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A randomized trial of a web-based tobacco treatment and online community support for people with HIV attempting to quit smoking cigarettes

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Abstract

Background: Persons with HIV (PWH) in the United States (US) smoke cigarettes at approximately triple the rate of the general adult population and are less successful in their quit attempts than other smokers. This randomized trial tested whether a novel web-based cessation program for PWH yielded higher cigarette quit rates compared to a control program.

Setting: Two urban HIV care sites in NYC and Baltimore

Methods: Between 2016 and 2020, 506 PWH were randomized to either Positively Smoke Free on the Web (PSFW+; N=255), a multimodal platform, interactive web intervention hosted within an online social network to support quitting among PWH who smoke, and an attention-matched web-based control intervention (American Heart Association Getting Healthy; AHA; N=251). All participants were offered 12 weeks of nicotine patch. Our primary outcome was biochemically-confirmed exhaled carbon monoxide (ECO)<10 parts per million (ppm) seven-day point prevalence abstinence at 6-months.

Results: Participants were middle-aged (mean 50.2 yrs; range 23–73), 57% male, and 19% Latinx, 83% Black, 13% White. At 6-months, a significantly greater percentage of PSFW+ participants (14.9%) achieved biochemically confirmed seven-day point prevalence abstinence in intent-to-treat analysis compared to 8.8% of AHA participants (O.R. =1.82 [95% C.I. =1.04–3.18], P=.03).

Conclusions: PSFW+ is a promising cessation intervention composed of empirically-tested content and real-time social support through an online social network that was found to promote abstinence. This digital approach has broad reach and scalability, can be easily integrated into comprehensive HIV care, and represents an advance in the fight against tobacco use among PWH.

Introduction.

Persons with HIV (PWH) in the United States (US) smoke cigarettes at approximately triple the rate of the general adult population[1–3] and are less successful in quitting than others who smoke.[1] One meta-analysis of tobacco treatment interventions for PWH found low-quality evidence suggesting early effects, i.e. increased quit rates at time points less than 6-months, but no long-term cessation advantage, i.e. at 6-months or greater.[4] There remains a significant need for more effective smoking cessation interventions for PWH that are capable of broader reach.

Web-based interventions are a promising modality to address the limitations of existing tobacco treatment efforts for PWH who smoke. A 2017 review of 67 randomized trials of web-based smoking cessation interventions involving over 110,000 participants found that interactive and tailored interventions are more effective than non-interactive interventions at 6 months or longer.[5] Web-based tobacco treatments with interactive components are superior to static ones, and can achieve cessation rates similar to those achieved by in-person or telephone counseling.[5,6] Unlike other treatment modalities, web-based interventions allow smokers to access support for as long as they need to quit successfully. Also unique to web-based interventions is the ability to deliver real-time, sustained social support through an online community. Active online communities allow for the dissemination of health-promoting information, opportunities for social learning and modeling, mitigation of loneliness and stigmatization, and immediate and sustained access to peer support for those experiencing cravings and/or slip-ups. Participation in online social networks for smoking cessation has been shown prospectively to increase quit rates.[7–9] Although there are several pilot trials of web-based tobacco treatments for PWH published in the medical literature,[10–14] we are not aware of any definitive trials, nor are we aware of any prior research on the role of online social networks to promote smoking cessation in PWH.

Positively Smoke Free (PSF) is an intensive, multisession, behavioral intervention based upon Social Cognitive Theory[15] that is specifically designed to promote cessation among PWH who smoke. It has been delivered via individual and group therapy,[16–18] web-based group therapy,[19] and both static[11] and interactive self-directed[10] computer and cellphone based formats. Trials of PSF have found that program participants achieve increased rates of both short and long-term smoking abstinence.[11,16–18] The promising results observed in our pilot studies of web-based versions of PSF[10,11] together with the burgeoning utilization of online communities for behavioral change led us to conduct the trial described herein.

To further enhance the intervention and address the needs of PWH who smoke, the PSF intervention was blended with an online community and integrated into the Positively Smoke Free on the Web (PSFW+) quit-smoking program in 2015. An online community is well suited to facilitate social connections and support in a lonely, stigmatized population,

and is well-aligned with the program's behavioral model in its provision of social support and observational learning. We hypothesized that exposure and access to the PSFW+ intervention as compared to a more generic online health intervention without an accompanying online community, each combined with an offer of 12-weeks of nicotine replacement therapy, would result in increased cessation rates at the 6-month timepoint. The enhanced intervention was evaluated in a multisite randomized controlled trial comparing cessation outcomes among PWH who smoke and were randomized to either PSFW+ or an attention-matched control, the American Heart Association Getting Healthy online program (AHA).

