Special Article – Tobacco and Smoking Cessation

Predictors of Adherence to Nicotine Replacement Therapy (Nicotine Patch) Among Homeless Persons Enrolled in a Randomized Controlled Trial Targeting Smoking Cessation

Ojo-Fati O[1,2]*, Thomas JL[2,3,4], Vogel RI[4,5], Ogedegbe O[6], Jean-Louis G[6] and Okuyemi KS[1,2,4]

[1]Department of Family Medicine and Community Health, University of Minnesota, Minneapolis, MN, USA
[2]Program in Health Disparities Research, University Of Minnesota, Minneapolis, MN, USA
[3]Department of Medicine, University of Minnesota, Minneapolis, MN, USA
[4]Masonic Cancer Center, University of Minnesota, Minneapolis, MN, USA
[5]Department of Obstetrics, Gynecology and Women's Health, University of Minnesota, Minneapolis, MN, USA
[6]Department of Population Health, New York University School of Medicine, New York, NY, USA

*Corresponding author: Ojo-Fati O, Program in Health Disparities Research, University of Minnesota Medical School, 717 Delaware Street SE, Suite 166, Minneapolis, MN 55414, USA

Abstract

Introduction: Adherence to smoking cessation treatment is generally low, especially among socio-economically disadvantaged groups including individuals experiencing homelessness and those with mental illnesses. Despite the high smoking rates in homeless populations (~70%) no study to date has systematically examined predictors of adherence to nicotine replacement therapy (NRT) in this population.

Objective: The aim of this secondary analysis was to identify predictors of adherence to NRT in a smoking cessation trial conducted among homeless smokers.

Methods: Secondary analysis of data from a randomized controlled trial enrolling 430 persons who were homeless and current cigarette smokers. Participants were assigned to one of the two study conditions to enhance smoking cessation: Motivational Interviewing (MI; 6 sessions of MI + 8 weeks of NRT) or Standard Care (Brief advice to quit+ 8 weeks of NRT). The primary outcome for the current analysis was adherence to NRT at end of treatment (8 weeks following randomization). Adherence was defined as a total score of zero on a modified Morisky adherence scale). Demographic and baseline psychosocial, tobacco-related, and substance abuse measures were compared between those who did and did not adhere to NRT.

Results: After adjusting for confounders, smokers who were depressed at baseline (OR=0.58, 95% CI, 0.38-0.87, p=0.01), had lower confidence to quit (OR=1.10, 95% CI, 1.01-1.19, p=0.04), were less motivated to adhere (OR=1.04, 95% CI, 1.00-1.07, p=0.04), and were less likely to be adherent to NRT. Further, age of initial smoking was positively associated with adherence status (OR= 0.83, 95% CI, 0.69-0.99, p=0.04).

Conclusion: These results suggest that smoking cessation programs conducted in this population may target increased adherence to NRT by addressing both depression and motivation to quit.

Trial Registration: clinicaltrials.gov: NCT00786149.

Keywords: Smoking cessation; Adherence; Homeless populations; Nicotine replacement therapy; Patch; Randomized controlled trials

Introduction

Tobacco use remains the most common preventable cause of death in the United States with more than 480,000 deaths reported annually [1]. The impact of tobacco use on health in the general population is overwhelming. In addition, secondhand smoke is associated with almost 50,000 deaths per year in the United Sates alone [2]. Efforts made to reduce the prevalence of tobacco use and the exposure to environmental tobacco smoke has contributed to a 50% decline in smoking rates in the past 25 years. However, smoking prevalence remains high among several socio-economically disadvantaged groups including the homeless (~70%) and patients with mental illnesses [3-6]. Tobacco related illnesses such as lung and esophageal cancer, coronary heart disease, and respiratory diseases are the primary causes of death among persons who are homeless [1,7-9].

