Original investigation

Feasibility of a Smartphone-Based Tobacco Treatment for HIV-Infected Smokers

Jonathan Shuter MD^{1,2}, Ryung S. Kim PhD¹, Lawrence C. An MD³,
Lorien C. Abrams ScD⁴

¹Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY; ²Department of Medicine, Albert Einstein College of Medicine, Bronx, NY; ³Department of Medicine, Center for Health Communications Research, University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; ⁴Department of Prevention and Community Health, Milken Institute School of Public Health, George Washington University, Washington, DC.

Corresponding Author: Jonathan Shuter, MD, AIDS Center, Montefiore Medical Center, 111 E 210th Street, Bronx, NY 10467, USA. Telephone: 718-920-7845; Fax: 18-405-0610; E-mail: jshuter@montefiore.org

Abstract

Background: Cigarette smoking is common among persons living with HIV (PLWH) in the United States. It is the leading cause of mortality in this group, and efforts to promote cessation have been largely unsuccessful.

Methods: From 2015 to 2017, we performed a randomized controlled trial of Positively Smoke Free–Mobile (PSF-M) versus standard care. PSF-M is a mobile Web site that offers a 42-day text message-based quit-smoking program with smartphone features including quit-day selection/calendar, educational/motivational videos, and HELP button for cravings.

Results: One hundred individuals enrolled, 48 were randomized to PSF-M (mean age = 45 years, 54% male, 81% black, 31% Latino) and 52 to the standard care condition. All participants were offered a 3-month supply of nicotine patches. Participants randomized to the mobile intervention visited the PSF-M home page a mean of 83 times, viewed 5.6/8 videos, logged in on 13 of 42 possible days, and received 131 texts. Among them, 77% tapped HELP for cravings, and craving response options were used by the following proportions: phone-a-friend, 58%; play-a-game, 29%; play-a-song, 4%. Older age and nonblack race were both associated with higher levels of engagement with the site. Of participants, 61% rated PSF-M very or extremely helpful, and 98% would recommend PSF-M to PLWH family or friends. Abstinence at 3 months, quit attempts, and daily cigarette intake all favored PSF-M over standard care but did not achieve statistical significance in our pilot sample.

Conclusions: Smartphone-based tobacco treatment for PLWH was feasible and achieved moderate–high rates of engagement and satisfaction in a middle-aged, ethnic or racial minority group in the poorest urban community in the United States.

Implications: Cigarette smoking has emerged as the leading killer of PLWH. Behavioral interventions have achieved only limited success in promoting cessation in this population. In this study, we explore the feasibility and preliminary efficacy of a multimodal, Web-based, quit-smoking intervention delivered to PLWH smokers via their smartphones.

Introduction

Persons living with HIV infection (PLWH) smoke at approximately triple the rate of the general adult population of the United States.^{1,2} In the highly active antiretroviral therapy era, cigarette smoking has emerged as the leading killer of PLWH.³ Instead of dying from opportunistic infections and HIV-related malignancies, PLWH are now dying from cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease, all driven by their high rates of tobacco use.^{4,5}

A growing body of research has explored a range of cessation strategies in PLWH-smokers. A recent meta-analysis paints a bleak picture though, noting that the various behavioral interventions tried to date have shown “no evidence of effect” on long-term cessation and that there was only “very low quality evidence that more intense tobacco cessation interventions were effective in achieving short-term abstinence.”⁶

Cell phones are an attractive tool for tobacco treatment. The vast majority of US adults have one, including those groups, that is ethnic or racial minorities, the poor, and the poorly educated, who are most heavily burdened with tobacco use and HIV infection.⁷ The effectiveness of text message, also known as short message service (SMS)-based tobacco treatments in the general population is supported by robust meta-analytic data.⁸ “Smartphones” have capabilities beyond simple text messaging that may add to their value as cessation tools. These include the ability to stream videos, play music, and accommodate graphic messages. A more basic aspect of the cell phone that may be critically important is its constant availability. In contrast to tobacco treatment counselors, quitline coaches, and even pharmacotherapy, most smokers have their cell phones within reach 24/7, and picking up a phone may provide a healthier alternative to picking up a cigarette when a craving episode occurs.

Smartphones are becoming ubiquitous in the United States, with national ownership rates of 35% in 2011 more than doubling to 77% in late 2016.⁹ The most recent uptick in ownership has been sharpest among the lower income strata and in those at least 50 years of age; 64% of those with annual household incomes less than \$30 000 and 74% of those aged 50–64 years (42% of those ≥65 years) owned smartphones in 2016. Seventy-two percent of blacks and 75% of owned smartphones in 2016.⁹ There are no significant differences in ownership between smokers and nonsmokers.¹⁰ Our prior work indicates that this important societal change reaches into the PLWH community as well.¹¹ The birth of mHealth has resulted in hundreds of quit-smoking apps available, and one study reported that these apps are accessed at a rate of more than 700 000 downloads per month.¹² Clearly, many smokers trying to quit are looking to their phones. However, only a tiny fraction of the available apps is guided by evidence-based treatment guidelines, and even fewer have any outcome data supporting their efficacy.^{12,13}

Positively Smoke Free is a multisession tobacco cessation intervention aimed at PLWH, guided by social cognitive theory principles,¹⁴ that has been studied, in its various forms, since 2007.^{15,16} In consonance with the behavioral model, the program aims to increase knowledge about nicotine addiction and the dangers of tobacco use, to promote observational learning (through vignettes and role-playing), to fortify abstinence self-efficacy (through encouragement, quit-day planning, and anticipation of cravings and tempting situations and appropriate responses to these), and to build short- and long-term outcome expectations. In this study, we developed a version of Positively Smoke Free that runs on a smartphone and incorporates

text messages. We describe herein the development and feasibility testing of the Positively Smoke Free–Mobile program (PSF-M).

