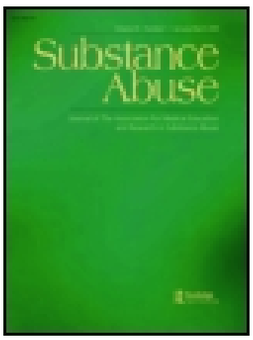

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ORIGINAL RESEARCH

Harm reduction treatment for smoking (HaRT-S): findings from a single-arm pilot study with smokers experiencing chronic homelessness

Susan E. Collins, PhD[a], Lonnie A. Nelson, PhD[b], Joey Stanton[a], Nigel Mayberry, RN[a], Tatiana Ubay, BS[a], Emily M. Taylor, BS[a], Gail Hoffmann, BS[a], Silvi C. Goldstein, BA[a], Andrew J. Saxon, MD[a,c], Daniel K. Malone, MPH[d], Seema L. Clifasefi, PhD, MSW[a], Kolawole Okuyemi, MD, MPH[e], and The HaRT-S Community Advisory Board[d]

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ABSTRACT

Background: Smoking prevalence and mortality is 5 times higher for the chronically homeless versus general population. Unfortunately, traditional smoking cessation treatment does not optimally engage this population. In a preliminary study, smokers experiencing chronic homelessness suggested providers avoid giving advice to quit and instead use a more compassionate, nonjudgmental style to discuss a broader menu of patient-driven options, including safer nicotine use. Most had negative perceptions of smoking cessation medications; however, 76% expressed interest in a switchover to electronic nicotine delivery systems (ENDS). *Methods:* Using a community-based participatory research approach, we codeveloped harm-reduction treatment for smoking (HaRT-S) together with people with lived experience of chronic homelessness and smoking and a community-based agency that serves them. In HaRT-S, interventionists embody a compassionate, advocacy-oriented "heart-set" and deliver manualized components: a) participant-led tracking of smoking-related outcomes, b) elicitation of harm-reduction goals and progress made toward them, c) discussion of relative risks of nicotine delivery systems, and d) distribution and instructions on use of safer nicotine products. We then conducted a single-arm, 14-week pilot of HaRT-S ($N = 44$). *Results:* Participants rated procedures "totally acceptable/effective," which was reflected in 26% overrecruitment within a 4-month period and 70% retention at the 14-week follow-up. For each week in the study, participants experienced an 18% increase in odds of reporting 7-day, biochemically verified, point-prevalence abstinence. All participants reporting abstinence used ENDS. Participants evinced reductions in cigarette dependence (−45%), frequency (-29%), and intensity (−78%; $ps < .05$). Participants who used ENDS experienced an additional 44% reduction in smoking intensity and a 1.2-point reduction in dependence compared to participants who did not. *Conclusions:* Harm-reduction counseling plus ENDS shows promise for smokers experiencing chronic homelessness. Randomized controlled trials are needed to establish the efficacy of this approach in decreasing smoking-related harm and improving health-related quality of life for this marginalized and disproportionately affected population.

KEYWORDS
Smoking; smoking treatment; harm reduction; homelessness; community based participatory research; smoking-related harm

The prevalence of cigarette smoking in the homeless population (73%) is substantially higher than in the general US population (15%)[1–3] and precipitates a disproportionate experience of smoking-related illness (e.g., chronic obstructive pulmonary disease and cardiovascular disease).[4–6] Thus, smoking-related mortality rates are 3 to 5 times higher in smokers experiencing homelessness than in the general population.[7]

Within the larger homeless population, 15% are affected by chronic homelessness, which is characterized by long or frequent episodes of homelessness (i.e., ≥1 year of homelessness or ≥4 or more episodes of homelessness in past 3 years) paired with physical and mental health disabilities.[8] Thus, by this federal definition, people who have experienced chronic homelessness are more severely impacted by psychiatric, medical and substance use disorders than the larger homeless population.

In the case of smoking, people experiencing chronic homelessness have a smoking prevalence that is 10% higher than in the general homeless population.[3] Although this aforementioned study is the only quantitative, population-based study to date that features smokers experiencing chronic homelessness, other studies have shown that people experiencing hallmarks of chronic homelessness—including co-occurring disorders and more extensive homelessness histories—use substantially more emergency healthcare services[9,10] than people experiencing homelessness without these

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complicating factors.[11–14] These health-disparities extend to smoking-related disease: Among frequent, homeless emergency department patients, 38% had a diagnosis of chronic obstructive pulmonary disease.[15]

Unfortunately, available smoking cessation treatments have not engaged this population. Outside a research context, smokers experiencing homelessness virtually never seek smoking cessation treatment.[16] This lack of treatment-seeking is likely due to multiple barriers this population faces, including the expense and perceived undesirability of existing treatments,[17] lack of insurance and access to treatment,[18] high prevalence of smoking among peers and staff,[19–21] and reliance on smoking for coping.[19, 21,22] There is also a mismatch between desire and readiness to quit among smokers experiencing homelessness. Although many report wanting to quit,[19] only a minority report readiness to quit in the next 1 (16.8-19%)[16, 23] to 6 (37%) months.[24]

Smoking cessation treatment has not typically been tailored to the needs of smokers experiencing homelessness. In fact, only 4 randomized controlled trials conducted with this population have been published to date, and 3 were small pilot studies. Researchers have openly noted that these interventions only reached people interested in an imminent quit attempt, and even among those participants, findings were mixed.[25–28] No treatment studies to date have been conducted with people experiencing chronic homelessness.

