Pathways to Health: A Cluster Randomized Trial of Nicotine Gum and Motivational Interviewing for Smoking Cessation in Low-Income Housing

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Despite high smoking rates among those living in poverty, few cessation studies are conducted in these populations. This cluster-randomized trial tested nicotine gum plus motivational interviewing (MI) for smoking cessation in 20 low-income housing developments (HDs). Intervention participants (10 HDs, $n = 66$) received educational materials, 8 weeks of 4 mg nicotine gum, and 5 MI sessions on quitting smoking. Comparison participants (10 HDs, $n = 107$) received 5 MI sessions and educational materials addressing fruit and vegetable consumption. Participants had a mean age of 46.3 years and were predominantly female (70%) and African American (83%). Biochemically-verified 7-day abstinence rates at 8 weeks were 6.1% and 5.6% in the intervention and comparison arms, respectively ($p = ns$); and at 26 weeks were 7.6% and 9.3%, respectively ($p = ns$). Results suggest that nicotine gum plus MI were not effective for smoking cessation in low-income housing. Programs are needed to enhance the effectiveness of pharmacotherapy and counseling in underserved populations.

Keywords: *smoking cessation; low-income housing; nicotine gum; motivational interviewing; cluster randomized trial*

Tobacco use is the leading cause of preventable death and disease in the United States, accounting for approximately 435,000 deaths yearly and 30% of all cancer

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deaths (U.S. Department of Health and Human Services [USDHHS], 1990, 1994). During the past few decades, there has been a significant decline in smoking prevalence among adults in the United States. However, the decline has not occurred in all subpopulations of smokers. Consequently, smoking rates remain significantly higher among certain segments of the population including some ethnic minorities, young adults (aged 18-24), those with lower education (less than high school), and those below poverty level (Centers for Disease Control and Prevention [CDC], 2002, 2004; Flint & Novotny, 1997). The 2000 National Health Interview Survey reported smoking prevalence for adults below the federal poverty status as 36.9% for male persons and 30.1% for female persons (CDC, 2004; Connor, Cook, Herbert, Neal, & Williams, 2002). These rates are nearly 50% higher than those for persons at or above poverty status.

Despite studies showing high prevalence and motivation to quit smoking among residents of low-income housing (Resnicow et al., 1996), few smoking cessation intervention studies have been conducted in these populations. This paucity is most pronounced in the area of pharmacological interventions. Although there are numerous studies about the efficacy of pharmacotherapy for smoking cessation, only a few studies have tested these medications in underserved populations (Mazas & Wetter, 2003) and none among residents of low-income housing. However, previous work has shown low-income housing to be effective settings for conducting or recruiting for health interventions (Ahluwalia, McNagny, & Clark, 1998) including smoking cessation and dietary research. Conducting research at these housing sites rather than traditional settings might reduce the number of barriers to participation and reduce attrition rates.

To address the gap in smoking cessation research among poor smokers, we conducted a cluster-randomized clinical trial titled Pathways to Health (PATH). The PATH project focused on smokers residing in low-income housing. The goal of the PATH project was to test the effects of nicotine polacrilex gum along with motivational interviewing (MI) counseling for smoking cessation in this population. The rationale for using the nicotine gum in this population was based on a number of considerations including the fact that it (a) delivers moderate levels of nicotine, (b) produces minimal side effects, (c) has few contraindications, (d) enables participants to individualize their dose, (e) is available without prescription, and (f) may be used ad hoc to counteract fluctuations in smoking urges. MI is a counseling approach that has been described in detail elsewhere (Miller & Rollnick, 1991). Briefly, it is directive, egalitarian, empathic, and uses client-centered techniques and strategies including reflective listening, agenda setting, and assessing motivation and confidence for behavior change. Strategies are designed to assist clients in working through ambivalence for behavior change, resolving their own barriers, and exploring potential sources of motivation. MI was initially developed for addictive behaviors such as alcohol abuse, but MI has been successfully applied to a wide range of health behaviors, including cigarette smoking and cessation (Miller & Rollnick, 1991). However, there is a paucity of published research using MI as an intervention for cigarette smokers in underserved populations. A combination of counseling and pharmacotherapy was chosen in light of evidence that counseling bolsters the long-term success of smoking cessation (Kottke, Battista, DeFriese, & Brekke, 1988; Law & Tang, 1995) and that adding pharmacotherapy to counseling significantly boosts quit rates (Hughes, Goldstein, Hurt, & Shiffman, 1999).