Methods

PSF-M is a mobile Web site developed cooperatively by the authors (J.S. and L.C.A.) and the University of Michigan Center for Health Communications Research (CHCR). The development process included several focus groups with HIV-infected smokers, independent review by outside experts, and thorough alpha and beta testing. PSF-M consists of a number of components integrated into a single Web site that is accessed by an icon on the smartphone home screen or by tapping a link in a text message. The program is 42 days in duration. PSF-M content encourages but does not require the use of pharmacotherapy to support cessation attempts. The various components of PSF-M are summarized in the following section:

Home Screen

The PSF-M home screen is secured by a user name and password. Users are permitted to store their login information and remain logged in (Figure 1). Once logged in, the home screen provides one tap options to view a program calendar (including countdown to quit day before quit day, number of days smoke-free after quit day,

Figure 1. Positively Smoke Free–Mobile home page.

and a quit-day reset for those still smoking after quit day), estimates of how many minutes of life and how much money have been saved on cigarettes (after quit day), an inspirational quote, a streaming PSF-M video (described in the following paragraph), and a HELP button for cravings or relapses (described in the HELP button section).

Positively Smoke Free Videos

Positively Smoke Free videos were created based upon constructs of the social cognitive theory model,¹⁴ and consisted of eight educational/motivational quit-smoking sessions, each 5–10 minutes in length, targeting HIV-infected smokers. The content was crafted to integrate HIV-referent topics into the quit-smoking process (eg, comparing smoking slip-ups to missed doses of antiviral medications). The subjects covered in the videos paralleled those of an earlier version of PSF described in detail in a prior publication.¹⁶ Session 5 is the quit-day session. Sessions 1–4 are released prior to quit day, session 5 on quit day, and sessions 6–8 after quit day. An optional session 9 is available for those experiencing cravings or slip-ups after quit day. The timing of session release is dictated by this calendar, and users have unlimited access to previously viewed sessions.

Short Message Service

The SMS content is timed around the quit day. Content is interactive and includes responses to daily text message check-ins (eg, “Have you smoked in the last 24 hours?”). Prior to quit day, users receive 2 texts/day, (1) an inspirational or motivational quote, and (2) a quit-smoking tip. A third text is sent with a link to a PSF-M video session on the day that it is released and the next day as well if it has not yet been viewed. On and after quit day, users receive 4 texts/day for the first 7 days and 3 texts/day thereafter, (1) an inspirational or motivational quote, (2) request for a pledge to “stay quit today” (daily for the first 7 days postquit, and weekly thereafter), (3) a quit-smoking tip aimed at maintaining abstinence, and (4) a check-in assessing current smoking status. A fifth text is sent on the day that a new PSF-M video session is released and the next day as well if it has not yet been viewed. Additional optional texts include referral to the supplemental PSF-M video session for those experiencing slip-ups or relapses as indicated on the daily check-in, crave response tips sent to the user if he or she texts the word, CRAVE, to the site, and a generic error message sent in response to unintelligible user-initiated text content. The STOP command discontinues all further SMS communication from PSF-M.

HELP Button

The HELP button is available on the home screen for the duration of the program. Users are instructed to tap the button when cravings occur, and the HELP menu (Figure 2) then offers the following choices: (1) a review of the “D-pack” (introduced in session 2)—Deep breathing, Drink water, Do something else, Discuss with a supportive individual, and Delay until the craving passes; (2) phone-a-friend; (3) call the free New York State quitline; (4) play-a-song; and (5) play-a-game.

Data Collection

Detailed time stamps of all PSF-M site activity are recorded for each user on the CHCR server.

Figure 2. Crave responses for users who tap the HELP button.

Enrollment

Participants were eligible for enrollment if they had serologically or virologically confirmed HIV infection; were current cigarette smokers; were interested in quitting in the next 6 months; had no contraindications to nicotine patch use; had a score of at least 4 on the REALM-SF literacy scale,¹⁷ corresponding to a seventh- to eighth-grade reading level (consistent with the written content of the PSF-M site); and owned a smartphone compatible with the PSF-M site (ie all iPhones and most Androids). Individuals who met enrollment criteria and granted informed consent were randomly allocated in a 1:1 ratio, using sequential opaque envelopes that had been preloaded with an assignment card, to PSF-M or standard care based on a random number table. The individual who performed the allocation was blinded to the envelope contents and the randomization key.

1. Standard care (control) consisted of brief (<5 minutes), structured advice to quit, a self-help brochure, and an offer of a prescription for a 3-month supply of nicotine patches dosed according to the participant's reported daily cigarette consumption (all study participants had full insurance coverage for the patches).

2. PSF-M (intervention) consisted of an offer of a prescription for nicotine patches identical to the standard care condition and access to PSF-M. At the enrollment visit, the research assistant together with the participant downloaded the program icon, created a secure PSF-M login password, selected a quit day on the site (participants could choose a quit day between day 5 and day 38 postenrollment), and reviewed all PSF-M features on the participant's smartphone. Before leaving, participants were sent a welcome text, viewed PSF-M video session 1 on their phones, and demonstrated to the research assistant that they could access the site in the event of a craving.

