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Predictors of attendance in a randomized clinical trial of nicotine replacement therapy with behavioral counseling

Freda Patterson, Christopher Jepson, Vyga Kaufmann, Margaret Rukstalis, Janet Audrain-McGovern, Susan Kucharski, Caryn Lerman*

University of Pennsylvania, Transdisciplinary Tobacco Use Research Center, 3535 Market Street, Suite 4100, Philadelphia, PA 19104, USA

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Abstract

Participant attendance at smoking cessation-counseling sessions is an important factor in treatment outcome. In this study, we examined the influence of demographic, psychological, and smoking history variables on attendance at a randomized clinical trial comparing transdermal nicotine and nicotine nasal spray that included seven sessions of behavioral group counseling. Of the 353 participants, 70.5% attended all seven sessions. Perfect attendance predicted abstinence from cigarettes at the end of treatment and at 6-month follow-up. In a logistic regression model, higher levels of education and higher body mass index were significant independent predictors of better attendance. There was a significant interaction between type of nicotine replacement (transdermal nicotine vs. nasal spray) and sex: females were less likely than males to have perfect attendance in the nasal spray group, but there was no sex difference in attendance for the transdermal nicotine group. These findings suggest that smokers with lower body mass index and less formal education may benefit from proactive counseling to address individual barriers to attendance at smoking cessation counseling. Additional research in this area would also be valuable to evaluate strategies to promote attendance in these high-risk groups.

Keywords: Attendance; Retention; Nicotine replacement therapy; Smoking cessation program

1. Introduction

Compliance with smoking cessation treatment (e.g. attendance at counseling sessions, taking medication regularly) has been shown to predict tobacco abstinence (Alterman et al., 1999). To date, however, only a small body of literature has identified predictors of attendance at smoking cessation programs. In a 6-session workplace smoking cessation program, participants with lower baseline carbon monoxide (CO) levels were significantly less likely to drop out of treatment (Klesges et al., 1988). In a population of smokers with a history of depression, participants who were older, had higher levels of education and smoked fewer cigarettes at baseline had higher attendance rates (i.e. attended more sessions) in a 13-week program (Ginsberg et al., 1997). Other pre-treatment variables identified as predictors of attendance include: higher levels of depression symptoms (Catley et al., 2003; Curtin et al., 2000), gender (Whitlock et al., 1997), and lower levels of body mass index (BMI) (Mizes et al., 1998). In addition, Caucasians have been reported to be more likely to seek assistance for smoking cessation (Zhu et al., 2000); thus it is plausible that there may also be racial differences in program attendance. Understanding factors that influence smoking cessation program attendance could help improve treatment outcome.

Nicotine replacement therapy (NRT) is now widely used as a first-line treatment for smoking cessation (USPHS, 2000). Transdermal nicotine (TN) and nicotine nasal spray (NS) have been shown to double the odds of long-term abstinence in smokers (Fiore et al., 1994; Silagy et al., 2002; Transdermal Nicotine Study Group, 1991). To our knowledge, the influence of different NRTs on attendance in a smoking cessation treatment program has yet to be evaluated. To fill this gap, we examined the influence of NRT type (TN vs. NS) and pre-treatment characteristics (e.g. race, education, gender, nicotine dependence, BMI) as

* Corresponding author. Tel.: +1-215-746-7141; fax: +1-215-746-7140.
E-mail address: clerman@mail.med.upenn.edu (C. Lerman).

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predictors of attendance at seven sessions of behavioral counseling in the context of a randomized, open-label smoking cessation clinical trial. We predicted that participants assigned to receive NS would have lower attendance rates than those assigned to TN, since aversive side effects during the first week of treatment are more common for NS than TN (Hjalmarson et al., 1994). To examine the possibility that different factors might predict attendance outcomes across the two treatment groups, we also tested for interaction effects of treatment type with participants' pre-treatment characteristics. Finally, we determined whether attendance was a significant predictor of abstinence from cigarettes at end of treatment and at 6-month follow-up.