One factor that has been shown to directly affect the success of smoking cessation treatment is adherence to pharmacotherapy, which might be an especially salient issue for homeless persons [10,11]. NRT use has been shown to increase cessation rates by 60% [12-14] and has been found to be effective even without behavioral treatment [10,15-17]. Despite proven efficacy, adherence to NRT has been poor in clinical trials especially among socioeconomically-

disadvantaged groups [4,11,18,19]. Adherence to smoking cessation treatments in the homeless population could be significantly affected by several variables unique to this community including high levels of high prevalence of illicit drug use, HIV/AIDS, and mental illness, stress, and competing needs [20,21]. In studies in non-homeless populations, some baseline variables have been found to influence adherence to therapy. A recent review examined the effectiveness of interventions to improve adherence to medications for nicotine dependence [22]. The review found that adherence interventions led to marginal improvements in adherence, with a relative risk (RR) of 1.14 (95% CI, 1.02 to 1.28, P = 0.02, n = 1630). In addition to the multiple barriers that homeless smokers face, studies have shown that psychological factors including depression, stress, and generalized anxiety disorder that might impact smoking cessation are also highly prevalent in homeless populations [23-25]. Thus, adherence to smoking cessation treatment under these circumstances can be challenging. Unfortunately, little is known about effective cessation interventions among homeless populations. Low rates of medication adherence among the homeless suggest that adherence to NRT might be low and merit special attention in any pharmacotherapy trials. To date there are no controlled trials of interventions to improve adherence to self-administered medications, such as nicotine replacement therapy, that specifically target homeless persons. Even in the general population, adherence to treatment has limited NRT's effectiveness especially in real-world settings [19]. Considering the presence of numerous barriers to medication adherence in homeless populations, problems with adherence to NRT is likely to be of a greater magnitude in homeless populations. This study broadly addresses these gaps in the literature.

To the best of our knowledge no published studies have identified the predictors of adherence to NRT in homeless populations. Most medication adherence studies among homeless persons focus on HIV and tuberculosis medication treatment. Studies indicate that even when these medications are provided free of charge, adherence rates can be low [26].

The purpose of this study was to conduct a secondary analysis to identify the predictors of adherence to smoking cessation treatment among 430 smokers who are homeless participated in a community-based smoking cessation trial. The randomized controlled trial [RCT] known as *Power To Quit (PTQ)* was the first published smoking cessation RCT in a homeless population [19,27]. Increased understanding of factors associated with adherence to nicotine patch in smokers who are homeless has a high potential to inform effective smoking cessation interventions for this population.

Methods

Study design

The PTQ study was approved and monitored by the University of Minnesota's Institutional Review Board. Study methodology, design and primary outcomes of the trial have been fully described elsewhere [4,27]. The PTQ study was a two-arm randomized controlled trial [RCT] of 430 homeless adult smokers that compared Standard Care (one-time brief advice to quit smoking) with six Motivational Interviewing (MI) sessions. All participants received nicotine patches (21mg) for eight weeks.

Participant eligibility and recruitment

Detailed eligibility criteria have been discussed and published elsewhere [19]. In summary, inclusion criteria included being currently homeless [2], smoked at least 5 cigarettes per day, smoked at least 100 cigarettes in lifetime, and smoked at least one cigarette every day over the past 7 days, aged 18 years or older, willing to use a nicotine patch for 8 weeks and participate in counseling sessions, and willing to complete 15 total appointments (6 during NRT treatment, 8 retention contacts, and a final exit interview survey) over a 26-week study period. Informed consent was obtained from each participant before the initiation of any study procedures. Additional eligibility criteria included living in the mid-west region of the United States for at least 6 months and planning to stay in the area for the next 6 months; and for women, not currently pregnant and willing to use birth control. Participants were deemed ineligible for the study if they had cognitive impairment, suicidal ideation in the last 14 days, a major medical condition (heart attack or stroke) within the prior month, or scored greater than 5 on items assessing psychotic symptoms from the Mini International Neuropsychiatric Interview (M.I.N.I.) [28] or used another tobacco cessation aid (e.g., patch, gum) in the previous 30 days.

Intervention components

Intervention components of the study have been described in detail elsewhere [27] and are summarized briefly below.

Nicotine patch

The patch was chosen as the NRT to use for this study among homeless smokers because of its cost-effectiveness, availability, easy dosing and efficacy [29,30]. The patch has been proven to be safe and effective for smoking cessation [16,17,30]. Further information gathered during the pilot clinical trial that informed the final design of this RCT found that 70% of participants chose the patch and 30% chose the lozenge when both were offered. All participants received 21mg nicotine patches along with use instructions at baseline. Study staff distributed a two-week supply of 21-mg nicotine patches to participants in both groups at randomization and each follow-up visit.