Follow-up and Measures

The selection of key feasibility outcomes in this trial was based on Liebreich et al.¹⁸ and focused on measures of recruitment, retention, engagement, adherence, usage, and satisfaction. *Recruitment* was defined as number of individuals enrolled into the trial/number of individuals screened. *Retention* was defined as the percentage of enrollees who completed the final study visit. *Engagement* and *usage* were defined by the primary measure of total number of visits to the PSF-M home page (additional secondary measures of engagement and usage are listed in Table 1). *Adherence* was defined as willingness to set a quit day, receipt of PSF-M program text messages, and viewing of PSF-M videos (additional secondary measures of adherence are listed in Table 1). *Satisfaction* was defined by a satisfaction survey that the investigators developed for PSF-M program participants.

Interviews focused on sociodemographic background, clinical history, cigarette smoking practices, baseline smartphone usage patterns, and a range of behavioral domains known to influence smoking behaviors were completed at baseline (day 1), and days 28 and 120 postenrollment. The 10-item smartphone usage survey was derived from a Pew Research Center instrument and contained Yes or No queries about any use of: E-mail, text messaging, Internet, online banking, app downloads, video recording, still photography, games, music, and online health information (one point was awarded for each Yes response and the sum of the response points defined the smartphone usage index score for each participant).¹⁹ Smoking-related behavioral measures included an 8-item tobacco knowledge questionnaire including HIV-referent questions (developed by the investigators), Fagerstrom Tolerance Questionnaire for nicotine dependence,²⁰ Abrams–Biener Readiness to Quit Ladder for motivation to quit,²¹ Self-Efficacy/Temptation Scale,²² Smoking Decisional Balance (Short Form),²³ modified-UCLA Loneliness Scale,²⁴ Center for Epidemiologic Studies Depression–20 Scale,²⁵ Generalized Anxiety Disorder 7-Item Scale,²⁶ Perceived Stress Scale 4,²⁷ and a modified Free Time Boredom Scale.²⁸ In the follow-up interviews, items probed for nicotine patch usage, PSF-M utilization and satisfaction (intervention participants only), and study condition contamination (control participants only). Interviews were completed via audio computer-assisted self-interview (ACASI QDS software; NOVA Research, Silver Spring, MD) on secure notebook computers. The primary cessation outcome was exhaled carbon monoxide (ECO)-verified (ie ECO < 10 parts per million),²⁹ self-reported 7-day point prevalence abstinence at the 120-day time point. The cessation outcome was evaluated using an intent-to-treat approach, with noncompleters considered nonabstinent. Participants received travel vouchers and a \$30 gift card after each completed interview.

Table 1. Positively Smoke Free–Mobile (PSF-M) Prespecified Feasibility Outcomes

Prespecified outcome	Result
Recruitment and retention	
Recruitment into the trial, N (%)	100/113 (88.5)
Completion of trial, N (%)	90/100 (90.0)
Engagement with PSF-M	
Mean number of visits to home page $\pm$ SD	83.3 $\pm$ 70.5
Mean number of days using the site $\pm$ SD ^a	13.0 $\pm$ 9.24
Pushed the HELP button, N (%)	37/48 (77.1)
Reviewed the D-pack, N (%)	36/48 (75.0)
Phoned a friend, N (%)	28/48 (58.3)
Played a game, N (%)	14/48 (29.2)
Played a song, N (%)	2/48 (4.2)
Used the text message CRAVE feature, N (%)	32/48 (66.7)
Adherence to the PSF-M program	
Set a quit day, N (%) ^b	48/48 (100.0)
Reset a quit day, N (%) ^c	10/48 (20.8)
Number of PSF-M text messages sent $\pm$ SD	131 $\pm$ 38.9
Number of video sessions viewed $\pm$ SD ^d	5.69 $\pm$ 2.32
Satisfaction^e	
Satisfaction with PSF-M, N (%)	
Not at all	1/44 (2.3)
A little	6/44 (13.6)
Moderately	13/44 (29.5)
Very	18/44 (40.9)
Extremely	6/44 (13.6)
Helpfulness of PSF-M, N (%)	
Not at all	1/44 (2.3)
A little	9/44 (20.5)
Moderately	7/44 (15.9)
Very	24/44 (54.5)
Extremely	3/44 (6.8)
Would recommend PSF-M to HIV-infected family or friend who wanted to quit smoking, N (%)	43/44 (97.7)

PSF-M = Positively Smoke Free–Mobile, SD = standard deviation, N = number of participants.

^aPSF-M is designed as a 42-day intervention with the site available continuously.

^bPSF-M participants were encouraged to set a quit day on the site at study enrollment.

^cPSF-M encourages a quit-day reset for those who fail to quit on or relapse after the original quit day.

^dThe PSF-M core program contains eight 5- to 10-minute videos, with a ninth optional video for those experiencing slip-ups.

^eData were missing for the program satisfaction items from four participants.

Data Analysis

Categorical variables were analyzed using chi-square or Fisher exact test. Comparisons of means were accomplished using Student's t-test or Mann–Whitney U test. Univariate testing was not adjusted for multiple analyses. Bivariate correlation of two continuous variables was performed with Spearman's rank correlation. Multivariate analyses (multiple linear regression and logistic regression) were performed by entering all covariates having statistically significant associations with the dependent variable into the model and then completing a backward, stepwise removal of those covariates that did not meet the statistical threshold for model improvement until only those variables having a statistically significant association with the dependent variable in the fully adjusted model remained. Statistical analyses were completed using the SPSS V24.0 software package.

