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ORIGINAL PAPER

Feasibility and Acceptability of the Sense2Quit App for Improving Smoking Cessation in PWH

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Abstract
An estimated 34-47% of PWH in the US report cigarette smoking, three to four times the prevalence observed in the U.S. adult population. Given the dearth of smoking cessation interventions for PWH, our study team used community based participatory feedback to design and develop the Sense2Quit App, an mHealth app linked to a smartwatch, whose sensor technology provides for collection of hand gesture movements to detect when a participant lifts their hand to smoke a cigarette. Participants receive messages through the app to encourage their quit attempts and maintenance of smoking cessation. The goal of this feasibility study was to conduct a randomized feasibility study in 60 PWH living in NYC to assess the feasibility and acceptability of the Sense2Quit App for smoking cessation. Findings from this study suggest that the intervention was highly feasible and acceptable in this population. There was high acceptability with only 1 participant withdrawing from the trial and overall app usage increasing over the course of the study. Participants wore the sensor and used the app and rated it as highly usable. The high retention rate and engagement with the app supports the overall acceptability of this approach. ClinicalTrials.gov Identifier: NCT05609032.

Keywords Smoking cessation · HIV · Tobacco · MHealth · Smartwatch

Introduction

There are an estimated 1.2 million persons living with HIV (PWH) in the U.S [1]. Of these, an estimated 34–47% report cigarette smoking, three to four times the prevalence observed in the U.S. adult population [2, 3]. These national statistics are consistent with the findings from our own samples across several large studies in New York City (NYC) in which we found an average of 45% of PWH are current smokers [4, 5]. Given the high rates of cigarette smoking in PWH, it's not surprising that there is substantial tobacco-related morbidity and mortality, including from tobacco-related cancers. Lung cancer is the leading cause of cancer death among PWH on ART and is one of the leading causes of death overall in this population [2]. It is estimated that 94% of lung cancer diagnoses among PWH could potentially be prevented by eliminating cigarette smoking in this population and that it is estimated that life expectancy among HIV-positive smokers is reduced by at least 16 years compared with HIV-positive nonsmokers [2, 6]. Furthermore, cigarette smoking is associated with lower adherence to ART and can influence HIV pathogenesis [7, 8]. After achieving and maintaining a suppressed viral load, smoking cessation is among the most important interventions to maximize both quality of life and life expectancy among PWH who smoke [2].

Numerous risk factors are associated with cigarette smoking among PWH, including but not limited to substance use or co-dependence on other substances, alcohol use, marijuana use, mental illness, depression, lack of social support,

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not achieving HIV viral suppression, and other HIV-related symptoms [9–12]. Some of these risk factors, particularly chronic stressors (e.g., poverty, racism/discrimination, stigmatization, lack of access to HIV treatment, emotional distress, pain, comorbid substance use), may serve as barriers to cessation [13, 14]. The high prevalence of cigarette smoking and the high incidence of smoking-related cancer and other smoking-related diseases among PWH point to the need to intervene with this population to reduce tobacco use. However, evidence to guide the care of PWH smokers is inadequate [2]. PWH who smoke have substantially lower quit rates compared with the general population [15].

Studies have shown the vital role of healthcare providers in helping PWH quit smoking [14]. Despite this, many providers have competing priorities and do not routinely provide necessary care for successful tobacco cessation [16]. Mobile health (mHealth) technology presents a useful solution to gaps in care as it allows for health information to be accessible via smartphones which nearly the entire US population own [17].

Existing smoking cessation mHealth interventions have utilized personalized quit plans, reminders, motivational messaging, gamification, progress tracking and integrated guidance for use of pharmacotherapy, and have shown promising results for the feasibility of mHealth interventions for smoking cessation [18–23]. Nonetheless, these studies were not specific to PWH who are likely to face additional barriers to quitting. Tailored tobacco cessation interventions designed for eventual dissemination and implementation are necessary to advance cancer control in PWH who use tobacco [2]. A 2024 meta-analysis of smoking interventions for PWH revealed a lack of study designs that guide development and implementation of effective smoking cessation support[12]. There are few randomized clinical trials examining smoking cessation treatment for PWH conducted to date, and the major methodological limitations of many smoking cessation studies (e.g., lack of randomization, comparison conditions, treatment fidelity assessments, abstinence verification tests), suggest there is a strong need for additional research in this area[2, 12, 24, 25]. It is not clear how best to structure or deliver evidence-based tobacco cessation treatment that will address the complex and unique needs of PWH.

