Predictors of Adherence to Nicotine Gum and Counseling among African-American Light Smokers

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BACKGROUND: A high proportion of African-American smokers are light smokers, and they experience low smoking cessation rates and disproportionately high tobacco-related morbidity; yet no studies have examined tobacco treatment adherence in this group.

OBJECTIVES: To determine the predictors of adherence to nicotine gum and counseling among African-American light smokers (defined as smoking ≤ 10 cigarettes/day), and the effects of adherence on smoking cessation.

DESIGN: Data were from a 2 $\times$ 2 randomized, placebo-controlled smoking cessation trial of nicotine gum (2 mg versus placebo) and counseling (motivational interviewing versus health education).

PARTICIPANTS: Seven hundred fifty-five African-American light smokers at a community-based clinic.

MEASUREMENTS: Demographic and health-related information, smoking behaviors, psychosocial variables, adherence to nicotine gum and counseling, and cotinine-verified 7-day abstinence from smoking at week-26 follow-up.

RESULTS: A logistic regression model showed that having a higher body mass index (OR=1.03, 95% CI=1.01 to 1.05), more quit attempts in the past year (OR=1.04, 95% CI=1.01 to 1.07), higher baseline exhaled carbon monoxide (OR=1.22, 95% CI=1.01 to 1.48), and higher perceived stress (OR=1.12, 95% CI=1.03 to 1.22) increased the likelihood of adherence to nicotine gum. Being a high school graduate was a predictor of adherence to counseling (OR=1.58, 95% CI=1.02 to 2.44). Surprisingly, being adherent to nicotine gum significantly reduced the odds of smoking cessation (OR=0.50, CI=0.28 to 0.87). On the other hand, adherence to counseling dramatically increased the likelihood of smoking cessation (OR=3.32, CI=1.36 to 8.08).

CONCLUSIONS: Individual risk factors may influence adherence to nicotine gum and counseling. Improving psychological interventions and promoting adherence to counseling may increase overall smoking cessation success among African-American light smokers.

KEY WORDS: smoking cessation; nicotine gum; counseling; African American.

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INTRODUCTION

Cigarette smoking remains one of the leading causes of preventable mortality and morbidity in the United States¹. Although the overall prevalence of cigarette smoking has decreased over the past few decades, the proportions of light smokers (i.e., smoke ≤ 10 cigarettes per day) among female smokers, young smokers, ethnic minority smokers, and lower income individuals who smoke are growing²⁻⁴. Up to 50% of African-American smokers (AA) smoke ≤ 10 cigarettes per day compared with about 20% smoking at this level in the general population³⁻⁵. Studying light smoking especially among African Americans is also important for other reasons. First, despite smoking fewer cigarettes per day than Whites, African Americans have higher cotinine levels for a similar level of tobacco use and experience disproportionately higher tobacco-related morbidity and mortality compared to Whites. Moreover, studies have shown that light smokers suffer from significant smoking-related morbidity and mortality compared to never smokers⁶⁻⁹.

As a result, improving smoking cessation interventions in African-American light smokers remains a public health priority. Effective pharmacologic interventions for moderate and heavy smokers include nicotine replacement therapy (NRT: gum, patch, nasal spray, inhaler, and lozenge) and non-NRT such as bupropion and varenicline. Behavioral counseling alone or in combination with pharmacotherapy is also effective for smoking cessation. While numerous studies have established the efficacy of various pharmacotherapy for smoking cessation^{10,11}, most studies have excluded light smokers. Results from our recent clinical trial of AA light smokers provided evidence contrary to the misperception that light smokers are less addicted and can quit more successfully than heavy smokers. In that study, at 6-month follow-up, quit rates among AA light smokers ranged from 6.8% to 18.0% depending on the treatment arm¹². These quit rates were no higher than quit rates found among heavier smokers of the same ethnicity^{10,11}. Moreover, the observed quit rates for nicotine gum were no better than for placebo.

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One important factor associated with poor cessation success is poor adherence to nicotine replacement therapy and counseling;¹³⁻¹⁷ however, treatment adherence information is limited in smoking cessation studies. Despite the fact that NRT remains the main thrust of smoking cessation pharmacotherapy and observed low cessation rates among African Americans, no studies have examined treatment adherence in this underserved population. Also, earlier studies implying high adherence rates have failed to define, measure, or report treatment adherence. Some studies on nicotine gum showed a positive relationship between quantity of gum used and abstinence, while others did not^{16,18-23}. One study found a negative association between the use of the 2-mg nicotine gum and tobacco abstinence²⁴. The study evaluated the effect of a brief tailored smoking control intervention delivered during basic military training on tobacco use in a population of military personnel (N=33,215). Participants were randomized to either a tobacco use intervention (smoking cessation, smokeless tobacco use cessation, or prevention depending on tobacco use history) or a health education control condition. All participants were given the option of using 2 mg nicotine gum. Those reportedly using nicotine gum after BMT were significantly less likely to be continuously abstinent from cigarette smoking (OR=0.54, 95% CI=0.47, 0.63) or smokeless tobacco (OR=0.61, 95% CI=0.46, 0.79) at 1-year follow-up. More recent studies on NRT adherence have mainly focused on nicotine patch use^{13,25-29}. These studies suggest that NRT adherence rates are lower than once observed, and attention to treatment adherence is needed to increase quit rates. There are even fewer studies on adherence to counseling among smoking cessation trials. Only two studies^{13,30} have reported detailed analysis of adherence to counseling treatments and one of the studies demonstrated that adherence was a significant predictor to smoking cessation³⁰.

