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The effects of nicotine gum and counseling among African American light smokers: a 2 × 2 factorial design

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ABSTRACT

Aim Approximately 50% of African American smokers are light smokers (smoke ≤ 10 cigarettes a day). The prevalence of light smoking in the United States is increasing, yet there has not been a single smoking cessation clinical trial targeting light smokers. The purpose of this 2 × 2 factorial, randomized clinical trial was to evaluate the efficacy of nicotine gum (2 mg versus placebo) and counseling (motivational interviewing versus health education) for African American light smokers. **Design** Participants were assigned randomly to one of four study arms: 2 mg nicotine gum plus health education (HE); 2 mg nicotine gum plus motivational interviewing (MI); placebo gum plus HE; and placebo gum plus MI. **Participants and setting** A total of 755 African American light smokers (66% female, mean age = 45) were enrolled at a community health center over a 16-month period. **Intervention and measurements** Participants received an 8-week supply of nicotine gum and six counseling sessions during the course of the 26-week study. Biochemical measures included expired carbon monoxide (CO) and serum and salivary cotinine. **Findings** Seven-day quit rates for nicotine gum were no better than for the placebo group (14.2% versus 11.1%, $P = 0.232$) at 6 months. However, a counseling effect emerged, with HE performing significantly better than MI (16.7% versus 8.5%, $P < 0.001$). These results were consistent across outcome time-points (weeks 1, 8, and 26). **Conclusions** Results highlight the potential positive impact of directive information and advice-oriented counseling on smoking cessation. Studies are needed to assess other interventions that may further improve quit rates among African American light smokers who are motivated to quit.

Keywords African American, health education, motivational interviewing, nicotine replacement, smoking.

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INTRODUCTION

Cigarette smoking remains one of the leading causes of preventable disease in the United States, despite efforts to decrease its prevalence [1]. While the prevalence of cigarette smoking has decreased over the past few decades, the proportion of those who maintain a low level of cigarette consumption, or 'light smokers', is growing. This is particularly evident among certain subpopulations in the United States, such as teens, young adults, women and ethnic minority groups [2,3].

The phenomenon of light smoking is understood poorly for a number of reasons. First, researchers have used a variety of terms to describe smokers who maintain a low level of cigarette consumption [2], including 'chippers [4]', 'low-rate smokers [5]' (≤ 5 cigarettes per day (cpd) on at least 5 days/week), 'occasional smokers [6]' (smoking on ≤ 25 of last 30 days) and 'light smokers [2]'. In defining light smokers, national surveys have previously used a cut-off of < 15 cpd [7]. This definition may be appropriate among whites, who smoke on average about 17 cpd [8]; however, a cut-off of < 15 cpd may be inappropriate when applied to other populations such as African Americans, smoke who on average 12 cpd [8].

Furthermore, there is no consensus about the phenomenon of light smoking. Some believe that light smoking is a transitional state leading to heavier smoking or cessation [2,9,10]. Others hold that light smoking is a stable pattern of low consumption that is maintained for a long period of time [2,5,11]. Previously, cross-sectional

data have shown that a majority of low-rate smokers (88%) exhibit a stable pattern of cigarette consumption [5]. However, more recent longitudinal data suggest that only a proportion of light smokers maintain a stable pattern of low consumption over time [10]. A population-based, prospective study revealed that a majority of low-rate smokers were once regular smokers (40.0%), former smokers (24.6%) or occasional smokers (13.4%).

There is also a prevailing perception among smokers that light smoking presents a reduced or minimal risk of health consequences. However, studies have shown that light smokers suffer from significant smoking-related morbidity and mortality compared to never smokers [12,13]. In addition, although approximately 50% of African Americans are light smokers, African Americans experience a disproportionate share of tobacco-related morbidity and mortality [14]. They also prefer high tar/nicotine and mentholated cigarettes [15], tend to inhale more deeply [16], have a slow rate of nicotine metabolism [16], have higher serum cotinine levels per cigarette smoked [17,18] and have greater difficulty quitting smoking compared to other ethnic groups [19]. These smoking characteristics of African Americans have been suggested as possibly contributing to the excess smoking-related morbidity experienced by African Americans.