Motivational interviewing

Motivational Interviewing (MI) is designed to enhance motivation for behavior change [31]. Participants randomized to the intervention arm were offered six 20-minute MI counseling sessions from trained counselors. MI counseling sessions occurred at baseline and weeks 1,2,4,6, and 8. The target behavior for the MI sessions was NRT adherence and smoking cessation.

At the initiation of the project, MI counselors received two full days of training on the theory and method of conducting MI counseling sessions followed by approximately 40 hours of supervised training by a licensed clinical psychologist trained in MI. Ongoing fidelity monitoring was conducted by weekly group meetings in which audio taped sessions were reviewed and corrective feedback provided. Approximately 10% of each counselor's weekly sessions were reviewed using the motivational interviewing treatment integrity (MITI) code 3.0 scoring criteria [32].

Table 1: Baseline Variables and Association with Adherence to NRT at Week 8 (End of Treatment) (N=430).

	Not Adherent to NRT N=246		Adherent to NRT N=184		
	N	%	N	%	p value
Randomized Group					0.29
Motivational interviewing	129	52.4	87	47.3	
Standard care	117	47.6	97	52.7	
Demographic Variables					
Age, mean±SD, years	245	44.3±10.1	183	44.4±9.8	0.88
Male	186	75.6	135	73.4	0.60
Race/ethnicity					0.15
African American/Black	147	59.8	95	51.6	
White, nonHispanic	78	31.7	75	40.8	
Other	21	8.5	14	7.6	
Monthly family income <$400	157	67.4	116	65.5	0.69
Education ≥ high school	185	75.2	145	78.8	0.38
General Health					0.19
Excellent	36	14.8	31	16.9	
Very Good	68	27.9	45	24.5	
Good	88	36.1	56	30.4	
Fair	39	16.0	45	24.5	
Poor	13	5.3	7	3.8	
Body mass index, mean±SD, kg/m2	242	29.7±7.5	184	30.7±7.7	0.16
Number of times homeless in past 3 years					0.98
1	106	43.3	79	43.2	
2	62	25.3	45	24.6	
3 of more	77	31.4	59	32.2	
Psychosocial Variables					
Depression PHQ9 ≥10	114	46.7	59	32.1	0.002
Stress (PSS4, past 30 days), mean±SD	246	8.7±2.8	184	8.2±2.5	0.06
Tobaccorelated variables					
Cigarettes per day, mean±SD	244	19.3±10.6	183	19.1±17.1	0.90
Time to first cigarette ≤30 minutes	216	87.8	158	85.9	0.56
Smoke menthol cigarettes	161	66.0	107	58.2	0.10
Number of 24 hour quit attempts past year, mean±SD	241	2.7±6.0	183	2.3±3.9	0.32
Age started smoking regularly, mean±SD	245	16.7±6.2	184	15.6±5.4	0.06
Motivation to quit, mean±SD	246	9.0±1.6	184	9.1±1.6	0.50
Confidence to quit, mean±SD	246	7.1±2.4	184	7.5±2.4	0.05
Substance abuse variables					
Ever use illicit drug more than 5 times in lifetime	204	83.3	151	82.1	0.74
Ever thought you were an excessive drinker	118	48.2	77	41.9	0.19
Ever been treated in outpatient alcohol/drug program	135	55.3	92	50.0	0.27
Baseline adherence measures					
Motivation to adhere, mean±SD	245	44.8±6.9	184	46.0±5.9	0.05
Self-efficacy to adhere, mean±SD	245	78.3±16.8	184	78.4±18.4	0.92

Standard care

Participants in the Standard Care control condition received one-session of brief advice to quit smoking. This session was based on the US Public Health Service's Guidelines [33] and was delivered by trained study counselors who did not provide MI counseling. During the 10-15 minute standard care session counselors assessed participant smoking history, current smoking and readiness to quit; provided direct advice about the health risks of smoking and the health benefits of quitting and strategies for coping with urges, and affirmed the participant's decision to quit.