Adherence to treatment may be improved by identifying individual factors and tailoring treatment to the factors most likely to facilitate success among patient subgroups. Several characteristics have been observed to predict adherence to nicotine patch therapy; however, predictive characteristics differed among the studies. Higher income, lower nicotine dependence, more intensive adjunct treatment, greater motivation for abstinence, and smoking fewer cigarettes per day are among the predictors of nicotine patch adherence^{13,25}. One study identified older age, male gender, higher education, experience of NRT use, perceiving quitting as more difficult, and willingness to pay as factors associated with NRT adherence³¹. On the other hand, the only study that reported analysis on nicotine gum adherence did not find any predictors of adherence to nicotine gum²⁸.

Given the paucity of information about adherence to nicotine gum and counseling among smokers, especially African-American light smokers, the current study examined the predictors of treatment adherence and the relationship between treatment adherence and smoking cessation among AA light smokers enrolled in a 2×2 factorial, randomized, placebo-controlled trial of nicotine gum and counseling (health education vs. motivational interviewing). Investigation of factors affecting adherence to nicotine gum and counseling could lead to improved treatment effectiveness and increased likelihood of quitting among African-American smokers.

METHODS

Study Setting and Design

Study design details including a flowchart (Fig. 1) have been previously described elsewhere^{12,32}. Briefly, KIS II was a double-blind, placebo-controlled, randomized trial of African-American light smokers conducted at a community-based clinic serving a predominately low-income African-American population. The study used a 2×2 factorial design in which 755 participants were randomly assigned to one of four study arms: 8-week treatment with placebo gum plus six health education (HE) sessions; 8-week treatment with placebo gum plus six motivational interviewing (MI) counseling sessions; 8-week treatment with nicotine gum plus six HE sessions; 8-week treatment with nicotine gum plus six MI counseling sessions. All study procedures were approved and monitored by the human subjects committee of the institution where the study was conducted. Recruitment for KIS II started in March 2003 and ended in June 2004. Final 6-month follow-up was completed in December 2004.

Eligibility and Flow of Participants

Participant's eligibility for inclusion in the clinical trial was assessed via telephone or in-person screening conducted by trained project staff. To be eligible, participants self-identified to be African American by answering "yes" to the question, "Do you consider yourself African American or Black?" Other eligibility criteria included ≥18 years of age, smoke ≤10 cigarettes per day for ≥6 months, smoke cigarettes on ≥25 of the last 30 days, be interested in quitting within 14 days of screening, and have a home address and functioning telephone number. They were asked to choose a quit date within 14 days and schedule a randomization appointment for the day before their quit date. Participants were excluded if they had used pharmacotherapy for smoking cessation in the past 30 days; had used other forms of tobacco in the past 30 days; reported having a myocardial infarction, irregular heart beat, heart attack, or stroke in the past 4 weeks; had a jaw problem that precluded chewing of nicotine gum; were pregnant or breast feeding; or had another household member enrolled in the study. At the randomization visit, participants were randomly assigned to receive an 8-week supply of either active nicotine gum or placebo. They were also randomly assigned to receive either MI or HE counseling. Instructions given for gum usage depended on number of cigarettes smoked at baseline. Individuals who smoked 8-10 cigarettes per day (cpd) at baseline were told to use 10 pieces of gum per day for the first four weeks, 8 pieces per day for weeks 5 and 6, and 6 pieces per day during weeks 7 and 8. Those who smoked 5-7 cpd at baseline were instructed to use 8 pieces per day of gum initially, 6 pieces per day during weeks 5 and 6, and 4 pieces per day for the last 2 weeks of treatment. Those smoking fewer than 5 cpd at baseline were told to use 6 pieces of gum per day for the first 4 weeks, 4 pieces per day during weeks 5 and 6, and 2 pieces per day during weeks 7 and 8. Over the course of the study, four HE or MI sessions were delivered in person at randomization, weeks 1, 8, and 16, and two were delivered by telephone at weeks 3 and 6. Motivational interviewing, described in detail elsewhere³³, is a counseling approach originally developed for addictive behaviors that has more recently been applied to other health behaviors, including smoking

Figure 1. Study flowchart (source¹²).

cessation. It is designed to enhance motivation for change and is based on the assumption that individuals with addictions are often not in an advanced stage of readiness to change their behavior. On the other hand, HE is a standard counseling technique that focuses on providing information and advice and encourages the development of strategies to improve health knowledge, attitudes, skills, and behavior. All of the MI and HE sessions were conducted by trained counselors following semi-structured counseling scripts. Participants in all four arms were followed for 6 months.