2. Methods

2.1. Study participants

Eligible participants were at least 18 years old and smoked ≥10 cigarettes per day for the last year. Exclusion criteria included pregnancy, uncontrolled hypertension, heart attack or stroke within the past 6 months, insulin dependent diabetes, daily medication for asthma, substance dependence, skin allergies or chronic dermatitis, current diagnosis or history of psychotic disorders, and current use of bupropion or nicotine products other than cigarettes.

Of the 388 participants who were enrolled into the study between February 2000 and August 2002, 353 (91%) received the first two sessions of treatment and were included in this intent-to-treat (ITT) analysis. The 35 non-ITT cases were excluded from analyses for two reasons. First, it was not possible to examine the effects of treatment type (TN vs. NS) on attendance in this group since they did not receive medication. Second, associations of attendance with smoking outcomes could not be evaluated in this group since they were not followed for smoking outcomes. When compared to ITT cases, non-ITT participants did not differ significantly in BMI, gender, education, nicotine dependence or number of cigarettes smoked per day at baseline. Non-ITT participants, however, were more likely to be non-white (X^2 ($N = 387$, 1 df) 9.23, $P = 0.002$).

2.2. Procedures

2.2.1. Recruitment and eligibility screening

Smokers responding to advertisements, and those referred by physicians, completed an initial eligibility screening by telephone and attended a study orientation. After participants provided written informed consent, a brief medical history and physical examination were performed to confirm eligibility. Eligible, consenting participants also provided a blood sample and completed pre-treatment self-report questionnaires (see Section 2.3, below). All procedures were reviewed and approved by the University of Pennsylvania Institutional Review Board.

2.2.2. Nicotine replacement therapy

Participants were randomized to receive either nicotine nasal spray (NS; Nicotrol) or transdermal nicotine (TN; Nicoderm CQ) treatment. NRT use was initiated on the target quit date (TQD; week 3) and continued for an 8-week period. NS participants were shown how to self-administer a 1.0 mg test dose (0.5 mg NS in each nostril) of NS during session 2 (week 2) and instructed to administer between 8 and 40 doses per day (with a maximum of 5 doses per hour) beginning on the TQD. During each session after the TQD (sessions 3–7), participants returned any unused NS and were given enough NS to last until the following session. Participants were also asked to report on how many NS doses per day they had used in the previous week. After the first 4 weeks of NS use, participants were instructed to taper the number of daily NS doses by one-third for a 2-week period and then by another third for the final 2 weeks of treatment.

TN participants received a single 21 mg TN patch during session 2 (week 2) and were instructed to apply it on the morning of session 3 (week 3, TQD). In addition, all participants were briefed on the appropriate usage and safety considerations for TN. A 24-h dose formulation was used. On the morning of session 6 (week 7) after 4 weeks of 21 mg, participants completed their first 'step-down' to the 14 mg TN patch. Two weeks later, on the morning of session 7 (week 9), participants tapered to the 7 mg TN patch for the final 2 weeks of treatment.

2.2.3. Behavioral counseling

All participants received 7 90-min sessions of standardized smoking cessation behavioral group counseling that included components of education about nicotine addiction, nicotine fading, identification and management of smoking triggers, stress management, problem solving, and relapse prevention. The first 2 weeks of treatment focused on the identification of smoking triggers and nicotine rate fading. During this time, all participants were asked to keep a record of every cigarette they smoked and the circumstances surrounding the smoking of that cigarette (e.g. after a meal, with coffee, while feeling stressed, etc.). In this way, awareness of smoking triggers and smoking rate could be raised, and appropriate coping strategies devised. Participants were asked to reduce the number of cigarettes they smoked by 15% in both the first and second week of the program in preparation for their target quit date (TQD).