Outcomes and measurements

Adherence: This study attempted to address the challenge of using self-reported data on patch adherence by using an innovation shown to address shortcomings adapted from the literature on ART adherence [34]. Adherence was defined as a total score of zero in a modified Morisky adherence scale at end of NRT treatment (8 weeks) [35]. The Morisky scale is comprised of 4 items with a scoring system of "Yes" = 1 and "No" = 0. The four items are; 1) Did you ever forget to use your nicotine patch? 2) Are you careless at times about using your nicotine patch? 3) When you feel better, do you sometimes stop using your nicotine patch? and 4) Sometimes if you feel worse when you use your nicotine patch, do you stop using it? The items were summed to give a range of scores from 0 to 4. Participants scoring >0 were classified as non-adherent. All data collected on the survey forms was entered directly into RED Cap (Research Electronic Data Capture; http://project-redcap.org/). The project manager monitored quality control and endeavored to "clean" the data after completing the study visits/data entry.

Measures: Demographic variables collected as part of the study included age, gender, race/ethnicity, monthly family income, education level, and history of homelessness including number of times homeless and duration of homelessness. Participants were asked when they started smoking regularly, how many cigarettes they smoked per day, time to first cigarette, if they smoked menthol cigarettes, number of 24 hour quit attempts in the past year, motivation to quit and confidence to quit. Psychosocial variables assessed included the patient health questionnaire (PHQ-9) for depression [36], the 4-item perceived stress scale for stress in past 30 days [37], the M.I.N.I. for screening psychosis or cognitive impairment and generalized anxiety disorder assessment [28]. Participants were also asked about drug and alcohol use dependence. The Motivation/Confidence to adhere scale [38], a 5-item scale with a score range of 1-10 for each item reflecting readiness and commitment to adhere to smoking cessation was used to assess motivation and confidence to adhere to NRT patch; Self-Efficacy to adhere [39] measure, a modified 10-item adapted from the Adult AIDS Clinical Trials Group (AACTG) were used to rate self-efficacy to adhere to treatment [40].

Statistical analysis

Demographic, psychosocial, tobacco-related, and substance abuse measures were compared between those who did and did not adhere to NRT using Chi-squared and Fisher Exact tests as appropriate for categorical variables and t-tests assuming unequal variances for continuous variables. A multivariate logistic regression analysis was conducted including randomization group in the model along with variables identified in the univariate analyses (p≤0.10),

Table 2: Multivariate model of factors associated with adherence to NRT.

Variable	Odds Ratio (95% CI)	p-value
Randomization group		0.40
Standard Care	1.00	
Standard Care + Motivational Interviewing	0.84 (0.57-1.25)	
Depression – PHQ-9		0.01
<10	1.00	
≥10	0.58 (0.38-0.87)	
Stress (PSS-4, past 30 days), per 1 point increase	0.93 (0.86-1.02)	0.12
Smoke menthol cigarettes		0.07
No	1.00	
Yes	0.68 (0.45-1.03)	
Age started smoking regularly, per 5 year increase	0.83 (0.69-0.99)	0.04
Confidence to quit, per 1 point increase	1.10 (1.01-1.19)	0.04
Motivation to adhere, per 1 point increase	1.04 (1.00-1.07)	0.04

including age they started regular smoking, whether they smoked menthol cigarettes, and baseline depression, stress, confidence to quit and motivation to adhere. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC) and p-values of <0.05 were considered statistically significant.

Results

As detailed in Table 1, the study sample consisted of 430 persons who were homeless and current cigarette smokers. Participants had a mean age of 44. 4 ± 9.9 years, were African American (56.3%), male (74.7%), unemployed (90.5%), and completed at least high school education or equivalent (76.7%). When looking at factors associated with adherence separately, those who were depressed (p=0.0002), had lower confidence in their ability to quit smoking (p=0.05) or who were less motivated to adhere to treatment at baseline (p=0.05) were less likely to adhere to NRT.

The multivariate analysis found that smokers who were depressed at baseline (p=0.01), had lower confidence to quit (p=0.04) and were less motivation to adhere (p=0.04) remained statistically significantly less likely to be adherent to NRT (Table 2). In addition, younger age at starting smoking was positively associated with adherence to NRT (p=0.04).

