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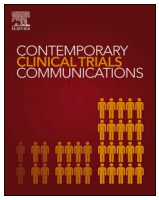

# Tobacco use behaviors and views on engaging in clinical trials for tobacco cessation among individuals who experience homelessness

Joshua Miller [a], Jordan Cuby [b], Sharon M. Hall [c], Maxine Stitzer [d], Margot Kushel [e], Donna Appiah [f], Maya Vijayaraghavan [a,b,e,*]

[a] Center for Tobacco Control Research and Education, University of California, San Francisco, USA
[b] Division of General Internal Medicine, University of California, San Francisco, USA
[c] Department of Psychiatry, And Weill Institute for Neurosciences, University of California, San Francisco, USA
[d] Friends Research Institute, USA
[e] Center for Vulnerable Populations, University of California, San Francisco, USA
[f] School of Medicine, University of California, San Francisco, USA

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ABSTRACT

*Background:* Clinical trials that include contingency management for smoking cessation have shown promising results for short-term quitting, but none have explored this approach for long-term abstinence in people experiencing homelessness. We designed a clinical trial of an extended contingency management intervention for smoking cessation for people experiencing homelessness. This study has two aims: (1) to explore tobacco use behaviors, and views toward smoking cessation, and (2) to explore factors influencing acceptability of engaging in such a trial in a sample of adult smokers experiencing homelessness.

*Methods:* We administered a questionnaire to obtain information on tobacco use behaviors and conducted in-depth, semi-structured interviews with 26 patients who had experienced homelessness and were patients at a safety net health clinic in San Francisco, California, where we planned to pilot the intervention. We obtained information on triggers for tobacco use, prior cessation experiences, attitudes toward cessation, attitudes toward engaging in a clinical trial for cessation, and factors that might influence participation in our proposed contingency management clinical trial. We analyzed transcripts using content analysis.

*Results:* Participants described the normative experiences of smoking, co-occurring substance use, and the use of tobacco to relieve stress as barriers to quitting. Despite these barriers, most participants had attempted to quit smoking and most were interested in engaging in a clinical trial as a method to quit smoking. Participants noted that desirable features of the trial include: receiving financial incentives to quit smoking, having a flexible visit schedule, having the study site be easily accessible, and having navigators with lived experiences of homelessness.

*Conclusion:* A patient-centric clinical trial design that includes incentives, flexible visits and navigators from the community may increase feasibility of engaging in clinical trials among individuals experiencing homelessness.

## 1. Introduction

Over 70% of people experiencing homelessness report current use of tobacco [1,37,38], compared to 14% in the general population [2]. Tobacco-attributable cancer and heart disease are the leading causes of morbidity and mortality among individuals experiencing homelessness who are aged 50 years and older [1,3]. People experiencing homelessness who smoke make quit attempts as frequently as the general population [1], but they face a unique set of barriers that hinder long-term abstinence [4].

Inadequate access to health care, smoking cessation services or smoke-free living environments are one set of structural barriers that hinder cessation attempts and increase relapse to smoking after a quit attempt among adults experiencing homelessness [4]. The high prevalence of co-occurring mental health and substance use disorders among people experiencing homelessness are associated with high nicotine dependence and low abstinence rates [5]. The COVID-19 pandemic has worsened existing challenges to obtaining healthcare access among

* Corresponding author. Division of General Internal Medicine/San Francisco General Hospital, 1001 Potrero Avenue Box 1394, San Francisco, CA, 94110, USA.
*E-mail address:* Maya.Vijayaraghavan@ucsf.edu (M. Vijayaraghavan).

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adults experiencing homelessness [6]. Smoking cessation may be less of a priority, particularly when people use tobacco to cope with the stressors of homelessness and unmet subsistence needs [7]. There is an urgent need for interventions that increase efficacy of quit attempts to initiate and sustain long-term abstinence among individuals experiencing homelessness.

Smoking cessation interventions that include behavioral counseling and pharmacotherapy are feasible and acceptable for people experiencing homelessness and in clinical trials have been efficacious in achieving short-term abstinence [4]. However, the ten randomized controlled trials (RCTs) of smoking cessation interventions for adults experiencing homelessness have demonstrated abstinence rates between 9% and 17% at 6 months follow-up [8–16], rates that are substantially lower than the observed 30%–40% abstinence rates in the general population [17].