Participants in our formative work identified needing additional interventions and support to successfully quit smoking amid everyday challenges and struggles despite their motivation to quit smoking due to health concerns [26, 27]. In response to this, our study team designed an mHealth intervention to facilitate smoking cessation in PWH. We completed extensive formative work to design and ensure the usability of the app. In summary, the Sense2Quit app is designed based on user feedback which was collected through extensive formative work comprised of focus groups, design sessions and usability testing and guided by the Information Systems Research Framework for designing mHealth technology [26, 28]. The final intervention was an mHealth app linked to a smartwatch. The sensor technology provided for collection of hand gesture movements to detect when a participant lifted their hand to smoke a cigarette. Users of the Sense2Quit app received feedback to encourage them not to smoke the cigarette and messages to support their cessation and quit attempts. Details of the Sense2Quit app components can be found elsewhere [29]. Following this extensive formative work, our study team conducted a pilot feasibility study with 60 PWH who smoke cigarettes and are living in the New York City area [29].

The primary objectives of the study were to assess the feasibility and usability of the Sense2Quit App; the study was not powered to assess efficacy. We chose a sample size of 60 since there is a general flat rule to include at least 30 subjects or greater which should be sufficient to estimate a parameter to conduct a t-test in a pilot study [30]. Usability was a key outcome of this study because the technology literature has demonstrated that if consumers do not perceive an app as usable then they are unlikely to use it [31–33]. Given the dearth of smoking cessation interventions for PWH, the goal of this feasibility study was to determine whether this intervention is appropriate for further testing; and enable us to assess whether the ideas and findings are relevant and sustainable [34].

Methods

Study Design and Participants

This study was a randomized clinical trial (RCT) of the Sense2Quit app vs control arm for smoking cessation among PWH at 4 and 12 weeks after baseline. It follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. Recruitment was completed in New York City at HIV clinics, community-based organizations and through posting advertisements on the Internet (i.e. Craig's List).

Inclusion criteria included 1) People living with HIV confirmed through medical records or pill bottles for antiretroviral therapy (ART) medications; 2) Aged 18 years or older; 3) Able to understand and read English; 4) Current smoker (smokes at least five cigarettes per day for the past 30 days); 5) Owns an Android smartphone; 6) Not pregnant or breastfeeding (due to contraindications for nicotine replacement therapy (NRT)); 7) living in the New York City area; 8) Interested in quitting smoking within 30 days; and 9) Exhaled carbon monoxide (eCO) ≥ 5 ppm (parts per million) at baseline with the added exclusion criteria of 1) Use of tobacco products other than cigarettes (i.e. vapes, electronic cigarettes),

cigars, piped tobacco, chew, and snuff); 2) Planning to move within 3 months of enrollment; 3) Alcohol dependence as measured through the Alcohol Use Disorders Identification Test-Concise (AUDIT-C); 4) Positive history of a medical condition that precludes nicotine patch use; 5) Current use of NRT or other smoking cessation medications; 6) Current enrollment in another smoking cessation program; and 7) Another household member already participating in the Sense2Quit study, to reduce study contamination. Our rationale for current smoker defined as five or more cigarettes per day is that this is standard for smoking cessation trials [35]. Further, those who smoke less than five cigarettes/ day (or intermittently) generally require a different cessation strategy. Finally, those who smoke less may not have had a CO level high enough to be eligible and it would have been difficult to biochemically-verify cessation in people who smoked less or intermittently [35–37].

Columbia University served as the single institutional review board for all study activities. An independent data safety and monitoring board was convened for this study to monitor the study. Electronic informed consent was obtained prior to study participation. Upon enrollment, participants were required to provide photo identification with date of birth to confirm age and identity. Incentives were provided for study visits ($40 initial visit, $50 at 4 weeks and $60 at 12 weeks). All study visits were completed at our study site at the Columbia University School of Nursing. The study procedures and protocol are described in detail elsewhere [29].