Discussion

The primary objective of this study was to examine the predictors of adherence to NRT (nicotine patch) among smokers who are homeless. This study found that depression and motivation to quit were associated with adherence to NRT treatment. Previous studies have shown that factors impacting adherence to smoking cessation in the homeless population are an important consideration due to the challenging circumstances that this population faces [4,6,23,24]. Our findings are consistent with previous studies in the general population that have reported variables, such as age, gender, racial/ethnic background, history of psychiatric co-morbidities [41] weight gain [33] craving and withdrawal symptoms as being potential predictors of patch adherence. Also, active drug, alcohol abuse or misuse and depression are a consistent predictor of poor adherence

[40,42]. These factors disproportionately affect the homeless, many of whom are uninsured, have high rates of poor physical and mental health and substance abuse problems. Depression is one of the most common mood disorders seen among persons who are homeless with a prevalence of about 50% [43] and is an important psychological factor associated with smoking cessation. Consistent with our findings, studies have reported that a higher prevalence of depressive symptoms could increase the risk of non-adherence to treatment [40]. In our study, smokers who were depressed at baseline as defined by a PHQ-9 score of 10 or higher were less likely to be adherent to NRT at end of an 8-week course of treatment. Cognitive–behavioral therapy sessions emphasizing social support have been found to increase adherence among smokers with a history of depression [44]. These findings have important implications for the treatment of depression prior to or concurrent with making a quit attempt.

Within the general population, adherence to NRT is variable, but those who do adhere to recommended doses usually achieve better cessation outcomes [14,30]. A large adherence study that investigated the predictors of adherence in two RCTs comparing active drug to placebo found that age, 7-day point prevalence abstinence at Week 2 and number of cigarette per day are strong predictors of adherence to treatment [45].

The current study also found that additional factors, such as younger age of smoking initiation, greater confidence to quit, and motivation to adhere, were positively associated with adherence to NRT, which is consistent with several studies in non-homeless populations [16]. Younger age of smoking initiation translates into longer duration of tobacco use, thus increasing the likelihood of dependence and ultimately, the risk of development of tobacco-related diseases and mortality [46]. Furthermore, younger age could be associated with increased regularity in smoking, increased cigarettes per day (CPD) and dependence which might increase motivation to use the patch because of increased withdrawal symptoms. A satisfactory explanation of this link will require further research. Alterman et al. [17] concluded that greater dependence on tobacco was associated with less patch use, indicating that patients who smoked more cigarettes per day were less adherent to treatment with patches.

Motivation is a key factor for adhering to treatment [47]; a positive association has been shown between motivation and adherence to medication. Therefore smoking cessation conducted in this population should target motivation [31,47] by integrating motivational interviewing, into their interventions. Counselors must be skilled in developing and increasing the confidence to quit and motivation to adhere to treatment in these smokers because, while most of the smokers in this population have been found to be highly motivated [11], they lack the confidence in their ability to adhere to treatment.

Strengths of the current study included being the first study to examine predictors of nicotine patch adherence among homeless smokers. Given that adherence to pharmacotherapy is key to quitting smoking, and adherence tends to be poor, better understanding of the factors relevant to adherence to nicotine patch and other medications is important. There are some limitations in this study. First, the results may not be generalizable to homeless populations in other regions of the US outside the Midwest. Recruitment and enrollment of participants for this study was specific to a subset of the population of smokers in designated homeless shelters. Second, patch count, a more rigorous measure of adherence, was not a feasible method to implement in the study due to the transient nature of this population and the challenging circumstances they face. Rather than this being a limitation, it served as practical lessons learned while conducting a randomized controlled trial of smoking in the homeless population. Future research done in this population should include sampling methods to validate the degree to which self-report should be trusted.

Conclusions

There are limited empirical data about how to help homeless smokers quit smoking. Further, quit rates are low in homeless populations. It is therefore critical to address factors including depression, confidence to quit, and motivation while developing clinical trials in this underserved population. Increasing NRT adherence among homeless smokers has the potential to enhance the ability of smokers who are homeless to quit smoking.

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