Contingency management, a behavior change strategy that reinforces positive health behaviors with incentives (e.g., cash), can effectively reduce tobacco and substance use behaviors in the general population [18–21]. Smokers who abstain periodically receive modest incentives that reinforce healthy behavior as it is sustained over time [19]. Short-term RCTs of tobacco cessation interventions with contingency management among populations experiencing homelessness have found higher abstinence rates in the intervention than control groups. At 4–8 weeks follow-up, rates of 22%–48% have been reported in intervention conditions compared to 8%–9% in controls [8,15]. While these studies hold promise, they are limited by small sample sizes and short duration of intervention (8 weeks), which may not be sufficient for individuals with high levels of nicotine dependence [22,23]. Studies are needed to evaluate the feasibility, acceptability, and efficacy of extended duration (i.e., 6 months or more) contingency management smoking cessation interventions among adults experiencing homelessness.

The majority of individuals experiencing homelessness in the U.S. seek health care in safety net health settings (Care., 2011b.). These safety net health clinics could provide optimal settings to scale up cessation interventions that are integrated with healthcare delivery. Features of these clinical trials that may increase engagement and optimize success with quitting among smokers experiencing homelessness include staff with lived experiences of homelessness, flexibility in patient contact schedules, and ability to provide nicotine replacement therapy in frequent allotments [24].

We developed a pilot protocol of a RCT of an extended duration contingency management tobacco cessation intervention for people experiencing homelessness who are engaged in primary care in a safety net clinic in San Francisco. In preparation for the RCT, we interviewed patients at the safety net clinic where we planned to conduct the trial who reported smoking and current or prior experiences of homelessness to obtain information on their tobacco use, prior experiences with tobacco cessation, their willingness to engage in a clinical trial for cessation, and their perspectives on the feasibility of the proposed contingency management intervention protocol. The primary research aims were to: (1) explore tobacco use behaviors, and views toward smoking cessation, and (2) explore factors influencing acceptability of engaging in such a trial in a sample of adult smokers experiencing homelessness. Such data could lead to better designed, more acceptable contingency management and extended interventions, and enhance recruitment and retention of people experiencing homelessness who smoke.

## 2. Methods

### 2.1. Study design

Between April 2021 and July 2021, we recruited participants from a safety net clinic in San Francisco, CA that serves a predominantly homeless population. The University of California, San Francisco institutional review board and the San Francisco Department of Public Health approved all study protocols (IRB # 20–31627).

### 2.2. Setting and participants

Eligible participants included patients who: 1) were 18 years or older, 2) were engaged in primary care and had a primary care provider at the safety net clinic in San Francisco, CA, 3) reported current smoking, and 4) reported current or past experiences of homelessness. Potential participants were identified using smoking and housing status information from the Epic electronic health record, a commonly used electronic health record in the U.S. that documents patient visits and health care delivered [39]. We asked primary care providers for permission to contact their patients to verify eligibility and to enroll interested patients into the study. The Epic data report (i.e., a list of patients who met our eligibility criteria) included 1534 potentially eligible patients, of whom we received permission to contact 733 patients. Providers informed study staff of patients who had cognitive impairment or who did not meet eligibility criteria because they were no longer smoking. Of the 733 patients, we called the first 163 patients on the list and were able to recruit N = 26 participants into the study. The most common reasons for excluding a participant was lack of a functioning telephone. Since our goal was to recruit a convenience sample of patients at the clinic who met eligibility criteria, we did not try to achieve representation of all providers' patients. We stopped recruiting participants once we reached thematic saturation in-depth interviews. We reimbursed participants $25 for the study.

### 2.3. Quantitative measures

#### 2.3.1. Tobacco and substance use

Participants reported whether they smoked every day or somedays as well as the number of days they smoked in the past 7 days and the number of cigarettes smoked on smoking days. With these data, we calculated average daily cigarette consumption. We asked participants to report the time it took to smoke their first cigarette upon waking (within 5 min, 6–30 min, 31–60 min, or after 60 min) and their intention to quit smoking ("never expect to quit", "may quit", "will quit in the next 6 months", or "will quit in the next month"). Participants reported whether they attempted to quit in the past year, and those who had, described the cessation methods they had used during their last quit attempt. We asked participants to report past 30 days use of e-cigarettes, cigars or little cigars, roll-your-own tobacco, and blunts and past 30 days use of alcohol, cannabis, cocaine or crack, amphetamines, and opioids.