Despite the growing prevalence of light smoking and its associated health risks, no clinical trial has focused exclusively on light smokers [20]. A secondary analysis from a larger clinical trial found the lozenge efficacious for whites who smoked ≤15 cpd [21]. Notwithstanding the high prevalence of light smoking among African Americans and disproportionately high smoking-related morbidity in this population, there have been no smoking cessation clinical trials targeting African Americans or other populations who smoke ≤10 cpd [20].

We proposed to evaluate the efficacy of nicotine gum (2 mg versus placebo) and counseling (motivational interviewing versus health education) in a randomized clinical trial for African American light smokers. Although national surveys have defined light smoking as < 15 cpd, we are defining light smoking at ≤10 cpd given the lower levels of smoking by African Americans relative to the general population [7,8]. A combination of counseling and pharmacotherapy was chosen in light of evidence that counseling enhances the long-term success of smoking cessation [22,23], and that adding pharmacotherapy to counseling significantly boosts quit rates [24].

METHODS

Study design

This study was a placebo-controlled randomized trial of 755 African American light smokers (= 10 cpd) enrolled at a community health center over a period of 16 months. We used a 2×2 factorial design in which participants were assigned randomly to placebo or active nicotine gum and health education (HE) or motivational interviewing (MI). All groups received a smoking cessation guide developed for the study. Participants provided written informed consent during the first visit and study procedures were approved and monitored by the University of Kansas Medical Center's human subjects committee.

Participants, screening and randomization

Eligible individuals self-identified themselves as either 'African American or black', were at least 18 years of age, smoked 10 or fewer cigarettes a day for at least 6 months prior to enrollment, smoked at least 25 of the last 30 days, were interested in quitting in the next 2 weeks, spoke English and had a permanent home address and working telephone. Only one smoker per household was allowed to enroll. Participants were excluded if they had a contraindication for nicotine gum (jaw problems, irregular heartbeat, recent myocardial infarction or stroke), used other pharmacotherapy for smoking cessation in the last 30 days, used other forms of tobacco within the last 30 days, were pregnant or planning to become pregnant within the next 6 months, were breast feeding or planning to move out of the local area within the next 6 months. Individuals demonstrating marked inappropriate affect or behavior were excluded from the study.

Smokers were recruited using clinic, media and community outreach efforts, including radio, television, gas pump, billboard advertising, community health fairs, posting signs in minority-owned businesses and mailing of referral letters from physicians. Participants were randomized between March 2003 and June 2004. The last 6-month follow-up session was completed in January 2005. Of the 1933 people screened, 1012 were eligible for the study and were invited to participate (Fig. 1). Enrollment continued until 755 participants were randomized. Randomization codes were generated in blocks of 36. The Investigative Pharmacy at the University of Kansas Medical Center packaged the study medication using codes to maintain blinding. At the randomization visit, a sealed envelope with pre-assigned randomization numbers was drawn to determine which form of counseling the participant would receive. The envelope and box of gum with matching randomization numbers were given to participants in the order in which they were randomized. Study staff and participants were blinded to whether participants received active gum or placebo. However, assignment to MI counseling versus HE was not blinded.