These research and treatment gaps have inspired calls for more flexible, patient-centered, community-based approaches for this population.[29–31] In response, we conducted a 3-phase, community-based participatory research (CBPR) project to develop, implement and initially evaluate a new treatment for smokers experiencing chronic homelessness. CBPR entails the more equitable involvement of nonacademic stakeholders—in this case agency staff and management and representatives of the community they serve (i.e., people with lived experience of smoking and chronic homelessness)—to design research that is more desirable, transformative, capacity-building and sustainable than traditional, researcher-driven approaches. (See Collins et al.[32] for more information about this approach.) Over the last decade, CBPR has been recommended by experts as an essential framework for addressing the needs of marginalized smokers, including smokers experiencing homelessness.[29,30]

In phase 1 of this CBPR project, we conducted qualitative interviews with 25 smokers receiving services at an emergency shelter that specifically serves a chronically homeless population to document their perceptions of existing approaches addressing smoking and their suggestions for improving these approaches.[17] Participants said they appreciated healthcare providers' initiation of conversations about smoking. Those conversations, however, typically culminated in simple advice to quit, which was perceived as inadequate, unhelpful, or judgmental. Instead, participants suggested providers approach them in a more compassionate and collaborative manner, offer more support and sustainable solutions, and discuss a broader menu of options, including safer nicotine use. Notably, 76% spontaneously expressed positive interest in more information about and support for a switch to electronic nicotine delivery systems (ENDS), whereas only 24% mentioned pharmacotherapy (e.g., varenicline), the majority of whom (67%) reported negative perceptions.[17]

In phase 2, we presented these data, paired with shelter staff perspectives on potential solutions, to a community advisory board (CAB) comprising people with lived experience of smoking and chronic homelessness, shelter service providers and management, and academic researchers. Over the course of 15 months, we worked together to design, implement, and evaluate what became Harm Reduction Treatment for Smoking (HaRT-S).

Harm-reduction approaches support realization of client-driven goals and recognize reduced substance-related harm and improved health-related quality of life (HR-QoL)—not abstinence from substances—as the primary aims.[33] HaRT-S entailed an initial group session followed by 3 individual harm-reduction counseling sessions comprising a) participant-led tracking of smoking outcomes, b) elicitation of participants' harm-reduction and HR-QoL goals and their progress toward achieving them, c) discussion of relative risks of various nicotine delivery systems, d) instruction in appropriate use of safer nicotine delivery systems, and e) provision of a subset of safer nicotine delivery systems (i.e., NRT and ENDS; see Footnote 1[1] for information about ENDS role in service of harm reduction).

Study aims

This study's aims were to assess initial feasibility, acceptability, and smoking and HR-QoL outcomes following HaRT-S for smokers who experienced chronic homelessness. It was hypothesized HaRT-S would be: a) feasible (i.e., an adequate sample size would be achieved and participants would present for HaRT-S sessions); b) acceptable (i.e., participants would report that HaRT-S is acceptable and effective and that they would be likely to continue use of safer nicotine delivery systems); and c) followed by improvements in smoking-related and HR-QoL outcomes.

[1]ENDS was deemed an appropriate pharmacological adjunct to harm-reduction counseling for a few important reasons. First, our preliminary study indicated it was perceived far more positively than NRT or other medications, and these findings were affirmed by community members on our CAB.[17] Additionally, considering the relative safety of this approach was important. Fortunately, in their 2018 comprehensive, systematic review, the National Academies of Sciences, Engineering and Medicine concluded ENDS use is safer than smoking.[64] The level of tobacco-specific nitrosamines (TSNAs), the primary group of carcinogens endogenous to tobacco, is up to 380 times higher in cigarette smoke than in ENDS vapor,[65] and the concentration of urinary TSNAs is 97% lower in ENDS users than smokers.[66] A study of cigarette smokers who switched to ENDS for 2 weeks showed nicotine exposure was unchanged, while exposure to toxicants was substantially reduced.[67] The observed reductions in toxicants paired with the National Academies'[64] observation that a complete switchover from smoking to ENDS results in reduced short-term adverse health outcomes have bolstered the conclusion in a recent *Nature Reviews: Cardiology* article that "the adoption of ENDs rather than cigarette smoking might result in an overall benefit for public health."[68] Unintended exposure for children was another important factor to consider; however, the proposed setting for this study serves only single adults, not children and family, and efforts were made to ensure packaging and flavorants were not appealing to children.

Methods

Participants

Participants ($N = 44$) were recruited at an emergency shelter in Seattle, Washington that serves people experiencing chronic homelessness.(See Footnote 2[2] for information on the shelter's smoking, alcohol and other drug use policy.)

Study inclusion criteria comprised a) being at least 18 years old, b) having lived experience of chronic homelessness (established by being a client at this agency),[34,35] and c) being a current smoker (i.e., ≥100 lifetime cigarettes and self-reported smoking in past week). Exclusion criteria were a) refusal or inability to consent to participation and b) constituting a risk to the safety and security of other clients or staff.

