

Motivational interviewing to enhance nicotine patch treatment for smoking cessation among homeless smokers: a randomized controlled trial

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ABSTRACT

Aims To assess the effects of adding motivational interviewing (MI) counseling to nicotine patch for smoking cessation among homeless smokers. **Design** Two-group randomized controlled trial with 26-week follow-up. **Participants and setting** A total of 430 homeless smokers from emergency shelters and transitional housing units in Minneapolis/St Paul, Minnesota, USA. **Intervention and measurements** All participants received 8-week treatment of 21-mg nicotine patch. In addition, participants in the intervention group received six individual sessions of MI counseling which aimed to increase adherence to nicotine patches and to motivate cessation. Participants in the standard care control group received one session of brief advice to quit smoking. Primary outcome was 7-day abstinence from cigarette smoking at 26 weeks, as validated by exhaled carbon monoxide and salivary cotinine. **Findings** Using intention-to-treat analysis, verified 7-day abstinence rate at week 26 for the intervention group was non-significantly higher than for the control group (9.3% versus 5.6%, $P = 0.15$). Among participants who did not quit smoking, reduction in number of cigarettes from baseline to week 26 was equally high in both study groups (-13.7 ± 11.9 for MI versus -13.5 ± 16.2 for standard care). **Conclusions** Adding motivational interviewing counseling to nicotine patch did not increase smoking rate significantly at 26-week follow-up for homeless smokers.

Keywords Brief advice, homeless, motivational interviewing, nicotine patch, smoking cessation.

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INTRODUCTION

The prevalence of cigarette smoking among homeless adults remains an alarming 70–80% or greater [1,2], which is two to three times that of the general adult population in the United States.

Because homeless individuals are faced with meeting competing basic survival needs such as finding food and shelter, it is often assumed that smoking cessation is not a priority for this population. However, recent cross-sectional surveys showed that homeless smokers reported a similar level of interest in smoking cessation and quit

attempts compared to the general population of smokers [3,4]. Nicotine replacement alone or in combination with other treatments was the most preferred treatment (42.2%), followed by counseling alone or in combination (24.6%).

Homeless smokers face multiple barriers to accessing and adhering to treatments [5], such as the daily need to find food, clothing and shelter as well as practical limits on accessing and storing medicines. Furthermore, high rates of psychiatric and other substance abuse comorbidity conditions [6] within homeless populations could create additional challenges to adherence to

smoking cessation treatment and ultimately to smoking cessation.

While studies on motivational interviewing (MI) for smoking cessation have yielded mixed results, a recent meta-analysis ($n = 23$ studies) suggests that MI outperformed comparison conditions significantly at long-term follow-up points [7]. Also, MI has been shown to improve treatment adherence and retention [8]. In a pilot study of nicotine patch use among homeless smokers, MI was shown to be a feasible and acceptable intervention; however, MI was not used to address adherence in that study [9]. To date, there are no controlled trials of interventions to improve adherence to self-administered medications that target homeless people specifically. To address this gap we conducted a smoking cessation randomized clinical trial (RCT) among smokers experiencing homelessness, called Power To Quit (PTQ). We tested the hypothesis that MI addressing smoking and nicotine replacement therapy (NRT) adherence will result in higher quit rates among homeless smokers compared to standard care. The current paper describes the smoking cessation (primary) and NRT adherence (secondary) outcomes of the study. Understanding the effectiveness of smoking cessation treatment for this underserved population will assist researchers and health-care providers in developing and implementing smoking cessation interventions for homeless and other vulnerable populations.

METHODS

Study design

This study was a community-based RCT of 430 homeless adult cigarette smokers that assessed the effectiveness of MI for smoking cessation. Participants were randomized to either the intervention arm (nicotine patch + MI) or the control arm (nicotine patch + standard care). At baseline, participants in both groups received a 2-week supply of 21-mg nicotine patches, and every 2 weeks they received an additional 2-week supply of 21 mg nicotine patches. Participants randomized to the intervention arm also received six individual MI counseling sessions, each lasting 15–20 minutes, while participants randomized to the standard care arm received a one-time brief (10–15 minutes) advice session to quit smoking. Participants provided written informed consent before they were enrolled into the study. The study procedures, which have been published elsewhere [10,11], were approved and monitored by the University of Minnesota's Institutional Review Board.