Eligible participants ($n = 1012$) were older (44.7 versus 42.4 years, $P < 0.001$) and smoked fewer cigarettes per day (7.5 versus 13.3, $P < 0.001$) than those who were

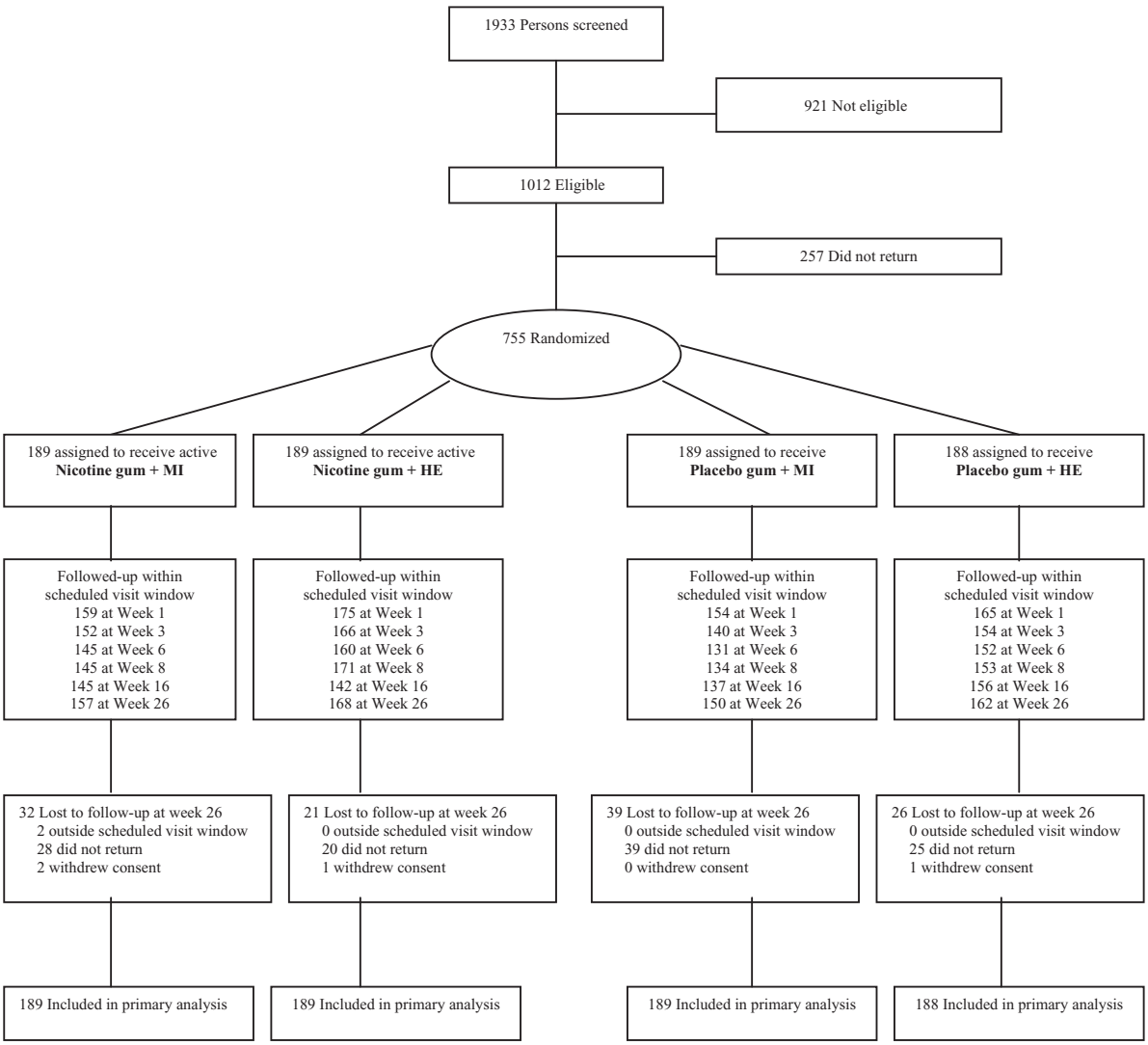

Figure 1 Study flowchart

ineligible ($n = 921$). Of those eligible, women (78.5% women versus 67.8% men, $P < 0.0001$) and those smoking fewer cigarettes per day (7.4 versus 7.8, $P < 0.05$) were more likely to return for the randomization visit. Baseline characteristics for participants in the four treatment groups are shown in Table 1.