Measures

Sociodemographics were documented using single items assessing age, birth sex, gender, race, and ethnicity.

The *Fagerström Test for Nicotine Dependence* (FTND) is a psychometrically sound measure of dependence on cigarette smoking.[36]

The *Timeline Followback for Nicotine* (TLFB-N) is a reliable and valid measure featuring calendars to retrospectively evaluate nicotine use for each day of a certain timeframe.[37–40] We administered a 1-week TLFB-N calendar and aggregated smoking variables (i.e., smoking intensity, frequency, abstinence) as well as use of safer nicotine delivery systems (i.e., NRT, ENDS).

Carbon monoxide (CO) parts per million in exhaled air were measured using the Micro + basic Smokerlyzer (Bedfont Scientific Ltd., Kent, England) to biochemically verify and, as necessary, correct self-reported abstinence (same day cutoff: 12 ppm;[41] primary outcome cutoff: 6 ppm).

Spirometry compared predicted lung function based on participants' height, age, and gender with forced expiratory volume in the first second of expiration as a percentage of the predicted value (FEV1% predicted). The LungLife (Bedfont Scientific Ltd., Kent, England) device measured forced expiratory volume and calculated FEV1%.

The *EuroQoL-Visual Analog Scale* (EQ-VAS) is a psychometrically sound, single item representing HR-QoL via participants' general assessments of their current health, where 0 = worst health imaginable and 100 = best health imaginable.[42–45]

Acceptability Rulers are 4, single, 10-point items,[46] on which participants rated perceived acceptability and effectiveness of HaRT-S; likelihood of HaRT-S attendance; and importance of safer nicotine use.

[2]Regarding the onsite substance-use policy, the shelter does not allow smoking, alcohol or other drug use onsite. If a shelter stayer is found smoking or with alcohol or other drugs, they have the choice to give up the substances to staff and continue to receive services or to keep the substances and receive a day-long bar from shelter services. People who are visibly intoxicated may receive shelter services as long as the person is deemed by staff to be "safe and in behavioural control" (A. Coak, personal communication, August 3, 2018).

HaRT-S treatment

HaRT-S was cocreated by the CAB and comprised an initial group session at week 0 followed by individual sessions at weeks 1, 2 and 6 (see Table 1 for treatment components).

Staff and training

Assessment interviewers were postbaccalaureate research assistants. Interventionists included a clinical psychologist, registered nurse, and peer counselor who had lived experience of smoking, NRT, and ENDS use. All staff received 16 hours of in-person training including research ethics and integrity, manual review, role-plays, shadowing, feedback, and weekly supervision from the first author, a licensed clinical psychologist with over 20 years of experience conducting substance-use assessment and treatment research. Interventionists and assessment staff audio recorded sessions to facilitate supervision.

Procedures

All participant procedures took place in an emergency shelter owned and operated by the partnering agency over a 4 month period (April 2017 through December 2017). Agency and research staff notified clients of the opportunity to attend an information session, and flyers were posted at the agency. Research staff conducted 20-minute information sessions onsite in groups of 4-8 interested clients. Research staff explained study procedures, participants' rights, and informed consent materials. Written, informed consent was obtained from participants prior to engagement in study procedures.

Following the information session, participants individually completed the measures listed in the Measures section and were administered spirometry and CO tests. Next, participants attended the initial HaRT-S group session. Afterwards, participants were scheduled for individual sessions (i.e., 2, weekly sessions plus a 1-month booster) and assessments at the 1-, 2-, 6-, and 14-week follow-ups. Participants were paid $10 for each assessment. Procedures were approved by the Institutional Review Board at the University of Washington and followed principles outlined in the Declaration of Helsinki. Participant procedures were completed in December 2017.

Data analysis plan

Analyses were conducted in Stata 13 and comprised generalized linear models[47,48] testing the effects of a) centered linear time representing weeks 0, 1, 2, 6 and 14 of the study; b) past-week NRT use (0 = no use, 1 = use); and c) past-week ENDS use (0 = no use, 1 = use). Additionally, we tested time x NRT and time x ENDS interaction effects. Because Wald tests of composite linear hypotheses showed these interactions did not significantly contribute to the models ($ps > .29$), we do not report further on them.

Table 1. Harm reduction treatment for smoking (HaRT-S).

Modality	Specific treatment components
	Style
Mindset	• Neither requiring nor directly advising abstinence from nicotine, tobacco or smoking • Supporting the realization of participant-driven goals • Recognizing any participant-led movement toward reducing harm and improving QoL as positive steps on a participant-defined pathway to recovery • Leveraging scientific knowledge (i.e., information about safer use) to empower participants to make their own informed decisions • Engaging with pragmatism (i.e., being creative and flexible to maximize interventionists' alignment with participants' harm-reduction goals)
Heart-set	• Being with the participant in a compassionate way (i.e., "feeling with" the participant coupled with an unconflicted desire to support participant-defined and -led treatment goals) • Supporting participants in setting, striving toward, and achieving exclusively participant-led goals • Providing the opportunity for transformative change through intrinsic rather than extrinsic motivation • Balancing support with complete transparency regarding interventionist's role and agenda • Engaging in advocacy for participants and encouraging self-advocacy.
	Behavioral
Group sessions	• Eliciting a group conversation about perceptions of smoking during which interventionists affirm (e.g., "You are well-informed about the fact that smoking can lead to breathing problems like asthma.") and correct (e.g., "While smoking does cause cancer, nicotine itself is not the cause of it.") information participants share about health aspects of smoking • Elucidating the mechanisms of action by which smoking causes health-related problems (e.g., "Your lungs put oxygen into your blood for all of your body parts and organs. So when you inhale cigarette smoke, your lungs also put those cancer-causing particles you have inhaled in the blood, and they are then spread throughout your whole body.") • Introducing the concepts of harm-reduction goal setting, assessment of relative risks, safer nicotine use • Introducing safer nicotine delivery systems as a means of meeting harm-reduction goals and reducing health risks involved in nicotine use • Demonstrating and distributing safer nicotine delivery systems (NRT and ENDS) to participants