All aspects of the study were reviewed and approved by the Albert Einstein College of Medicine Institutional Review Board.

Results

Between December 2015 and December 2016, a total of 100 PLWH smokers enrolled. Thirteen candidates were excluded prior to enrollment, 12 because of incompatible phones and 1 because of low literacy. Ninety of the 100 (90%) participants completed the study, including 43 of the 48 (89.6%) in the PSF-M condition (Figure 3). Participants who were lost to follow-up were younger (40.1 ± 11.7 vs. 46.5 ± 10.0 years, $p = .06$), and were more likely to be employed [5/10 vs. 13/90, OR = 5.92 (95% CI = 1.50 to 23.4), $p = .02$] or to be unstably housed/homeless [5/10 vs. 12/90, OR = 6.49 (95% CI = 1.63 to 25.6), $p = .01$]. There were no significant differences between study completers and losses to follow-up by gender, race/ethnicity, educational attainment, or daily cigarette consumption.

Baseline Sociodemographic and Clinical Characteristics

Table 2 summarizes the baseline characteristics of PSF-M and standard care participants. The two groups were well-balanced on sociodemographic variables. PSF-M participants were less likely than controls to have an undetectable HIV-1 viral load measurement at or about the time of enrollment (58.3% vs. 76.9%, $p = .05$).

Baseline Behavioral Data

There were no significant differences between the PSF-M and standard care participants at baseline in tobacco knowledge, motivation to quit, decisional balance, abstinence self-efficacy, loneliness, perceived stress, boredom, or current or past alcohol, marijuana, cocaine, heroin, or methadone use. The proportion of PSF-M participants with a low nicotine dependence score was lower than controls, but this finding did not achieve statistical significance [5/48 vs. 13/52, OR = 0.35 (95% CI = 0.11 to 1.07), $p = .07$]. PSF-M participants had significantly higher scores on the depression scale 26.1 ± 11.5 versus 21.5 ± 11.7 ($p = .05$) and the anxiety scale 10.3 ± 6.59 versus 7.83 ± 6.05 ($p = .05$) than standard care participants.

Feasibility Measures

Recruitment and Retention

We recruited most of the screened individuals into the trial: 100/113 (88.5%) candidates consented to participate after the study was fully explained to them. No one declined out of lack of interest. Twelve had incompatible phones and one had inadequate literacy. Ninety participants (90%) completed the trial.

Engagement and Usage (PSF-M Participants Only)

The absolute number of times logged into or navigated to the home page was calculated for each user. The mean number of home page visits was 83.3 ± 70.5 (range: 2–386), and the median was 64.5 (interquartile range: 33.8–113). Participants visited the site a mean of 13.0 ± 9.24 out of a possible 42 days. The mean number of video

Consort Diagram

Figure 3. Flow of study participants.

Table 2. Baseline Characteristics of the Study Cohort

Characteristic	Control condition (N = 52 ^a)	Intervention condition (N = 48 ^a)	p
Age (Range) ± SD	46.9 (25–64)±10.8	44.7 (26–64)±9.7	.30
Gender			
Male	27 (51.9%)	26 (54.2%)	.76
Female	24 (46.2%)	20 (41.7%)	
Transgender	1 (1.9%)	2 (4.2%)	
Ethnicity			
Latino	18 (34.6%)	15 (31.3%)	.72
Non-Latino	34 (65.4%)	33 (68.8%)	
Race			
Black/African American	41 (78.8%)	39 (81.3%)	.96
White	8 (15.4%)	7 (14.6%)	
American Indian or Alaskan native	2 (3.8%)	1 (2.1%)	
Hawaiian or Pacific Islander	1 (1.9%)	1 (2.1%)	
Educational attainment			
≤8th grade	2 (3.8%)	2 (3.8%)	.57
Some high school	16 (30.8%)	13 (27.1%)	
High school graduate or GED	14 (26.9%)	19 (39.6%)	
Some college	12 (23.1%)	6 (12.5%)	
College graduate	8 (15.4%)	8 (16.7%)	
Housing status			
Stable	43 (82.7%)	40 (83.3%)	.20
Transitional	6 (11.5%)	8 (16.7%)	
Homeless	3 (5.8%)	0 (0.0%)	
Employment status			
Unemployed/disabled	42 (80.8%)	40 (83.3%)	.94
Part-time employment	6 (11.5%)	5 (10.4%)	
Full-time employment	4 (7.7%)	3 (6.3%)	
HIV risk behavior			
Heterosexual contact	23 (44.2%)	24 (50.0%)	.73
Same-sex contact	15 (35.7%)	17 (35.4%)	
Injection drug use	2 (3.8%)	1 (2.1%)	
Transfusion	1 (1.9%)	0 (0.0%)	
Other/unknown	11 (21.2%)	6 (12.5%)	
Most recent CD4+ count (range) ± SD	704 (4–1785) ± 329	660 (15–1882) ± 430	.56
Undetectable HIV1 viral load	40 (76.9%)	28 (58.3%)	.05
Daily cigarette consumption	10.3 ± 6.3	12.1 ± 7.4	.18
Nicotine dependence score ^b	4.2 ± 2.4	4.9 ± 2.2	.09
Nicotine dependence category			
Low	13 (25.0%)	5 (10.4%)	.23
Low–moderate	16 (30.8%)	14 (29.2%)	
Moderate	18 (34.6%)	22 (45.8%)	
High	5 (9.6%)	7 (14.6%)	
Motivation to quit ^c	5.8 ± 1.6	6.3 ± 1.5	.13
Depression score ^d	21.5 ± 11.7	26.1 ± 11.5	.05
Anxiety score ^e	7.83 ± 6.05	10.3 ± 6.59	.05

SD = standard deviation, GED = general education development.