Participant recruitment and randomization

Recruitment occurred from May 2009 to August 2010 at a total of eight homeless shelters in Minneapolis/St Paul,

Minnesota. Recruitment was conducted at health fairs and via staff informational sessions and posted flyers at the study sites. Study eligibility criteria included being currently homeless and having lived in the Twin Cities for ≥ 6 months, having smoked at least one cigarette per day in the past 7 days and at least 100 cigarettes in their life-time, aged ≥ 18 years, and willing to use nicotine patches for 8 weeks and participate in counseling sessions. Participants were classified as homeless based upon the Stewart B. McKinney Act passed by the US congress in 1987, in which homelessness was defined as anyone lacking 'a fixed, regular and adequate nighttime residence' or anyone staying at 'a supervised publicly 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' [12]. Smoking status was confirmed with an exhaled carbon monoxide (CO) monitor using a cut-off of 5 parts per million (p.p.m.). Exclusion criteria included: pregnancy, use of another tobacco cessation aid in the previous 30 days, severe cognitive impairment, suicidal ideation in the last 14 days, a major medical condition within the prior month or scoring >5 on items assessing psychotic symptoms from the nine-item Mini International Neuropsychiatric Interview (MINI) [13].

At the baseline visit, pre-assigned randomization numbers prepared by the study statistician determined into which study arm the participant would be enrolled. The assignment to MI versus standard care was not blinded to participants. Sequential enrollment continued until a total of 430 participants were randomized into the study.

Treatment period

Eligible participants were scheduled for the baseline appointment 7–10 days after the initial contact. At the baseline visit participants were assigned randomly to either the MI intervention arm or to the standard care control arm. All participants received a health educational resource called 'The Power to Quit: A Quit Smoking Guide', a 23-page guide developed by the project investigators. The guide included messages on the health risks of smoking, common reasons for smoking and cognitive exercises to improve self-directed quit attempts.

Intervention components

Motivational interviewing (MI)

Participants randomized to the MI intervention arm received six individual MI counseling sessions, each lasting 15–20 minutes. The MI counseling sessions were conducted by trained counselors and occurred at baseline

and follow-up at weeks 1, 2, 4, 6 and 8. The focus of the MI sessions was encouraging cessation and NRT adherence. Although MI has been used typically to build motivation to quit [7], we also applied the principles and strategies to encourage adherence to the patch.

Standard care

Participants in the standard care control condition received a one-time session of brief advice to quit smoking lasting approximately 10–15 minutes and delivered by trained study counselors [10]. Topics covered in the standard care session included smoking history, current smoking, direct advice about the health risks of smoking and the health benefits of quitting, affirmation of the participant's decision to quit, an assessment of preparedness to quit and addressing strategies for coping with smoking cues.

Retention

To minimize attrition, study staff made reminder calls to participants during the week prior to each appointment, both pending and missed, until the window for completing appointments closed. Calls were placed from the project office and made either to each participant's cell-phone or to the shelter identified as the most recent nighttime residence in the participant's file. At each of the 15 visits, participants received incentives. For participants who attended all 15 sessions, the monetary incentives totaled \$275 over 6 months [10,11].