Treatment period

Prior to the randomization visit, participants received the 'KIS II Quit Smoking Guide'. The 'KIS II Smoking Guide' is a 36-page booklet developed for African American light smokers. The culturally sensitive guide was developed by the project investigators through an iterative process of expert feedback and cultural relevance analysis using the suitability of assessment materials (SAMS), an instrument developed to assess the difficulty and suitability of education materials for patients with low literacy skills [25]. The final guide was rated as superior by SAMS standards and was written at the 7th grade reading level.

At the randomization visit, participants were assigned randomly to receive an 8-week supply of either active 2 mg nicotine gum or placebo. Instructions given for gum usage depended on number of cigarettes smoked at baseline. Individuals who smoked 8–10 cpd were told to use 10 pieces of gum per day for the first 4 weeks, eight pieces for weeks 5 and 6 and six pieces during weeks 7 and 8. Those who smoked five to seven cpd were prescribed eight pieces of gum initially, six pieces during weeks 5 and 6 and four pieces for the last 2 weeks of treatment. Those smoking fewer than five cpd were told to use six pieces of gum per day for the first 4 weeks, four pieces during weeks 5 and 6 and two pieces during weeks 7 and 8. This dosing regimen was arrived at by expert consensus and review of the manufacturer's recommendations for usage. Participants were also assigned randomly to

Table 1 Baseline characteristics of the participants.

	Nicotine gum		*Placebo gum*	
Characteristics	*MI (n = 189)*	*HE (n = 189)*	*MI (n = 189)*	*HE (n = 188)*
Age in years, mean (SD)	45.2 (10.7)	43.5 (11.8)	46.5 (10.0)	45.2 (10.0)
Female, no. (%)	125 (66.1%)	129 (68.3%)	123 (65.1%)	128 (68.1%)
Married or living with a partner, no. (%)	82 (43.4%)	77 (41.0%)	72 (38.1%)	53 (28.2%)
Monthly family income < $1,800, no. (%)	111 (60.7%)	106 (57.0%)	117 (63.2%)	99 (54.7%)
< High school graduate, no. (%)	28 (14.8%)	32 (17.0%)	40 (21.2%)	24 (12.8%)
No. of cigarettes smoked per day, mean (SD)	7.8 (3.5)	7.5 (2.9)	7.5 (3.5)	7.3 (2.8)
Duration of smoking in years, mean (SD)	23.5 (12.1)	22.8 (12.8)	25.1 (11.4)	24.2 (11.5)
Smoke mentholated cigarettes, no. (%)	153 (81.4%)	156 (83.0%)	158 (83.6%)	148 (78.7%)
Fagerström score, mean (SD)*	4.1 (2.16)	4.3 (2.0)	4.2 (2.2)	4.5 (2.2)
No. of serious quit attempts in the last year, mean (SD)	2.8 (4.4)	2.8 (5.1)	4.0 (10.0)	3.4 (5.6)
Serum cotinine in ng/mL, mean (SD)	241.8 (140.0)	229.9 (147.1)	256.6 (171.5)	248.6 (157.2)
Exhaled carbon monoxide in p.p.m., mean (SD)	13.7 (9.0)	14.2 (9.8)	14.0 (8.5)	13.5 (8.4)
Use of smoking cessation pharmacotherapy in the last year, no. (%)	24 (12.7%)	25 (13.2%)	20 (10.6%)	20 (10.6%)
Other smokers in household, no. (%)	65 (34.4%)	71 (37.6%)	87 (46.0%)	71 (37.8%)
Weight in kg, mean (SD)	86.1 (22.9)	85.7 (23.0)	84.6 (25.0)	89.1 (24.7)
Body mass index in kg/m^2 mean (SD)	30.7 (8.1)	30.4 (7.4)	29.8 (8.3)	31.6 (8.5)
CES-D, mean (SD)**	3.4 (2.8)	3.5 (2.6)	3.4 (2.5)	3.5 (2.5)
Possible clinical depression, no. (%)	84 (44.4%)	89 (47.1%)	83 (43.9%)	90 (47.8%)
Motivation to quit, mean (SD)	9.1 (1.6)	9.0 (1.7)	9.0 (1.8)	9.1 (1.6)
Confidence to quit, mean (SD)	7.3 (2.6)	7.0 (2.5)	7.2 (2.6)	7.0 (2.7)

