BRIEF REPORT

Smoking Cessation in Homeless Populations: Who Participates and Who Does Not

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ABSTRACT

Introduction: Although homeless individuals smoke at an alarmingly high rate, few smoking cessation clinical trials have focused on this vulnerable population. Little is known about recruitment efforts and suitable eligibility criteria for tobacco control research in homeless populations.

Methods: The aim of this article is to describe the recruitment, eligibility, and enrollment of homeless smokers who participated in the Power to Quit smoking study, a randomized smoking cessation clinical trial funded by the National Institutes of Health. The study compared motivational interviewing and standard counseling while participants received an 8-week treatment of the nicotine patch.

Results: Working with local emergency shelters, a total of 839 adult smokers were screened for study eligibility, 580 of whom (69.1%) met eligibility criteria. Of those eligible, 430 (74.1%) returned for randomization. Those who returned for randomization were older and more likely to have a phone number compared with eligible participants not enrolled. The most common reasons for exclusion included exhaled carbon monoxide levels less than or equal to 5 parts per million (indicating nonsmoking status), use of smoking cessation aid during the past 30 days, and not meeting the study definition of homelessness.

Conclusion: Knowledge of these factors may help researchers tailor criteria that accurately identify and include homeless smokers in future research.

INTRODUCTION

Approximately three out of four homeless people smoke cigarettes, a rate about 3 times higher than in the general population (Baggett & Rigotti, 2010; Connor, Cook, Herbert, Neal, & Williams, 2002). Many would like to quit and are interested in interventions to help them (Arnsten, Reid, Bierer, & Rigotti, 2004; Connor et al., 2002). However, few studies have focused specifically on interventions to help homeless smokers quit, and homeless persons are often excluded from tobacco control research because they do not meet eligibility criteria. We conducted a community-based randomized clinical trial titled Power to Quit (PTQ) that tested the efficacy of the motivational interviewing (MI) to improve adherence to the nicotine patch in homeless individuals. Here we report our experiences related to trial eligibility that may assist other researchers conducting

community-based cessation trials with this population. We provide a description of individuals who completed eligibility screenings but were not eligible, the reasons for ineligibility, and factors associated with returning for randomization.

METHODS

The PTQ study was a community-based randomized controlled study with methods previously described (Goldade et al., 2011), comparing the effects of six MI sessions versus standard care (a one time, advice-oriented counseling session). The study was approved by the Institutional Review Board of the University of Minnesota.

Participants were recruited using several methods. Study staff connected with potential participants at health fairs

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conducted at Minnesota Homeless Connect, a gathering for persons experiencing homelessness to find resources available throughout the twin cities. Recruitment posters were hung in various local organizations serving homeless persons, including the eight emergency and transitional shelters used as interview sites during the study. Most of the individuals who completed the screening heard about the study from other participants, and many screenings occurred on a walk-in basis. All written materials included the program name, logo, and contact information. Study staff could be reached in person while conducting interviews at the shelters, by office phone during business hours (and after hours by voicemail), or via e-mail.

All potential participants completed an initial eligibility survey at the first screening appointment. Upon passing the first screening survey, individuals were scheduled for a separate randomization appointment within the next 7–14 days. At this second visit, written consent was obtained. If an eligible subject missed the second appointment by more than 14 days, the person had to repeat the eligibility survey. This subsequent screening could result in eligibility or ineligibility, depending on if the person's situation had changed. If a person missed three randomization appointments, they were no longer allowed to enroll in the study. This was a practical consideration given limited staff time and favored selection of subjects who were more likely to complete the program.

At the very beginning of the study, if the potential participant was deemed ineligible, they were allowed to rescreen again after 30 days. This happened with less than five individuals who were excluded for time-related variables such as not living in the twin cities for the past 3 months or use of another smoking cessation aid in the last 30 days. However, the protocol was changed approximately 1 month after the study began to not allow any individual to rescreen if initially ineligible, as we observed that allowing people to rescreen may make them more likely to misreport answers to eligibility questions.

Eligibility was determined using a 40-item survey that included questions relating to physical health, mental health, smoking habits, current living situation, and willingness to comply with the study requirements. Inclusion criteria were related to age, current tobacco consumption (confirmed by exhaled carbon monoxide), and current homelessness. For this study, homelessness was operationalized based on the federal definition passed by the U.S. Congress in 1987 and updated in 2004 in which a homeless person is defined as “any individual who lacks a fixed, regular and adequate nighttime residence,” or “one whose primary nighttime residence is a supervised public or privately operated shelter designed to provide temporary living accommodations, transitional housing, or other supportive housing program, or a public or private place not meant for human habitation (e.g., on the streets or in abandoned buildings, tents, or automobiles)” ([US Code, Title 42, Chapter 119, Subchapter I, Section 11032, 2004](#)). To assess this, individuals were asked where they had slept the previous night. Those who had been in an emergency or long-term shelter, transitional or supportive housing, a campsite, vehicle, abandoned building or house, parking garage, or on the street were considered homeless and thus eligible for participation. Conversely, individuals who responded they had slept in a public housing development or section 8 housing, a home or apartment they owned or rented, a boarding or half-way house, or a detoxification center were ineligible as these are not included in the federal definition of homelessness. Per the study protocol, individuals who reported living with a friend or family for less than 3 months were also eligible.