Intervention

The Sense2Quit app (Fig. 1) is a mHealth app connected via Bluetooth to a smartwatch that tracks smoking gestures and distinguishes them from other hand gestures movements such as eating, drinking, talking on the phone, scratching, waving etc. Through the app, participants view their smoking trends which are recorded using the smartwatch, including how often/how much they smoke and the amount of money that they are spending on cigarettes. The Sense2Quit app has additional features such as reminders, chat with the study team, videos, quitting tips, and games like Pac-Man and Tetris to allow participants to distract themselves from a craving to smoke a cigarette.

Randomization

REDCap was used to assign randomization to study participants. We randomized by sex assigned at birth which results in 31 male sex assigned at birth enrolled and 29 female sex assigned at birth enrolled. We concealed randomization status from staff and participants until after completion of the baseline assessment to minimize bias. The study statistician who performed the data analysis was blinded to the treatment groups.

Study Assessments

Participants completed standardized quantitative assessments of demographic characteristics (age, race and ethnicity), tobacco, substance and alcohol use, HIV status and

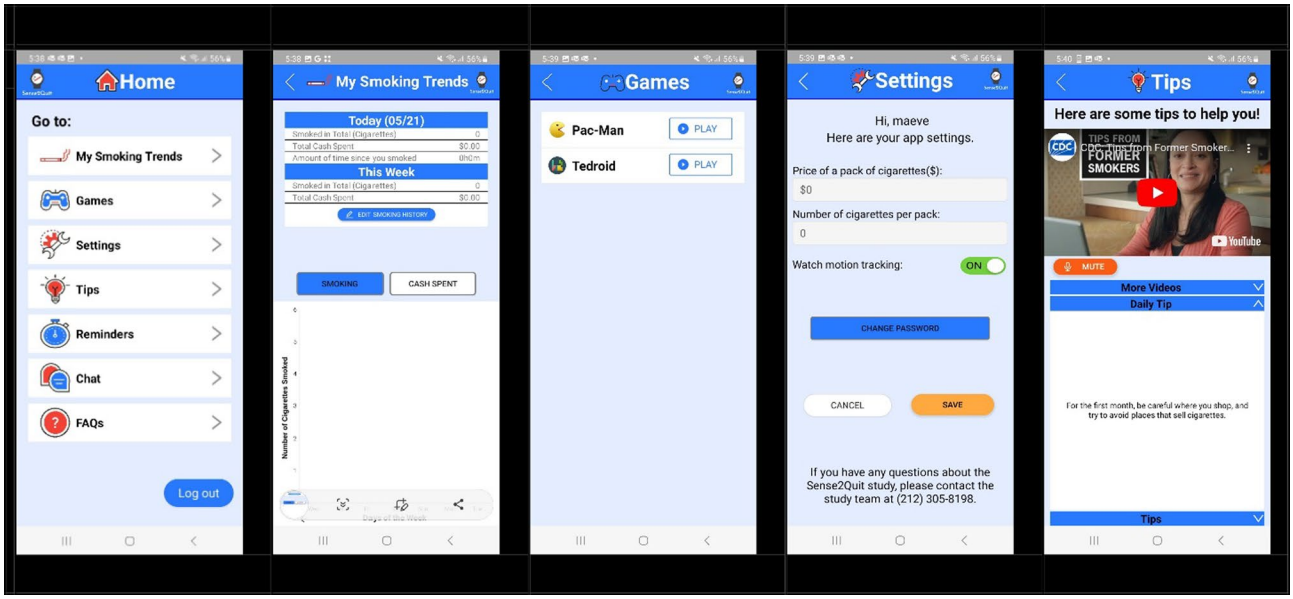

Fig. 1 Sense2Quit App

pharmacotherapy use at baseline, 4 and 12 weeks. Usability measures, (The Health Information Technology Usability Evaluation Scale (Health-ITUES) [38] was collected at the 4 and 12 week follow-up visit from participants randomized to the Sense2Quit App. The Health-ITUES is scored from 1 (strongly disagree) to 5 (strongly agree) with higher scores indicating greater usability. It consists of four sub-scales: quality of work life, perceived usefulness, perceived ease of use, and user control. We collected exhaled carbon monoxide (eCO) level at baseline, 4 and 12 weeks through a breathalyzer (Micro + TM basic Smokerlyzer, coVita). We also asked the number of quit attempts made since the last study visit at 4- and 12-weeks post intervention.