Measures

All questionnaire items were read to or along with the participants by trained research assistants. Baseline mea-

sures assessed demographic and health-related information, smoking behaviors, and psychosocial variables (Table 1). Nicotine dependence was assessed with the 6-item Fagerström Test of Nicotine Dependence (FTND)³⁴, the Nicotine Dependence Syndrome Scale (NDSS)^{35,36}, and the Cigarette Dependence Scale (CDS-5)³⁷. The NDSS is a 19-item multi-factorial instrument to measure nicotine dependence. The CDS-5 is a 5-item instrument that includes questions on self-rated level of addiction, number of cigarettes smoked, time to first cigarette of the day, difficulty with quitting, and urge to smoke. Psychosocial measures included the 10-item Center of Epidemiologic Studies-Depression (CES-D) scores (range 0–10), with scores of 4 or higher indicating the likelihood of clinical depression³⁸.

Adherence to gum was defined as using greater than or equal 75% of the total prescribed gum usage during the

Table 1. Baseline Characteristics by Nicotine Gum Adherence Groups

Baseline predictors	Total N=662	Non-adherent N=420	Adherent N=242	P-value
Age in years, mean (SD)	45.3 (10.7)	44.7 (11.0)	46.2 (9.9)	0.08
Female, (%)	67.4	66.9	68.2	0.74
Married or living with partner, (%)	38.9	37.5	41.3	0.33
Employed (%)	48.3	52.6	40.9	<0.01
High school graduate (%)	84.9	86.2	82.6	0.23
Income >\$1,800/month (%)	42.6	45.7	37.4	0.04
Smokes menthol cigarettes (%)	81.7	80.6	83.5	0.36
Experience use of pharmacotherapy to quit (%)	18.9	18.2	20.0	0.58
Depressed (%)	45.5	43.6	48.8	0.20
KIS manual usage at week 1 (%)	81.5	81.5	81.7	0.95
KIS manual usage at week 8 (%)	89.8	88.6	91.8	0.23
BMI in kg/m ² , mean (SD)	30.6 (8.1)	30.1 (7.4)	31.6 (9.0)	0.03
Quit attempts in past year, mean (SD)	3.4 (7.0)	2.7 (4.4)	4.5 (9.9)	<0.01
Years smoked, mean (SD)	24.2 (12.0)	23.9 (12.1)	24.7 (11.9)	0.40
No. CPD in past 7 days, mean (SD)	7.5 (3.3)	7.7 (3.3)	7.4 (3.1)	0.28
Baseline exhales CO, mean (SD)	13.8 (9.0)	13.1 (8.7)	15.0 (9.4)	0.01
Motivation to quit, mean (SD)	9.1 (1.7)	9.0 (1.7)	9.2 (1.6)	0.09
Confidence to quit, mean (SD)	7.1 (2.6)	7.1 (2.6)	7.0 (2.6)	0.56
Alcohol use (days in past month), mean (SD)	5.0 (7.8)	5.1 (7.9)	4.7 (7.5)	0.46
Nicotine dependence (CDS), mean (SD)	14.9 (3.7)	14.6 (3.7)	15.4 (3.7)	<0.01
Perceived stress, mean (SD)	8.7 (2.1)	8.5 (2.0)	9.0 (2.3)	<0.01
Withdrawal score, mean (SD)	9.4 (5.9)	9.2 (5.7)	9.7 (6.4)	0.31

8 weeks of treatment with gum. In smoking cessation studies, there is no consensual standard for what constitutes adequate adherence. The current study therefore adopted the 75% threshold level being used in an ongoing NIH-funded smoking cessation study. Research has shown that adherence is inversely proportional to frequency of dosing³⁹. Investigators therefore considered the 75% threshold to be adequate for the gum given the requirement for multiple dosing. At every follow-up contact during gum treatment, i.e., weeks 1, 3, 6, and 8, the number of pieces of gum used was assessed by participants' response to the question: "In the last week, on average, how many pieces of gum have you been using per day?" The gum usage for weeks 2 and weeks 4 was extrapolated forward from that of week 1 and week 3, respectively. The gum usage for weeks 5 and weeks 7 was extrapolated backward from that of week 6 and week 8, respectively. We excluded the gum usage adherence data if a subject reported adherence data for fewer than two contact points, resulting in the exclusion of 93 out of 755 total participants from the gum adherence analysis. Adherence to counseling was defined as attending at least five out of the expected six counseling sessions. The threshold of five out of six (83%) counseling sessions for counseling is consistent with the threshold of 80% to 95% used for treatment that require less frequent dosing or attendance⁴⁰. All 755 subjects were used for counseling adherence analysis since there were no missing data for any of the participants.

Serum cotinine and expired carbon monoxide (CO) were assessed at randomization, and salivary cotinine was assessed at week 26. The primary outcome variable for the study was 7-day point prevalence smoking cessation at week-26 follow-up verified by salivary cotinine; this was defined as having smoked no cigarettes—not even a puff—for the previous 7 days and salivary cotinine level of ≤ 20 ng/ml.