Individual sessions	• Participant-led tracking of preferred treatment outcomes
	  • Providing tailored feedback on self-reported and biological measures of nicotine use, use of safer nicotine delivery systems, smoking-related harm, and HR-QoL
	  • Affirming participants' reductions in smoking and smoking-related harm, use of safer nicotine delivery systems, and improvements in HR-QoL, while focusing on outcomes preferred by participants and/or that improved since prior assessment
	  • Cocreating a visual representation (i.e., line graph) of longitudinal tracking of preferred participant outcomes
	• Harm-reduction goal-setting
	  • Eliciting and recording participants' narratives about their smoking-related, harm-reduction goals and progress made toward them using open-ended questions and strengths-based affirmations
	  • Engaging in troubleshooting to help participants remove barriers to goal achievement
	• Safer nicotine use
	  • Continuing ongoing discussion of relative risks and benefits of cigarette smoking versus safer nicotine delivery systems
	  • Using the study brochure and handouts to facilitate this discussion
	  • Eliciting and recording progress toward safer nicotine use using open-ended questions and strengths-based affirmations
	  • Troubleshooting to better ensure participants' ability to use products effectively

	Pharmacological[a]
Nicotine replacement therapy (NRT)	• Nicotine gum (cinnamon flavor; 4mg) • Nicotine patches (14mg and 21 mg) • Nicotine lozenges (4mg)
Electronic nicotine delivery systems (ENDS)	• Replacement items: EVOD battery, USB cable, VOCC-T atomizer, TOPTANK EVOD tank, AC adapters • VapPuro e-liquid base (12mg/cc or 18mg/cc) • Tobacco, menthol, clove e-liquid flavor

Access to these products were provided via interventionists and front-desk staff up to 1 month after the 14-week follow-up. However, participants were encouraged to purchase their own.

[a]All types of nicotine delivery systems were discussed in terms of their relative risks; however, in the context of HaRT-S, interventionists provided access to the specific types of NRT and ENDS noted above.

Smoking-related outcomes were selected to represent the hypothesized harm reduction HaRT-S is meant to achieve. Because smoking abstinence would result in the greatest reduction in harm, we examined biochemically verified continuous and point-prevalence abstinence. Smoking was assumed if participants were not present at a follow-up or if the participants' CO was above the thresholds noted in the measures section. Additionally, we examined more incremental variables that have been shown to correlate with later abstinence attainment and toxicant exposure:[49] self-reported smoking frequency and intensity. FTND was included to address the concern that harm-reduction approaches could foster dual use of nicotine products leading to increased dependence and subsequent smoking.[50] HR-QoL was assessed using both biological (FEV1%) and client-centered, self-report measures (EQ-VAS). We used 10-point rulers to assess participants' ratings of HaRT-S acceptability and effectiveness as well as their assessment of importance of safer nicotine use and likelihood of attendance at HaRT-S sessions.

When outcomes were normally distributed (FTND, FEV1%, EQ-VAS), dichotomous (i.e., abstinence), ordinal or nonnormally distributed (i.e., smoking frequency, rulers), or overdispersed counts (i.e., smoking intensity), we used Gaussian, logistic, ordered logistic, and negative binomial regression models, respectively.[48] We addressed data nonindependence using the modified sandwich estimate of variance, which is robust to clustering resulting from repeated measures.[48] Where possible, we used diagnostics in modeling, including assessing link functions, overdispersion, and standardized residual plots.[48] To enhance interpretability of the treatment effect sizes, exponentiated coefficients are presented for logistic, ordered logistic, and negative binomial models, where $IRR/OR < 1$ indicates an inverse association, $IRR/OR = 1$ indicates no association, and $IRR/OR > 1$ indicates a positive association. Alpha was set to $p = .05$. Confidence intervals were set to 95%.

Results

The sample description is in Table 2, and the participant flowchart is in Figure 1.

Perceptions of safer nicotine use and HaRT-S acceptability and effectiveness

As shown in Table 3, participants reported using nicotine more safely than smoking was "very important" to them, and an ordered logistic regression showed importance of safer nicotine use remained constant over the study ($OR = 1.00$, $SE = .03$, $p = .94$). According to median ratings, HaRT-S was deemed "totally acceptable," and participants reported attendance at HaRT-S appointments as "very likely" (see Table 3). These assessments of HaRT-S did not significantly change over the 14-week follow-up ($ps > .63$). Participants' assessment of HaRT-S effectiveness, however, did significantly change. For each 1 week that passed during the 14-week study, participants' assessment of HaRT-S effectiveness increased by 5% ($OR = 1.05$, $SE = .02$, $p = .04$).