Measures

All questionnaire items were read to, or along with, the participants by trained research assistants that included master's level public health students, medical students or community mobilizers. Community mobilizers were individuals who had experienced homelessness either themselves or with a family member. At the baseline visit, we assessed demographic and smoking behaviors, psychosocial variables, environmental factors and biological measurements. Demographic variables included age, ethnicity, gender, income, education level, marital status and employment status and homelessness history, including duration and type of homelessness. Psychosocial variables included social support [14,15] and self-efficacy to refrain from smoking using the Smoking Self-Efficacy Questionnaire (SEQ-12) [16]. Psychiatric comorbidities of depression and anxiety were assessed with the four-item Rost–Burnham screener for depression [17], the patient health questionnaire (PHQ-9) for depression [18], the four-item perceived stress scale for stress in past 30 days [19] and the MINI generalized anxiety disorder assessment [13]. Further, study participants were asked

questions about life-time drug treatment history and drug and alcohol use and dependence [17]. Adherence to nicotine patch use was measured by direct observation by study staff at weeks 2, 4, 6 and 8. Participants were asked if they were wearing the patch; for those who answered in the affirmative, study staff then asked to see the patch. Motivation and confidence for adherence to NRT patch was assessed with the Motivation/Confidence to Adhere Scale [20], which is a five-item scale with score range of 1–10 for each item and reflects participants' level of commitment, desire, need and readiness to adhere to smoking cessation. Higher totals indicate higher levels of motivation for adherence (Cronbach's $\alpha = 0.84$); Self-Efficacy to Adhere [21] is a modified 10-item Adult AIDS Clinical Trials Group (AACTG) measure which asks participants to indicate their level of confidence in performing specific adherence tasks relating to treatment. Responses range from 0 (cannot do at all) to 10 (certain I can do). Higher scores indicate higher adherence self-efficacy.

The primary outcome was biochemically verified self-reported 7-day point prevalence abstinence from smoking assessed at week 26 post-randomization, defined as having smoked no cigarettes (not even a puff) during the previous 7 days. Those who self-reported abstinence were verified using an expired carbon monoxide (≤ 10 p.p.m.) test. Salivary cotinine testing was performed if the expired CO was greater than 10 p.p.m. for those who self-reported abstinence. A cut-off of ≤ 20 ng/ml for salivary cotinine was used to verify abstinence. The secondary outcome was adherence to the nicotine patch, measured by direct observation at in-person appointments during the treatment period.

Analysis

The sample size was determined a priori assuming a two-tailed type I error of 0.05, a power of at least 80% and a week 26 biochemically verified quit rate of 18% and 8% for MI intervention and standard care conditions, respectively, based on previous research [9]. The primary analysis was a Yates-corrected χ^2 test of the difference between the proportions quit in the two groups. With these assumptions, using the χ^2 test we needed 214 participants per study arm. With the final sample of 430 participants achieved, we had 83% power (at a 5% significance level) to detect statistically significant main effects. Following intention-to-treat analyses, participants who did not attend the 26-week visits were assumed to be smokers. We also compared CO-verified repeated 7-day abstinence at weeks 8 and 26 using the χ^2 test as a secondary outcome measure. The repeated point prevalence abstinence was defined as participants who

self-reported and verified by CO or cotinine that they were abstinent both at weeks 8 and 26. All the other participants were treated as smokers. We also performed longitudinal analysis using repeated-measures logistic regression with generalized estimating equations for the CO-verified abstinence at weeks 1, 2, 4, 6, 8 and 26, including time (continuous) and intervention group as predictors, using PROC GENMOD in SAS version 9.2 (SAS Institute Inc., 2009 #6990).

RESULTS

Of the 839 individuals screened for study eligibility, 568 were eligible and 430 were randomized, 216 to the MI intervention and 214 to the control group (Fig. 1). Eligible participants who returned for randomization were older and more likely to have a telephone number compared to eligible participants who were not enrolled into the study. Of the 430 enrolled, 76.1% completed their week 8 visit (end of treatment) and 75.4% completed the final week 26 visit. There were no significant differences in attrition rates (Table 4) between the two study groups.

There were no significant differences in baseline characteristics of participants between treatment groups (Table 1). Participants' mean age was 44 years and the majority were male; African American or white; unemployed; high school graduate or equivalent; with a monthly income of less than US\$400. Nearly two-thirds reported often sleeping in emergency shelters and 15% slept in transitional housing in the past 6 months. Participants smoked about a pack of cigarettes a day and 87% smoked their first cigarette of the day within 30 minutes of awakening. More than 80% of the sample screened positive for life-time history of drug abuse or dependence. Self-reported and verified 7-day point prevalence abstinence rates for the MI and control study groups at various assessment points are shown in Table 2.