Counseling sessions after the TQD focused on behavioral coping skills (e.g. deep breathing and relaxation techniques, time management, soliciting social support and slip management) and the evaluation of coping methods participants were using to manage withdrawal symptoms and smoking triggers. Typically, each session would provide participants the opportunity to describe any challenging

situations or notable events they may have encountered in their quit attempt since the last session and to receive feedback from group members and/or the counselor. Each group had approximately 10–15 participants. All counseling was delivered by two Masters level counselors, who led an equal number of TN and NS groups and received weekly supervision to ensure protocol adherence. TN and NS groups were held separately, to avoid communication between participants receiving different forms of treatment. Participants who missed a session were contacted and offered an opportunity to make up the session. During a make-up session, participants watched a video of the missed session, talked briefly (about 15 min) with their smoking cessation counselor, and received NRT for the following week. Participants who did not complete a make-up session (i.e. were documented as absent for that session) generally did not receive NRT. Participants earned $5 for each counseling session attended (up to $35) and $15 for completing end-of-treatment surveys. Study paraphernalia (e.g. pen, water bottle, squeezable stress ball, and a t-shirt) were also distributed at three different sessions. All participants who reported quitting smoking at end of treatment (EOT) were given $30 for in-person biochemical verification (they were informed of the incentive for the in-person clinic visit only after smoking status was determined).

A standard timeline follow-back self-report method (Brown et al., 1998) was used to assess smoking behavior from the target quit date (TQD) to EOT (8 weeks post-TQD) and to 6-month follow-up (6 months post-TQD).

2.3. Measures

2.3.1. Pre-treatment variables

2.3.1.1. Demographics. Gender, race, and educational attainment were assessed.

2.3.1.2. Body mass index. Body mass index (BMI) was calculated by dividing weight in kilograms by height in millimeters squared. For participants whose height and weight were not measured ($n = 41$), self-reported data were used. BMI was calculated using a correction for self-report developed by Rowland (1990).

2.3.1.3. CES-D. The Center for Epidemiologic Studies-Depression Scale was used to assess the severity of depression symptoms. A score of ≥16 (range 0–60) identifies clinical symptoms of depression (Lerman et al., 1996; Radloff, 1977).

2.3.1.4. Nicotine dependence. The Fagerström Test for Nicotine Dependence (FTND), a six-item self-report measure derived from the Fagerström Tolerance Questionnaire (Heatherton et al., 1991), was used to assess nicotine dependence. This instrument yields a summary nicotine dependence score with a possible range of 0 (low dependence) to 10 (high dependence). One item from this measure was used to assess number of cigarettes smoked per day.

2.3.1.5. Alcohol use. Participants reported the number of glasses of beer, wine, and hard liquor they drank in a typical week. Responses to the three categories were totalled to create an index of drinks consumed per week.

2.3.2. Outcome variables

2.3.2.1. Attendance. Previous studies have utilized either a dichotomous (completed all vs. completed some sessions, e.g. Klesges et al., 1988; Mizes et al., 1998) or continuous (Ginsberg et al., 1997; Patten et al., 2003) outcome attendance variable for analyses. To ensure a comprehensive assessment of predictors of attendance, we performed the analyses using both a dichotomous and continuous attendance variable. Specifically, the dichotomous variable distinguished participants who attended all seven sessions from those who missed at least one session. Participants who completed a make-up session were considered as attenders of that session. This breakpoint was based on the distribution of attendance: 70.5% of the 353 participants included in these analyses attended all seven sessions. These two groups are referred to here as perfect and less-than-perfect attenders. The continuous attendance variable was defined as the number of sessions out of a possible seven attended.

2.3.2.2. Smoking status at follow-up. We used continuous abstinence as the primary outcome measure and 7-day point prevalence as the secondary measure of smoking status at follow-up. For continuous abstinence, treatment failure was defined as 7 consecutive days of smoking at any time between the TQD and the date of follow-up (Hughes et al., 2003). The point-prevalence measure required 7 days of complete abstinence immediately prior to the follow-up point. All participants who reported 7 days of abstinence were asked to complete an in-person session during which a carbon monoxide (CO) test was performed to assess current abstinence status. The CO assessment visit was scheduled after self-report smoking status was obtained. A CO level < 10 ppm was considered to support self-reports of abstinence (SRNT Subcommittee on Biochemical Verification, 2001). Participants who reported 7 days of abstinence but either failed to complete the CO test or provided a CO reading >10 ppm were coded as non-abstinent on the point prevalence measure.