Exclusion criteria were related to recent use of another smoking cessation aid, duration of residency in the Minneapolis/St Paul metropolitan area, and inability to comply with study procedures. Medical exclusion criteria included heart attack or stroke within the past month, current pregnancy or breastfeeding status, and planning pregnancy in the next 6 months. Exclusion criteria related to mental health included current active psychosis as determined by a score of 5 or greater on the Mini-international psychiatric interview (MINI) psychotic symptoms survey, severe cognitive impairment defined as a score of 20 or greater on the Short Blessed Test, unstable suicidal ideation, and incoherence as assessed by study staff observing the potential participant exhibiting disorganized speech or marked loosening of associations.

Analysis

Categorical variables were summarized by frequencies and percentages, and continuous variables were summarized by means and standard deviations. Responses to eligibility survey questions were compared between those who were randomized and those who were eligible but did not return for randomization. Chi-square tests or Fisher exact tests for categorical variables and *t* tests for continuous variables were used to examine the factors that are associated with enrollment.

RESULTS

Over two thirds ($n = 580$, 69.1%) of the 839 individuals screened were eligible to participate in the study. Of those eligible, 430 (74.1%) consented and were randomized. Eligible participants who returned for randomization were older and more likely have a phone number where staff could reach them ([Table 1](#)). Other variables such as gender, having a mailing address, number of cigarettes smoked per day, and where the individual usually slept were not significantly different between those randomized and not randomized.

The most frequent reasons for ineligibility were a CO level below 5 ppm, use of another smoking cessation aid within the last 30 days, not being homeless according to the study definition, and not meeting residency requirements ([Table 2](#)). Other reasons for ineligibility included suicidal ideation, smokeless tobacco use, and unwillingness to use nicotine replacement therapy. Among the least frequent reasons were preexisting conditions like heart attack and stroke. There were a few individuals deemed ineligible due to very high scores on the Short Blessed or MINI surveys, indicating that they had mental health or cognitive issues that could interfere with study participation. Although most individuals were ineligible for a single reason (137 [53%]), others had more than one exclusionary item, with 74 (28.5%) having two exclusionary items and 48 (18.5%) having more than three exclusionary items.

A few people ($n = 15$) became ineligible at the randomization visit. The two most common reasons for ineligibility at the randomization visit were refusal to sign the consent form and refusal to provide a salivary sample for cotinine testing (used to confirm smoking status). Other reasons included having a “reaction” to the patch, refusing to wear the patch, refusing for “personal issues,” unwilling to commit to attending future appointments, and stating that the study asked for “too much information that we don’t need.”

Table 1. Comparison of Eligible Subjects Who Were Randomized Versus Those Not Randomized

Variable	Overall (<i>n</i> = 580)	Randomized (<i>n</i> = 430)	Not randomized (<i>n</i> = 150)	<i>p</i> value
Age				
Mean in years, <i>n</i> (SD)	43.5 (10.4)	44.3 (10.0)	41.1 (11.2)	.002
Gender				
Male, <i>n</i> (%)	430 (74.1)	321 (74.7)	109 (72.7)	.630
Participant has a phone number where s/he can be reached, <i>n</i> (%)	524 (90.8)	400 (93.5)	124 (83.2)	<.001
Participant has a mailing address, <i>n</i> (%)	563 (97.4)	418 (97.7)	145 (96.7)	.550
Average cigarettes smoked per day, mean (SD)	18.8 (13.3)	19.3 (13.7)	17.5 (11.8)	.140
Where did you sleep last night? <i>n</i> (%)				
• Emergency shelter	354 (61.4)	260 (60.8)	94 (63.1)	.900
• Campsite, vehicle, abandoned building/ house, parking garage, street	23 (4)	18 (4.2)	5 (3.4)	
• Transitional housing	126 (21.8)	97 (22.7)	29 (19.5)	
• With relative or friend for less than 3 months	70 (12.1)	50 (11.7)	20 (13.4)	
• Other	4 (0.7)	3 (0.7)	1 (0.7)	

Note. Italicized *p* values are significant.