Methods.

We conducted a two-arm, parallel-group randomized controlled trial comparing PSFW+ to AHA. This study was approved by the IRBs at Montefiore Medical Center and the Johns Hopkins University School of Medicine. The trial was registered at clinicaltrials.gov (NCT02781090). Results are reported according to CONSORT-eHealth (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online TeleHealth)[20] and TIDieR (Template for Intervention Description and Replication)[21] recommendations.

Setting and participants

Between July 2016 and March 2020, we enrolled consenting adults into the trial at two clinical sites: (1) Montefiore Medical Center's Center for Positive Living in the Bronx, New York, and (2) Johns Hopkins Bartlett Clinic for Infectious Diseases in Baltimore, Maryland. Inclusion criteria were: (1) Laboratory confirmed HIV infection (2) Current cigarette smoker (defined as responding in the affirmative to "Have you smoked at least 100 cigarettes in your entire life?" AND "Have you smoked cigarettes (even a puff) in the last seven days, including today?") (3) Motivation to quit smoking (affirming having strong feelings about quitting smoking at least sometimes AND planning to quit smoking in the next 6 months) (4) Possession of a device, e.g. cellphone, with access to the internet at least weekly (5) REALM-SF literacy score≥4 (i.e. ability to read at at least seventh grade level) (6) No contraindication to nicotine patch use (contraindications included known allergy to any patch component, recent myocardial infarction, recent heart rhythm abnormality, unstable angina, uncontrolled hypertension, and/or diffuse skin disorder such that patch could not be placed on normal skin) (7) Not pregnant or breastfeeding (8) Not currently receiving other tobacco treatment (9) Not living with a current participant in the trial. Enrollment was terminated four months prematurely due to the COVID-19 pandemic at 93.1% of the project's original recruitment target (512 enrolled of a planned 550). Participants were recruited primarily through provider referral from the two sites, but also by direct contact in the clinics' waiting areas, and by self-referral in response to flyers distributed locally.

Randomization

After consent and screening, we performed stratified block randomization (allocation [1:1]) to PSFW+ or AHA. Randomization was stratified on study site, sex at birth, and educational level. Block sizes were randomly chosen from the set (4,6,8). Randomization

was centralized with an independent data manager who generated and uploaded the randomization sequence onto a secure server at the Albert Einstein College of Medicine. Outcomes assessors and investigators were blinded to group assignments; neither the study coordinator nor participants were blinded.

Intervention

PSFW+ (intervention). PSFW+ was a mobile-optimized, multimodal, interactive web intervention hosted within a third party online community platform (Vanilla Forums, Inc.) to support quitting among PWH who smoke (Figure 1). It was designed specifically for PWH and was anchored around eight lessons (didactic web content and/or video). The lessons were meant for delivery over 42 days (roughly one per week), with the default quit day linked to Lesson 5, on day 28. The topics covered in the lessons have been summarized in a prior publication and may be found in Supplemental Table 1.[16] In contrast to the original, static version of the web-based program,[11] PSFW+ offered a flexible schedule, i.e. participants could select and reset the quit day of their choice, view any of the lessons at any time, and access an online community. Additionally, eight 5–10 minute video sessions were available for viewing that were intended to correspond one-to-one with the eight lessons. A lesson schedule was created for each participant depending on the quit day that s/he selected. Intervention engagement was promoted via text-message and email reminders that users requested during program enrollment. A reminder was sent on the day that the lesson was due to be viewed and on the following day if the participant had not yet viewed it. A reminder was also sent encouraging the participant to visit the PSFW+ site if s/he had not visited in more than seven days. No specific cessation counseling was offered via text or email. The lesson schedule ended at day 42, but the PSFW+ site was in the public domain throughout the trial.

The PSFW+ online community was launched prior to study initiation in order to create an active, meaningful community experience for all study participants. “Seed users” (current or former PWH smokers from clinical sites) were recruited to be part of the study team prior to participant recruitment. Their role was to foster cessation-related discussions, respond on the site to comments within 24 hours, and encourage a sense of community between and among study participants. They were instructed to refrain from mentioning their official roles on the site or the fact that they received stipends for their activities. A professional community manager oversaw the work of seed users, addressed any software issues, monitored site usage, and responded to any inappropriate or abusive language or behavior. The manager and the seed users participated in a monthly call to raise and address any concerns. Throughout the course of the study, individuals from outside the study accessed the PSFW+ website as a result of dissemination efforts by study team members. Community members could post personal reactions and insights related to lesson themes, e.g., “We’ve been talking about slip-ups today. Please tell us about any experiences that you’ve had with slip-ups when you were trying to quit.” Responses could also take the form of emojis. Participants could visit the online community any time independent of the lesson schedule, read prior posts, and enter new content.