^aResponse totals do not equal the cohort size for all items because of incomplete reporting. ^bAs measured using the Fagerstrom Tolerance Questionnaire²⁰ ^cAs measured using the Abrams–Biener Readiness to Quit Ladder²¹ ^dAs measured using the Center for Epidemiologic Studies Depression–20 Scale²⁵ ^eAs measured using the Generalized Anxiety Disorder 7-Item scale.²⁶

sessions viewed was 5.69 ± 2.32 out of a possible eight (the ninth video session was optional). Thirty-seven of 48 (77.1%) PSF-M participants used the HELP button at least once, and the mean number of HELP button taps among participants who ever used the HELP button was 3.84 ± 3.90 . HELP feature utilization was as follows (proportion who ever used the feature, mean number of usages among those who ever used the feature): review the D-pack 36/48 (75.0%), 1.81 ± 1.31 ; phone-a-friend 28/48 (58.3%), 1.21 ± 0.69 ; play-a-game 14/48 (29.2%), 2.00 ± 1.41 ; and play-a-song 2/48 (4.2%), 7.50 ± 6.36 . Thirty-two PSF-M participants (66.7%) texted

CRAVE at least once to obtain a cigarette craving tip via SMS. The mean number of CRAVE texts among those who texted CRAVE at least once was 9.09 ± 25.3 . We analyzed all baseline sociodemographic and behavioral scale scores for association with PSF-M engagement, and only older age (Spearman's $\rho = 0.39$, $p = .007$), nonblack race (129 ± 73.9 vs. 72.6 ± 66.2 mean visits to home page, $p = .03$), lack of employment (91.8 ± 73.8 vs. 40.6 ± 23.4 mean visits to home page), and past or present methadone treatment (153 ± 75.2 vs. 78.6 ± 65.9 mean visits to home page) were found to be significantly associated with the primary measure of PSF-M engagement.

On multiple linear regression including these four covariates, only age [$\beta = 2.55$ (95% CI = 0.55 to 4.55), $p = .01$; ie 2.55 more visits to the home page for each additional year of life] and nonblack race [$\beta = 50.6$ (95% CI = 2.86 to 98.3), $p = .04$; ie 50.6 additional visits to the home page for nonblack vs. black participants] were independently associated with higher levels of engagement.

Consistent with prior reports,^{30–33} male sex was associated with fewer home page visits (73.5 ± 77.1 vs. 98.6 ± 63.4) as was heavy smoking,^{32,34} that is more than 10 cigarettes/day, (65.1 ± 51.2 vs. 98.6 ± 81.3), but neither of these findings attained statistical significance ($p = .24$ and $.10$, respectively).

Lower baseline smartphone usage index score corresponded to higher PSF-M engagement, although this association failed to attain statistical significance (Spearman's $\rho = -0.27$, $p = .06$).

Adherence

Setting a quit day: All 48 PSF-M participants set a quit day at the time of enrollment, and the mean time to quit day was 24.7 ± 7.77 days after enrollment (day 28 was the recommended quit day for those who did not express any preference). Ten participants (20.8%) reset their quit dates in the course of the intervention.

Text messages: The program sent out a mean of 131 ± 38.9 text messages to PSF-M participants. Five (10.4%) of the PSF-M participants texted STOP to discontinue the text messages. Two of these texted STOP on the first day of the program, and one each on days 6, 7, and 35.

Satisfaction

All PSF-M participants were asked to complete a satisfaction survey as part of the exit interview. Levels of satisfaction were moderate, with 61.3% of respondents rating PSF-M as very or extremely helpful, and 54.5% describing themselves as very or extremely satisfied. All but one (97.7%) stated that they would recommend PSF-M to HIV-infected family or friends who wanted to quit smoking. Program elements that received the highest scores were the video sessions, site content that pertained specifically to HIV infection, and the inspirational quotations. Elements that received the lowest scores were the play-a-game, phone-a-friend, and call-the-quitline features.

Study Contamination

Rates of study contamination were low, with 0%–8.5% of standard care participants indicating familiarity with the PSF-M elements in the various questions that probed for such exposure.

Nicotine Patch Use

Seventy-five percent of PSF-M participants versus 63.5% of standard care participants reported using nicotine patches at any point during the study [OR = 1.70 (95% CI = 0.69 to 4.20), $p = .25$].

Program Efficacy

In the intent-to-treat analysis, 5/48 PSF-M participants (10.4%) and 5/52 standard care participants (9.6%) achieved the primary end point of ECO-confirmed 7-day point prevalence abstinence at 120 days [OR = 1.09 (95% CI = 0.30 to 4.04), $p = 1.0$]. Secondary efficacy end points included ECO-confirmed 30-day point prevalence abstinence at the 120 day time point: 5/48 (10.4%) in the PSF-M group and 4/52 (7.7%) in the standard care group [OR = 1.40 (95% CI = 0.35 to 5.53), $p = .73$]; 7-day point prevalence abstinence (without ECO confirmation) was 10/48 (20.8%) in the PSF-M group and

6/52 (11.5%) in the standard care group [OR = 2.20 (95% CI = 0.67 to 6.06), $p = 0.21$]; mean number of quit attempts during the course of the study were 7.27 ± 6.69 in the PSF-M group and 5.85 ± 4.65 in the standard care group ($p = .28$); mean change in daily cigarette consumption from baseline to the 120 day time point was -7.47 ± 8.86 in the PSF-M group and -4.66 ± 4.16 in the standard care group ($p = .06$).