Table 2. Reasons for Study Exclusion

Exclusion reason	Ineligible participants <i>n</i> (%)
CO level ≤ 5 ppm	105 (40.5)
Use of other cessation aid in the past 30 days	65 (25.1)
Not homeless per study definition	56 (21.6)
Living in twin cities less ≤ 3 months	50 (19.3)
Suicidal ideation in the last 14 days	43 (16.6)
Current other smokeless tobacco product use (chewing tobacco, etc.)	23 (8.9)
Unwilling to use patch	14 (5.4)
Not planning to stay in twin cities for the next 6 months	14 (5.4)
Unwilling to use birth control (females)	14 (5.4)
Currently pregnant, breastfeeding, or planning pregnancy in the next 6 months	11 (4.2)
Incoherent	10 (3.9)
Does not smoke everyday or some days	10 (3.9)
Mini-international psychiatric interview score > 5	8 (3.1)
Smoked < 100 cigarettes in lifetime	8 (3.1)
Unable to attend seven appointments over 6 months	7 (2.7)
Other	7 (2.7)
Not smoking any cigarettes in the past 7 days	5 (1.9)
Short Blessed score > 20	4 (1.5)
Heart attack or stroke within last 30 days	4 (1.5)

Note. Subjects could have more than one reason for exclusion, such that the sum of percentages could be greater than 100%.

DISCUSSION

The main finding of this analysis was that almost three quarters of the homeless smokers screened were eligible to enroll in the study, with high rates of consent and enrollment.

Studies involving homeless participants have reported varying eligibility and enrollment rates. One study of chronically ill homeless patients reported that 75% of participants screened were eligible, 89% of whom were enrolled (Sadowski, Kee, VanderWeele, & Buchanan, 2009). Another study of HIV-positive homeless patients reported an enrollment rate of 68% among participants screened and deemed eligible (Buchanan, Kee, Sadowski, & Garcia, 2009). However, a recent clinical trial among mentally ill individuals utilizing homeless drop-in centers enrolled only 16% of those who initially indicated an interest in participating (Ball, Cobb-Richardson, Connolly, Bujosa, & O'Neill, 2005).

The only other prior attempt to recruit homeless individuals to smoking cessation trials was a small pilot study that noted

similar screening and enrollment rates, despite having less stringent eligibility criteria (Shelley, Cantrell, Wong, & Warn, 2010). Our study represents the first experience with a large randomized smoking cessation trial in the homeless. Attempts to maximize recruitment rates included the hiring and training of formerly homeless individuals as study staff who worked directly with shelters, meeting potential participants where they lived.

Older age and having a phone number were positively associated with returning for randomization. Studies of African American smokers and young adult smokers also found that eligible participants who enrolled were older (Audrain-McGovern, Hughes-Halbert, Rodriguez, Epstein, & Tercyak, 2007; Woods et al., 2002). Older participants may be more motivated to make positive health behavior change, which may be due to higher rates of smoking-related health problems with aging. Having a working phone number likely made reminder phone calls more feasible for the study staff, and follow-up phone calls have been shown to increase response rates in

other studies (Bell, Butler, Herring, Yancey, & Fraser, 2005). Thus, participants with working phones had a greater chance of receiving reminder phone calls, contributing to attendance at the randomization appointment. Future researchers could consider providing participants a cell phone with prepaid minutes to enhance communication and likelihood of enrollment and retention.

We identified several factors responsible for ineligibility, with the absence of biological verification of recent smoking (defined as a CO level of > 5 ppm) being most common. CO levels reflect smoking behavior within the last few hours, and smokers who only have intermittent access to cigarettes (a very real possibility in the homeless) or who are light or occasional smokers may not test positive. However, our data suggest that few screened individuals were light or occasional smokers (Table 1). It is also possible that people with low CO may be misreporting their smoking status to receive incentives.

The next most common reason for ineligibility, somewhat surprisingly, was the use of nicotine replacement therapies in the prior 30 days. This belies the notion that homeless people will not attempt to quit because they are occupied with other issues and is consistent with a national survey of homeless smokers (Baggett & Rigotti, 2010). Though some of the participants said they bought their product from a pharmacy, others indicated that they obtained products from a friend, family member, or doctor's prescription.

The third most common reason for ineligibility was not meeting the federal criteria for homelessness. Our study did not include those residing in public housing, a treatment or detoxification program, or a boarding or half-way house. However, these individuals may consider themselves to be homeless and access many of the same services as those considered homeless according to the study definition. Other tobacco investigators have used broader definitions of homelessness, including simple self-identification (Arnsten et al., 2004) and living in or receiving services from a homeless shelter (Shelley et al., 2010). Although these may be more inclusive approaches, they also may include those who are not truly homeless, thus confounding the development of an intervention targeted to homeless persons.

CONCLUSION

These eligibility and enrollment rates demonstrate the feasibility of conducting smoking cessation clinical research in homeless populations, a priority population for public health engagement due to high smoking prevalence yet limited cessation efforts. Rigorous eligibility criteria do not preclude adequate study recruitment in the homeless population.

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DECLARATION OF INTERESTS

None declared.

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