retention
Participant retention is not a criterion for PrEP intervention studies tested with one-group, pre-post or historical comparison designs.

Significant Findings on Relevant Outcomes
- When measured by pill count, the mean number of days when medication was not taken significantly decreased from pre- to post-intervention (Relative Risk [RR] = 0.50; 95% Confidence Interval [CI]: 0.29 – 0.84; p = 0.008).
- When measured by pill count and the analysis was restricted to include the two visits just before and after entering iText, there was a significant decrease in the proportion of missed doses from pre- to post-intervention (RR = 0.23; 95% CI: 0.08 – 0.67; p = 0.007).
- When measured by medication possession ratio and the analysis was restricted to include the two visits just before and after entering iText, there was a significant percent increase from pre- to post-intervention (Percent increase = 28.4%; 95% CI: 0.2 – 64.6; p = 0.048).

Strengths
- None reported

Considerations
An updated version of iText, called PrEPmate, has been evaluated in a randomized controlled trial and identified as an Evidence-Based Intervention (EBI) in the PRS PrEP chapter.

Additional significant positive findings on non-relevant outcomes
- None reported

Non-significant findings on relevant outcomes
- There were no significant intervention effects for self-reported adherence from pre- to post-intervention (RR= 0.51; 95% CI: 0.23 – 1.17; p = 0.11) or visits just before and after entering the intervention (RR= 0.45; 95% CI: 0.19 – 1.06; p = 0.07).
- There was no significant intervention effect for the percent increase in medication possession ratio from pre- to post-intervention (Percent increase = 27.8%; 95% CI: -0.2 – 63.7; p = 0.05).

Negative findings
- None reported

Other related findings
- The iText pilot uses a convenience sample of participants on PrEP at the San Francisco and Chicago sites in iPrEx OLE.
- Due to the relatively short follow-up period and the timing of implementation near the conclusion of iPrEx OLE, measuring the persistence of effects was limited.

Implementation research-related findings
- None reported

Process/study execution findings

- iText was developed in part by feedback from focus groups consisting of 59 iPrEx OLE participants from San Francisco (n = 21), Chicago (n = 22), and Boston (n = 16). The focus groups assessed interest in and informed the adaptation of a SMS-based support strategy based on the WelTel intervention.
- More than half of enrollees (56%) reported that the messaging strategy was helpful.
- Younger participants (less than 30 years of age) were more likely to say that they would use the iText support strategy if available to them (odds ratio [OR] = 14.8, 95% CI: 1.66 – 131.4; p = 0.004).
- Compared to white participants, non-white participants were more likely to state that the iText support strategy was helpful (OR = 7.3, 95% CI: 1.4 – 37.5; p = 0.017) and were more likely to use the strategy if offered to them (OR = 4.7, 95% CI: 1.3 – 17.7; p = 0.024).
- Over 20% of participants did not respond to the initial SMS or e-mail communication, which then required study staff to follow-up and contact them by phone.
- Over one-third of participants opted to receive weekly emails rather than SMS, with most (94%) of the email recipients enrolled in the San Francisco site.
- 60% of participants selected a PrEP-specific outgoing message (i.e., “How is PrEP going?”).
- Participants preferred receiving weekly messages in the morning (63%), followed by the afternoon (30%), with few electing to receive evening messages.
- Most (80%) preferred weekly messages that were sent at the beginning of the week.
- Several San Francisco participants stated that the strategy may be most useful to people when they first start taking PrEP and less helpful for those who have been taking it for awhile
- A number of Chicago participants suggested it may be helpful to integrate the strategy with social networking sites they already use.
- In both sites, study staff members found the iText support strategy easy to use; however, they recommended:
    - Designating a staff member to engage with the iText system to reduce the extra time when interacting with iText outside of their existing visit scheduling
    - If feasible, future versions of iText should be integrated into existing retention strategies

Adverse events

- None reported

Funding

National Institute of Mental Health (grant number RO1MH095628)
National Institute of Allergy and Infectious Diseases (grant numbers UO1AI4002 and RO1AI062333)
The study drug was provided by Gilead Sciences

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Researcher: Jonathan D. Fuchs, MD, MPH
San Francisco Department of Public Health
Center for Learning and Innovation
25 Van Ness Ave. Suite 500
San Francisco, CA 94102

Email: **jonathan.fuchs@sfdph.org**