Statistical Analysis

First, we calculated descriptive statistics to describe the study sample by study condition and as a total sample. We used the Chi-square test (or Fisher's exact test) and independent samples t-test to assess the differences in baseline characteristics between the intervention and control groups. Next, we compared the two outcome measures: eCO level and the number of quit attempts made since the last study visit, by study arms at each time point (baseline, 4 weeks, and 12 weeks post-intervention). We also calculated effect size measure (Cohen's d) at each time point. We used regression models with generalized estimating equations (GEE), which considered the correlations between repeated measures and time trends, to assess the intervention effect between the two groups. In these models, we first assessed the interaction effects between time and group on outcomes. If there was no significant interaction effect, we used models with the main effects of group and time. We used linear regression for outcome eCO and Poisson regression for number of quit attempts. All analyses were conducted using SAS version 9.4 [39].

Results

Sample Characteristics

From March to October 2023, 211 individuals were screened, 60 were enrolled and randomly assigned to one of two study conditions: 30 individuals were assigned to the active (Sense2Quit) intervention, and 30 were assigned to the control condition (Fig. 2). Twenty-seven people were eligible but not enrolled. The demographic characteristics of enrolled participants are detailed in Table 1. There were significant differences by race in the active and control conditions, with more participants who self-identified as White in the intervention arm and more participants who identified as "other" in the control arm. The overall number of both

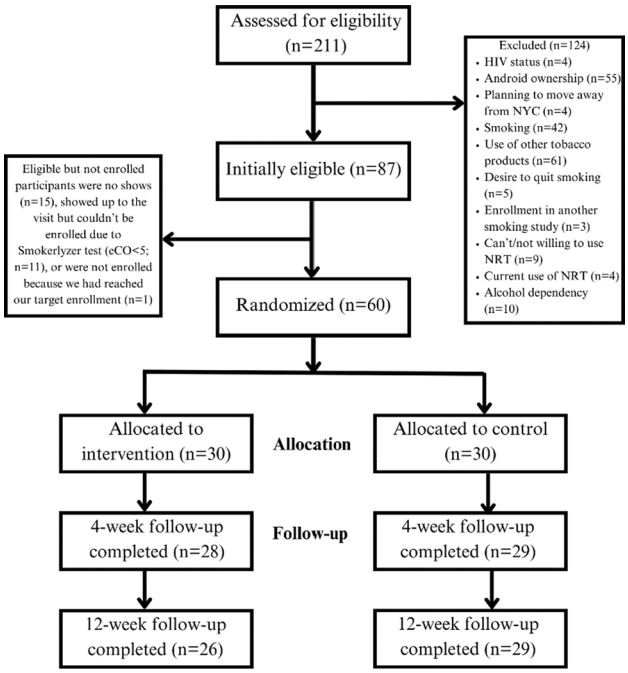

Fig. 2 CONSORT

was small however since 80% (48/60) of the study sample identified as Black/African American. Further there were significantly more participants who identified as Hispanic/Latino in the control arm (n = 8) as compared to the intervention arm (n = 1). The mean age of study participants was 56.4 years (S.D. 10.4), 48.3% (29/40) of participants identified as male, and most participants had a high school diploma (20/60) or equivalent and an annual income less than $20,000 (49/60).

Feasibility and Acceptability

This study focused on several constructs related to the feasibility and acceptability of the Sense2Quit intervention for cigarette smoking cessation in PWH including eligibility, recruitment and retention rates, app usage, usability of the app and preliminary efficacy.