2.4. Statistical analysis

Bivariate associations of the dichotomous attendance variable with demographic characteristics, BMI, nicotine dependence, group (NS vs. TN), alcohol use and smoking status were assessed using χ^2- and t-tests. For the purposes

Table 1
Bivariate associations of continuous abstinence success with attendance (attended all sessions vs. missed >1 session) for overall sample and by treatment group (TN vs. NS)

Attendance	Continuous abstinence at end of treatment				Continuous abstinence at 6 months			
	N abstinent	% abstinent	X^2	*P*	*N* abstinent	% abstinent	X^2	*P*
Overall sample ($n = 353$)			38.1	< 0.001			15.6	< 0.001
Attended all sessions ($n = 249$)	159	63.9			82	32.9		
Missed >1 session ($n = 104$)	29	27.9			13	12.5		
TN group ($n = 176$)			21.5	< 0.001			1.81	0.18
Attended all sessions ($n = 139$)	99	71.2			46	33.1		
Missed >1 session ($n = 37$)	11	29.7			8	21.6		
NS group ($n = 177$)			12.9	< 0.001			14.93	< 0.001
Attended all sessions ($n = 110$)	60	54.5			36	32.7		
Missed >1 session ($n = 67$)	18	26.9			5	7.5		

of these analyses, dichotomous versions of race (white vs. nonwhite) and education (college graduate vs. nongraduate) were used. Bivariate analyses were also repeated separately for participants in the NS and TN groups. A logistic regression model of attendance was estimated that included demographic characteristics (race, gender, and education), BMI, nicotine dependence, group, and all two-way interactions between group and the other predictors. Standardized (Z-transformed) BMI and nicotine dependence scores were used to increase the interpretability of odds ratios. All predictors, including interaction terms, were initially forced into the model as a block, and interaction terms were then allowed to drop out in stepwise fashion (*P*-to-enter = 0.05, *P*-to-remove = 0.10). The Wald statistic was used to assess the contribution of each predictor. SPSS (Statistical Package for the Social Sciences) software was used for all analyses.

All analyses were repeated using the continuous version of the attendance variable. Although the continuous version of the attendance variable is technically a ratio-level variable, it includes only six values (2–7), and is not normally distributed (70% of cases have values of 7). Thus we chose to take the conservative approach and utilized non-parametric tests. Specifically, Mann–Whitney tests and Spearman correlations were used for bivariate analyses and linear regression for the multivariate analysis.

3. Results

3.1. Characteristics of the sample

Over half the sample were female (54%), Caucasian (66%), and college graduates (53%). The mean Fagerström nicotine dependence score was 5.38 (SD = 2.17) while the average number of cigarettes smoked per day was 21.6 (SD = 10.3). Mean BMI was 27.3 (SD = 5.4) (obesity is defined by the National Heart Lung and Blood Institute as having a BMI ≥ 30 (NHLBI, 1998)), and mean number of alcoholic drinks per week was 4.4 (SD = 6.1). The two treatment groups did not differ significantly on any of these variables.

3.1.1. Distribution of attendance

Of the 353 ITT participants in the analysis, 249 (70.5%) attended all seven sessions. Another 38 (10.8%) attended six sessions, and 35 (9.9%) attended 5. The remaining 31 (8.8%) attended between 2 and 4 sessions. Of the perfect attenders, 129 (51.8%) attended at least one make-up session, while 188 (53.3%) of the less-than-perfect attenders attended a make-up session. When non-ITT cases are included ($N = 388$), the attendance rate drops to 64.2%.