Table 2. Baseline descriptive statistics for the study sample ($N = 44$).

Variable	*M* (*SD*)/%
Sex assigned at birth	
Male	64%
Female	34%
Intersex	2%
Age	48.24 (11.46)
Ethnicity	11% Hispanic/Latinx
Race	
American Indian/Alaska Native	7%
Asian	0%
Black/African American	7%
Native Hawaiian/Pacific Islander	0%
White/European American	75%
More than one race	7%
Other	5%

Percentages may not total 100% due to rounding.

Exposure to HaRT-S and safer nicotine delivery systems

HaRT-S session attendance reached 100%, 70%, 70% and 68% for weeks 0, 1, 2, and 6. On average, participants attended 3.89 ($SD = 1.35$) or 78% of 4 treatment sessions. All participants received safer nicotine delivery systems at week 0 (see Table 1). Participants showed a 24% and 27% weekly uptick in NRT and ENDS use, respectively (see Figure 2). At the 14-week follow-up assessment, participants who used ENDS said they were "very likely" to continue ($Median = 5$). Participants who used oral and transdermal NRT reported being "somewhat likely" ($Medians = 4.5$ and 4, respectively) to continue.

Biochemical verification

There was 72% (18/25) agreement between self-reported abstinence the day of the assessments and corresponding CO measurements.

Smoking-related outcomes

Smoking abstinence

The omnibus model testing the time and safer nicotine delivery system effects on biochemically validated, 7-day, point-prevalence abstinence was significant, Wald $\chi^2(2, N = 92) = 11.85$, $p = .003$. As shown in Table 4, the time coefficient was a significant predictor, such that each passing week in the study was associated with an 18% increase in odds of abstinence. NRT use was not a significant predictor ($p = .25$). ENDS use was dropped from the model as it perfectly predicted abstinence (see Table 4). Because only one participant achieved continuous abstinence, we did not conduct inferential analyses involving that outcome.

Smoking frequency

The omnibus model was significant, Wald $\chi^2(3, N = 170) = 32.14$, $p < .001$. Time but not safer nicotine use predicted smoking frequency. Specifically, as a group, participants were 12% less likely to report an additional smoking day for each week after study enrollment (see Tables 3 and 4).

Smoking intensity

The omnibus model was significant, Wald $\chi^2(3, N = 170) = 12.48$, $p = .006$. Neither time nor NRT use were significant predictors; however, participants who used ENDS reported smoking 44% fewer cigarettes than those who did not use ENDS (see Table 4 for parameter statistics).

FTND summary score

The omnibus model was significant, Wald $\chi^2(3, N = 170) = 10.46$, $p < .001$. For each week in the study,

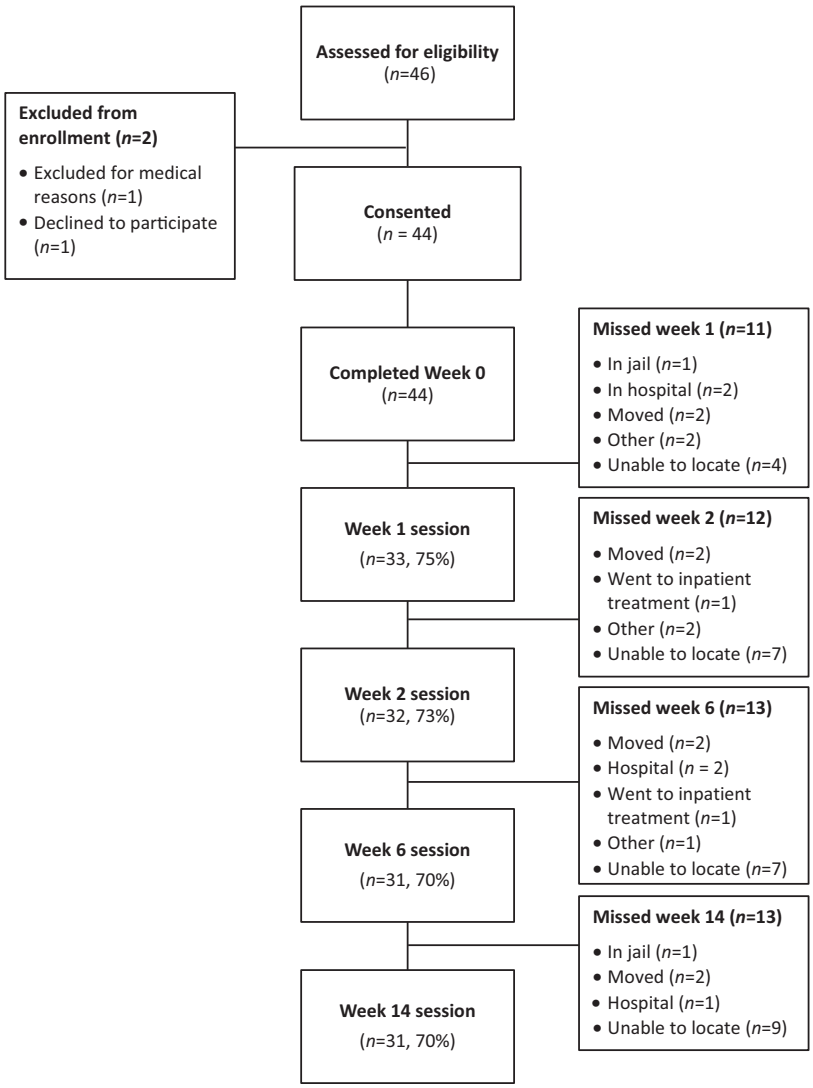

Figure 1. Participant flowchart.