Eligibility During the recruitment and enrollment period, 211 people were screened for eligibility with 58.8% screening ineligible. Use of other tobacco products (N = 61) and not owning an Android (N = 55) were the most frequently cited reasons for ineligibility. Exclusion criteria were not mutually exclusive. During the study's 8-month recruitment and enrollment period, approximately 7.5 participants were enrolled per month. 41.2% of people who screened were eligible for study participation. 11 people reported that they were eligible during phone screening but were ineligible when they arrived at our study site since their eCO < 5. Of

Table 1 – Demographic Characteristics of Study Participants

	Study Condition				
	Intervention (N = 30)	Control (N = 30)	Total (N = 60)	Statistic value	*P* Value
Age					
Mean (SD)	53.97 (12.05)	58.83 (7.90)	56.40 (10.40)	−1.85[a]	0.07
Number of times not having enough money					
Mean (SD)	3.07 (3.74)	1.63 (3.54)	2.35 (3.68)	1.52[a]	0.13
Gender-N(%)					
Male	13 (43.33)	16 (53.33)	29 (48.33)	NA[a]	0.63
Female	15 (50.00)	12 (40.00)	27 (45.00)		
Transgender Female/Transwoman/MTF	2 (6.67)	1 (3.33)	3 (5.00)		
Other	0 (0.00)	1 (3.33)	1 (1.67)		
Sex at birth-N(%)					
Male	14 (46.67)	16 (53.33)	30 (50.00)	0.2667[a]	0.61
Female	16 (53.33)	14 (46.67)	30 (50.00)		
Sexual orientation-N(%)					
Homosexual/gay/lesbian	12 (40.00)	10 (33.33)	22 (36.67)	NA[a]	0.8
Heterosexual/straight	15 (50.00)	17 (56.67)	32 (53.33)		
Bisexual	2 (6.67)	3 (10.00)	5 (8.33)		
Asexual	1 (3.33)	0 (0.00)	1 (1.67)		
Race/Ethnicity-N(%)					
Hispanic Black/African American	0	2 (6.67)	2(3.33)	NA[a]	0.006**
Hispanic White	1 (3.33)	0 (0)	1(1.67)		
Hispanic Other	0(0)	6 (20.00)	6(10.00)		
Non-Hispanic Black/African American	24 (80)	22(73.33)	46(76.67)		
Non-Hispanic White	3(10)	0(0)	3(5.00)		
Non-Hispanic Other	2 (6.67)	0(0)	2(3.33)		
Education-N(%)					
None	1 (3.33)	1 (3.33)	2 (3.33)	NA[a]	0.26
Some high school, no diploma	6 (20.00)	8 (26.67)	14 (23.33)		
High school diploma or equivalent (e.g., GED)	13 (43.33)	7 (23.33)	20 (33.33)		
Some college	5 (16.67)	9 (30.00)	14 (23.33)		
Associate degree or technical degree	1 (3.33)	2 (6.67)	3 (5.00)		
Bachelor/college degree	1 (3.33)	3 (10.00)	4 (6.67)		
Professional or graduate degree	3 (10.00)	0 (0.00)	3 (5.00)		
Annual income-N(%)					
Less than $10,000	14 (46.67)	9 (30.00)	23 (38.33)	NA[a]	0.17
$10,000-$19,999	9 (30.00)	17 (56.67)	26 (43.33)		
$20,000-$39,999	5 (16.67)	4 (13.33)	9 (15.00)		
$40,000-$59,999	1 (3.33)	0 (00.00)	1 (1.67)		
Don't know	1 (3.33)	0 (0.00)	1 (1.67)		

Note:[a]t statistic for continuous variable and Chi-square statistic for categorical variable, and NA indicating that statistic value not available as the p-value was based on Fisher's exact test

*$p < 0.05$

**$p < 0.01$

those scheduled for study visits 15 (17.4%) did not show up for their baseline study visit.

App Usage The Sense2Quit App usage was measured by data usage and participant activities recorded on our secure server. The plots in Fig. 3 display essential trends in data usage and participant engagement in the Sense2Quit app.

