A Mobile Health Strategy to Support Adherence to Antiretroviral Preexposure Prophylaxis

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FEATURED ARTICLE

A Mobile Health Strategy to Support Adherence to Antiretroviral Preexposure Prophylaxis

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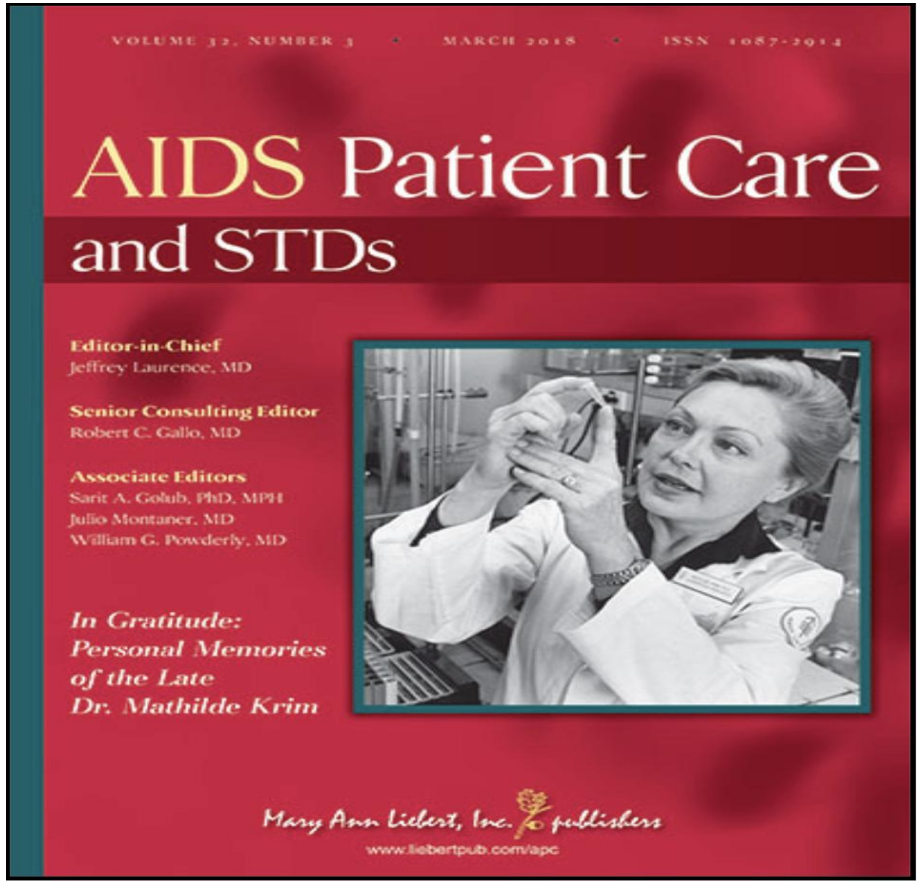
Abstract

Preexposure prophylaxis is a highly protective HIV prevention strategy, yet nonadherence can significantly reduce its effectiveness. We conducted a mixed methods evaluation of a mobile health intervention (iText) that utilized weekly bidirectional text or e-mail support messages to encourage preexposure prophylaxis (PrEP) adherence among participants in the multi-site iPrEx open-label extension study. A convenience sample of PrEP users from the San Francisco and Chicago sites participated in a 12-week pilot study. Fifty-six men who have sex with men were enrolled; a quarter of them were less than 30 years of age, 13% were black/African American, 11% were Latino, and most (88%) completed some college. Two-thirds opted for text message delivery. Of the 667 messages sent, only 1 individual requested support; initial nonresponse was observed in 22% and was higher among e-mail compared to text message recipients. Poststudy, a majority of participants would recommend the intervention to others, especially during PrEP initiation. Moreover, younger participants and men of color were more likely to report that they would use the iText strategy if it were available to them. Several participants commented that while they were aware that the messages were automated, they felt supported and encouraged that "someone was always there." Study staff reported that the intervention is feasible to administer and can be incorporated readily into clinic flow. A pre–post intervention regression discontinuity analysis using clinic-based pill counts showed a 50% reduction in missed doses [95% confidence interval (CI) 16–71; $p = 0.008$] and 77% (95% CI 33–92; $p = 0.007$) when comparing pill counts at quarterly visits just before and after iText enrollment. A mobile health intervention using weekly bidirectional messaging was highly acceptable and demonstrated promising effects on PrEP adherence warranting further evaluation for efficacy in a randomized controlled trial.