Data Analysis and Statistical Consideration

Descriptive statistics were used to summarize the demographic variables, smoking characteristics, and health information. Chi-square tests and t-tests were conducted to compare the

demographic, smoking, and other health-related characteristics between those adherent to the gum or to the counseling sessions and those non-adherent. Multiple logistic regression (MLR) was used to examine the association of adherence with baseline demographic and smoking-related variables. The MLR models included variables that were found to be associated with adherence in univariate analysis with a significance level of p-value <0.1. Separate models were completed for gum adherence and counseling adherence. The model for gum adherence included the counseling adherence group variable and vice versa for the counseling model. To examine the effect of adherence on cotinine-verified smoking cessation at week 26, a separate MLR analysis was conducted with a model that included treatment group assignment, adherence to gum and counseling and clinically relevant variables from the univariate analysis. A supplemental analysis was conducted in which adherence to gum and counseling were treated as continuous variables in the MLR.

RESULTS

There were 662 participants eligible for the gum adherence analysis, 242 (36.6%) of whom were categorized as adherent to recommended pieces of nicotine (or placebo) gum. The baseline characteristics by gum adherence group are presented in Table 1. Univariate predictors of adherence to gum use included being unemployed, higher income, higher BMI, more quit attempts in the past year, higher baseline exhaled CO level, higher nicotine dependence, and higher perceived stress.

Of the 755 participants included in the counseling adherence analysis, 542 (71.8%) were categorized as adherent to counseling. The baseline characteristics of participants by counseling adherence status are presented in Table 2. Univariate predictors of adherence to counseling were older age, being a high school graduate, and longer smoking history.

Results of the multiple logistic regression analysis of predictors of adherence to gum use are shown in Table 3. This model included variables from Table 1 that had p-values <0.1 plus counseling adherence status. Four variables emerged as

Table 2. Baseline Characteristics by Counseling (HE/MI) Adherence Groups

Baseline predictors	Total N=755	Non-adherent N=213	Adherent N=542	P-value
Age in years, mean (SD)	45.1 (10.7)	43.4 (11.0)	45.7 (10.5)	<0.01
Female, (%)	66.9	65.7	67.3	0.67
Married or living with partner, (%)	37.7	34.7	38.8	0.30
Employed (%)	48.0	47.4	48.2	0.87
High school graduate (%)	83.6	78.3	85.6	0.02
Income >\$1,800/month (%)	41.1	36.5	42.9	0.12
Smokes menthol cigarettes (%)	81.7	85.9	80.0	0.06
Previous use of pharmacotherapy to quit (%)	18.6	16.7	19.3	0.44
Depressed (%)	45.8	46.0	45.8	0.95
KIS manual usage at week 1 (%)	81.6	85.4	80.7	0.23
KIS manual usage at week 8 (%)	89.8	87.7	90.0	0.56
BMI in kg/m ² , mean (SD)	30.6 (8.1)	30.2 (8.0)	30.8 (8.1)	0.42
Quit attempts in past year, mean (SD)	3.3 (6.6)	3.3 (8.2)	3.3 (5.9)	0.99
Years smoked, mean (SD)	23.9 (11.9)	21.9 (12.1)	24.7 (11.8)	<0.01
No. CPD in past 7 days, mean (SD)	7.6 (3.2)	7.7 (3.3)	7.5 (3.2)	0.36
Baseline exhaled CO, mean (SD)	13.9 (8.9)	14.0 (9.5)	13.8 (8.7)	0.79
Motivation to quit, mean (SD)	9.1 (1.7)	9.0 (1.6)	9.1 (1.7)	0.47
Confidence to quit, mean (SD)	7.1 (2.6)	7.4 (2.4)	7.0 (2.7)	0.09
Alcohol use (days in past month), mean (SD)	5.0 (7.8)	5.4 (7.8)	4.8 (7.8)	0.30
Nicotine dependence (CDS), mean (SD)	15.0 (3.7)	15.1 (3.6)	14.9 (3.7)	0.59
Perceived Stress, mean (SD)	8.7 (2.1)	8.7 (2.0)	8.7 (2.1)	0.92
Withdrawal score, mean (SD)	9.5 (6.0)	9.8 (5.6)	9.3 (6.1)	0.29

independent predictors of gum adherence, including having a higher body mass index, making more quit attempts in the past year, having a higher baseline exhaled CO, and higher perceived stress score.

Results of a multiple logistic regression to predict adherence to counseling are shown in Table 4. This model included variables from Table 3 that had p-values <0.1 plus gum adherence status. Only one variable, being a high school graduate, significantly increased the odds of adherence to counseling.