Table 3. Descriptive statistics for longitudinal outcomes.

Variables	Week 0 (n = 44)	Week 1 (n = 33)	Week 2 (n = 32)	Week 6 (n = 31)	Week 14 (n = 31)
Participants' Perceptions of HaRT-S					
Acceptability	8.53 (2.09)	8.97 (1.33)	8.5 (2.08)	8.87 (1.93)	8.84 (1.73)
	10	9.5	9.5	10	10
Effectiveness	7.72 (2.43)	7.88 (1.84)	7.75 (2.08)	8.29 (2.05)	8.45 (2.05)
	8	8	8	9	9
Likelihood of attending HaRT-S	9.14 (1.68)	9.18 (1.33)	9.5 (1.11)	9.42 (1.15)	9 (1.97)
	10	10	10	10	10
Importance of safer nicotine use	8.84 (1.60)	8.33 (2.15)	8.75 (2.02)	9.23 (1.18)	8.48 (2.35)
	10	9	10	10	10
Smoking-related Outcomes					
PP-abstinence	0%	2.3%	4.6%	6.8%	9.09%
Smoking intensity	12.81 (10.41)	9.88 (8.90)	8.09 (8.05)	9.19 (9.48)	8.90 (11.78)
	9	6	5.5	5	2
Smoking frequency (days)	6.58 (1.22)	6.03 (1.99)	5.56 (2.46)	5.61 (2.51)	4.06 (2.99)
	7	7	7	7	5
FTND score	5.32 (2.69)	4.39 (2.44)	4.28 (2.19)	3.81 (2.43)	3.29 (2.87)
	5.5	4	4	4	3
HR-QoL Outcomes					
FEV1%	65.45 (25.35)	71.09 (26.12)	69.28 (25.72)	70.61 (25.33)	68.11 (24.91)
	67.5	77	71.5	71	71
EQ-VAS	57.5 (23.02)	57.18 (20.98)	62.28 (21.73)	68.61 (18.28)	61.77 (21.47)
	54.5	60	70	70	65

PP: point-prevalence; FTND: Fagerström Test of Nicotine Dependence; HR-QoL: health-related quality of life; FEV1%: forced expiratory volume in the first second of expiration as a percentage of the predicted value; EQ-VAS: EuroQoL-Visual Analog Scale.

Means and standard deviations are presented in the top row of each cell, and medians are presented in the bottom row due to the nonnormality of many outcomes. All items in the section called "Participants' Perceptions of HaRT-S" were scored on a 10-point Likert-type scale, where 1 = not at all acceptable/effective/likely/important and 10 = totally acceptable/effective/likely/important.

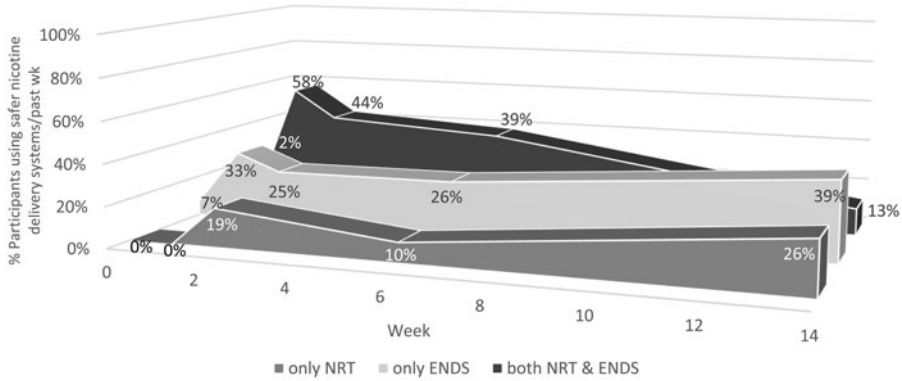

Figure 2. This graph depicts the percentage of participants who reported using safer nicotine delivery systems—nicotine replacement therapy (NRT) and electronic nicotine delivery systems (ENDS)—in the week prior to that assessment point. Logistic models testing the effects of time on self-reported use of safer nicotine delivery systems were significant for both NRT, Wald $\chi^2(2, N = 170) = 19.61$, $p < .001$, and ENDS, Wald $\chi^2(2, N = 170) = 13.50$, $p = .001$. After accounting for the quadratic time effect, the linear time parameters showed a significant uptick in any use of NRT ($OR = 1.24$, $SE = .06$, $p < .001$) and ENDS ($OR = 1.27$, $SE = .09$, $p = .001$) for each passing week in the 14-week study. *Ns* for each timepoint were as follows: time 0 ($n = 43$), time 1 ($n = 33$), time 2 ($n = 32$), time 3 ($n = 31$), time 4 ($n = 31$).