Using intention-to-treat analysis, 7-day verified smoking abstinence rates at week 8 were 9.3% versus 8.9% ($P = 0.89$) and at week 26 were 9.3% versus 5.6% ($P = 0.15$) for the intervention and control groups, respectively. The repeated point prevalence abstinence rate was 3.24% for the MI group and 1.40% for the standard care group (Fisher's exact test $P = 0.338$). We

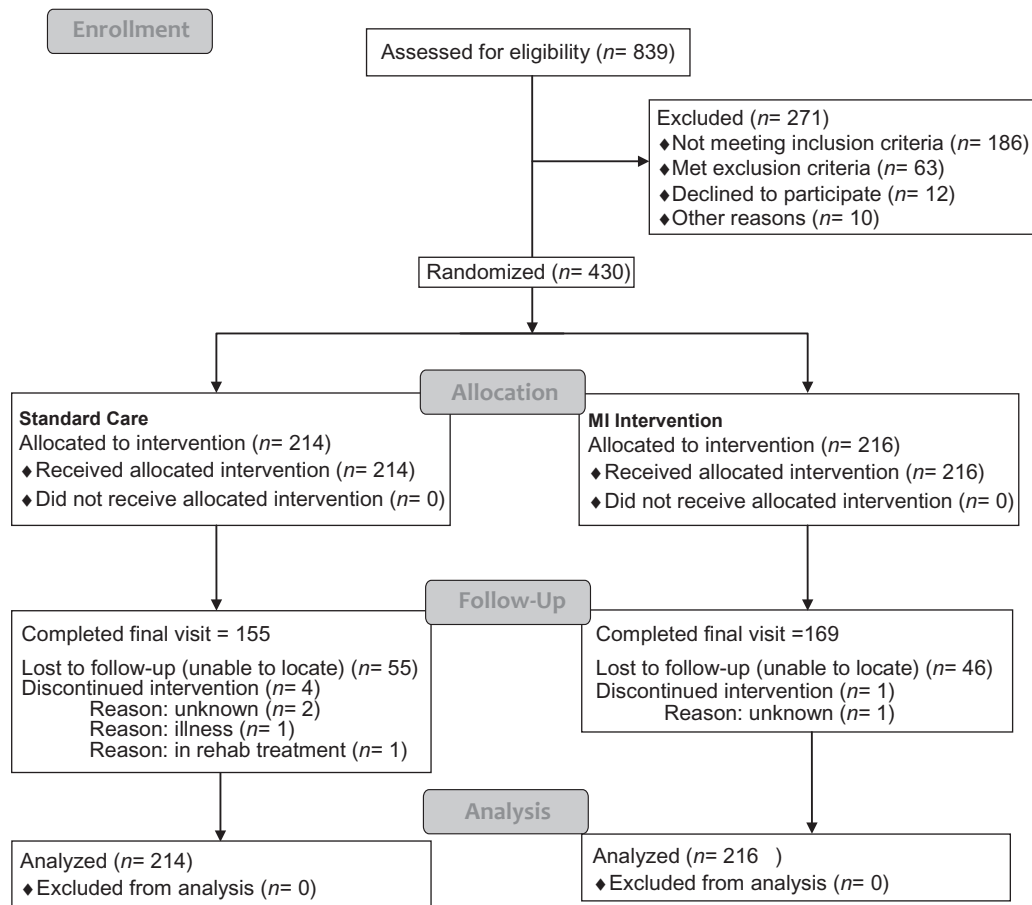


Figure 1 Consolidated Standards of Reporting Trials (CONSORT) [22] flow diagram for the study

Table 1 Baseline characteristics of 430 study participants enrolled into the Power to Quit (PTQ) study.