Figure 2 shows the cotinine-verified abstinence rates for the four study groups. As previously reported¹², the primary outcome of the parent study was that the verified abstinent rate at week 26 for 2 mg nicotine gum was no better than for placebo (14.2% versus 11.1%, $P=0.232$). However, a counseling effect was observed, with health education (HE) performing significantly better than motivation interviewing (MI) (16.7% versus 8.5%, $P<0.001$). In the current study, adherence rates to nicotine gum (Fig. 3) were not significantly different among the four study groups (global $p=0.53$). However, as shown in Figure 4, there were significant differences in counseling adherence rates among the four study groups, with the placebo + MI group (62.4%) having the lowest rate, while the NRT + HE group (78.8%) had the highest adherence rate (global $p<0.01$). The verified quit rates at week 26 for the counseling adherent and non-adherent groups were 16.1% and 3.76%, respectively

($P<0.0001$). Unexpectedly, the verified quit rates at week 26 for the gum adherent and non-adherent groups were 9.5% and 16.7%, respectively.

We also performed a multiple logistic regression model to determine predictors of cotinine-verified week 26 abstinence rates (Table 5). Consistent with the univariate analysis above, being adherent to nicotine gum significantly reduced the odds of smoking cessation (OR=0.50, CI=0.28 to 0.87). On the other hand, adherence to counseling dramatically increased the likelihood of smoking cessation (OR=3.32, CI=1.36 to 8.08). When supplemental analyses were performed that treated gum adherence (parameter estimate=-0.1689; $p=0.001$) and counseling adherence (parameter estimate=0.6769; $p<0.001$) as continuous variables, the relationship between gum adherence and cessation as well as between counseling adherence and cessation were essentially unchanged. Other baseline predictors of smoking cessation were consistent with those previously reported⁴¹, including higher body mass index and older age, female gender, and higher baseline exhaled carbon monoxide reduced the odds of quitting.

DISCUSSION

The purpose of this study was to determine the rates of adherence to nicotine gum and counseling and identify factors associated with adherence to nicotine gum and counseling. We also sought to determine the effects of adherence on smoking

Table 3. Full Regression Model of Baseline Predictors of Adherence to Nicotine Gum

Variables in the model	Odds ratio	95% CI	P value
Age	1.01	1.0–1.03	0.10
Employed	0.72	0.50–1.03	0.07
Income	0.83	0.58–1.21	0.33
BMI in kg/m ²	1.03	1.01–1.05	0.02
Past year quit attempts	1.04	1.01–1.07	0.01
Baseline exhaled CO	1.22	1.01–1.48	0.04
Baseline motivation to quit	1.05	0.95–1.17	0.36
Nicotine dependence	1.04	0.99–1.09	0.09
Perceived Stress	1.12	1.03–1.22	0.01
Counseling adherence	1.29	0.92–1.82	0.14

Table 4. Full Regression Model of Baseline Predictors of Adherence to Counseling

Variables in the model	Odds ratio	95% CI	P value
Age	1.01	0.98–1.03	0.65
High school graduate	1.7.	1.12–2.57	0.01
Smoked menthol	0.75	0.47–1.19	0.23
Years smoked	1.02	0.99–1.04	0.19
Baseline confidence	0.95	0.89–1.01	0.10
Gum adherence	1.27	0.91–1.75	0.16

Figure 2. Verified quit rates by four treatment groups.

Figure 4. Adherence to counseling by treatment groups.

cessation rates among AA light smokers. In this study, only 36.6% of participants were adherent to recommended doses of nicotine gum, while 71.8% were adherent to attending required counseling sessions. Although there are no data regarding adherence to nicotine replacement or counseling among African Americans or light smokers, these results showing low adherence to nicotine gum are consistent with reports from the general populations^{16,42}. In the current study, four predictors of adherence to gum therapy and one predictor of adherence to counseling were identified. Having more quit attempts in the past year, higher body mass index, a higher baseline exhaled CO, and higher perceived stress increased the likelihood of adherence to gum usage.

Some of these baseline predictors of adherence to gum use in the current study are consistent with factors identified in previous studies that used nicotine patches exclusively or as the predominant method of NRT. A study among Chinese smokers identified older age, male gender, higher education, experience of NRT use, perceiving quitting as more difficult, and willingness to pay as significant predictors of adherence²⁷. Two studies^{13,25} that used the nicotine patch conducted among a predominantly White sample identified several different predictors. One of the studies reported higher nicotine dependence scores, higher number of cigarettes smoked per day (CPD), higher motivation to quit, and concurrent use of psychosocial co-therapy as predictors of adherence¹³. The other study indicated that male gender, not dropping out of the study, and intensive psychosocial treatment were associated with greater adherence to nicotine patch therapy²⁵.

Figure 3. Adherence to nicotine gum by treatment groups.

One baseline predictor of adherence to counseling was identified in the current study, being a high school graduate. This finding is consistent with other studies that have reported positive associations between education and adherence to non-smoking and other healthy lifestyle behaviors⁴³⁻⁴⁵.

The overall adherence rate to nicotine gum was 36.6%, while the adherence rate to counseling was 71.8% in the current study. A wide variation (5% to 96%) in the prevalence of adherence to smoking cessation therapy among studies has been reported in a recent WHO publication⁴⁶. The variation is likely due to the differences in the definition of adherence, the nature of the interventions, adjunctive supports, and the population studied. The relatively low rate of adherence to nicotine gum among light smokers in the current study is consistent with findings among heavier smokers. Although we did not specifically assess reasons for adherence in current study, it is possible that providing participants with a monetary incentive for attending counseling sessions might have contributed to the relatively high adherence rate for counseling in the current study.