3.2. Association of attendance with smoking status

Table 1 shows the associations of the dichotomized attendance variable with the primary measure of smoking status (continuous abstinence success). In the overall sample, participants with perfect attendance were significantly more likely than the less-than-perfect attenders to be abstinent at end of treatment (X^2 ($N = 353$, 1 df) = 38.13, $P < 0.001$) and at 6-month follow up (X^2 ($N = 353$, 1 df) = 15.57, $P < 0.001$). At 6 months, however, the association was limited to participants in the NS group (X^2 ($N = 177$, 1 df) = 14.93, $P < 0.001$); attendance was not significantly associated with abstinence at 6 months in the TN group (X^2 ($N = 176$, 1 df) = 1.81, $P = 0.18$). Similar results were found when the analyses were repeated using the point prevalence abstinence measure. Specifically, at EOT, 41.8% of participants with perfect attendance were abstinent compared to 9.6% of the less-than-perfect attenders (X^2 ($N = 353$, 1 df) = 34.68, $P < 0.001$); and at 6 months the percentages were 22.5 and 6.7% (X^2 ($N = 353$, 1 df) = 12.43, $P < 0.001$). The association at 6 months was limited to the NS group (22.7% of NS participants with perfect attendance were abstinent compared to 3.0% of the less-than-perfect attenders; X^2 ($N = 177$, 1 df) = 12.55, $P < 0.001$); and was nonsignificant in the TN group (22.3 vs. 13.5%; X^2 ($N = 176$, 1 df) = 1.39, $P = 0.24$). All the analyses reported in this section were repeated using the

Table 2
Bivariate associations of predictor variables with attendance (attended all sessions) for the overall sample and by treatment group (TN vs. NS)

Categorical variables	Level	Overall sample			Patch			Spray		
		Attended all			Attended all			Attended all		
		n	%	P^a	*n*	%	P^a	*n*	%	P^a
Group	Patch ($n = 176$)	139	79.0	0.001	–	–	–	–	–	–
	Spray ($n = 177$)	110	62.1		–	–	–	–	–	–
Sex	Male ($n = 163$)	122	74.8	0.100	67	75.3	0.22	55	74.3	0.005
	Female ($n = 190$)	127	66.8		72	82.8		55	53.4	
Race	Caucasian ($n = 232$)	166	71.6	0.22	91	81.3	0.43	75	62.5	0.89
	Non-Caucasian ($n = 120$)	83	69.2		48	76.2		35	61.4	
Education	Non-graduate ($n = 165$)	107	64.8	0.03	69	77.5	0.63	38	50.0	0.004
	College Graduate ($n = 188$)	142	75.5		70	80.5		72	71.3	
Continuous variables	Group	Mean	SD	*P*	Mean	SD	*P*	Mean	SD	*P*
Body mass index	Attended all sessions	27.64	5.38	0.05	27.66	5.58	0.15	27.62	5.14	0.20
	Missed ≥1	26.43	5.26		26.19	4.95		26.57	5.46	
Nicotine dependence	Attended all sessions	5.35	2.24	0.72	5.13	2.19	0.46	5.63	2.29	0.57
	Missed ≥1	5.44	2.06		5.43	2.19		5.45	1.90	
CES-depression	Attended all sessions	11.11	8.21	0.32	11.54	8.72	0.97	10.58	7.53	0.16
	Missed ≥1	12.16	9.19		11.59	9.19		12.47	9.24	
Alcoholic drinks per week	Attended all sessions	4.55	6.37	0.47	4.59	6.58	0.96	4.49	6.13	0.41
	Missed ≥1	4.03	5.45		4.54	5.60		3.75	5.38	

[a] Pearson χ^2 tests for catefgorical variables; *t*-test for continuous variables.

continuous attendance variable and Mann–Whitney tests. The results were essentially identical.