AHA (control). The American Heart Association Getting Healthy website, later changed in name to the AHA My Life's Check, Life's Simple 7 website (https://www.heart.org/en/healthy-living/healthy-lifestyle/my-life-check--lifes-simple-7), is a health-promotion intervention targeting cardiovascular health and fitness. It has a welcome page and seven online modules, including one on smoking cessation. The other six topics are healthy diet, exercise, blood pressure control, blood sugar control, cholesterol, and weight management. The website does not include an online community. To track utilization of the control intervention, participants logged into a study portal developed by Truth Initiative which then redirected them to the AHA website. Metrics captured through the portal included date and time-stamped logins.

During the enrollment visit, all trial participants were offered a 12-week course of nicotine patches dosed according to average daily cigarette intake.

Measures

All participants were scheduled to attend four in-person study visits: enrollment, four weeks, 12-weeks, and 24-weeks during which they completed audio computer assisted self-interviews (QDS ACASI software). Abstinence was determined based on a negative answer to the question, "Have you smoked a cigarette, even a single puff, in the past seven days?"[22] along with biochemical verification. Participants underwent exhaled carbon monoxide (ECO) measurement using the piCO+™ Smokerlyzer (coVita) maintained and calibrated according to manufacturer's recommendations. For the small number of participants who reported abstinence from cigarettes but had ECO measures in smoker range (ECO≥10ppm),[23] a phenomenon commonly seen in persons with heavy marijuana use, a salivary swab (Orasure Technologies) for cotinine was collected.

The COVID-19 pandemic surge in New York City and Baltimore triggered an embargo on in-person research visits from April until July 2020. During that time, nine of the 12-week visits and 19 of the 24-week visits were completed by telephone. ECO measurements were not possible for these visits. Respondents who reported 7-day abstinence at the 24-week visit (the primary study outcome) were asked to provide ECO measurements, generally several months later, to biochemically verify their smoking status.

The pre-planned primary trial outcome was biochemically confirmed 7-day point-prevalence abstinence at 6-months post-enrollment utilizing intention-to-treat (ITT) (i.e., lost to follow-up assumed non-abstinent) strategy. Secondary, pre-planned outcomes included 30-day point-prevalence abstinence, self-report of a quit attempt on the selected quit day, and mean number of days quit among participants who made a quit attempt. Among those who did not quit, change in cigarettes per day from baseline was examined. Late in the course of the trial, updated recommendation lowered the suggested ECO cutoff for non-smoker status to <6ppm.[24] This prompted us to repeat our primary analyses with the updated cutoff, and include them in the supplemental materials.

Sociodemographics (age, sex, race, ethnicity, annual income, housing status, educational attainment), HIV-status (CD4+ count, viral load <40 copies/ml), tobacco related variables (nicotine dependence via the Modified Fagerström Tolerance Questionnaire[25], self-efficacy

to quit[26], mean daily cigarette consumption, past 30-day (P30D) e-cigarette use, P30D other tobacco use[22], living with a smoking partner, and the number of smokers living together), and substance use (alcohol use disorder[27] and P30D marijuana, cocaine, heroin, and current methadone treatment[28]), and website utilization statistics (e.g. number of logins, number of active days on the site) were examined to describe the sample and explore as covariates.

Statistical analysis

We compared baseline characteristics between PSFW+ and the control group by chi-squared tests for categorical variables and by Student's t-tests for continuous variables. We performed chi-squared tests to compare 7-day abstinence between PSFW+ and control groups at 3-months and 6-months using ITT and complete case strategies (analytic sample included only participants who completed at least one session of the intervention in each arm and completed the 6-month visit). Then, we compared secondary abstinence outcomes such as 30-day abstinence and quit day attempt using chi-squared tests and the number of abstinent days, and the change in cigarettes-per-day since baseline by Student's t-tests. Similarly, we compared nicotine patch use by chi-squared test and intervention utilization by Student's t-tests. Baseline factors associated with the 6-month 7-day abstinence in the entire study cohort, employing the ITT strategy, were identified via chi-squared tests for categorical variables and by Student's t-tests for continuous variables. To test the adjusted effect of intervention condition on 6-month 7-day abstinence, employing ITT strategy, we fit a multivariable logistic regression model. We selected potential confounders using forward stepwise model selection by AIC (Akaike information criterion).[29]

Results.