Correlates of Cessation

The range of sociodemographic and behavioral variables collected at baseline was analyzed for association with biochemically verified abstinence at 120 days. The four variables that approached or achieved statistical significance, lower baseline daily cigarette intake ($p = .09$), higher abstinence self-efficacy total score ($p = .06$), higher abstinence self-efficacy on the positive affect/social situation subscale ($p = .06$), and higher anxiety score ($p = .03$) were entered into a logistic regression model using a backward hierarchical removal methodology. The only covariate that remained in the final model was total abstinence self-efficacy [OR = 3.02 (for each one unit increase in total self-efficacy score), 95% CI = 1.18 to 7.74, $p = .02$].

Discussion

This trial demonstrates the feasibility of the smartphone as a delivery platform for tobacco treatment targeting PLWH smokers. In a group of 48 middle-aged, poor, urban, ethnic or racial minority, undereducated, and underemployed PLWH smokers, we found moderate rates of uptake, engagement with, adherence to, and satisfaction with a multimodal smoking cessation intervention delivered over their own smartphones. On average, participants visited the PSF-M home page 83.3 times (median = 64.5 times) during a 42-day intervention, and on 31% of the possible days. The video sessions, the HIV-referent contents, and the inspirational quotations were rated the most helpful features, whereas the play-a-game, phone-a-friend, and call-the-quitline features were rated the least helpful.

Notwithstanding theoretical concerns about the “digital divide”³⁵ that could limit our patient population's full usage of the site, we found moderate–high levels of engagement with and adherence to the program. Technical difficulties with access to the site or its features were distinctly rare.

Little is known about user characteristics that are associated with engagement with smartphone or Web-based tobacco treatments, especially among underserved populations. Several investigators have described greater engagement among females and among lighter smokers.^{30–34} We made similar observations, although the differences were not statistically significant in our sample. We additionally found significant associations of nonblack race, lack of employment, and methadone maintenance treatment with increased engagement, as well as a highly significant direct correlation of older age with higher levels of PSF-M engagement (Figure 4). We were unable to find reports of similar associations of race, employment status, or methadone maintenance in other studies of smartphone or Web-based tobacco treatments, but the relationship of increased engagement with older age has been observed by others.^{31,33,34,36,37} It is interesting that our data suggested an inverse relationship between baseline smartphone feature usage and engagement with the site. A priori, one may have expected that younger, more active smartphone users would have engaged with a technology-driven, smartphone-based program at higher levels, but we found the opposite. It is possible that older, less tech-savvy users appreciated the novelty and ease of use of the

Figure 4. Number of visits to home page according to age (with regression line).

site, especially because they received a one-on-one tour of PSF-M at study enrollment, and thus became more frequent visitors. Whatever the explanation, concerns that smartphone-based tobacco treatment for PLWH smokers represents a “niche” intervention limited to a young, tech-savvy audience appear to be unfounded.

The other feasibility measures that we explored, that is adherence to program components and user satisfaction, yielded favorable findings. Users were willing to set their quit dates as advised, 90% received all of the text messages, and they viewed 5.69 of the eight video sessions (the ninth session was optional and not routinely offered). The video sessions and the inspirational quotations received the highest ratings from the users whereas, disappointingly, some of the unique, smartphone-based crave-response features, for example play-a-song and play-a-game, received the lowest ratings.

We did not find any difference in the primary abstinence outcome, between the intervention and control groups, although the trial was not powered to detect such a difference. Our quit rates were similar to those reported in other randomized, controlled tobacco treatment trials for HIV-infected smokers.^{15,16,38,39} Other tobacco use end points, including number of quit attempts and reduction in daily cigarette consumption, favored the intervention over the control group, but did not achieve statistical significance. It is likely that the trial was underpowered to demonstrate these effects, and it is also possible that the universal offer of nicotine replacement therapy obscured the effect of PSF-M, as described in one larger study of a popular text-based quitting program.⁴⁰ Of note, similar to multiple other studies in our clinic and elsewhere, abstinence self-efficacy was identified as a key predictor of successful quitting in PLWH smokers.^{15,16,41–43}

This trial had certain limitations deserving of mention. The primary measure of engagement, visits to the site’s home page, is subject to variability that may not reflect actual engagement in all cases, for example inflated counts for a user who for technical reasons. However, there is no scientific standard for Web site engagement,

and we believe that the primary and secondary engagement and usage data that we present provide a reasonable reflection of our participants’ interactions with the site. Our cessation outcome analyses may have underestimated the program’s efficacy, because 20.8% of our PSF-M participants versus 11.5% of controls reported 7-day point-prevalent abstinence at the 120-day time point, but ECO measurement categorized six of these individuals (five PSF-M and one control) as active smokers. ECO may misclassify some non-smokers, especially those exposed to secondhand smoke, as smokers.⁴⁴ Results were all obtained from a single clinic in the Bronx, NY. Although our patient population is sociodemographically similar to many inner-city PLWH populations, our findings may not be generalizable to other health care settings or other geographic regions. In addition, the sample size in our pilot feasibility trial was small. It was not powered to detect differences in relevant outcomes, and the likelihood that important associations were missed due to beta errors was high. Larger multicenter trials may be warranted to remedy these shortcomings and to test PSF-M in a more definitive manner.