METHOD

Study Design

This study was a 6-month cluster-randomized trial in which 20 public housing and section 8 developments (HDs) were randomly assigned to a treatment (smoking cessation) or a comparison intervention (10 HDs to each arm) to increase fruit and vegetable (FV) consumption. Both groups received educational materials and MI counseling related to their targeted behavior (smoking cessation for the treatment group, FV for the comparison). Participants in the treatment arm also received 4 mg nicotine gum. Participants provided written informed consent at the time of the baseline survey. The study protocols were approved and monitored by the University of Kansas Medical Center's Human Subjects Committee.

Recruitment and Randomization

Health fairs were conducted monthly between October 2001 and May 2003 to recruit participants. At each HD, all residents were invited to attend a community health fair held on-site on a Saturday. Promotional signs and in-person promotion by HD managers were used to encourage health fair attendance. Smokers who attended the health fair were further screened to determine eligibility for the randomized trial. Inclusion criteria included smoking at least five cigarettes per day, not using any other form of tobacco (i.e., pipes, cigars, smokeless tobacco) or pharmacotherapy for smoking cessation in the previous 30 days, being at least 18 years of age, being a current resident of the targeted housing development with no plans of moving in the next 6 months, ability to speak English, and access to a working telephone. Exclusion criteria included contraindications for pharmacotherapy: rapid or irregular heart beat, heart attack in the last month, stroke in the last 6 months, allergy/sensitivity to nicotine gum, jaw problems that would make chewing nicotine gum difficult, systolic blood pressure equal to or greater than 220, diastolic blood pressure equal to or greater than 120, or blood sugar less than or equal to 50 or equal to or greater than 400. Study personnel remained blinded to randomization at the time of the health fair.

Housing developments were stratified by elderly versus nonelderly (i.e., "family") developments, as determined by the Kansas City (Kansas and Missouri) Housing Authorities, and randomization occurred within each stratum. Treatment assignment was revealed to the research staff only after each health fair was completed. A timed e-mail was sent to the study coordinator at 6:00 p.m. after each health fair was complete along with a sealed envelope containing the randomization code. Sequential enrollment continued until 20 HDs were randomized, of which 10 were randomized to the smoking cessation arm and 10 to the comparison arm. A total of 813 residents attended the 20 health fairs. Of the 273 smokers identified and screened, 204 met screening criteria, and 173 were enrolled into the trial (see Figure 1).

Intervention Components

Randomization (Week 0) appointments were completed within 10 days of the health fair. At the randomization visit, participants in the smoking cessation arm received an 8-week supply of 4 mg nicotine gum, instructions for using the gum, and educational