A total of 613 individuals were screened and 512 were enrolled. Reasons for screen failure are shown in Figure 2. Six of the 512 trial enrollees were excluded from the final trial dataset for reasons enumerated in the consort diagram. The final study cohort consisted of 251 randomly allocated to the control condition and 255 to PSFW+.

Supplemental Table 1 summarizes the baseline characteristics of participants. Completion rates for almost all items in the ACASI's exceeded 99%, and the few missing data points were excluded from the analyses. As expected, the two groups were well balanced on all baseline variables. Participants were middle-aged (mean 50.2 yrs; range 23–73), 57% male, 19% Latinx, 83% Black, and 13% White. Ninety percent reported annual household incomes of less than $30,000, 23% were in transitional housing or were homeless, and 59% had an educational attainment of high school or less. At baseline, the mean number of cigarettes smoked per day was 11.5±8.8. The majority of the sample had high or moderate levels of nicotine dependence and about a third also used another nicotine/tobacco product.

Primary study outcome.

At 6-months (Table 1), a significantly greater percentage of PSFW+ participants (14.9%) achieved biochemically confirmed (ECO<10ppm) seven-day point prevalence abstinence in ITT analysis compared to 8.8% of AHA participants (O.R.=1.82 [95% C.I. =1.04–3.18], P=.03). Salivary cotinine levels were sent on five participants who reported abstinence at

6-months but had ECO levels≥10ppm. All of these specimens returned in smoker range, and none of these participants reported current use of other nicotine products. These five individuals did not meet the biochemical verification criteria and were thus considered non-abstinent. For the n=8 who reported abstinence during the COVID-19 research visit ban and lacked biochemical verification, we accepted their self-report as evidence of abstinence. We were able to recall half of them (n=4) several months later and all four had ECO levels in the abstinent range. The ITT approach assumed participants lost to follow-up (n=128; 25.3%) were non-abstinent. Table 1 also includes complete-case analyses at 3- and 6-months. A higher percentage (20.1%) of PSFW+ participants achieved biochemically confirmed 7-day abstinence at 6-months compared to 11.6% of controls (O.R.=1.91 [95% C.I.=1.08–3.38], P=.02).

Secondary outcomes and quitting behaviors.

For the endpoint of 30-day point-prevalence abstinence at 6-months (Table 1), in ITT analyses 11.4% of the PSFW+ participants were abstinent compared to 6.4 % of controls which approached statistical significance (O.R.=1.89 [95% C.I.=0.997–3.56], P<0.05). Additional variables related to quitting behavior were examined at 3- and 6-months. At 6-months, 35.4% of PSFW+ participants reported making a quit attempt on the selected quit day in the program compared to 23.3% in the control condition (O.R.=1.81 [95% C.I.=1.15–2.84], P=0.009). There were no differences between conditions in the mean number of days quit among participants who made a quit attempt. Among those who did not quit, there were no intervention effects on change in cigarettes per day since baseline.

Recent literature suggests that previously standard cut-points such as the ECO<10ppm[23] used in this trial may be too high.[24] Thus, all models were also run on seven-day point-prevalence abstinence using a lower cut-point of ECO<6ppm.[24] Although power was reduced, results showed similar trends and effect sizes (Supplemental Tables 3 and 4).

Baseline factors associated with the primary abstinence endpoint.

We first performed bivariate analyses to assess the association of each baseline factor with the primary abstinence endpoint, employing the ITT strategy. The results of these analyses are listed in Supplemental Table 4. To test the adjusted effect of the intervention on the primary outcome under ITT analysis, we fit a multivariable logistic regression model. We considered 18 potential confounders (Table 2) based on a priori hypotheses and selected seven covariates with forward stepwise model selection by AIC. Table 2 reports the final model with factors that were retained. After adjusting for other covariates, 6-month 7-day ITT abstinence rates remained higher for the PSFW+ intervention condition OR_{adj}=1.79 (95% CI=1.01–3.24, P=0.05) compared to the control condition.