In conclusion, PSF-M is a smartphone-based tobacco treatment program for PLWH smokers that showed promise in a pilot trial that enrolled a poor, urban, middle-aged, undereducated, and underemployed patient sample. Measures of acceptance, adherence, engagement, and satisfaction provide encouragement that this may be a viable treatment approach for this vulnerable and underserved population. We found that engagement with the program was highest among the older and less tech-savvy subset of our participants, challenging the view that the “digital divide” may limit the reach of mobile health interventions. Further research is needed to optimize mobile health interventions for tobacco treatment and for other health issues in PLWH.

Funding

This work was supported by award 1R34DA037042 (JS and LCA) from the National Institutes of Health (NIH)/National Institutes on Drug Abuse

(NIDA) and by the Einstein-Rockefeller-CUNY Center for AIDS Research (P30-AI124414) which is supported by the following NIH co-funding and participating institutes and centers: NIAID, NCI, NICHD, NHBL, NIDA, NIMH, NIA, FIC and OAR. None of these sources were involved in the design, analysis, data interpretation, writing, or decision to publish the completed manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Drug Abuse or the National Institutes of Health.

Declaration of Interests

None declared.

Acknowledgments

The authors acknowledge the expert insights of Cassandra A. Stanton, PhD, and Nathan K. Cobb, MD, during the PSF-M development process. The authors acknowledge with gratitude the efforts of Sean Durant and Eileen Dolce in helping to conduct the trial. They also extend their gratitude to the patients and staff of Montefiore Medical Center's Center for Positive Living and to the all of the trial participants.

References

1. Mdofo R, Frazier EL, Dube SR, et al. Cigarette smoking prevalence among adults with HIV compared with the general adult population in the United States: cross-sectional surveys. *Ann Intern Med*. 2015;162(5):335–344.
2. Tesoriero JM, Gieryic SM, Carrascal A, Lavigne HE. Smoking among HIV positive New Yorkers: prevalence, frequency, and opportunities for cessation. *AIDS Behav*. 2010;14(4):824–835.
3. Helleberg M, Afzal S, Kronborg G, et al. Mortality attributable to smoking among HIV-1-infected individuals: a nationwide, population-based cohort study. *Clin Infect Dis*. 2013;56(5):727–734.
4. Helleberg M, May MT, Ingle SM, et al. Smoking and life expectancy among HIV-infected individuals on antiretroviral therapy in Europe and North America. *AIDS*. 2015;29(2):221–229.
5. Drummond MB, Kunisaki KM, Huang L. Obstructive lung diseases in HIV: a clinical review and identification of key future research needs. *Semin Respir Crit Care Med*. 2016;37(2):277–288.
6. Pool ER, Dogar O, Lindsay RP, Weatherburn P, Siddiqi K. Interventions for tobacco use cessation in people living with HIV and AIDS. *Cochrane Database Syst Rev*. 2016 Jun 13;(6):CD011120.
7. Pew Research Center. Technology device ownership: 2015. October 29, 2015. at <http://www.pewinternet.org/2015/10/29/technology-device-ownership-2015/> Accessed September 25, 2017.
8. Free C, Phillips G, Watson L, et al. The effectiveness of mobile-health technologies to improve health care service delivery processes: a systematic review and meta-analysis. *PLoS Med*. 2013;10(1):e1001363.
9. Pew Research Center. Record shares of Americans now own smartphones, have home broadband. January 12, 2017. at <http://www.pewresearch.org/fact-tank/2017/01/12/evolution-of-technology/> Accessed September 26, 2017.
10. Heffner JL, Mull KE. Smartphone ownership among US adult cigarette smokers: 2014 Health Information National Trends Survey (HINTS) data. *J Med Internet Res*. 2017;19(8):e305.
11. Pearlman BK, Abrams LC, Shuter J. Cell phone usage patterns in HIV-infected smokers. *J Subst Abuse Alcohol*. 2015;3(3):1038–1041.
12. Abrams LC, Lee Westmaas J, Bontemps-Jones J, Ramani R, Mellerson J. A content analysis of popular smartphone apps for smoking cessation. *Am J Prev Med*. 2013;45(6):732–736.
13. Haskins BL, Lesperance D, Gibbons P, Boudreaux ED. A systematic review of smartphone applications for smoking cessation. *Transl Behav Med*. 2017;7(2):292–299.
14. Bandura A. Social cognitive theory: an agentic perspective. *Annu Rev Psychol*. 2001;52:1–26.
15. Moadel AB, Bernstein SL, Mermelstein RJ, Arnsten JH, Dolce EH, Shuter J. A randomized controlled trial of a tailored group smoking cessation intervention for HIV-infected smokers. *J Acquir Immune Defic Syndr*. 2012;61(2):208–215.
16. Shuter J, Morales DA, Considine-Dunn SE, An LC, Stanton CA. Feasibility and preliminary efficacy of a web-based smoking cessation intervention for HIV-infected smokers: a randomized controlled trial. *J Acquir Immune Defic Syndr*. 2014;67(1):59–66.
17. Arozullah AM, Yarnold PR, Bennett CL, et al. Development and validation of a short-form, rapid estimate of adult literacy in medicine. *Med Care*. 2007;45(11):1026–1033.
18. Liebreich T, Plotnikoff RC, Courneya KS, Boulé N. Diabetes NetPLAY: a physical activity website and linked email counselling randomized intervention for individuals with type 2 diabetes. *Int J Behav Nutr Phys Act*. 2009 Mar 27;6:18.
19. Pew Research Center. How Americans use their cell phones. August 15, 2011. at <http://www.pewinternet.org/2011/08/15/how-americans-use-their-cell-phones/> Accessed September 25, 2017.
20. Fagerstrom KO, Schneider NG. Measuring nicotine dependence: a review of the Fagerstrom Tolerance Questionnaire. *J Behav Med*. 1989;12(2):159–182.
21. Abrams DB, Biener L. Motivational characteristics of smokers at the workplace: a public health challenge. *Prev Med*. 1992;21(6):679–687.
22. Velicer WF, Diclemente CC, Rossi JS, Prochaska JO. Relapse situations and self-efficacy: an integrative model. *Addict Behav*. 1990;15(3):271–283.
23. Stanton CA, Lloyd-Richardson EE, Papandonatos GD, de Dios MA, Niaura R. Mediators of the relationship between nicotine replacement therapy and smoking abstinence among people living with HIV/AIDS. *AIDS Educ Prev*. 2009;21(suppl 3):65–80.
24. Russell DW. UCLA Loneliness Scale (version 3): reliability, validity, and factor structure. *J Pers Assess*. 1996;66(1):20–40.
25. Bing EG, Hays RD, Jacobson LP, et al. Health-related quality of life among people with HIV disease: results from the Multicenter AIDS Cohort Study. *Qual Life Res*. 2000;9(1):55–63.
26. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166(10):1092–1097.
27. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385–396.
28. Ragheb MG, Merydith SP. Development and validation of a multidimensional scale measuring free time boredom. *Leis Stud*. 2001;20(1):41–59.
29. Lloyd-Richardson EE, Stanton CA, Papandonatos GD, et al. Motivation and patch treatment for HIV+ smokers: a randomized controlled trial. *Addiction*. 2009;104(11):1891–1900.
30. Heminger CL, Boal AL, Zumer M, Abrams LC. Text2Quit: an analysis of participant engagement in the mobile smoking cessation program. *Am J Drug Alcohol Abuse*. 2016;42(4):450–458.
31. Nash CM, Vickerman KA, Kellogg ES, Zbikowski SM. Utilization of a web-based vs integrated phone/Web cessation program among 140,000 tobacco users: an evaluation across 10 free state quitlines. *J Med Internet Res*. 2015;17(2):e36.
32. Zeng EY, Vilardaga R, Heffner JL, Mull KE, Bricker JB. Predictors of utilization of a novel smoking cessation smartphone app. *Telemed J E Health*. 2015;21(12):998–1004.
33. Wangberg SC, Bergmo TS, Johnsen JA. Adherence in Internet-based interventions. *Patient Prefer Adherence*. 2008;2:57–65.
34. Coa K WK, Augustson E. Associations between engagement and cessation outcomes in the SmokefreeTXT program: a growth mixture modeling analysis. Presented at the 23rd annual meeting of the Society for Research on Nicotine & Tobacco; Florence, Italy, March 8–11, 2017. Abstract POS3-53.
35. Estacio EV, Whittle R, Protheroe J. The digital divide: examining socio-demographic factors associated with health literacy, access and use of