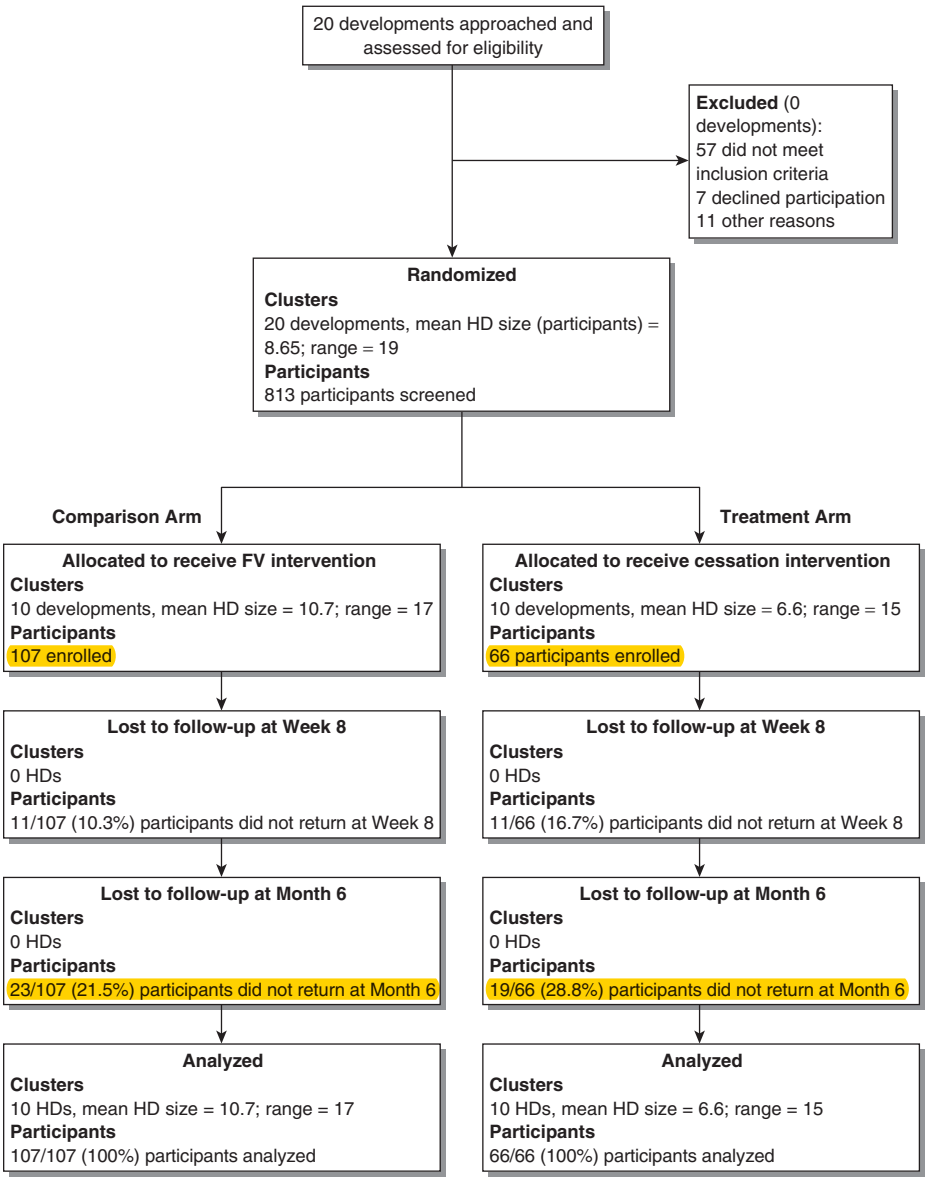

Figure 1. Diagram of PATH cluster randomized trial.
NOTE: PATH = Pathways to Health; HD = housing development; FV = fruit and vegetable.

materials related to quitting smoking. Participants in the comparison (FV) arm received a package that included a bag of fresh fruits and vegetables, a cookbook, dietary education materials, and two videos on fruits and vegetables. Participants in both arms received five sessions of MI counseling on their respective topic (smoking or fruits and vegetables). MI sessions were conducted in-person at each HD at Weeks 0 and 3, and via telephone at Day 10 and Weeks 5 and 20.

Motivational Interviewing (MI). MI is a counseling approach that has been previously described elsewhere (Miller & Rollnick, 1991). Briefly, it is directive, egalitarian, and empathic and uses a client-centered set of techniques and strategies including reflective listening and agenda setting designed to help clients work through their ambivalence about behavior change, resolve their own barriers, and explore potential untapped sources of motivation (Miller, 1996; Resnicow et al., 2002). In the present study, MI was conducted by trained master's-level counselors who followed semi-structured counseling scripts. In general, participants received counseling from the same person for all five sessions. The MI sessions explored the positive and negative aspects of changing the behavior (e.g., quitting smoking); the pros and cons of change; and participants' ambivalence, motivation and confidence, and plans for change. Counselors received ongoing supervision for the duration of the trial and met weekly with other MI counselors and supervisors to review audiotapes and discuss ongoing issues.

Retention

Telephone calls and postcards reminded participants of upcoming visits to minimize attrition. Participants who missed an appointment were called up to six times to reschedule their visit. To further enhance retention, participants received incentives at each visit (e.g., movie tickets, T-shirt, water bottle, tote bag) and were reimbursed a total of $120 during the 6-month follow-up period: $40 at the health fair, $40 at Week 8, and $40 for their time at Month 6.

Measures

Primary and Secondary Outcome Variables. The primary outcome variable for the study was biochemically verified 7-day point prevalence smoking cessation at Month 6, defined as having smoked no cigarettes (not even a puff) in the previous 7 days. Secondary outcomes included 7-day point prevalence smoking cessation at Week 8. Self-reported abstinence was confirmed with expired air carbon monoxide (CO) assessments (≤ 10 ppm indicated abstinence), and discrepancies were resolved by obtaining saliva for cotinine analysis (≤ 20 ng/mL). Several other behavioral variables were assessed, including number of quit attempts that lasted at least 24 hours or longer and efforts to reduce cigarettes per day. Questions also assessed program process variables, including self-reported use of the nicotine gum and perceptions of its helpfulness.