3.3. Bivariate associations

In the overall sample, the proportion of participants with perfect attendance was significantly greater in the TN group than the NS group (X^2 ($N = 353, 1$ df) $= 12.03, P = 0.001$), and among participants with a college degree (X^2 ($N = 353$, 1 df) $= 4.83$, $P = 0.03$). Males were more likely than females to have perfect attendance (X^2 ($N = 353, 1$ df) $= 2.71$, $P = 0.10$). Perfect attenders had higher BMI (body mass index) than less-than-perfect attenders ($t = -1.94$, df $= 351$, $P = 0.05$). Analyses stratified by treatment group assignment indicated that the effects of college education and gender on attendance were observed in the NS group, but not in the TN group (see Table 2). The association between BMI and attendance was in the same direction for both groups (i.e. TN and NS) as in the overall sample, and was not significant in either group ($t = -1.46$, df $= 174$, $P = 0.15$ for TN; $t = -1.29$, df $= 175$, $P = 0.20$ for NS). When bivariate analyses were repeated using the continuous version of the attendance variable, the only notable difference was that the association between BMI and attendance approached significance in the TN group ($r_s = 0.13$, $P = 0.09$).

3.4. Regression modeling

The final logistic regression model of the dichotomized attendance variable is shown in Table 3. Education (OR = 1.92; 95% CI = (1.15, 3.21); $P = 0.012$) and BMI (OR = 1.36; 95% CI = (1.05, 1.77); $P = 0.02$) were significant predictors of attendance. Individuals with at least a college education were about 1.9 times more likely to attend all sessions that those with less educational attainment. An increase of one standard deviation from the mean of BMI was associated with a 36% increase in the odds of perfect attendance. In addition, there was a significant interaction effect between treatment group and sex (OR = 0.23; 95% CI = (0.08, 0.64); $P = 0.005$). Females had significantly lower attendance rates than males in the NS treatment group, and (nonsignificantly) higher attendance rates in the TN group.

Table 3
Final logistic regression model of attendance (1 = attended all 7 sessions)

Variable	Odds ratio	95% Confidence interval	*P*
Group (1 = NS)	0.88	0.42, 1.82	0.72
Sex (1 = female)	1.82	0.84, 3.93	0.13
Race (1 = nonwhite)	0.90	0.54, 1.53	0.71
Body mass index (standardized)	1.36	1.05, 1.77	0.02
Nicotine dependence (standardized)	0.99	0.77, 1.28	0.97
Education (1 = college graduate)	1.92	1.15, 3.21	0.012
Group × sex interaction	0.23	0.08, 0.64	0.005

χ^2 for overall model = 34.2; $P < 0.001$. Original model included all main effect variables shown and all two-way interactions between group and the other predictors. Interaction terms were then allowed to drop out in stepwise fashion (P-to-enter = 0.05, P-to-remove = 0.10).

A linear regression of the continuous attendance variable was carried out using the same predictors. The results were essentially identical; the only notable difference was the less pronounced significance of the group by sex interaction ($B = -0.528$; SE $= 0.242$; $P = 0.03$).

3.5. Exploratory analyses to explain gender by treatment interaction

One possible explanation for the finding that women had poorer attendance than men in the NS group but not the TN group is that women may have had more negative side effects to NS than men. We performed post-hoc analyses to explore this possibility using responses to a side-effect checklist completed by NS and TN recipients at session 4 (1 week after NS and TN treatment began). On this self-report measure participants indicated the extent to which they had experienced each of 17 side effects in the past week, using a scale ranging from 1 ('none') to 4 ('severe'). Three of these side effects were positive (alertness, calmness, and good or 'high' feeling); the rest were negative (e.g. nausea, pounding heart). We created two scales—negative effects (the sum of the 14 negative effect items) and positive effects (the sum of the three positive effect items). Internal consistency of these scales in the overall sample, as measured by Cronbach's alpha, was 0.74 and 0.53, respectively. Among NS participants, mean scores on the negative effect scale were 21.08 (SD = 5.56) for men and 20.91 (SD = 3.81) for women; on the positive effect scale, mean scores were 6.40 (SD = 1.64) for men and 6.34 (SD = 1.57) for women. These differences did not approach significance. We also examined gender differences in the NS group on each of the 17 individual side effect items. For this analysis, a Mann–Whitney (non-parametric) test was used because the variables were ordinal (not interval) and had only four values that in most cases were strongly non-normal in distribution. Only one significant difference among participants in the NS group was found—women reported more headache than men ($Z = 2.05$; $P = 0.04$). In addition, among women in the NS group, none of the items were significantly associated with either the dichotomous attendance variable (using Mann–Whitney tests) or the continuous attendance variable (using Spearman correlations). These results provide little support for the side effect explanation. It should be noted, however, that the results may be affected by participation bias. Eleven (10.7%) of the 103 women in the NS group, and 7 (9.5%) of the 74 men, missed session 4 and thus were excluded from the analyses of side effects reported here. It is possible that some of those who chose not to attend session 4 did so because of side effects.