	Total <i>n</i> = 430	Motivational interviewing arm <i>n</i> = 216		Standard care arm <i>n</i> = 214	
		Mean (SD)	<i>n</i>	Mean (SD)	<i>n</i>
Demographic variables					
Age, mean \pm SD, years	44.4 (9.9)	44.5 (9.7)	216	44.2 (10.1)	214
Male, <i>n</i> (%)	321 (74.7)	158 (73.1)	216	163 (76.2)	214
Race/ethnicity, <i>n</i> (%)					
African American/black	242 (56.3)	130 (60.2)	216	112 (52.3)	214
White, non-Hispanic	153 (35.6)	69 (31.9)		84 (39.3)	
Hispanic/Latino	10 (2.3)	5 (2.3)		5 (2.3)	
Native American/Alaska Native	10 (2.3)	5 (2.3)		5 (2.3)	
Other	14 (2.3)	7 (3.3)		7 (3.3)	
Monthly family income <\$400, <i>n</i> (%)	273 (63.5)	140 (64.8)	216	133 (62.1)	214
Education \geq high school, <i>n</i> (%)	330 (76.8)	166 (76.9)	216	164 (76.6)	214
BMI, mean (SD)	30.1 (7.6)	30.3 (7.8)	215	30.0 (7.5)	211
Psychosocial variables					
Depression (PHQ9, in past 2 weeks), mean (SD)	8.5 (6.4)	8.8 (6.7)	216	8.1 (6.1)	212
PHQ9 \geq 10 in past 2 weeks, <i>n</i> (%)	148 (34.6)	92 (42.5)	216	81 (38.2)	212
Stress (PSS-4, in past 30 days), mean (SD)	8.4 (2.3)	8.5 (2.5)	215	8.3 (2.1)	213
Tobacco-related variables					
Serum cotinine in ng/ml, mean (SD)	213.7 (159.0)	229.2 (179.9)	204	198.3 (133.8)	205
Exhaled carbon monoxide in p.p.m., mean (SD) ^a	15.6 (9.0)	15.0 (8.3)	202	16.2 (9.65)	207
Cigarettes per day, mean (SD)	19.3 (13.7)	19.1 (11.1)	215	19.4 (16.0)	212
Time to first cigarette, \leq 30 minutes, <i>n</i> (%)	374 (87.0)	188 (87.0)	216	186 (87.0)	270
Smoke menthol cigarettes, <i>n</i> (%)	268 (62.6)	138 (64.2)	216	130 (61.0)	214
Number of 24 hours quit attempts in the past year, mean (SD)	2.5 (5.2)	2.5 (5.3)	212	2.6 (5.1)	212
Age started smoking regularly, mean (SD)	16.2 (5.9)	16.3 (6.0)	215	16.1 (5.7)	214
Motivation to quit, mean (SD)	9.1 (1.6)	9.0 (1.8)	216	9.1 (1.5)	214
Confidence to quit, mean (SD)	7.3 (2.4)	7.3 (2.4)	216	7.3 (2.5)	214
Substance abuse variables					
Ever used illicit drug ^a more than 5 times in life-time, <i>n</i> (%)	355 (82.8)	182 (84.3)	216	173 (81.2)	213
Ever needed larger amount of illicit drugs to get an effect, <i>n</i> (%)	170 (39.6)	80 (37.0)	216	90 (42.3)	213
Ever had emotional or psychological problems from using illicit drugs, <i>n</i> (%)	140 (32.6)	65 (30.1)	216	75 (35.2)	213
Ever thought you were an excessive drinker, <i>n</i> (%)	195 (45.5)	95 (44.0)	216	100 (46.9)	213
Ever drank one-fifth of liquor in one day, <i>n</i> (%)	179 (41.7)	90 (41.7)	216	89 (41.8)	213
Ever drank 7 or more alcoholic drinks daily for 2 weeks, <i>n</i> (%)	174 (40.7)	83 (38.6)	216	91 (42.9)	213