Data Management

All data forms were completed by study staff, then reviewed by a study coordinator prior to data entry. Primary and verification Access databases were created to capture all study data, and all data were double-entered into these databases. Access databases were converted to SAS databases, and compares were run to ensure the identical number of records and that each record was identical. Any discrepancies identified in the compares were resolved by going to the survey instrument and entering the correct data into the database; subsequently, compares were run again until there were no discrepancies between the primary and verification databases. Upon completion of data entry for all subject and compares, logic, range, and edit checks were performed. Any queries that resulted were resolved by going to the survey and then entering the correct

data. Upon completion of all data checks, a final Access database was created and locked.

Statistical Analyses

Statistical Power and Sample Size. Because randomization occurred by HD, statistical power was assessed over a range of potential intraclass correlation coefficients (ICCs). Assuming a scenario of 20 participants in each of the 20 HDs, a moderate ICC of 0.02, a 6-month quit rate of 6% in the comparison arm, and a 18% quit rate in the cessation arm, there would be 89% power to detect a difference using the adjusted Mantel-Hansel chi-square statistic (Donald & Donner, 1987).

Analysis Plan

Baseline categorical variables were summarized by frequencies, and percentages and baseline quantitative variables were summarized by means and standard deviations. Analysis of smoking cessation at the end of treatment and end of study was performed using the adjusted Mantel-Haenszel chi-square statistic to account for the intraclass correlation due to clustering (Donald & Donner, 1987). To be conservative, those with missing outcome data were imputed as smokers for the primary analyses of comparing cessation between the two groups. All analyses were conducted under the intention-to-treat principle. All statistical analyses were conducted using SAS (SAS Institute, 1999).

RESULTS

Twenty HDs (clusters) participated in the study. The mean (*SD*) cluster size was 8.7 (5.3). Housing development size ranged from 82 to 397 adult residents. On average, 21% of adult residents attended the health fair (range 8%-66%). Table 1 describes the housing developments and characteristics of enrolled participants by treatment arm. Motivation and confidence to quit were moderately high at baseline in both groups. Baseline motivation was 7.0 (*SD* = 2.52) for the comparison group and 8.0 (*SD* = 2.38) in the intervention group. Baseline confidence was 7.0 in both groups.

Point-prevalence abstinence levels for the treatment and comparison groups are shown in Table 2. Using an intent-to-treat analysis, the biochemically verified cessation rate for the treatment arm was not significantly different from that in the comparison arm at either Week 8 (6.1% vs. 5.6%) or Month 6 (7.6% vs 9.35%). Similar results were found when treating those lost to follow-up as missing.

There were not significant differences between the groups in stages of change for quitting smoking (see Table 3). Table 3 also shows proportion of participants in both arms at various time points who reported reducing their smoking or made at least one quit attempt of 24 hours or longer duration. At Day 10, a statistically nonsignificant higher proportion of participants in the treatment arm (40.9%) than in the comparison arm (25.2) had made at least one quit attempt lasting 24 hours or longer. However, the proportions of participants who made quit attempts were no different among both groups at Week 8 and Month 6. Both arms also did not differ on the self-reported cigarettes per day smoked at various time points.

Table 1. Characteristics of the Enrolled Sample at the Cluster and Individual Level at Baseline

	Treatment		Comparison	
Housing development factors				
No.	10		10	
Development type				
Elderly housing development	3		3	
Family housing development	7		7	
Participants' factors at baseline				
Number of participants	66		107	
Demographic characteristics				
Age (in years), mean (*SD*)	43	(14.3)	48	(13.1)
Female, no. (%)	53	(80.3)	68	(63.6)
Race/ethnicity, no. (%)				
African American	50	(75.8)	93	(86.9)
White	11	(16.7)	7	(6.5)
Hispanic	3	(4.6)	2	(1.9)
Other	2	(3.0)	4	(3.7)
Married or living with a partner, no. (%)	5	(7.6)	10	(9.4)
≤ high school education, no. (%)	51	(77.3)	84	(78.5)
Unemployed, no. (%)	30	(45.5)	42	(39.3)
Monthly income ≤ $800, no. (%)	49	(74.2)	78	(72.9)
Insured, no. (%)	49	(74.2)	85	(79.4)
Body Mass Index (BMI), mean (*SD*)	30.5	(8.2)	29.5	(9.1)
Smoking-related variables				
Cigarettes smoked per day, mean (*SD*)	19	(13.0)	16	(9.2)
Age of initiation (in years), mean (*SD*)	18	(5.2)	19	(6.6)
Cigarette in first 30 minutes of awakening, no. (%)	58	(87.9)	80	(74.8)