Table 4. Model parameters for primary analyses.

Predictors	Coefficients (*IRR*/*OR*/*B*)	Robust *SE*	*CI*(95%)	*Z*	*p*
Point-prevalence abstinence					
Time	1.18	.07	(1.05, 1.33)	2.73	.006
NRT	2.31	1.68	(.56, 9.63)	1.15	.25
ENDS	Omitted from model due to perfect prediction of ENDS use and abstinence				
Constant	.06	.02	(.03, .14)	−6.95	<.001
Smoking frequency[a]					
Time	.88	.02	(.84, .93)	−5.09	<.001
NRT	.70	.33	(.28, 1.78)	−.74	.46
ENDS	.67	.24	(.33, 1.36)	−1.10	.27
Smoking intensity					
Time	.98	.01	(.95, 1.00)	−1.69	.09
NRT	1.33	.34	(.80, 2.19)	1.10	.27
ENDS	.56	.11	(.38, .82)	−2.97	.003
Constant	11.71	1.59	(8.98, 15.29)	18.12	<.001
FTND					
Time	−.12	.03	(−.18, −.06)	−4.16	<.001
NRT	.95	.50	(−.07, 1.96)	1.89	.07
ENDS	−1.20	.39	(−1.98, −.41)	−3.07	.004
Constant	4.59	.39	(3.81, 5.37)	11.89	<.001
FEV1%					
Time	.002	.01	(−.02, .03)	.15	.88
NRT	.28	.20	(−.14, .69)	1.35	.18
ENDS	.08	.16	(−.24, .40)	.50	.62
Constant	2.14	.16	(1.82, 2.46)	13.54	<.001
EQ-VAS					
Time	.31	.24	(−.17, .79)	1.32	.20
NRT	5.24	3.68	(−2.18, 12.67)	1.42	.16
ENDS	−1.32	3.89	(−9.15, 6.52)	−.34	.74
Constant	59.95	3.38	(53.13, 66.77)	17.72	<.001

NRT: nicotine replacement therapy; ENDS: electronic nicotine delivery systems; FTND: Fagerström Test of Nicotine Dependence; Smoking frequency: number of smoking days in the past week; Smoking intensity: mean number of cigarettes smoked per day in the past week; FEV1%: forced expiratory volume in the first second of expiration as a percentage of the predicted value; EQ-VAS: EuroQoL-Visual Analog Scale.

Each analysis included all 44 participants, except for the model that involved point-prevalence abstinence as an outcome, which dropped 6 participants' data (i.e., those who achieved abstinence during the study) due to perfect correlation between ENDS use in the prior week and abstinence achievement.

[a]No constant in this model.

participants' FTND score decreased by .12 points (see Tables 3 and 4). Further, people who used ENDS had an FTND score that was 1.2 points lower overall than people who did not use ENDS. NRT use was not a significant predictor ($p = .07$).

HR-QoL

The models for FEV1% and EQ-VAS were not significant ($ps > .06$).

Discussion

Primary outcomes

HaRT-S is feasible and acceptable for smokers experiencing chronic homelessness

Safer nicotine use was rated by participants as "very important," and this finding was consistent over the 14-week follow-up. HaRT-S consistently achieved the highest rating of "totally acceptable," and these ratings were

bolstered by high study enrollment and completion rates. Of the 46 people who attended the information session, only one declined to participate, and despite the short 4-month recruitment duration, we recruited 26% more participants than originally planned due to high interest and demand. Once recruited, participants attended a mean of 78% of HaRT-S sessions and a median of 4 out of 4 sessions. Although it is challenging to directly compare recruitment and retention across studies that have used different methods and treatments, this pilot shows favorable initial engagement and retention compared to prior studies of smoking cessation treatments in the larger homeless population.[25–28]

Participants showed a commitment to trying and using safer nicotine delivery systems

Over the course of the study, 70% and 90% of participants tried NRT and ENDS, respectively. Analyses showed a rapid peak in weeks 1 and 2 subsiding into a gradual decline for overall use. Further parsing these curves, however, showed decreased dual use corresponding with increased exclusive use of NRT or ENDS. This finding likely reflects participants' initial experimentation with various nicotine delivery systems, followed by adoption of one, with ENDS use dominating.

These rates compare favorably to those in prior smoking cessation treatment studies conducted in the larger homeless population.[25–27] Of note, no other studies to date have tested a smoking treatment involving ENDS in smokers with lived experience of homelessness or chronic homelessness.

In future studies, systematic data should be collected on participants' longer-term ENDS use as well as reasons for discontinued use. However, this study does establish this population's interest in trying ENDS and their ongoing, if slightly decreasing, use of safer nicotine delivery systems over the short term. This finding corresponds to qualitative studies in the literature that have indicated people experiencing homelessness view ENDS positively, are interested in trying ENDS, and believe ENDS can help them with their smoking.[17, 51,52]

Harm-reduction counseling paired with ENDS is a promising means of reducing smoking and smoking-related harm

While participants' ratings of their engagement in, importance of, and acceptability of HaRT-S remained constant over the 14-week study, their ratings of its effectiveness significantly increased. Increases in perceived effectiveness of HaRT-S might have been engendered through their own experience of smoking behavior change. In fact, participants experienced consistent and statistically significant decreases in smoking and dependence on cigarettes. For each week that passed in the study, participants were 18% more likely to report 7-day point-prevalence abstinence, were 12% less likely to add a smoking day to their week, and showed a .12-point decrease in their cigarette dependence.