Nicotine patch use

There were no significant differences in the proportion of individuals who reported ever using the patch in the course of the study in the PSFW+ intervention compared to controls (57.6% vs. 65.3%, O.R.=0.72 [95% C.I.=0.50–1.03], P=0.08), and there was no significant difference between patch users and non-patch users in achieving the abstinence end-point at 6-months. Of those who used the patch, the majority (87.5%) of participants who were

abstinent at 6-months were still using the patch at the one-month visit compared to 68.8% of those non-abstinent (O.R.=3.17 [95% C.I.=1.07–9.43], P=0.03).

Intervention Utilization.

Utilization of the PSFW+ website was significantly higher than utilization of the AHA website based on total number of logins, with almost twice as many logins as the control condition (mean 14.5, SD 23.8 vs. mean 7.8, SD 12.6; P<.001). The mean number of active days was more than 4 times higher for PSFW+ compared to the control condition (mean 18.0, SD 14.8 vs. mean 4.2, SD 4.4; P<.001). Table 3 summarizes program utilization metrics among PSFW+ participants overall, as well as by 6-month ITT biochemically confirmed abstinence versus non-abstinence. On average, PSFW+ participants logged into the site a mean 14.5 times (SD 23.8) and contributed comments to the site an average of 12.7 (SD 25.5) times. Although not statistically different, those who achieved abstinence had more active days of program participation than those who were still smoking. The total number of unique lessons viewed (P=0.03) was higher among PSFW+ participants who achieved abstinence compared to those who did not.

Study condition contamination.

We assessed contamination by asking participants whether they had visited and/or discussed the other study condition's website with any trial participant and whether they had ever visited the other study condition's website (both websites were in the public domain throughout the course of the trial). Five percent of the PSFW+ participants discussed the AHA website with another individual, and 8.2% affirmed ever visiting the AHA website. Twelve percent of AHA participants discussed the PSFW+ website with another individual, and one participant affirmed ever visiting the PSFW+ website. Based on these results, contamination risks were deemed to be small.

Discussion.

This multicenter randomized controlled trial of a web-based, culturally targeted intervention hosted within an online community platform showed significantly higher biochemically verified cessation rates at 6-month follow-up compared to an attention-matched control. The result was robust for a range of cessation outcomes and persisted after controlling for potential confounders in adjusted models. These findings are particularly notable given the sociodemographic profile of our study cohort. In aggregate, our participant sample was largely middle-aged and predominantly racial/ethnic minority, with low income and educational attainment. These results provide reassurance that an urban PWH population in the US can use and benefit from e-health interventions including those that incorporate social networks and depend upon digital literacy.

There is a growing literature on the role and efficacy of online communities in promoting smoking cessation. Although not all studies have shown efficacy,[30] there is a significant body of evidence supporting their value in assisting tobacco users to quit, and our trial adds to this evidence base.[7–9] Less is known about how online communities contribute to the quitting process, and this is an area of active research.[31,32] Our trial was not designed

to assess the independent effects of the various intervention components, i.e. online text content, videosessions, online discussions and community support, and nicotine replacement therapy. Compared to the AHA control condition, PSFW+ participants had significantly greater utilization of the intervention site based on logins and four times the average number of active days engaged in the program. The novel integration of the didactic portion of the intervention into an online community allowed the exchange of cessation-relevant peer support throughout the quitting journey. This ongoing real-time social support may have contributed to higher utilization/engagement and ultimately more success. Indeed, web-based smoking cessation interventions have been tested in dozens of randomized trials in the general population,[5,6,33,34] and level of engagement in online communities has been predictive of abstinence.[7–9] Analyses of the online interaction dynamics of PSFW+ users are ongoing[35] and will be the focus of a separate publication.

Participants in both treatment conditions were offered 12-weeks of nicotine patches, and there were no differences in patch use by treatment condition. Regardless of treatment condition, a greater percentage of those using nicotine patches one month into the intervention around their quit date were abstinent at 6-months compared to those who were not using nicotine patch at one month. While the patch is an empirically supported cessation aid in the general population, adherence challenges to patch use among PWH have been found to be an obstacle to cessation.[36] These findings suggest that nicotine replacement therapy may have a role in promoting cessation in PWH smokers, especially early in the quit attempt.

In this population, unstable housing, having a partner who smokes, and living with other smokers were strong predictors of continued smoking. Among the 29 persons with past 30-day heroin use, zero were abstinent at 6-months. Only four of the 86 people who used cocaine in the past 30-days had quit at 6-months. Given that heroin use was a perfect predictor of continued smoking, a combined variable, “other illicit substance use” was included in the multivariable model. The highly vulnerable subset of PWH with heroin, cocaine, and other illicit substance use face a range of daunting obstacles to quitting cigarettes and other substances, and different approaches to the treatment of tobacco and other substance use may be necessary for this segment of the PWH population.