Of those who answered the Month 6 survey, 87% (41/47) of those in the treatment arm and 2% (2/84) in the comparison arm reported using any nicotine gum during the study. Participants in the treatment arm reported that they used some (61.7%) or most (25.5%) of the gum that was provided, wheras 12.8% used none. Those who reported using any of the gum had mixed perceptions of its usefulness: 32.6% found it not helpful, 44.2% found it somewhat helpful, and 23.3% found it very helpful. Seventy percent reported reading all of the educational material; 15.2% said the materials were not helpful, 28.3% found them somewhat helpful, and 56.5% said the materials were very helpful. The majority of participants received most of their planned counseling sessions; 60.6% of those in the intervention arm and 71.0% of those in the comparison arm attended at least four of the five MI sessions.

DISCUSSION

This clinical trial was the first to examine the effects of nicotine polacrilex gum and MI among residents of low-income housing. The quit rate at 6 months (7.6%) for the smoking cessation treatment group was not significantly different from that in the

Table 2. Verified 7-Day Prevalence of Smoking Abstinence for Each Treatment Group at Week 8 and Month 6

Time Point	Treatment (n = 66)	Comparison (n = 107)	p Value
Week 8, n (%)	4 (6.1)	6 (5.6)	.94
Month 6, n (%)	5 (7.6)	10 (9.3)	.73

NOTE: Intent-to-treat analysis where nonresponse is categorized as no change. Intraclass correlations at Week 8 and Month 6 were .181 and .034, respectively.

comparison arm of the study (9.3%). This suggests that the combined nicotine gum and MI intervention was not effective for smoking cessation among smokers in low-income housing. However, the quit rates in either of the two study groups are slightly higher than the spontaneous quit rates (approximately 5%) in the United States found among smokers who try to quit without formal intervention (USDHHS, 2000). Whereas studies in specialized clinics have demonstrated efficacy of nicotine gum, studies in real-world settings have not consistently found benefits from the gum. The research on the effectiveness of nicotine gum as a treatment for smoking was reviewed through a meta-analysis of 33 studies (Cepeda-Benito, 1993). Results from the meta-analysis showed that the positive effects of nicotine gum in smoking treatment are a function of an interaction between the gum's pharmacological properties and the effectiveness of intensive treatment strategies. Although we did not quantitatively assess participants' adherence to the gum during the study, process data about gum usage showed that most participants did not use the gum as recommended. Only 26% in the treatment arm reported using most of the gum, and 62% reported using some of the gum. Within the general population, adherence to nicotine replacement therapy (NRT) is variable, but those who do adhere to recommended doses usually achieve better cessation outcomes (Lam, Abdullah, Chan, & Hedley, 2004; Shiffman et al., 2002). In an analysis of 1,186 smokers prescribed NRT (78% patch, 12% gum, 6% inhaler, and 6% combination of any two) in a smoking cessation clinic (Lam et al., 2004), 44% reported using NRT for 1 week or less, 13% for 1 to 2 weeks, 5% for 2 to 3 weeks, and only 16% reported using NRT for 4 weeks or more. A stepwise logistic regression analysis showed that adherence to NRT use, higher income, good perceived health, and having higher confidence in quitting were significant predictors of quitting (Lam et al., 2004). Another study (Shiffman et al., 2002) reported that those who used the recommended nine or more pieces per day of the gum had significantly greater abstinence at 6 weeks compared with those using fewer pieces of gum per day. Low usage of the gum in our study may have been a partial explanation for the lack of effectiveness of the treatment. One way to overcome the low adherence is to use an NRT such as the patch, which has been shown to have better adherence in the general population of smokers. Because the patch is also available without prescription like the gum, its accessibility to smokers wanting to quit is similar to that of the gum.