#### 2.3.2. Demographics and other covariates

Participants reported their age, gender (female, male, or transgender), race/ethnicity (American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, Black/African American, Hispanic/Latinx, White, other/more than one race), and education (less than high school, high school or GED, some college, or college or professional training). We asked participants how the pandemic impacted them (moved from unsheltered environments like the street or vehicles to non-congregate [i.e., single rooms] or congregate shelters [i.e., dormitory style rooms]) and their tobacco use (i.e., change in tobacco use and motivation to quit) [25].

### 2.4. Qualitative measures

We used an open-ended interview guide to explore experiences with homelessness during the COVID-19 pandemic, triggers for tobacco use, attitudes towards tobacco cessation, previous quit attempts and use of cessation aids, and perspectives on engaging in clinical trials for tobacco cessation. Study staff described the proposed contingency management intervention protocol, including the purpose of the clinical trial, the frequency of study visits, the starting incentive amount ($13.00), the

escalating incentive of $0.50 with each negative expired carbon monoxide sample, and the potential final amount at 6 months follow-up ($475). The staff described the potential for including patient navigators to support recruitment and retention, the requirement that participants engage in smoking cessation care at their clinic, and for study staff to engage with participants' clinical team to facilitate cessation. We asked participants to provide their opinions on all aspects of the protocol, and to describe modifications, if any, to improve the feasibility and acceptability of the protocol. Interviews lasted between 30 min and 60 min and were conducted by study staff either in person or by telephone.

### 2.5. Data analysis plan

#### 2.5.1. Quantitative data analysis

We described sample characteristics and tobacco use using proportions for categorical variables and median (interquartile range [IQR]) for continuous variables.

#### 2.5.2. Qualitative data analysis

The audio recorded in-depth, semi-structured interviews were transcribed verbatim by a contracted professional transcription service, and transcribed texts were redacted of any personal identification data. We used Atlas. ti.8 qualitative data analysis software to facilitate efficient coding, and analyzed transcripts using content analysis [26]. J.M, J.C., and D.A. coded the transcripts, and the PI (M.V.) reconciled codes. During the initial phase, we used deductive coding using a pre-defined set of codes developed through our prior work and that were relevant to the current analysis [27–29]. We used inductive coding to assign new codes to emergent themes from the transcripts. After independently coding the first four transcripts, the research team met to develop the first iteration of the consolidated codebook. We used this codebook to code subsequent transcripts and met regularly during the coding process to refine the codebook by resolving disagreements in assignment or description of codes. The Cohen Kappa score for interrater reliability was used to assess agreement between the two coders for each transcript (kappa = 0.72). We further refined and reduced the number of overall codes by grouping them into broad categories, after which we identified themes and subthemes in an iterative process. Exemplar quotations were selected to reflect each theme.

## 3. Results

### 3.1. Sample characteristics and tobacco use behaviors

Of the 26 participants, 12 (46.2%) were female, 9 (34.6%) were Black/African American, and 6 (23.1%) were Hispanic/Latino (Table 1). The median age was 48.5 years. Of the 26 participants, 1 was unsheltered, 7 stayed in a shelter-in-place hotel, 15 stayed in short-term single room occupancy hotels, 2 were doubled-up with family and friends, and 1 stayed in their vehicle. The majority of participants reported cannabis use in the past 30 days, and over half reported amphetamine use in the past 30 days. Of the 26 participants, 8 (30.8%) had moved from unsheltered environments to non-congregate or congregate shelters during the first year of the pandemic.

Almost all participants reported daily smoking (88.5%), with over half reporting smoking within 30 min of waking (Table 2). Over half reported using an e-cigarette in the past 30 days. A third of the participants reported making a quit attempt in the past 30 days, and among those, quitting "cold turkey" was the most common method of quitting. Participants did not change their smoking behaviors during the COVID-19 pandemic.