Surprisingly, adherence to nicotine gum use decreased the smoking cessation rate in our study. Although the reason for this finding is not clear, we suggest a few possibilities. It is possible that adherence to nicotine gum is a marker for greater nicotine dependence that is related to negative cessation outcome. In univariate analyses in the current study, those classified as adherent had higher nicotine-dependent scores, higher expired CO, and a greater number of quit attempts in

Table 5. Full Regression Model of Baseline Predictors of Cotinine-verified Quitting at Week 26

Variables in the model	Odds ratio	95% CI	P value
Counseling (HE = 1, MI = 0)	2.20	1.32-3.68	<0.01
NRT (gum = 1, placebo = 0)	1.46	0.89-2.38	0.13
Gum adherence	0.50	0.28-0.87	0.01
Counseling adherence	3.32	1.36-8.08	0.010
Female	0.45	0.27-0.74	<0.01
Income	1.49	0.91-2.43	0.11
Age	1.03	0.98-1.07	0.26
Cigarettes per day	0.97	0.88-1.06	0.47
Smoked menthol cigarettes	0.70	0.38-1.27	0.24
Years smoked	1.00	0.96-1.04	0.98
Baseline confidence	1.07	0.96-1.18	0.23
Nicotine dependence	0.98	.091-1.06	0.65
BMI in kg/m ²	1.05	1.02-1.08	<0.01
Baseline exhaled CO	0.94	0.91-0.98	<0.01

the previous year compared to the non-adherent group. Therefore, participants may have used more nicotine gum because they had greater difficulty quitting, and their lower cessation outcome was due to their higher nicotine dependence rather than their use of the gum. This explanation is supported by a study²⁴ that found that individuals who chose to take the 2 mg nicotine gum were significantly less likely to be abstinent at follow-up (OR=0.54, 95% CI=0.47, 0.63). Another possibility is that smokers who quit smoking may have thought they no longer needed the gum because they had quit smoking and therefore quit using the gum. Because adherence to NRT in general or 2 mg nicotine gum in particular has not been studied in light smokers, studies are needed to determine what cessation therapies are effective for light smokers so that adherence to such effective treatments can be promoted by healthcare providers.

We observed a significant impact of adherence to counseling on smoking cessation rate from this study. In fact, adherence to counseling is the most significant predictor of quitting according to our study. The finding that adherence to HE/MI counseling significantly increased the smoking cessation rate was expected. Numerous clinical trials have confirmed the efficacy of counseling in smoking cessation, either alone or in combination with NRT. Available evidence suggests that increasing the intensity of counseling interventions improves treatment outcomes^{47,48}. However, only one other study has reported an association between adherence to counseling and smoking cessation outcome. Thyrian et al. reported a statistically significant correlation between adherence to MI and smoking cessation among postpartum women³⁰. The finding that adherence to cessation counseling improves likelihood of cessation has clinical significance for the treatment of light smokers. While there is limited evidence for using NRT or other medication for smoking cessation for light smokers, the current study suggests that counseling is effective for cessation among light smokers and that increasing adherence to counseling is beneficial. This therefore provides health care providers with an evidence-based tool to promote smoking cessation among light smokers. The counseling in the current study was also provided by trained non-clinicians. Therefore, when necessary and with adequate training, physicians could delegate cessation counseling for light smokers to non-clinician office staff.

Strengths of the current study included being the first study to assess adherence to NRT and counseling among African Americans or light smokers, assessment of gum use at multiple time points, large sample size, as well as assessments of multiple variables that could affect adherence. There are also some limitations in this study. First, this study was conducted at a single health care facility, although a wide variety of community-based recruitment strategies was used to reach potential participants from a large metropolitan area. Second, the study was conducted in a Midwestern city in the US, and findings may therefore not be generalized to all African-American light smokers. Third, nicotine gum was provided free to participants during the study period, and the results could have been different if participants were required to pay for the gum. However, the availability of medication at no cost to participants removes one barrier to medication adherence in real life, especially in underserved populations⁴⁰. Also, the pharmacotherapy used in this study was 2 mg nicotine gum; therefore, the findings may not generalize to a

higher dosage of the gum or other smoking cessation pharmacotherapy such as other forms of NRT (patch, lozenge, inhaler, and spray) or non-NRT (bupropion or varenicline). Finally, since adherence to gum was assessed by self-report, it is possible that the actual adherence rates were lower than what participants reported. Future studies of adherence with the gum may consider including the use of daily adherence logs or a gum count devised for more detailed monitoring.

CONCLUSION

In summary, the current study found that a number of individual factors including, education, past quit attempts, BMI, and perceived stress may influence adherence to nicotine gum and counseling among African-American light smokers. In order to reduce or eliminate smoking-related health disparities experienced by underserved populations, it is critical that researchers and health care providers continue efforts to better understand factors associated with adherence to effective treatments in these populations. More research is warranted to further determine the relationship between adherence to nicotine gum and smoking cessation, especially among African Americans and light smokers.