- internet to seek health information. [published online ahead of print Feb 1, 2017]. *J Health Psychol*. 2017.
36. Japuntich SJ, Zehner ME, Smith SS, et al. Smoking cessation via the internet: a randomized clinical trial of an internet intervention as adjuvant treatment in a smoking cessation intervention. *Nicotine Tob Res*. 2006 Dec;8 (suppl 1):S59–S67.
37. Zbikowski SM, Hapgood J, Smucker Barnwell S, McAfee T. Phone and web-based tobacco cessation treatment: real-world utilization patterns and outcomes for 11,000 tobacco users. *J Med Internet Res*. 2008;10(5):e41.
38. Gritz ER, Danysh HE, Fletcher FE, et al. Long-term outcomes of a cell phone-delivered intervention for smokers living with HIV/AIDS. *Clin Infect Dis*. 2013;57(4):608–615.
39. Stanton CA, Papandonatos GD, Shuter J, et al. Outcomes of a tailored intervention for cigarette smoking cessation among Latinos living with HIV/AIDS. *Nicotine Tob Res*. 2015;17(8):975–982.
40. Hoepfner BB, Hoepfner SS, Abroms LC. How do text-messaging smoking cessation interventions confer benefit? A multiple mediation analysis of Text2Quit. *Addiction*. 2017;112(4):673–682.
41. Ingersoll KS, Cropsey KL, Heckman CJ. A test of motivational plus nicotine replacement interventions for HIV positive smokers. *AIDS Behav*. 2009;13(3):545–554.
42. Vidrine DJ, Arduino RC, Lazev AB, Gritz ER. A randomized trial of a proactive cellular telephone intervention for smokers living with HIV/AIDS. *AIDS*. 2006;20(2):253–260.
43. Vidrine DJ, Kypriotakis G, Li L, et al. Mediators of a smoking cessation intervention for persons living with HIV/AIDS. *Drug Alcohol Depend*. 2015 Feb;147:76–80.
44. Deveci SE, Deveci F, Açık Y, Ozan AT. The measurement of exhaled carbon monoxide in healthy smokers and non-smokers. *Respir Med*. 2004;98(6):551–556.