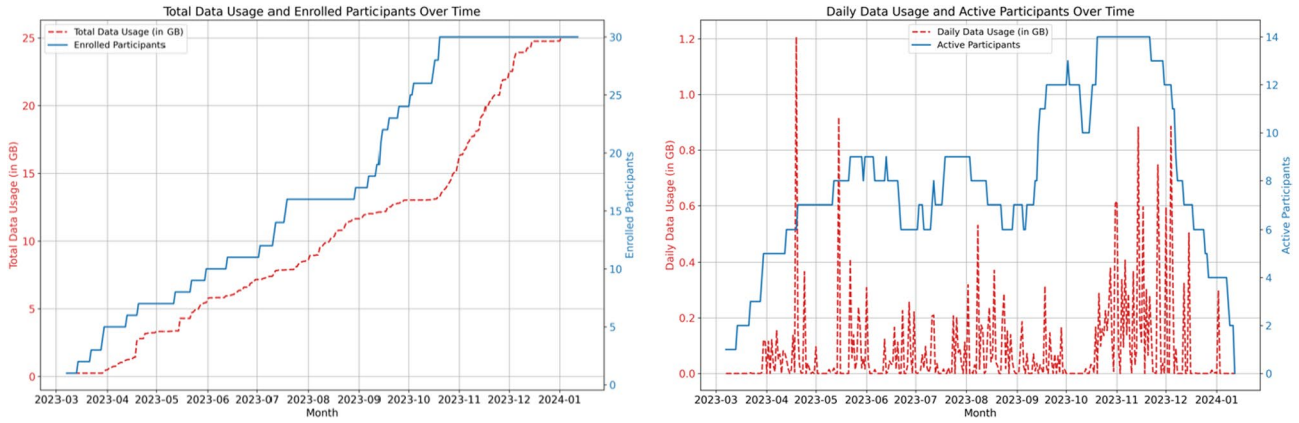

Fig. 3 Trends in Daily and Total Data Usage & Participant Engagement

Figure 3(a) shows a continuous increase in both total participation and data usage throughout the study. The red dashed line represents the total data usage (in GB), and the blue solid line shows the number of enrolled participants. The steady upward trend in both lines indicates growing engagement and consistent app usage over time. Figure 3(b) reveals daily data usage trends and highlights the daily participation of active participants. The red dashed line represents the daily data usage (in GB), while the blue solid line indicates the number of active participants daily. The plot shows fluctuations in daily data usage, reflecting varying participant activity levels during the pilot study. Figure 4 illustrates the daily usage rate, which is defined as the daily data consumption divided by the number of daily active users. This plot provides insight into the dynamic participation levels throughout the study. The variation in the daily usage rate shows how participant activity influenced data volumes, contrasting with the steady increase observed in total data usage and enrollment. By the end of the observed period, total data usage had significantly increased, reaching nearly 25 GB. This substantial increase underscores study subjects' active and ongoing participation, highlighting the app's growing adoption and consistent use over time.

Usability of the App The Sense2Quit app was rated by participants in the intervention arm using the Health Information Technology Usability Evaluation (Health-ITUES). The overall mean score of the Health-ITUES was 4.37 (SD 0.61) at week 4, and was 4.38 (SD 0.69) at week 12. The internal consistency of the scores were high (Cronbach's alpha = 0.94 a week 4 and 0.96 at week 12). Notably an optimal cut-point of 4.32 on the Health-ITUES total score indicates usability and the mean score of our study participants was above this cut-point [40].