BMI = body mass index; MI = motivational interviewing; SC = standard care; SD = standard deviation; PHQ9 = Patient Health Questionnaire-9 Depression Scale; PSS-4 = Perceived Stress Scale, four items; p.p.m. = parts per million. ^aList of drugs included marijuana (hashish, pot, grass); amphetamines (stimulants, uppers, speed); barbiturates (sedatives, downers, sleeping pills, Seconal, Quaaludes); tranquilizers (Valium, Librium); cocaine (coke, crack); heroin; opiates (codeine, Demerol, morphine, methadone, Darvon, opium), psychedelics [lysergic acid diethylamide (LSD), mescaline, peyote, psilocybin, dimethyltryptamine (DMT), phencyclidine (PCP)].

used repeated-measures logistic regression with generalized estimating equations (Fig. 2) for the CO-verified abstinence at weeks 1, 2, 4, 6, 8 and 26, while treating those lost to follow-up as smokers, and included time (continuous) and intervention group as predictors. This yielded an odds ratio for the MI versus standard care group of 1.33 [95% confidence interval (CI): 0.88, 2.02; $P = 0.17$]. If those lost to follow-up were treated as missing, the odds ratio for the MI versus SC group was

1.40 (95% CI: 0.93, 2.11; $P = 0.11$). Among participants that did not quit smoking, reduction in number of cigarettes from baseline to week 26 was equally high in both study groups (-13.7 ± 11.9 for MI versus -13.5 ± 16.2 for standard care).

Table 3 shows results of various measures of adherence. Motivation for adherence scores at week 6 were marginally higher for participants in the intervention group than those in the control group (45.8 ± 6.9 for MI

versus 44.4 ± 7.4 for control, $P = 0.08$). Table 3 also shows results of 'patch checks', i.e. the proportion of participants who had their nicotine patches on at various study visits. There were no differences between study groups in the proportion of participants who had their

nicotine patches on at various study visits. Table 4 shows the attendance for various study contact points.

DISCUSSION

Results from this study show that verified quit rates at weeks 8 and 26 for MI were not significantly better than those for standard care. Although the quit rates for MI were consistently higher at all study time-points, the magnitude of the effects was small.

The 9.3% verified quit rate at week 26 is comparable to findings from a cluster-randomized trial that tested

Table 2 Self-report and biochemically verified 7-day point-prevalence abstinence rates of 430 study participants enrolled into the Power to Quit (PTQ) study.^a

	MI	Standard care	P-value
Self-report			
Quit at week 8, n (%)	33 (15.28%)	26 (12.15%)	0.350
Quit at week 26, n (%)	36 (16.67%)	25 (11.68%)	0.140
Verified			
Quit at week 8, n (%)	20 (9.26%)	19 (8.88%)	0.890
Quit at week 26 n (%) ^b	20 (9.26%)	12 (5.61%)	0.150

^aThose lost to follow-up were treated as smokers; ^bcarbon monoxide (≤ 10 parts per million) or cotinine (≤ 20 ng/ml) verified. MI = motivational interviewing.

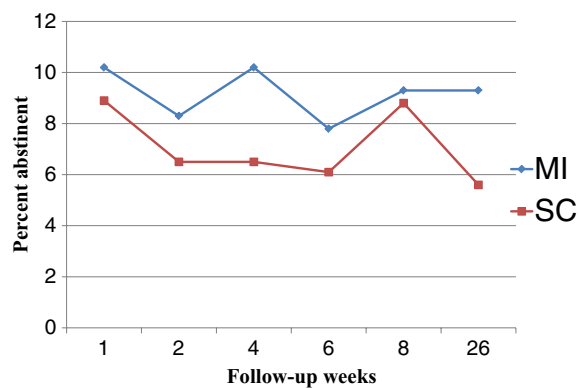


Figure 2 Verified abstinence by time

Table 4 Summary of attendance at study visits of 430 study participants enrolled into the Power to Quit (PTQ) study.