Since participants in the treatment arm also received MI for smoking cessation, the null findings of treatment effects also suggest that MI did not have any significant effect on smoking cessation in this population. Although several studies have shown the efficacy of MI for smoking cessation and other drug abuse, some studies have found no effect for MI (Miller, Yahne, & Tonigan, 2003). Although we did not screen for

Table 3. Motivation to Change, Cigarette Reduction, and Quit Attempts by Treatment Group at Various Time Points

	Baseline[a]		Day 10[a]		Week 8[a]		Week 26[a]	
	Treatment	Comparison	Treatment	Comparison	Treatment	Comparison	Treatment	Comparison
Reduced cigarettes per day smoked in past 7 days, % yes	NA	NA	42.4	43.9	39.4	49.5	34.9	40.2
Made at least one 24-hour quit attempt in last 7 days, % yes	NA	NA	40.9	25.2	36.4	29.9	34.6	31.8
Cigarettes per day smoked, mean	19	16	10	10	9.2	11.6	9.3	8.4

NOTE: NA = not assessed.

a. None of these differences were statistically significant.

motivation as part of our study inclusion criteria, motivation to quit was moderately high in both groups at baseline. This can affect our study findings in several ways. First, it may be that because participants in the comparison group were already motivated and confident regarding quitting, they may have quit without intervention. Second, it may be that smokers were highly motivated and had unsuccessfully tried to quit in the past, creating a pool of smokers who have historically had a difficult time quitting (the intervention group reported four serious quit attempts in the year before baseline, and the comparison group reported five serious quit attempts in the same time frame). Last, there is some evidence that MI is best suited for clients who exhibit lower motivation and readiness for behavior change (Butler et al., 1999; Heather, Rollnick, Bell, & Richmond, 1996) and that clients who have high motivation and high readiness may fare better with a skill-based rather than an motivation-based approach (Rollnick, Mason, & Butler, 1999). Because motivation (and confidence) were already relatively high at the onset of the study, the MI intervention may not have been as effective as it would be in a pool of participants less motivated to change their behavior.

Our study also found that at 6 months, participants in the comparison arm had similar quit rates than those in the intervention arm. However, the quit rate at 6 months in the comparison arm was higher than expected. Because participants in the comparison arm received intervention to promote increasing fruits and vegetables, we thought that these participants may have decided to also quit smoking while eating more fruits and vegetables. However, further subgroup analyses did not show any difference in quit rates between those who increased intake of fruits and vegetables during the 6-month study and those who did not. Another possible explanation for the higher-than-expected quit rates in the comparison arm is that participants in this arm were prompted about their smoking status several times when follow-up surveys were administered. Although these participants were not specifically advised to quit smoking, repeatedly asking them about their smoking may have added another component to the intervention, thereby resulting in a higher-than-expected quit rate in the comparison group.

This study has some limitations. First, this is not a nicotine gum efficacy trial because we did not have a placebo arm. Given that numerous studies have showed efficacy of the gum in the general population, an effectiveness study such as ours would be an important contribution to the field. Second, there were wide variations in the number of participants enrolled in each housing development, and most did not meet the anticipated accrual number, which may have limited our ability to detect intervention effects.

Practice Implications

The current study has a number of practice implications for practitioners in the field of health behavior and education. First, it shows that smokers in low-income housing are interested in quitting and will participate in formal smoking cessation programs, especially those that offer pharmacotherapy and counseling. Second, nicotine gum along with MI had no significant effects for smoking cessation in this population. This may be due to poor adherence and satisfaction with nicotine gum as well as moderately high baseline motivation to quit. Qualitative research with smokers in the population assessing their preferences for smoking cessation treatment would be invaluable in informing development of effective cessation programs for this underserved population. Third, we did not find health fairs as efficient locations for recruiting smokers interested in quitting, even when the health fairs are held on the housing development premises. This may be because nonsmokers are the vast majority (approximately 75%) of potential

health fair attendees. It is however possible that recruitment of research participants at health fairs could be more efficient for interventions aimed at changing behaviors such as nutrition and physical activity that are applicable to a larger proportion of the target populations.

In summary, this study found that nicotine gum and MI were not effective for smoking cessation among smokers in low-income housing. In addition to poor usage of the gum by participants, there were also social environmental barriers that made quitting difficult in this population. Future smoking cessation studies in this population should include strategies to promote treatment adherence and address social and environmental barriers to cessation. Reducing smoking-related health disparities in low-SES populations such as residents in low-income housing require interventions that will result in cessation rates similar to that in the general population.

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