4. Discussion

The current study is one of the first to examine predictors of attendance to a smoking cessation program in which two treatments (i.e. TN and NS) were delivered. The perfect attendance rate of 70.5% achieved by ITT participants appears comparable with former studies, where retention rates of 66–83.5% have been reported (Curtin et al., 2000; Dobkin et al., 2002). In the final multivariate models, having a college degree and a higher BMI were independent, significant predictors of perfect attendance and number of sessions attended. In addition, the key novel finding of this study was the presence of a treatment group by sex interaction, where females had significantly lower attendance rates than males in NS treatment, but comparable attendance rates to males in TN treatment.

One plausible explanation for the significantly higher dropout rate among females in the NS group as compared to males could be that they experienced more aversive side effects from using NS. Anecdotal reports from group counselors suggested that female participants seemed more likely to comment on the aversive side effects. Although our side-effect data did not support this explanation, it is possible that some relevant side effects were not included in our measure (e.g. watering eyes affecting make-up as reported anecdotally by participants). In addition, anecdotal reports suggested that female participants were more likely to have difficulty using the NS during the test dose (e.g. some women reported that their hands were too small and nails too long to activate the pump effectively).

Another possible explanation may involve differences in both the pharmacokinetic properties of NS and TN, and gender differences in reinforcement sought from smoking. Following administration of TN, levels of nicotine rise slowly and then plateau, providing relief from withdrawal symptoms but minimum positive reinforcement from nicotine (Henningfield, 1995; Henningfield and Keenan, 1993; Hughes, 1993). In contrast, nicotine NS produces rapid peak levels of nicotine, with positive rewarding effects that more closely approximate those achieved from cigarette smoking (Benowitz, 1996; Henningfield, 1995; Johansson et al., 1991). There is a growing body of evidence to suggest that males are more sensitive than females to the positive rewarding effects of nicotine (Killen et al., 1990; Perkins, 1999). Thus, in males, the positive reinforcement derived from rapid nicotine delivery may have compensated for unpleasant side effects, while females may have been less motivated to continue NS. This may have, in turn, prompted reduced attendance to NS treatment sessions among females.

Our finding that higher BMI levels predicted better attendance has been reported previously in a small number of studies (Borrelli et al., 2002; Mizes et al., 1998). Consistent with this, smokers with higher BMI levels have also been found to be more likely to quit and remain quit as compared to those with lower BMI levels (Borrelli et al., 2002; Osler et al., 1999; Perkins et al., 2001). It is plausible that, compared to smokers with a lower pre-treatment BMI, smokers with higher BMI levels may have fewer concerns about

post-cessation weight gain and therefore may be less likely to drop out of a formal smoking cessation program should they experience any weight gain (Borrelli et al., 2001; Klesges et al., 1989; Osler et al., 1999). Given that the average weight gain post-cessation is between 2.4 and 5.0 kg (Froom et al., 1998), this can be a salient issue for many smokers. This line of reasoning is further supported by reports that smokers who are more concerned about post-cessation weight gain are significantly more likely to drop out of treatment (Mizes et al., 1998; Streater et al., 1989) and less likely to sustain abstinence from smoking (Jeffery et al., 2000; Meyers et al., 1997; Streater et al., 1989). Taken together, these data identify pre-treatment BMI and any associated post-cessation weight gain concerns as being integral to both treatment attendance and outcome.