*The Fagerström Test for nicotine dependence ranges from 0 to 10. Scores of 7 or higher indicate greater levels of nicotine dependence. **10-item Center for Epidemiologic Studies Depression Scale. Scores range from 0 to 10. Score of 4 or higher indicate likelihood of clinical depression.

receive either MI or HE counseling. In general, participants received counseling from the same person for all six counseling sessions; three in-person visits (at randomization, week 1, week 8) and three by telephone (week 3, week 6 and week 16). Each of these visits consisted of brief (approximately 20 minutes) counseling sessions. Participants were encouraged to set a target quit date for the day following their randomization visit. In addition, all participants completed a battery of assessments.

Health education (HE) is a standard counseling approach, based on current treatment guidelines [26] that focuses on providing information and advice. During HE sessions, trained counselors used the 'KIS II Quit Smoking Guide' and semistructured scripts to review the addictive nature of nicotine, health consequences of smoking and benefits of quitting, and provided concrete strategies on developing a quit plan and identifying alternatives against triggers to smoke. Motivational interviewing (MI) is a counseling approach initially developed for addictive behaviors and applied more recently to nicotine dependence; details are described elsewhere [27]. MI sessions in the study were conducted by trained counselors who followed semistructured scripts that explored the pros and cons of smoking/quitting and motivation and confidence to quit. A values clarification strategy based on the work of Miller & Rollnick [27] was used. Both HE and MI counselors participated in separate weekly supervision throughout the study period to ensure the integrity of the respective counseling protocols was maintained. In addition, each session was tape-recorded to maintain fidelity and consistency throughout the study.

Retention

Participants were called and postcard appointment reminders were mailed before every visit. Participants who missed appointments were called to reschedule their visits. Study promotional items were also given to participants for every visit completed (e.g. tote bag, magnet, pen, drinking cup, T-shirt, coffee mug) as well as Wal-Mart vouchers: $40 at baseline and at week 26, $20 each for weeka 1, 3, 6, 8 and 16. Vouchers earned for completing telephone visits were dispersed at the next in-person visit.

Measures

All questionnaire items were read to, or along with, the participants by a trained research assistant. Baseline measures assessed demographic and health-related information, smoking behaviors, psychosocial variables and

biological measurements (Table 1). Nicotine dependence was assessed with the six-item Fagerstrom Test of Nicotine Dependence (FTND) [28]. Withdrawal symptoms were measured at randomization, weeks 1, 3, 6 and 8, and 26 visits using a well-validated scale developed by Hughes & Hatsukami [29]. Psychosocial measures included the 10-item Center of Epidemiologic Studies—Depression scale (CES-D) [30] and a single item assessing motivation to quit smoking and confidence to quit smoking on a 10-point continuum ranging from 'Not at all motivated/confident to 'Extremely motivated/confident' [31,32].

Serum cotinine was assessed at randomization, expired carbon monoxide (CO) at randomization, weeks 1, 8 and 26; and salivary cotinine was assessed at week 26. A salivary cotinine cut-off of ≤20 ng/ml was used to verify abstinence at 26 weeks and a cut-off of ≤10 parts per million (p.p.m.) was used for CO [33]. The primary outcome variable for the study was cotinine-verified 7-day abstinence at week 26, defined as having smoked no cigarettes—not even a puff—for the previous 7 days. Secondary outcome was 7-day abstinence at week 8.