Study visit time-points	Study visit completed			
	SC (n = 214)		MI (n = 216)	
	n	%	n	%
Week 1	191	89.3	189	87.5
Week 2	190	88.8	172	79.6
Week 4	184	86.0	174	80.6
Week 6	171	79.9	159	73.6
Week 8	168	78.5	162	75.0
Week 10	146	68.2	145	67.1
Week 12	143	66.8	155	71.8
Week 14	140	65.4	145	67.1
Week 16	137	64.0	143	66.2
Week 18	142	66.4	146	67.6
Week 20	136	63.6	146	67.6
Week 22	139	65.0	155	71.8
Week 24	141	65.9	156	72.2
Week 26	155	72.4	169	78.2

SC = standard care; MI = motivational interviewing.

Table 3 Adherence measures of 430 study participants enrolled into the Power to Quit (PTQ) study.

Variables	Total (n = 430)	MI (n = 216)	Standard care (n = 214)	P-value
Baseline motivation to adhere, mean (SD)	45.4 (6.5)	45.4 (6.3)	45.3 (6.7)	0.77
Week 6 motivation to adhere, mean (SD)	45.1 (7.3)	45.8 (7.0)	44.4 (7.5)	0.08
Motivation to adhere change in scores from baseline to week 6, mean (SD)	0.02 (8.2)	0.4 (8.4)	-0.4 (8.1)	0.40
Baseline self-efficacy to adhere, mean (SD)	78.4 (17.6)	78.2 (18.0)	78.7 (17.1)	0.76
Week 6 self-efficacy to adhere, mean (SD)	84.1 (18.3)	85.4 (19.1)	82.9 (17.5)	0.22
Self-efficacy to adhere change in scores from baseline to week 6, mean (SD)	5.7 (20.8)	5.7 (22.5)	5.7 (19.2)	0.99
Had nicotine patch on at visit ('patch check'), % yes				
Week 1	52.8	49.1	56.5	0.12
Week 2	52.6	49.1	56.1	0.15
Week 4	44.7	46.8	42.5	0.38
Week 6	38.6	40.7	36.5	0.36
Week 8	33.7	33.8	33.7	0.97

SD = standard deviation; MI = motivational interviewing.

nicotine gum plus five MI sessions for smoking cessation in 20 low-income housing developments ($n = 173$) [23]. For that study, biochemically verified 7-day abstinence rates were 6.1% versus 5.6% at week 8 and 7.6% versus 9.3% at week 26 for the intervention and comparison groups, respectively. However, the quit rates in our current study are lower than rates reported from two pilot studies with homeless smokers [9,24]. In one study ($n = 46$) [9], which utilized five individual MI, six group meetings and a choice of NRT, CO-verified abstinence rates at week 26 were 17.4% versus 8.7% for intervention and comparison groups, respectively. The second study [24] ($n = 58$), which had no control group, tested the effects of a 12-week group cognitive-behavioral therapy and choice of NRT, bupropion or varenicline and reported a CO-verified quit rate of 13.6% at 24 weeks. These pilot studies had more intensive counseling interventions that may have contributed to higher quit rates. There are other reasons that could contribute to the low quit rates in our current study. In addition to multiple competing challenges that being homeless could pose to smoking cessation, our study sample had characteristics suggestive of high nicotine dependence, including factors such as smoking a pack of cigarettes per day on average, and nearly all participants smoked their first cigarette of the day within 30 minutes of awakening.

In addition, our study sample showed high rates of comorbidities with depression, alcohol and other substance abuse, with nearly 40% having PHQ-9 scores in the moderate or worse depression range; nearly half considered themselves as alcoholic or chemically dependent. Studies in other populations have shown that these comorbidities make quitting smoking more challenging [2,25,26]. In essence, our study had a lower dose of counseling and higher rate of comorbidities than the two studies described above. Unlike the protocol of most smoking cessation studies in the general population, that excludes smokers with these comorbid conditions, smokers with these conditions were allowed to enroll in this study provided they were medically stable, as determined by a psychiatrist. This protocol decision was made to ensure that the study sample was similar to homeless smokers in general, which would enhance the study's external validity.