Interestingly, Latino/a ethnicity was a significant predictor of 6-month abstinence in both bivariate and multivariate analyses. An earlier study of Positively Smoke Free offered via in-person, group therapy similarly found significantly higher quit rates in Latino/a PWH smokers,[16] while a subsequent trial showed trends in the opposite direction.[18] Against a background of health disparities that work to the disadvantage of US Latino/a smokers in the realm of tobacco control,[37] these findings were unexpected and worthy of further investigation.

Our trial had several limitations. The two study conditions were not perfectly “attention-matched” with one fewer module in the AHA control and reminders sent only to the PSFW+ participants who were due to visit the site. Participants were recruited from two urban centers in the Northeast and may not be representative of PWH in other geographic regions. The study sites have higher rates of heterosexual transmission and lower rates of

same-sex transmission than the national average, so our findings may not be generalizable to PWH populations with other risk profiles. Nicotine replacement monotherapy is no longer considered first-line pharmacotherapy,[38] although it was at the time that the trial was originally designed.[39] As a result, the pharmacologic component of the tobacco treatments that we offered may not have been optimal. Disruptions from the COVID-19 pandemic resulted in premature termination of recruitment and biochemical verification of smoking status among several follow-ups was not possible. Finally, the standard non-smoker ECO cutoff was lowered late in the project timeline, but secondary analyses demonstrated that findings were robust to assessment using the new, lower cut point.

In conclusion, PSFW+ is a promising cessation intervention composed of empirically tested content fully integrated with real-time social support through an online social network. Results from this RCT suggest that a multicomponent digital approach with an online community to provide real time social support has promise in promoting abstinence and preventing relapse among PWH smokers. Digital approaches such as the one described herein provide broad reach and scalability, can be integrated into comprehensive HIV care, and represent an advance in the fight against tobacco use in PWH. PSFW+ materials are currently being integrated into BecomeAnEX (available at www.becomeanex.org), and the authors of this work look forward to the day, in the near future, that providers can refer their PWH patients who smoke cigarettes to access these free, evidence-based tools to assist them in their quitting journeys.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Conflicts of Interest and Source of Funding

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Human-human interaction	Server-human interaction
• Onboarding of participants by research assistant (select login identifiers, install icon onto screen or desktop, tour of the site, post a first message) • Communication with the online community via posted messages <u>Seed users</u> • Hired by principal investigator and community manager • Initial training by manager • Monthly meetings with manager • Contact via posted messages with trial participants in the online community. All posted messages responded to within 24 hours	• Eight online lessons consisting of themed text content and punctuated by prompts to communicate with the online community (e.g. “We’ve been talking about slip-ups today. Please tell us about any experiences that you’ve had with slip-ups when you were trying to quit.”) • Eight 5-10 minute videosessions corresponding to online lessons • Reminder texts and emails to log into the site • Backend collection of utilization metrics (e.g. # of logins, # of videos started)
All participants were offered 12-weeks of nicotine patches to assist in their quit attempts.	

Figure 1.
The Positively Smoke Free on the Web + online community (PSFW+) intervention.