Keywords: HIV, preexposure prophylaxis, adherence, mobile health, text messaging



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BACKGROUND

High HIV incidence → PrEP → Adherence → mHealth

STUDY OBJECTIVE

Evaluate the feasibility, acceptability, and adherence effects of a weekly, bidirectional SMS- or email-based adherence support system (iText) for HIV negative men who have sex with men taking PrEP in two urban centers in the United States to inform future randomized controlled trial

WHAT'S GOING TO BE STUDIED?

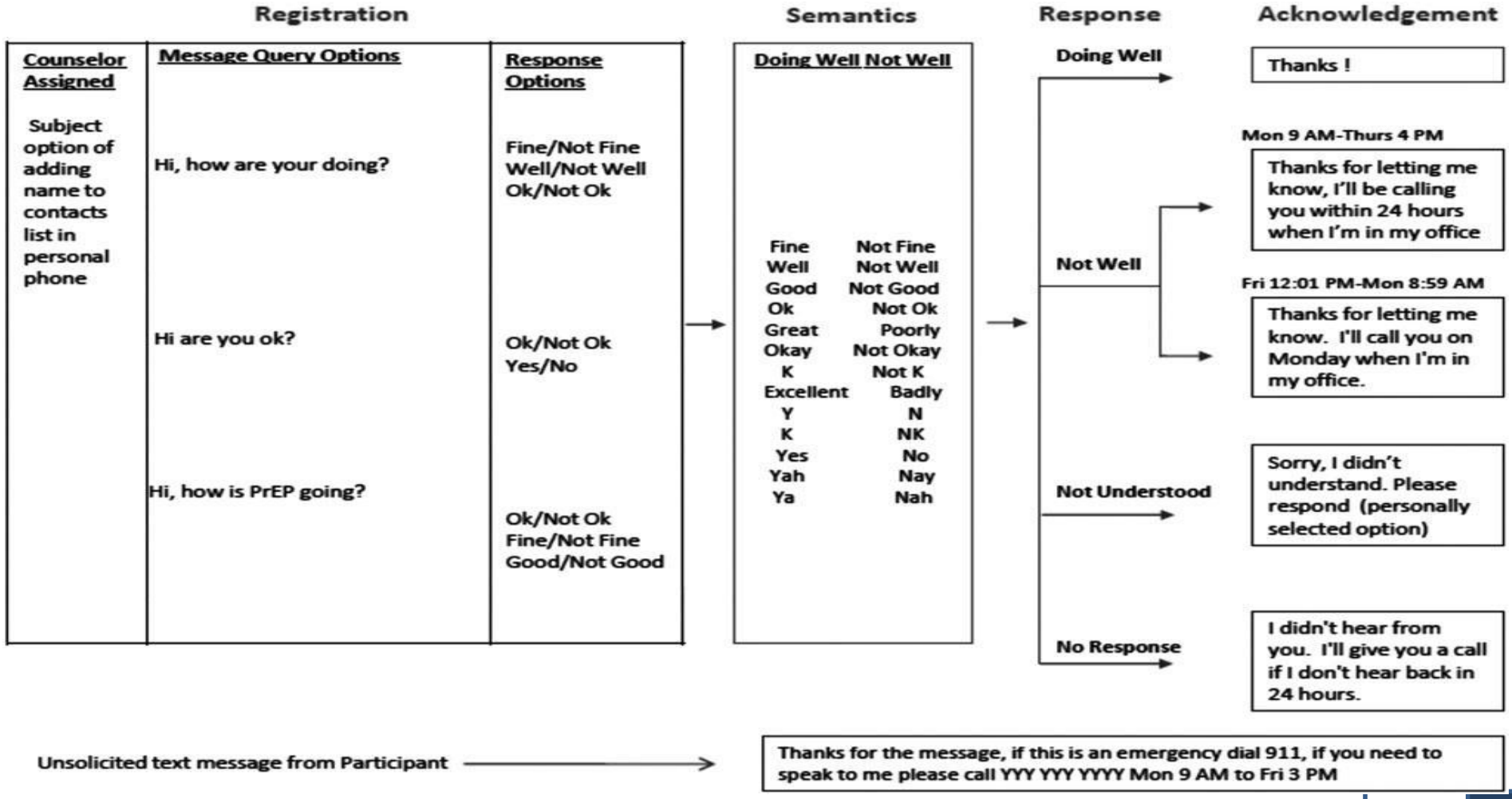
- **Feasibility study –** Any sort of study that can help investigators prepare for full-scale research leading to intervention.