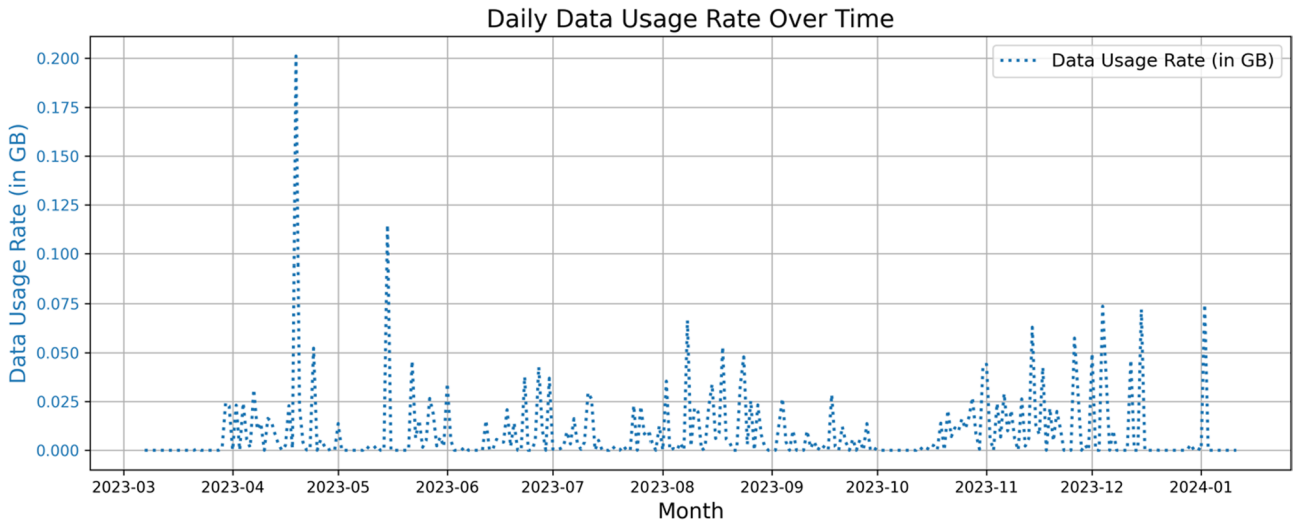

Fig. 4 Daily Data Usage Rate

Study Measures and Missing Data Among the 172 total completed survey responses, missing data was evenly distributed across study arms. On average, study participants completed the baseline survey in 78 (SD: 32) minutes and completed the follow-up survey in 43 (SD: 20) minutes.

Preliminary Efficacy was measured by the number of quit attempts and eCO at 12 weeks. Table 2 displays descriptive statistics, effect sizes, and intervention effects for outcomes eCO and the number of quit attempts. Neither of the interaction effects between group and time on outcome measures was significant in the multi-level regression models. Thus, the efficacy of intervention was assessed based on models with main effects of group and time. For eCO, the effect sizes between the two arms was small (Cohen's $d < 0.20$) at both the 4- and 12-week marks. There was a greater than medium effect size (Cohen's $d = 0.67$) at week 4 and a small-medium effect size (Cohen's $d = 0.41$) at week 12 for the number of quit attempts made since the last study visit.

Results from Poisson regression model with GEE, which accounted for the correlations between repeated measures and time trend effects, indicated that the intervention group had a significantly greater number of quit attempts than the control arm (Incidence Rate Ratio = 1.62, 95% CI: 1.05–2.48 $p = 0.028$): the intervention group reported 62% greater number of quit attempts. There was no significant intervention effect on eCO.

Retention Rates Of the 60 participants who enrolled in the study, 57 completed their 4-week follow-up study assessment and 55 completed the 12-week follow-up study assessments. The overall retention rate across both study groups was 91.7%. 3 participants from the intervention group and 1 participant from the control group did not complete the 12-week follow up study visit. One participant withdrew from the study.

Discussion

Smoking cessation efforts have largely been aimed at the general population of people who smoke. Consequently, it is not clear whether they are suitable or effective for cohorts with population-specific concerns and clinical issues such as PWH [8, 41–43]. There has been little research conducted on the use of mHealth technology for PWH who smoke. In one study that focused on providers who deliver HIV care, the decision-T app increased HIV-care providers' engagement in offering smoking prevention and cessation behavioral and pharmacotherapy recommendations to their patients briefly and accurately but the providers noted that changes were needed to the app [44]. In another study, ambivalent smokers were receptive to the app-based intervention, but preferred an enhanced care version, which combined best-practice cessation advice with self-paced, experiential exercises.

Table 2 Outcome measures by study arm and time point

		User group assignment						
		Intervention		Control				
	Timepoint	Mean	Std	Mean	Std	Cohen's d	z statistic	P_value[b]
Exhaled CO in ppm	Baseline	15.13	7.21	17.07	10.44	− 0.22		
	4-week	13.46	7.96	12.07	7.73	0.18	0.65	0.52
	12-week	13.46	7.44	12.27	9.85	0.14		
Number of quit attempts made since last study visit.[a]	4-week	3.08	2.68	1.7	1.46	0.67	2.19	0.023*
	12-week	2.64	1.98	1.86	1.85	0.41		

		Intervention		Control		Overall		
	Timepoint	N	%	N	%	Timepoint	N	%
Retention	4-week	28	93.3	29	96.7	4-week	57	95
	12-week	26	86.7	29	96.7	12-week	55	91.7

	Health ITUES	Quality of Work Life		Perceived Usefulness		Perceived Ease of Use		User Control		Overall	
	Timepoint	Mean	Std	Mean	Std	Mean	Std	Mean	Std	Mean	Std
Usability (Intervention only)	4-week	4.64	0.68	4.42	0.58	4.30	0.96	4.12	0.92	4.38	0.61
	12-week	4.54	0.68	4.40	0.68	4.35	0.84	4.24	0.86	4.38	0.69

[a]Data were collected at week 4 and 12 only

[b]*P*_value from regression models with GEE accounting for the correlations among repeated measures and time effect

*P_value<0.05

Finally, using a commercially available smoking cessation app, Schnall et al. found that PWH used the app but desired a tool which was tailored to the linking smoking to health effects specific to PWH[45].