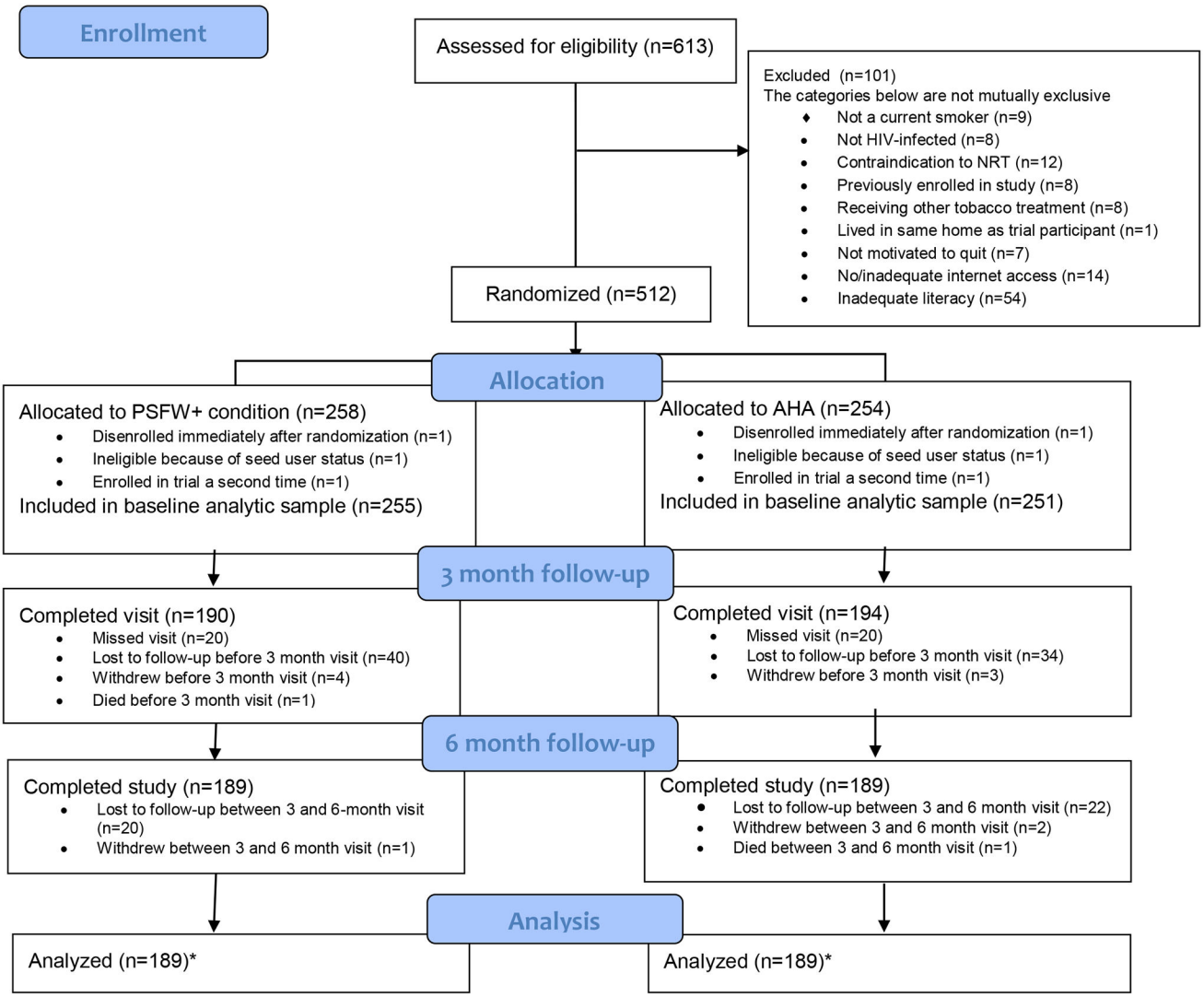

Figure 2.

Consort Diagram

*In the intention to treat (ITT) analyses, all participants in the baseline sample (n=255 in the PSFW+ condition, and n=251 in the AHA condition) were included.

Table 1:

Biochemically confirmed (ECO<10ppm) point-prevalence abstinence (PPA) rates and secondary outcomes at 3- and 6-months by treatment arm

	3-months			6-months		
	PSFW	**Control**	**P-value**	**PSFW**	**Control**	**P-value**
Intent-to-Treat[a]						
7-day PPA, N (%)						
Abstinent	35 (13.7%)	33 (13.1%)	.85	38 (14.9%)	22 (8.8%)	.03
Non-abstinent	220 (86.3%)	218 (86.9%)		217 (85.1%)	229 (91.2%)	
Complete-case[b]						
7-day PPA, N (%)						
Abstinent	35 (18.1%)	33 (16.9%)	.75	38 (20.1%)	22 (11.6%)	.02
Non-abstinent	158 (81.9%)	162 (83.1%)		151 (79.9%)	167 (88.4%)	
Secondary Outcomes						
30-day PPA ITT,N (%)						
Abstinent	26 (10.2%)	15 (6.0%)	.08	29 (11.4%)	16 (6.4%)	.05
Non-abstinent	229 (89.8%)	236(94.0%)		226 (88.6%)	235 (93.6%)	
Quit day attempt, N (%)						
Yes	72 (37.3%)	56 (28.7%)	.07	67 (35.4%)	44 (23.3%)	.01
No	121 (62.7%)	139 (71.3%)		122 (64.6%)	145 (76.7%)	
Longest number of days stayed quit, Mean (SD)	17.6 (27.0)	17.6 (29.8)	.99	25.8 (39.7)	22.4(40.0)	.42
Change since baseline in cigarettes-per-day, Mean (SD) *	−4.2 (11.9)	−4.9 (12.7)	.58	−5.2 (6.8)	−5.3 (11.1)	.93

Note-ECO=exhaled carbon monoxide, ppm=parts per million, PPA=point prevalent abstinence, PSFW+=Positively Smoke Free on the Web, SD=standard deviation, ITT=intention to treat

*Cigarettes per day, this analysis excluded participants who were abstinent at the specified timepoint.