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REFERENCES

1. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA*. 2004;291(10):1238-45.
2. Kandel DB, Chen K. Extent of smoking and nicotine dependence in the United States: 1991-1993. *Nicotine Tob Res*. 2000;2(3):263-74.
3. Okuyemi KS, Ahluwalia JS, Richter KP, Mayo MS, Resnicow K. Differences among African American light moderate and heavy smokers. *Nicotine Tob Res*. 2001;3:49-54.
4. Okuyemi KS, Harris KJ, Scheibmeir M, Choi WS, Powell J, Ahluwalia JS. Light smokers: Issues and recommendations. *Nicotine Tob Res*. 2002;4(Suppl 2):103-12.
5. CDC. Cigarette smoking among adults—United States. *MMWR Morb Mort Wkly Rep*. 2007;56(44):1157-61.
6. Garfinkel L, Stellman SD. Smoking and lung cancer in women: findings in a prospective study. *Cancer Res*. 1988;48:6951-5.
7. Luoto R, Uutela A, Puska P. Occasional smoking increases total cardiovascular mortality among men. *Nicotine Tob Res*. 2000;2:133-9.
8. Prescott E, Scharling H, Osler M, Schnohr P. Importance of light smoking and inhalation habits on risk of myocardial infarction and all cause mortality. A 22-year follow-up of 12,149 men and women in The