Our results also showed that smokers with higher levels of formal education were significantly more likely to have perfect attendance, but did not support a main effect of gender. These findings contribute to a small body of literature examining the relationship between pre-treatment demographic variables and attendance, which to date has yielded mixed results. Specifically, while some studies have found demographic factors such as gender and education to be unrelated to smoking cessation program attendance (Curtin et al., 2000; Pohl et al., 1998), other studies have shown that females are more likely to enroll in and attend smoking cessation sessions than men (Whitlock et al., 1997; Zhu et al., 2000). With regard to education, higher levels of education have been found to be highly correlated with better attendance in a sample of females with a history of depression (Ginsberg et al., 1997). Similarly, lower levels of education have been hypothesized to contribute to absenteeism from counseling interventions that incorporated numerous paper-based assessments and supplemental written materials (Wilcox et al., 2001). Interestingly, when we conducted some exploratory post-hoc analyses with the sex, education and BMI variables, female college graduates were found to have significantly lower BMIs than non-graduates, while no such difference was reported among males. Given the small body of literature that documents these relationships, further study is warranted to clarify attendance differences based on gender and education and to identify the mediating mechanisms of these relationships.

In contrast to previous studies, our results did not identify a significant relationship between nicotine dependence and program attendance. Studies have shown that individuals who drop out from smoking cessation counseling tended to score higher on indices of nicotine dependence (Curtin et al., 2000; Hall et al., 1984). For example, study drop-outs tended to smoke more cigarettes per day (Curtin et al., 2000) and have higher pretreatment blood cotinine levels (Hall et al., 1984) compared to participants who were retained by the counseling program. One notable difference between these studies and the present study that may account for this disparity is that participants in the present study all received NRT. In the absence of nicotine replacement, highly nicotine dependent participants in the studies cited here may have been more vulnerable to relapse and study attrition; whereas in the present study, the support provided in terms of NRT and NRT tapering may have prompted greater attendance, particularly for highly nicotine dependent participants. This explanation, however, is speculative and requires evaluation.

Our study had some limitations that warrant consideration. First, our assessments did not include a follow-up with participants who dropped out to evaluate why they stopped coming to group. Such an assessment could have provided valuable information about reasons for study attrition. Second, we did not assess other variables that may have influenced attendance, such as the presence of another smoker in the household. Such information would have enabled us to provide a more comprehensive evaluation of attendance to a smoking cessation program. Third, our sample was comprised of mostly Caucasians (66%) and college graduates (53%). The generalizability of our findings to other groups of smokers may be limited. Fourth, although NRT usage was assessed in this study, usage data for each week were collected at the next week's session. As a result, in 91% of instances in which a participant missed a session, that participant had missing usage data for that week, precluding the examination of potentially interesting associations among background characteristics, attendance, and NRT usage. Finally, in the analysis of association of attendance with abstinence, we utilized CO levels to 'verify' self-reports of abstinence. However, given that CO levels provide a reliable biochemical verification of tobacco use in the last 4 h (SRNT Subcommittee on Biochemical Verification, 2001), the possibility of discrepancy between reported and actual smoking status should be considered.

Nevertheless, this study is the first to present data on the predictors of attendance to a NRT based smoking cessation program. An improved understanding of predictors of attendance to a smoking cessation program could provide an empirical basis for tailored counseling to improve attendance, and might therefore enhance treatment outcomes. Data from this study have identified females utilizing NS and participants with lower levels of BMI and education as being particularly vulnerable to dropout and poorer treatment outcome. Future studies should identify the mechanisms that mediate the effects of pre-treatment characteristics on attendance to identify barriers that can be targeted in proactive counseling to smokers at risk for poor attendance.

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