These findings provide initial information regarding the effects of an explicitly harm-reduction treatment for smoking. Despite the fact that providers did not ask participants to change their smoking in a predetermined way, participants showed statistically significant and clinically meaningful improvements on smoking-related outcomes. These promising findings align with findings from other harm-reduction treatment studies conducted in the homeless population.[53,54]

The lack of significant improvements in HR-QoL has various potential explanations

First, the relative brevity of the 4-session HaRT-S and the 14-week follow-up period may not have allowed adequate time for significant improvements to emerge. One population-based study showed that the largest improvements in HR-QoL occurred 2 to 5 years following smoking cessation.[55] Although shorter-term improvements in HR-QoL in the context of smoking treatment studies have been documented, such quick changes are likely mediated by full smoking cessation.[56,57] Most important, achievement of sustainable and clinically meaningful changes on HR-QoL in this population likely also requires meeting other basic needs, including food security, permanent housing, and adequate medical and mental health services.

Limitations

This study did not include a randomized design or control group and thus precludes causal interpretations of study findings. Other factors besides HaRT-S could have accounted for the observed improvements on smoking outcomes. Further, these improvements could reflect statistical artifacts, including the ceiling effect (i.e., participants may not be physically or financially able to increase smoking beyond current levels) or regression to the mean.[58] A randomized controlled trial is the obvious next-step in providing a rigorous test of HaRT-S efficacy in reducing smoking-related harm among smokers experiencing chronic homelessness.

There are some measurement limitations. First, most measures used in this study have not been psychometrically tested for use in homeless and chronically homeless populations. Second, self-report data are subject to reporting bias.[59] That said, we did make efforts to mitigate bias by making timeframes for recall relatively short, not stigmatizing the target behaviors, not tying negative consequences to disclosure, not using excessive compensation, and using biochemical verification.[40, 60–63] Finally, the small-scale nature of this pilot precluded the use of a larger assessment battery collecting data on additional and more nuanced potential covariates, moderators and mediators (e.g., experience of psychiatric, medical and other substance-use disorders; continuous TLFB data for use of all nicotine products; readiness to change smoking; and housing histories). For this initial study, we sought to establish basic feasibility, desirability and initial outcomes following administration of HaRT-S. Future, large-scale randomized controlled trials should include additional variables to a) establish psychometrics for

use of these measures in this population and b) provide a more accurate and nuanced understanding of the population, treatment effects, and potential mechanisms of action.

Conclusions and future directions

This study is the first to examine initial feasibility, acceptability and smoking-related outcomes for explicitly harm-reduction counseling for smoking with support of safer nicotine delivery systems, including ENDS. Taken in context with other smoking cessation treatment studies in homeless populations,[25–28] HaRT-S findings indicated favorable initial feasibility and acceptability in a chronically homeless population. Additionally, participants evinced expected, significant, linear increases in likelihood of point-prevalence abstinence as well as decreases in smoking frequency and dependence on cigarettes over the 14-week follow-up. Participants who reported using ENDS were even more likely to report decreases in smoking intensity and cigarette dependence. A larger-scale RCT that involves an expanded assessment battery assessing potential covariates, moderators and mediators is a necessary next-step to provide a rigorous test of harm-reduction counseling with support of ENDS in facilitating smoking-related harm reduction.

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Disclosure statement

All other authors declare that they have no conflicts of interest pertaining to this manuscript.

Author contributions

Dr. Collins codeveloped the original study idea with Mr. Malone. She led the study design, implementation and evaluation efforts; conducted the primary statistical analyses; and serves as lead author. She has had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the analyses. Dr. Nelson contributed to study design, HaRT-S development, and study implementation. He codeveloped the training and then trained and supervised interventionists. Mr Stanton, Mr. Mayberry and Ms. Ubay contributed to the study design, HaRT-S development, implementation, and data interpretation. In addition, Ms. Ubay created tables for the current manuscript. Ms. Taylor, Hoffmann, and Goldstein contributed to data management and preliminary analyses for the manuscript. Mr. Malone codeveloped the original study idea and oversaw study implementation onsite at DESC. Dr. Clifasefi contributed to the original study conceptualization. Drs. Okuyemi and Saxon contributed to intervention design and made suggestions and edits for the paper. The HaRT-S Community Advisory Board members codeveloped the treatment, oversaw the implementation of the study, conducted analyses to support the study, interpreted study data, and contributed to and edited interim drafts. All authors critically reviewed, provided edits for and approved the final article. There is no one else who fulfills these criteria but has not been included as an author.

Note on Authorship

The HaRT-S Community Advisory Board members include (in alphabetical order): Andrew Coak, Susan E. Collins, Elizabeth Duffie, Maria Metzler, Joey Stanton, Tatiana Ubay, and Grover "Will" Williams. We also acknowledge the early contributions of an initiating member, Danielle Burt.

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