  Acceptability – To what extent is a new idea, program, process or measure judged as suitable, satisfying, or attractive to program deliverers? To program recipients? (satisfaction, intend to continue use, fit within organizational structure, actual use, expressed interest or intention to use etc.)

- **Adherence –** the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider.

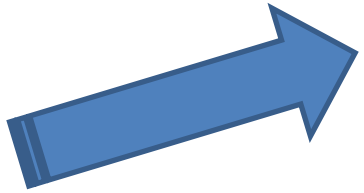
(subjective: self-report, pill counts; objective: tenofovir diphosphate levels in dried blood spots)

ITEXT PREVENTION INTERVENTION



STUDY SAMPLE

1225 PrEP users (iPrEx OLE study)[1]



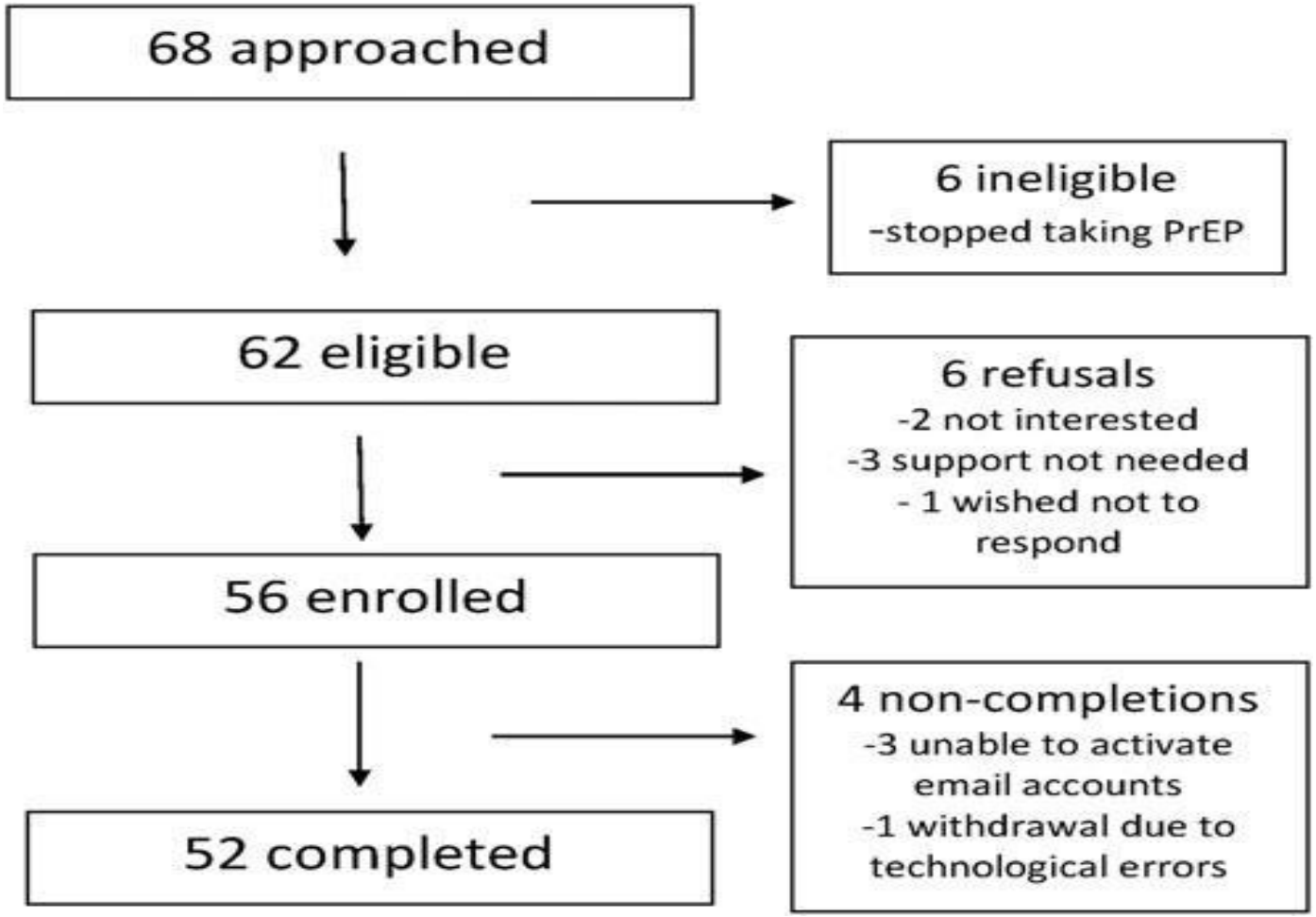
56 MSM PrEP users

Convenience sample from San-Francisco (n=48) and Chicago (n=8) sites[1]

1603 HIV-negative people, of whom 1225 (76%) received PrEP

[1] Grant, Robert M., et al. "Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study." *The Lancet infectious diseases* 14.9 (2014): 820-829.

STUDY ENROLLMENT



STUDY DESIGN

12-week pilot multi-site open-label interventional uncontrolled study augmented by qualitative interviews (mixed methods evaluation) with pre-post evaluation design

STUDY FLOW

Formative research n=59

- Were asked to reflect on existing WelTel intervention strategy
- Explored the need for e-mail alternative and personalizing content and timing of the messages
- Basis for iText Support platform

iText enrolment n=56

- Baseline questionnaire

12 weeks of receiving weekly check-in messages

iPrEx OLE quarterly visit n=52

- Follow-up questionnaire
- Clinic-based pill count