Given the challenges to smoking cessation in homeless populations, it could be argued that even these low cessation rates are probably higher than secular trends in this population and are therefore encouraging. These results highlight that homeless smokers are interested in quitting smoking and will enroll in a smoking cessation trial. Also, 75% of eligible participants returned for randomization and 75% of those enrolled completed their final week 26 visit. These results, regarding interest

within homeless populations in smoking cessation, are consistent with findings from earlier studies [3,27,28]. However, these findings are in direct contrast to the presumption by some that homeless people would not be interested in smoking cessation due to many competing daily challenges, or that follow-up for longitudinal studies would be nearly impossible because of their transient housing situation.

This study also found that, contrary to expectations, MI did not improve adherence measures among participants who received MI. The lack of effect of MI to promote treatment adherence is contrary to several studies [8] that have reported large effects of MI in promoting treatment adherence. It should be noted, however, that despite not requiring motivation to quit or adhere to treatment as study enrollment criteria in the current study, participants reported high motivation to quit smoking as well as high motivation and self-efficacy to adhere to nicotine patch use. Having less favorable outcomes with MI is consistent with other studies in non-homeless settings that have shown that MI works better among people who are resistant, angry or demonstrate low motivation to change a particular health behavior [29], and therefore may be contraindicated for patients who are ready for action. Another study [30], in a non-homeless sample, found that MI was less effective than health education for smoking cessation among a sample of African American light smokers who were highly motivated to quit smoking at study enrollment.

This study has many strengths. To our knowledge, this is the largest and the first adequately powered randomized smoking cessation clinical trial in homeless populations. We successfully randomized a diverse sample of 430 homeless smokers in 15 months. We were able to achieve a study sample that is reflective of the general homeless population of the same community [1,31]. We also achieved 75% retention for 26 weeks. This suggests that smokers, regardless of their housing situation, want to quit and can be successful in doing so when provided with the opportunity.

This study has limitations. First, it was conducted at a single metropolitan area in the upper Midwest of the United States and there may be differences between cities, states or regions within a country and between countries that limit external validity. However, this generalizability concern is somewhat mitigated by the fact that participants were recruited from a variety of emergency shelters and transitional housing units. Data about emergency shelters from a tri-annual state-wide survey (Wilder Foundation, 2009 #5998) shows that the mean age for homeless people in Hennepin and Ramsey Counties encompassing the Twin Cities were 42.4 years and 42.9 years, respectively, compared to 44.4 years in our study sample. Also, our study sample was 74.7% male, which is

comparable to that in Hennepin (72.7%) but lower than that in Ramsey (86.5%) Counties [31]. Secondly, because this was a treatment study, the sample was self-selected and motivated to quit smoking and thus may not be representative of homeless smokers generally. The high motivation of participants may also have made MI less effective, as MI is best suited for less motivated people [7,30]. However, the sample represents the group of smokers who would seek smoking cessation treatment if it were to become available in homeless populations.

Our results reveal that despite many competing daily challenges, homeless smokers are interested in smoking cessation and that motivational interviewing and nicotine replacement showed promising effects for smoking cessation for homeless populations. The low quit rate in this study calls for more studies and programs to enhance smoking cessation rates in homeless populations. It is possible that other counseling approaches, besides MI, might be more effective, or perhaps more intensive interventions are needed for smokers experiencing homelessness. Due to the high rates of psychiatric and substance abuse comorbidities in this population, will intervening in these comorbid conditions concurrently or in sequence result in improved smoking cessation rates? Because of the strikingly high prevalence of smoking and associated morbidity in homeless populations, developing and implementing programs to improve smoking cessation outcomes is critical for reducing the tobacco-related health disparities in homeless and other underserved populations.

Clinical trial registration

Trial Registration: clinicaltrials.gov: NCT00786149.

Declarations of interest

None.

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