Table 2.

Multivariable analysis of baseline factors associated with biochemically confirmed (ECO<10) intent-to-treat 7-day abstinence at 6-months.

Baseline variable	Bivariable Analysis		Multivariable Analysis*	
	OR (95% C.I.)	P-value	OR_{adj} (95% C.I.)	P-value
Study condition=PSFW+	1.82 (1.05–3.21)	0.04	1.79 (1.01–3.24)	0.05
Stable Housing	3.59 (1.54–10.50)	0.008	3.72 (1.56–11.03)	0.007
Smoking Partner - Yes	0.40 (0.19–0.77)	0.009	0.38 (0.18–0.74)	0.007
Not Hispanic or Latino/a	0.45 (0.25–0.84)	0.01	0.44 (0.24–0.84)	0.01
P30D Any illicit substance use**	0.58 (0.30–1.06)	0.09	0.55 (0.27–1.03)	0.07
Low Nicotine dependence	2.47 (0.85–9.01)	0.12	3.26 (1.08–12.24)	0.05
Low/Moderate Nicotine dependence***	1.43 (0.49–5.21)	0.54	1.52 (0.51–5.64)	0.49
Moderate Nicotine dependence***	1.20 (0.43–4.25)	0.75	1.48 (0.52–5.34)	0.51

Note-OR=odds ratio, OR_{adj}=adjusted odds ratio, 95% C.I.=95% confidence intervals, PSFW+=Positively Smoke Free on the Web, P30D=past 30 day.

* Variables tested in stepwise regression models and eliminated due to poor model fit were site, sex, race, income, P30D average daily cigarettes, P30D any other tobacco, P30D e-cigarette use, P30D marijuana use, alcohol use disorder, # of smoking partners, living with smoker, self-efficacy, and daily smoking.

** Any illicit substance use is defined as P30D use of cocaine (coke, dust, snow, lady); crack, freebase, rock, heroin (horse, China white, H, smack, junk), opiates, pain killers (codeine, methadone), amphetamines (ecstasy, MDMA, speed, crystal meth), hallucinogens (LSD, acid, mescaline), PCP or angel dust; sedatives, tranquilizers, or sleeping pills that weren't prescribed to you; prescription medications that weren't prescribed for you that you used only for the experiences or feelings it caused (Klonopin, Xanax, Valium).

*** Reference Group is heavy dependence based on the Modified Fagerstrom Tolerance Questionnaire

Table 3:

Program utilization metrics among PSFW+ participants by 6-month ITT biochemically confirmed abstinence versus non-abstinence.

Utilization metrics	Abstinent n=38	Non-abstinent n=217	P-value
Active Days, mean (SD)	20.1 (14.9)	17.6 (14.8)	0.34
Total Logins, mean (SD)	15.4 (25.6)	14.4 (23.5)	0.80
Time on Site * (hours), mean (SD)	50.8 (50.8)	42.0 (60.1)	0.40
Page views, mean (SD)	196 (170)	173 (189)	0.48
Unique Lessons Viewed, mean (SD)	5.8 (2.5)	4.8 (2.5)	0.03
Unique Sections Viewed, mean (SD)	34.7 (20.1)	29.4 (17.6)	0.10
Video Starts, mean (SD)	4.7 (4.6)	3.8 (3.7)	0.16
Total Comments, mean (SD)	17.9 (19.7)	11.8 (26.3)	0.18

Note: PSFW+=Positively Smoke Free on the Web, ITT=intention to treat, SD=standard deviation. Active Days: Total number of unique active days. Total Logins: Average number of website logins per user. Time on Site: Total time on site in minutes per user. Page views: Average number of page views per user. Unique Lessons Viewed: Number of unique lessons viewed per user. Unique Sections Viewed: Number of unique sections across lessons per user. Video Starts: Total number of videos initiated per user. Total Comments: Average number of comments per user.

* The distribution of Time on Site in hours was skewed. We therefore note that among abstinent the median=30.9, IQR 19.9—65.9 compared to the non-abstinent median 20.9, IQR 11.3—43.9.