- 14 participants and staff engaged in focused groups and in-depth interviews

QUANTITATIVE DATA ANALYSIS

Primary outcome for evaluation adherence – reduction in missed doses (using clinic-based pill counts and self-report)

Pre-post intervention regression discontinuity analysis

QUALITATIVE DATA ANALYSIS

Framework analysis of post-iText focus groups and in-depth interviews with two investigators coding the transcripts to ensure consistency and agreement over coded themes.

5 stages of analysis:

1. Noting key content areas
2. Laying out a thematic framework
3. Indexing or coding the data
4. Charting salient quotes
5. Interpreting the results

RESULTS

ITEXT PARTICIPANT DEMOGRAPHIC CHARACTERISTICS, CELL PHONE OWNERSHIP AND USE, AND MODE OF MESSAGING SELECTED

	Total (n=56)		*San Francisco (n=48)*		*Chicago (n=8)*	
Variables	N	%	N	%	N	%
Age						
<=30 years	14	25.0	6	12.5	8	100.0
>30 years	42	75.0	42	87.5	0	0.0
Race/ethnicity						
Latino/Hispanic	6	10.7	4	8.3	2	25.0
White	38	67.9	38	79.2	0	0.0
Black	7	12.5	3	6.3	4	50.0
Other	5	8.9	3	6.3	2	25.0
Education						
Completed some college	49	87.5	45	93.8	4	50.0
Living situation						
Alone	15	26.8	13	27.1	2	25.0
W/male sexual partner	21	37.5	20	41.7	1	12.5
Family/friends	9	16.1	4	8.3	5	62.5
Other/roommates	11	19.6	11	22.9	0	0.0
Mobile phone and plans						
Mobile phone ownership	55	98.2	47	97.9	8	100.0
Have unlimited SMS plan[a]	43	81.1	35	77.8	8	100.0
Smartphone ownership[a]	51	92.7	45	95.7	6	75.0
Mode of messaging selected						
E-mail	18	32.1	17	35.4	1	12.5
SMS	38	67.9	31	64.6	7	87.5

[a]Of mobile phone owners.
SMS, short message service.