### 3.2. Qualitative results

We identified five themes: 1) experiences related to homelessness and tobacco use, 2) attitudes toward tobacco cessation, 3) attitudes toward engaging in a clinical trial for cessation, 4) barriers to engaging in a clinical trial for cessation, and 5) factors that would increase feasibility of participating in a clinical trial (Table 3).

**Table 1**
Sample characteristics (N = 26).

| Sample characteristics | |
|---|---|
| Age (Median, interquartile range [IQR]) | 48.5 (20.0) |
| Gender (N, %) | |
| Male | 10 (38.5) |
| Female | 12 (46.2) |
| Transgender | 4 (15.4) |
| Race/Ethnicity (N, %) | |
| Black/African American | 9 (34.6) |
| Hispanic/Latinx | 6 (23.1) |
| Native Hawaiian/Pacific Islander | 1 (3.9) |
| White | 8 (30.8) |
| Other/More than one race | 2 (7.7) |
| Substance use in the past 30 days (N, %) | |
| Alcohol | 11 (44.0) |
| Cannabis | 19 (79.2) |
| Cocaine or crack | 5 (25.0) |
| Amphetamines | 10 (58.8) |
| Opioids | 6 (35.3) |
| COVID-19 related personal experiences | |
| Unsheltered to congregate or non-congregate shelters during in the past year (N, %) | 8 (30.8) |

**Table 2**
Tobacco use and COVID-19 risk perceptions related to tobacco use (N = 26).

| Sample characteristics | |
|---|---|
| Tobacco and nicotine product use | |
| Cigarettes smoked per day (Median, IQR) | 7 (5) |
| Daily use (N, %) | 23 (88.5) |
| Non-daily use (N, %) | 3 (11.5) |
| Time to first cigarette after waking (N, %) | |
| Within first 5 min | 7 (26.9) |
| 6–30 min | 9 (34.6) |
| 31–60 min | 2 (7.7) |
| After 60 min | 8 (30.8) |
| Use of other tobacco products in the past 30 day (N, %) | |
| E-cigarettes | 10 (58.8) |
| Cigars or little cigars | 5 (23.8) |
| Roll-your-own tobacco | 10 (52.6) |
| Blunts | 9 (45.0) |
| Intention to quit smoking (N, %) | |
| Never expect to quit | 3 (11.5) |
| May quit | 13 (50.0) |
| Will quit in the next 6 months | 6 (23.0) |
| Will quit in the next month | 4 (15.4) |
| Past year quit attempt (N, %) | 10 (38.5) |
| Products/methods used in previous attempts to quit (N, %) | |
| Cold turkey | 9 (34.6) |
| Advice from healthcare professional | 1 (4.2) |
| Smoking cessation class | 1 (3.5) |
| Zyban/Wellbutrin for smoking cessation | 1 (4.2) |
| E-cigarette | 1 (4.2) |
| COVID-19 and tobacco use (N, %) | |
| Increased cigarette use | 6 (23.1) |
| Decreased cigarette use | 4 (15.4) |
| Cigarette use stayed the same | 16 (61.5) |
| COVID-19 and motivation to quit (N, %) | |
| Motivation to quit has increased | 10 (38.5) |
| Motivation to quit has decreased | 1 (3.9) |
| Motivation to quit remained unchanged | 15 (57.7) |

#### 3.2.1. Experiences related to homelessness and tobacco use

*3.2.1.1. Tobacco use and homelessness.* Participants described how tobacco use factored into their lives before and during periods of