- Copenhagen City Heart Study. *J Epidemiol Community Health*. 2002;56(9):702-6.
9. **Rosengren A, Wilhelmsen L, Wedel H.** Coronary heart disease, cancer and mortality in male middle-aged light smokers. *J Intern Med*. 1992;231(4):357-62.
 10. **Lancaster T, Stead LF.** Individual behavioural counselling for smoking cessation. *Cochrane Database Syst Rev*. (2):CD001292.
 11. **Stead LF, Perera R, Bullen C, Mant D, Lancaster T.** Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* 2008(1):CD000146.
 12. **Ahluwalia JS, Okuyemi K, Nollen N, et al.** The effects of nicotine gum and counseling among African American light smokers: a 2×2 factorial design. *Addiction*. 2006;101(6):883-91.
 13. **Alterman AI, Gariti P, Cook TG, Cnaan A.** Nicodermal patch adherence and its correlates. *Drug Alcohol Depend*. 1999;53(2):159-65.
 14. **Jolicœur DG, Ahluwalia JS, Richter KP, et al.** The use of nicotine patches with minimal intervention. *Prev Med*. 2000;30:504-12.
 15. **Kenford SL, Fiore MC, Jorenby DE, Smith SS, Wetter D, Baker TB.** Predicting smoking cessation—Who will quit with and without the nicotine patch. *JAMA*. 1994;271(8):589-94.
 16. **Shiffman S, Rolf CN, Hellebusch SJ, et al.** Real-world efficacy of prescription and over-the-counter nicotine replacement therapy. *Addiction*. 2002;97(5):505-16.
 17. **Stapleton JA, Russell MAH, Feyerabend C, et al.** Dose effects and predictors of outcome in a randomized trial of transdermal nicotine patches in general practice. *Addiction*. 1995;90:31-42.
 18. **Fortmann SP, Killen JD, Telch MJ, Newman B.** Minimal contact treatment for smoking cessation. A placebo controlled trial of nicotine polacrilex and self-directed relapse prevention: initial results of the Stanford Stop Smoking Project. *JAMA*. 1988;260(11):1575-80.
 19. **Jackson PH, Stapleton JA, Russell MA, Merriman RJ.** Nicotine gum use and outcome in a general practitioner intervention against smoking. *Addict Behav*. 1989;14(3):335-41.
 20. **Killen JD, Fortmann SP, Newman B, Varady A.** Evaluation of a treatment approach combining nicotine gum with self-guided behavioral treatments for smoking relapse prevention. *J Consult Clin Psychol*. 1990;58(1):85-92.
 21. **Mooney M, Babb D, Jensen J, Hatsukami D.** Interventions to increase use of nicotine gum: a randomized, controlled, single-blind trial. *Nicotine Tob Res*. 2005;7(4):565-79.
 22. **Riley W, Jerome A, Behar A, Weil J.** Computer and manual self-help behavioral strategies for smoking reduction: initial feasibility and 1-year follow-up. *Nicotine Tob Res*. 2002;4(Suppl 2):S183-8.
 23. **Sachs DPL.** Effectiveness of the 4-mg dose of nicotine polacrilex for the initial treatment of high-dependent smokers. *Arch Intern Med*. 1995;155:1973-80.
 24. **Klesges RC, DeBon M, Vander Weg MW, et al.** Efficacy of a tailored tobacco control program on long-term use in a population of US military troops. *J Consult Clin Psychol*. 2006;74(2):295-306.
 25. **Cooper TV, DeBon MW, Stockton M, et al.** Correlates of adherence with transdermal nicotine. *Addict Behav*. 2004;29(8):1565-78.
 26. **King A, Sanchez-Johnsen L, Van Orman S, Cao D, Matthews A.** A pilot community-based intensive smoking cessation intervention in African Americans: feasibility, acceptability and early outcome indicators. *J Natl Med Assoc*. 2008;100(2):208-17.
 27. **Lam TH, Abdullah AS, Chan SS, Hedley AJ.** Adherence to nicotine replacement therapy versus quitting smoking among Chinese smokers: a preliminary investigation. *Psychopharmacology (Berl)*. 2005;177(4):400-8.
 28. **Millard RW, Waranch HR, McEntee M.** Compliance to nicotine gum recommendations in a multicomponent group smoking cessation program: an exploratory study. *Addict Behav*. 1992;17(3):201-7.
 29. **Wiggers LC, Smets EM, Oort FJ, et al.** Adherence to nicotine replacement patch therapy in cardiovascular patients. *Int J Behav Med*. 2006;13(1):79-88.
 30. **Thyrian JR, Freyer-Adam J, Hannover W, et al.** Adherence to the principles of Motivational Interviewing, clients' characteristics and behavior outcome in a smoking cessation and relapse prevention trial in women postpartum. *Addict Behav*. 2007;32(10):2297-303.
 31. **Lam TH.** Commentary: adolescent smoking, school leavers, youth smoking prevention and the WHO Framework Convention on Tobacco Control. *Int J Epidemiol* 2004.
 32. **Okuyemi KS, Cox LS, Nollen NL, et al.** Baseline characteristics and recruitment strategies in a randomized clinical trial of African-American light smokers. *Am J Health Promot*. 2007;21(3):183-91.
 33. **Miller CE, Johnson JL.** Motivational interviewing. *Can Nurse*. 2001;97(7):32-3.
 34. **Fagerstrom KO, Schneider NG.** Measuring nicotine dependence: a review of the Fagerstrom Tolerance Questionnaire. *J Behav Med*. 1989;12(2):159-82.
 35. **Shiffman S, Sayette MA.** Validation of the nicotine dependence syndrome scale (NDSS): a criterion-group design contrasting chippers and regular smokers. *Drug Alcohol Depend*. 2005;79(1):45-52.
 36. **Shiffman S, Waters A, Hickcox M.** The nicotine dependence syndrome scale: a multidimensional measure of nicotine dependence. *Nicotine Tob Res*. 2004;6(2):327-48.
 37. **Etter JF, Le Houezec J, Perneger TV.** A self-administered questionnaire to measure dependence on cigarettes: the cigarette dependence scale. *Neuropsychopharmacology*. 2003;28(2):359-70.
 38. **Irwin M, Artin KH, Oxman MN.** Screening for depression in the older adult: criterion validity of the 10 item center for epidemiological studies depression scale (CES-D). *Arch Intern Med*. 1999;159:1701-4.
 39. **Claxton AJ, Cramer J, Pierce C.** A systematic review of the associations between dose regimens and medication compliance. *Clin Ther*. 2001;23(8):1296-310.
 40. **Osterberg L, Blaschke T.** Adherence to medication. *N Engl J Med*. 2005;353(5):487-97.
 41. **Nollen NL, Mayo MS, Sanderson Cox L, et al.** Predictors of quitting among African American light smokers enrolled in a randomized, placebo-controlled trial. *J Gen Intern Med*. 2006;21(6):590-5.
 42. **Lam TH, Abdullah AS, Chan SS, Hedley AJ.** Adherence to nicotine replacement therapy versus quitting smoking among Chinese smokers: a preliminary investigation. *Psychopharmacology (Berl)* 2004;1-18; electronic pre-print release.
 43. **King DE, Mainous AG 3rd, Carnemolla M, Everett CJ.** Adherence to healthy lifestyle habits in US adults, 1988-2006. *Am J Med*. 2009;122(6):528-34.
 44. **Miller RR, Sales AE, Kopjar B, Fihn SD, Bryson CL.** Adherence to heart-healthy behaviors in a sample of the US population. *Prev Chron Dis*. 2005;2(2):A18.
 45. **Pronk NP, Anderson LH, Crain AL, et al.** Meeting recommendations for multiple healthy lifestyle factors. Prevalence, clustering, and predictors among adolescent, adult, and senior health plan members. *Am J Prev Med*. 2004;27(2 Suppl):25-33.
 46. **Sabate E.** Adherence to long-term therapies: evidence for action. In: World Health Organization, Geneva. http://www.who.int/chp/knowledge/publications/adherence_report/en/. Accessed April 20, 2010.
 47. **Aveyard P, Brown K, Saunders C, et al.** Weekly versus basic smoking cessation support in primary care: a randomised controlled trial. *Thorax*. 2007;62(10):898-903.
 48. **Brendryen H, Drozd F, Kraft P.** A digital smoking cessation program delivered through internet and cell phone without nicotine replacement (happy ending): randomized controlled trial. *J Med Internet Res*. 2008;10(5):e51.