CHANGES IN ADHERENCE

50% reduction in missed doses [95% confidence interval (CI) 15-71; p=0,008] and 77% (95% CI 33-92; p =0.007) when comparing pill counts at quarterly visits just before and after iText enrollment.

TABLE 2. CHANGES IN ADHERENCE AFTER ENTRY INTO iTEXT

	All visits				*Visits just before and after entering iText*			
Adherence measure	N	*RR*	*CI*	p	N	*RR*	*CI*	p
Pill count[a]	355	0.50	0.29–0.84	0.008	95	0.23	0.08–0.67	0.007
Self-report[b]	359	0.52	0.23–1.17	0.11	91	0.45	0.19–1.06	0.07
	N	*% increase*	*CI (%)*	p	N	*% increase*	*CI (%)*	p
Medication possession ratio[c]	357	27.8	–0.2–63.7	0.052	96	28.4	0.2–64.6	0.048

N refers to the number of included observations. RR refers to the relative risk reduction in missed doses before and after intervention. All estimates are adjusted for age, race, iPrEx OLE entry date, days since entry, and study site.

[a]Days missed in period, as measured by clinic-based pill counts, with length of period as offset.

[b]Self-reported missed days in reporting period.

[c]Sum of days supply for all pills in period/Number of days in period; treatment effects are summarized as percent increases.

CI, confidence interval; OLE, open label extension.

IMPORTANT THEMES FROM FOCUS GROUPS AND IN-DEPTH INTERVIEWS

Participants:

“ …getting those messages made me feel like there was always somebody there just in case something went wrong.it’s kind of like I was on my own before iText.’’—Chicago participant

“That sense of security; that makes a huge difference. A big difference because you get the support you need when you come to the clinic but when you’re going back to your daily routine, you have to take the pill, you you’re not telling every single body about it.’’—Chicago participant

‘‘So if you’re starting out [on PrEP] and maybe you would have some symptoms or something you wanted to talk to somebody about, maybe that makes sense.’’—San Francisco participant

Staff:

Staff from Chicago mitigated this, in part, by designating a staff member to engage with the iText system: “What we did was have one person be the point person to login to the portal every day and make sure participants were responding, and if they weren’t, following up with them. Overall it was a pretty good setup because it didn’t get too overwhelming.”

“If the system was more incorporated in our existing retention strategies, it actually could have really helped with retention as well.”—San Francisco staff

“I really think this could have helped people if we started it at the beginning of the participant’s pill taking”—Chicago staff and in San Francisco

ASSESSING VALIDITY OF AN ARTICLE ABOUT MHEALTH INTERVENTION

- Are the results valid?
- How can I apply the results to patient care?

ARE THE RESULTS VALID?

- Was the sample representative?
- Was follow-up sufficiently complete?
- Were objective and unbiased outcome criteria used?

WAS THE SAMPLE REPRESENTATIVE?

HIV-negative MSM using PrEP; median age was 49 years, majority completed some college, 68% white.

Inclusion criteria:

Participants from iPrEX OLE study, who:

- ✓ had to take TDF/FTC as PrEP for at least 12 weeks;
- ✓ were willing to take TDF/FTC for an additional 12 weeks;
- ✓ had an SMS-capable phone or active e-mail account

Will it work on new PrEP users?

WAS FOLLOW-UP SUFFICIENTLY COMPLETE?

- Follow-up period was short, longer periods can reveal more information about relative benefits of different messaging strategies, message frequency, content and staff support
- Short follow-up limits the ability to measure persistence of intervention effects

WERE OBJECTIVE AND UNBIASED OUTCOME CRITERIA USED?

Pill counts and self-report are **subjective** measures of adherence

Number of pills does not guarantee that those missing were actually ingested

HOW CAN I APPLY THE RESULTS TO PATIENT CARE?

- Were the study patients and their management similar to those in my practice?

- What barriers do we have to use this method for increasing PrEP adherence?

DISCUSSION

- PrEP: World vs Russia
- Mixed methods evaluation
- mHealth applications