**Table 3**
Quotes reflective of themes.

| Themes | Subthemes | Illustrative Quote |
|---|---|---|
| Experiences related to homelessness and tobacco use | Tobacco use and homelessness | "Yeah, I mean, the housing, the housing is the biggest thing, I'm not going to sit here and run around, and I don't think I'll be able to stop smoking until I get this housing thing under control you know, [laughter] it's stressful." *58 year old Black/ African American male participant* |
| | Experiences among sexual and gender minority groups | "Basically I, do think there's a lot of people out there that use, that smoke cigarettes and they're trans. For me it soothes me, it kind of relaxes me. But it don't, how am I saying what cigarettes … it just gives me a calm feeling, when I smoke cigarettes. And then sometimes if I don't have a cigarette, I crave for a cigarette a lot." *44 year old Black/African American Transgender participant* |
| | Tobacco and substance use | "One element is like, you know, the cigarette would be the land and then the alcohol would be like the ocean, you know, like the other element, and they go, they go great together, you know, like one after the other. So when the opiates are wearing off a cigarette will bring the opiates back a little bit. Yeah, the alcohol was a little different, it was, yeah, with alcohol it just seems, it just seemed right, it just seems to go hand-in-hand. With opiates it was more like a tool." *41 year old transgender multiracial participant* |
| Attitudes Towards Tobacco Cessation | Motivation to quit | "I have never really tried to quit smoking because I haven't really wanted to. I was such a light smoker before, I would only have like one to three cigarettes a day, and I really valued them, You know, I didn't feel that it was really necessary for me to quit or even that harmful to me. I was maybe in denial, but when I found out my mom had lung cancer, that definitely made me more aware of the harshness of the effects of tobacco. But she smoked a lot, you know, a lot, so I always felt like, well, she got it, she got it but I'm not going to smoke that much so I'm probably not going to get it, but I don't know that, I don't know that." *41 year old white female participant* |
| | Attitudes toward treatment for cessation | "I started off real slow, like during my 20s I was only, I was barely smoking, and then all of a sudden in my late 30s I just went to half a pack. And now, now I'm feeling the, the side effects of just how, how addicted I am. Cigarettes make me feel normal, I feel happy. If I remember to put on my patch and I have my cigarette in the morning and stuff I feel great. So when I wake up and I forget to put on my patch, halfway through that 3 h I start to not want to be at my volunteer job, just things start going wrong for me in different ways and then I realize, Oh, I forgot my patch." *41 year old multi-racial transgender participant* |
| Attitudes toward engaging in a clinical trial for cessation | Engaging in a clinical trial as a means to quit smoking | "I got excited when you just said all that [information on the clinical trial] so when it comes about, if you could call me and let me know, or a flyer out there or something. I probably would participate just because maybe I'll get the desire [to quit] by doing it." *63 year old white female participant* |
| Barriers to participating in clinical trial for cessation | Safety and needing to self-isolate | "Not me personally but, but, yeah, just depending on the type of person that you're going to have doing this, a lot of smokers tend to isolate so getting them to come out of their home once a day just to meet with you might be a problem." *51 year old white female participant* |
| | Location and frequency of study visits | " I thought that [the study] was just going to be for a week and I said that was why I was going to do this interview, but thinking about the future and coming in frequently, it kind of concerns me a lot because I, you know, I'm a transgender, and so I have challenges a lot with different people that I encounter throughout the day, and so I'm more content being at home now than I ever have been." *63 year old Black/African American transgender participant* |
| Patient-centric factors to increase feasibility of engaging in a clinical trial | Clinical trial features | " So I think the [location] is, you know, fine, it's, I think it's easy to get to for most people. I'll say for me it's a good place to meet because, you know, it's a bus ride for me, you know what I mean" *62 year old white male participant* |
| | | "Oh, the meetings, the frequency of the meetings, now that, sounds pretty cool and I think that would be helpful. Well, for myself, you know what I'm saying, because I could learn a lot about what the cigarette does to the body so I can learn a whole lot from that. So that would be a great |

(*continued on next page*)

**Table 3** (*continued*)

| Themes | Subthemes | Illustrative Quote |
|---|---|---|
| | | help, too." *44 year old Black/ African American transgender participant*<br>" I think that's a good idea [patient navigator from the community] because you know what they're going to tell you, sometimes you bring people in to talk to people, you know, who have no extreme experience. You bring all of these doctors, they, people don't even know [what it feels likle] so how can you relate to the people who are coming from the clinical aspect only." 44 year *old Black/African American female*<br>"Participant: I guess just meeting people in a convenient location really helps, and then also I guess the time factor, it's about time, a lot of people, don't meet up in the morning. I'm not sure when you guys are planning on meeting up with people but I think the evening is much better. Or not evening but like, you know, late afternoon. Interviewer: Yes there will be flexibility around that Participant: That would be good" *41 year old white female* |
| | Financial incentives for cessation | "It would be something that I would be interested in because I do want to quit smoking and why not start, you know, and at the same time it's like I can make money to do other things like to pay, pay bills and help my grandkids." *45 year old American Indian female participant*<br>"If a person is, you know, interested in quitting, or participating in the program, which means they're going to [abstain] from tobacco, I don't, personally I don't think that, it should take, money as far as it goes [to stop]" *62 year old white male participant* |