Therefore, this study focused on testing a tailored intervention using the Sense2Quit App to improve smoking cessation in PWH. This is especially important given that tobacco use causes significant morbidity and mortality in PWH, and tobacco-related harm is substantially higher in PWH than smokers in the general population. The Sense2Quit App was developed using extensive community-informed participatory feedback with PWH who smoke cigarettes or have quit smoking cigarettes [26, 28]. This approach has proven useful in supporting the efficacy of interventions for PWH or those at risk for HIV seroconversion[5, 46, 47]. Given the dearth of current evidence and the complex socioecological factors that contribute to tobacco use in PWH, our study team use community based participatory research methods guided by the Information Systems Research Framework [48] to design an intervention delivered via a mobile platform and smartwatch to help PWH quit smoking. Notably, the Sense2Quit study is an innovative approach combining mHealth technology with a smartwatch to guide PWH through the process of quitting cigarette smoking.

Findings from this study suggest that the intervention was feasible and acceptable in this population. There was high acceptability with only 1 participant withdrawing from the trial and overall app usage increasing over the course of the study. Participants wore the smartwatch and used the app. Importantly, retention rates were high which is a testament to the feasibility and acceptability of this intervention. The high retention rates are notable in a study population who can oftentimes have complex social determinants of health and some of these factors (low income, food insecurity, lack of transportation) make study participation complex. Preliminary efficacy of the intervention was not demonstrated during this trial, however the study was not powered to detect such differences, and efficacy was not the goal of this pilot study. The goal of this study was largely focused on demonstrating feasibility and acceptability of the Sense2Quit intervention which was largely achieved through this study.

Nonetheless, there were several limitations during the pilot trial. Our goal is to overcome these issues in a future study to strengthen the user experience and increase the potential implementation of the intervention for broad dissemination. The app was not available to iOS users and was limited to participants who owned an Android smartphone. This presented challenges for enrollment and ultimately, we purchased Android smartphones for our last 3 study participants since recruitment and enrollment was languishing since many of those who would be eligible owned iOS smartphones. The second challenge was related to the hand gesture algorithm. Several participants mentioned throughout the study that the smartwatch was not properly sensing smoking gestures and that it was instead recording other hand movements such as those caused by eating, drinking, or talking with their hands as smoking. Some participants defaulted to manually correcting the smoking data in the bar graph on the "Smoking Trends" page. Due to the inaccuracy of smoking detection, we performed additional testing with confounding hand gestures to improve the smartwatch algorithm. Reinforcing the smoking detection AI algorithm using these confounding gestures will help the model reduce incorrect predictions and improve smoking detection in future studies. A third challenge was the app onboarding process. Our app was not published in the Android Play Store and required downloading two supporting apps to connect the app to the smartwatch. Because of this, any time a participant got a new phone, which happened with four participants, or misplaced their watch and needed a replacement, which happened with one participant, or any time the app required an update, participants would have to come into the office, which was not always possible. This led to delays in re-downloading or updating the app. Additionally, we plan to deploy the mobile application for future studies on iOS and Android stores, streamlining the onboarding process and making it accessible to more participants. Finally, our study did not include an acceptability measure despite including many other metrics related to the acceptability of the study procedures and intervention.

Conclusions

Findings from this study support the feasibility and acceptability of the Sense2Quit App for promoting smoking cessation in PWH. High usability, usage and retention rates are testament to the acceptability of the intervention. In summary, the recruitment pace, high retention rate and engagement with the app supports the overall acceptability of this intervention for improving smoking cessation in PWH.

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Declarations

Conflicts of interest The authors have not disclosed any conflict of interest.

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