homelessness. Most participants initiated tobacco use between the ages of 11 years and 20 years. By the time they had experienced their first episode of homelessness, they had been smoking for years. Early exposure to tobacco through family and friends was common and one of the primary triggers for tobacco use. Most participants described increased displacement due to the COVID-19 pandemic, with frequent moves from unsheltered environments to non-congregate or congregate shelters. Participants reported smoking more while being homeless than housed, and using tobacco to cope with the stressors of homelessness. While a few participants preferred to smoke alone, most liked the social connection that smoking facilitated.

*3.2.1.2. Experiences among sexual and gender minority participants.* Four of the participants described their experiences of coming out in the transgender community during their youth or young adulthood. Participant experienced stigma and discrimination during the process of coming out into the transgender community, and described using tobacco as a way to cope with those stressors. Others described smoking as accepted and widely prevalent in the transgender community.

*3.2.1.3. Tobacco and substance use.* Participants reported that spending time with people who were current users of tobacco and other substances were triggers for tobacco use. Substance use lowered their inhibitions, which triggered other high-risk behaviors. Alcohol and cannabis went "hand-in-hand" with tobacco use, and their ready availability, unlike other illicit substances where a "dealer" might be needed, also facilitated co-use. Tobacco mellowed out the effects of crack/ cocaine or methamphetamine, and mitigated the "low" from the effects of these substances wearing off.

### *3.2.2. Attitudes toward tobacco cessation*

*3.2.2.1. Motivation to quit.* Participants' attitudes toward smoking cessation were shaped by their motivation to quit as well as the barriers they faced in trying to sustain abstinence. Almost all participants were motivated to quit because of their own health or that of their family members, and others were concerned with the impact of secondhand smoke on their children and families. One transgender participant was motivated to quit because smoking cessation was a requirement for gender affirming surgery.

Some participants were unmotivated to quit. These participants described high levels of nicotine addiction and the anxiety they experienced from nicotine withdrawal during prior quit attempts. Having friends in their social network who smoked and/or used other substances was a barrier to quitting. There was a prevailing belief that quitting other substances was more important than quitting cigarettes. Participants described experiences of forced quit attempts while in prison; however, they resumed smoking after release despite long periods of abstinence.

*3.2.2.2. Attitudes toward treatment for cessation.* About half the participants had tried cessation medications at residential drug treatment facilities. Participants described scenarios of not being able to smoke in those facilities and needing either to use chewing tobacco or nicotine replacement to mitigate withdrawal symptoms. These participants had limited success with prior uses of nicotine replacement therapy, and preferred to use medications such as bupropion or varenicline. However, the use of psychiatric medications with varenicline was a concern for some participants because they had heard about its neuropsychiatric adverse effects.

### *3.2.3. Attitudes toward engaging in a clinical trial for cessation*

*3.2.3.1. Engaging in a smoking cessation trial as a means to quit smoking.* Most participants responded positively to participating in a clinical trial as a means to get additional support for smoking cessation. A few participants indicated that they had temporary positive experiences with smoking cessation programs or nicotine replacement therapy, but they relapsed to smoking. However, others expressed negative attitudes towards smoking cessation trials because their previous attempts with nicotine replacement therapy were unsuccessful, they were not motivated to quit smoking, or they enjoyed smoking. Despite these hesitations, there was more of a consensus around wanting to quit tobacco use than continuing tobacco use. Despite prior unsuccessful attempts, participants expressed an eagerness to try a smoking cessation clinical trial as a means to achieve abstinence.

#### 3.2.4. Barriers to participating in a clinical trial for cessation

*3.2.4.1. Safety and needing to self-isolate.* Participants described several barriers to engaging in clinical trials including competing priorities from being homeless. A few participants raised safety concerns. One participant described his home environment as being unsafe, and feared that if he left his home for too long, his belongings would be stolen. Another described how a trial that required frequent visits would be difficult for them because of general stigma associated with identifying as transgender. A few participants reported that engaging in clinical trials would be challenging because they isolated themselves as a coping strategy for depression. A clinical trial with many visits and interactions with study staff could potentially exacerbate these challenges.

*3.2.4.2. Location and frequency of study visits.* Participants described barriers to accessing clinical trial sites, particularly if the trial site was not co-located in their medical homes or they lacked money for public transportation. Some reported that getting to the clinical trial location for frequent visits would be challenging due to work schedules.

#### 3.2.5. Patient-centric factors to increase feasibility of engaging in a clinical trial

*3.2.5.1. Clinical trial features.* All participants responded favorably to having a clinical trial site location that was a short distance from their clinic and/or home. While two participants expressed that many study visits would be challenging, others felt that having frequent visits with study staff would be a motivator for smoking cessation. Participants expressed enthusiasm for having their primary care providers involved in prescribing medications for cessation, and felt that engagement in a clinical trial would support and increase motivation for them to engage in clinical care for smoking cessation. Participants described the bidirectional relationship between the clinical trial team and their clinical team as a positive feature that would increase behavioral control over smoking. All but two participants expressed interest and enthusiasm in serving in a navigator role calling on personal attributes such as wanting to be helpful to the study team, being good with people, knowing a lot of people, and wanting to assist others with smoking cessation.

*3.2.5.2. Financial incentives for cessation.* All participants responded favorably to financial incentives for smoking cessation. Tobacco use was a financial burden, and quitting smoking while also receiving financial incentives was a motivator for smoking cessation. "You get paid to quit" was one of the participant's slogans for advertising the clinical trial. Participants differed in their opinions on whether incentives should be offered for behavior change, particularly for addictions, which came with associations of personal blame and/or failure. Almost all participants felt that external motivators such as financial incentives were important for behavior change. But one participant believed that external motivators would not help if there was no will to quit. Another participant felt that providing money that could be used to support other substance use behaviors was counterproductive. Despite these varying opinions, almost all participants were willing to engage in a clinical trial that offered financial incentives for smoking cessation and were supportive of frequent visits during the rapid escalation of incentives. All but one participant felt that a starting amount of $13 with escalating incentives up to $475 over a period of 6 months was adequate as a motivation for cessation.

## 4. Discussion

In this study of people with current and past experiences of homelessness who were currently smoking, a third of the sample reported having made a quit attempt in the past year and about half expressed an intention to quit smoking in the next six months. Prior quit attempts were generally unassisted. However, most participants expressed an interest in participating in a clinical trial for cessation, as a potential method for quitting, particularly if the trial incorporated features like convenient visit site and schedule, monetary incentives, and patient navigators.

Participants' beliefs around tobacco use were shaped by co-occurring substance use and their addiction to nicotine. Stressors were prevalent in their lives and despite its acknowledged negative impact on health, smoking played an integral role as anxiety and stress relief. Most participants did not reduce their smoking behavior during the COVID-19 pandemic despite its potential negative health risks. Findings from our study were similar to those from a study of adults experiencing homelessness who were engaged in a clinical trial for smoking cessation [7]. Participants described the normative experiences of smoking in shelters, and relying on smoking to pass time, which detracted from efforts to find housing [7]. Smoking incurs a substantial financial toll, accounting for up to 30% of monthly income, which is the amount that people may have to pay for renting a subsidized apartment [30]. Thus, smoking cessation could increase financial and housing stability, if the money saved from tobacco use could be directed to meeting basic needs such as housing [7,30].

Consistent with prior studies [4], most participants in our study had attempted to quit smoking but were unsuccessful and relapsed to smoking. In a recent study of individuals experiencing homelessness, the majority preferred to "quit cold turkey" rather than using supportive smoking cessation medications, findings that were consistent with participants in this study [31]. These findings highlight the need for interventions that increase engagement in cessation treatment to increase efficacy of quit attempts. A clinical trial for cessation could be one such approach that would promote access to treatment, and participants in this study supported that approach.

However, competing priorities of finding housing and previous experiences of trauma could pose barriers to smoking cessation and engaging in a smoking cessation clinical trial. Several participants described avoiding group situations because they were triggering for other substance use behaviors. Others, including a few transgender participants, preferred self-isolation for personal safety. Women who described lifetime experiences of homelessness and trauma also shared a similar perspective of self-isolation as a pathway to healing and recovery [32]. Thus, the commonly used model of group based cessation treatment may not be well suited to individuals experiencing homelessness preferring to self-isolate [32]. Training study staff to use a trauma-informed approach to engage with participants and offering individual meetings at convenient locations may be critical to engage individuals experiencing homelessness in a clinical trial [32].

Barriers to participating in clinical trials included time and resource constraints such as lack of transportation. Other barriers include mistrust of the clinical trial system and lack of comfort with the clinical trial process [33,34]. While few of our participants expressed not trusting clinical trials, most participants described barriers to transportation.

We proposed to hold the clinical trial in a public outdoor space, to minimize exposure to COVID-19, while also being co-located with shelters and clinics. Other features that may increase retention in long clinical trials include providing multiple attempts to make a study visit, scheduling visits at a time convenient for participants, frequent communication via text messaging, phone calls, or leaving messages through their friends or healthcare providers [24]. Allowing for a one week wait time between enrollment and the first study visit may also ensure that enrolled participants are committed to attending clinical trial visits and may reduce attrition [24].

Participants supported receiving financial incentives for a finite period of time (e.g., 6 months) to support smoking cessation and to relieve financial burden. Financial incentives may work by providing external motivation to engage in a health behavior. This in turn may facilitate good outcomes by increasing self-efficacy for smoking

cessation, and encouraging the use of smoking cessation medications [35,36].

Participants supported bi-directional communication between the clinical trial team and their healthcare team. The clinical trial team could facilitate smoking cessation by providing the healthcare team information on their patients' progress during the clinical trial. The relationship with the healthcare team could also facilitate retention in clinical trials by allowing for another point of contact for patients.

A significant number of the participants endorsed a peer navigation program. Participants believed that having peers from their community to help them navigate a smoking cessation program could increase their engagement in a clinical trial. Peers from the same community share life experiences, cultural beliefs and norms, who can provide culturally sensitive messaging on smoking cessation. Peers can also help with recruitment, coordination and retention activities [34].

Our study has limitations. We recruited participants from one clinic in San Francisco, and only those who had a functioning cell phone or landline. Therefore, the views of participants enrolled may not be generalizable to other populations experiencing homelessness in San Francisco and elsewhere. Attitudes and norms of the participants in this study could be shaped by local tobacco control policies which, could be different in other localities and states. Response bias toward expression of attitudes perceived as desirable may be present in a paid interview managed by researchers who have described the features of their proposed protocol to participants.

### 4.1. Conclusion

This study suggests best practices for conducting smoking cessation clinical trials for people experiencing homelessness. We found that most adults experiencing homelessness are interested in smoking cessation, and would be willing to engage in clinical trials for cessation if they included financial incentives, flexible scheduling for study visits, patient navigators with lived experiences of homelessness, and staff who were familiar with addressing participants' experiences of trauma and need for self-isolation. These findings will be used to modify our proposed clinical trial protocol for restructuring study visits to take place in the preferred afternoon time, for training staff in trauma-informed approaches, and to increase opportunities for participants to engage in recruitment efforts as navigators to the study.

## Author statement

**Joshua Miller:** Conceptualization, Formal analysis, Writing-Original Draft, Writing-Review & Editing. **Jordan Cuby**: Investigation, Formal analysis, Project administration, Writing-Review & Editing. **Sharon Hall:** Conceptualization, Writing-Review & Editing. **Maxine Stitzer**: Conceptualization, Writing-Review & Editing. **Margot Kushel:** Conceptualization, Writing-Review & Editing. **Donna Appiah**: Investigation, Formal analysis, Writing-Review & Editing. **Maya Vijayaraghavan:** Conceptualization, Writing-Original Draft, Project administration, Funding acquisition, Writing-Review & Editing.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Data availability

The data that has been used is confidential.

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