Process measures included counseling attendance at the randomization, weeks 1, 3, 6 and 8, and 16 counseling visits and self-reported gum usage in the past 7 days at weeks 1, 3 and 8 (end of gum treatment).

Data analysis and statistical consideration

The sample size was determined a priori assuming an overall two-tailed type I error of 0.05, a power of 80% and a 6-month biochemically verified (carbon monoxide) quit rate of 7% (placebo/HE), 16% (placebo/MI), 16% (gum/HE) and 24% (gum/MI). Sample size calculations were based upon detecting the marginal effects of both gum and counseling. Based upon these assumptions, we expected that those randomized to placebo would have an 11.5% cessation rate compared to 20% for those randomized to gum; the same cessation rates were expected for HE and MI, respectively. Marginal tests resulted in 378 participants in each margin, which resulted in the 80% power to detect these differences. To control the overall type I error rate, the power calculation was performed assuming a type I error rate of 2.5% for each test. The a priori assumptions did not indicate an interaction effect; however, we still tested for it for each endpoint.

The primary outcome for the study was cotinine-verified 7-day abstinence at 26 weeks after the quit date. The primary analyses were a comparison of the verified abstinence rates at 6 months. For descriptive purposes we summarized the self-report and CO-verified 7-day abstinence at weeks 1, 8 and 26 as well as cotinine-verified 7-day abstinence at week 26 across the four groups. We also summarize our primary end-point, cotinine-verified 7-day abstinence using a 2×2 table to assess both the marginal and joint effects of both treatments. Inferential analyses were conducted using logistic regression, with smoking status coded as 1 for quitters and 0 for smokers. The logistic regression model included main effects terms for nicotine gum (active or placebo), counseling (HE or MI) and a term for the interaction of gum and counseling. Adjusted odds ratios for quitting (and their confidence intervals) were computed for each main effect and for the interaction term. For the primary and secondary end-points the interaction term was not significant and was dropped subsequently from the models. Secondary analyses included self-report and CO-verified 7-day abstinence at weeks 1, 8 and 26 using the same logistic regression modeling as for the primary end-point. We then subsequently utilized generalized estimating equations to longitudinally model self-report and CO-verified 7-day abstinence. All statistical analyses were performed on an intent-to-treat basis and those lost to follow-up were imputed as smokers for primary analyses. Classifying all those lost to follow-up as smokers is a conservative approach; we performed sensitivity analyses to assess the effect of this assumption on our conclusions. Mixed linear models were used to assess longitudinally the effects for nicotine gum (active or placebo), counseling (HE or MI) and their interaction on withdrawal symptom scores.

RESULTS

Of the 755 randomized participants, 603 (79.9%) were followed-up at week 8 and 637 (84.4%) at week 26 (Fig. 1). For the 118 participants lost to follow-up at 26 weeks, two were seen outside the study window, 112 did not return and four withdrew consent. To assess differential attrition due to counseling and nicotine gum, a multiple logistic regression model with counseling and gum as main effects was used to predict whether or not a patient returned. Adjusted odds ratios were calculated, along with corresponding 95% confidence intervals. Differential attrition analyses indicated that participants randomized to HE were more likely to return for in-person visits at week 1 (OR = 1.9, 95% CI = 1.2–2.9, $P = 0.003$), week 8 (OR = 2.2, 95% CI = 1.5–3.2, $P < 0.001$) and week 26 (OR = 1.6, 95% CI = 1.1–2.4, $P = 0.02$). Additionally, those assigned to active gum were more likely to return at week 8 (OR = 1.6, 95% CI = 1.1–2.3, $P = 0.01$). The interaction between gum and counseling was not significant and was therefore not included in the model.

Self-report and biochemically confirmed abstinence rates for the four groups at various time-points are shown in Table 2. One hundred and ninety-four participants reported quitting at week 26. Of these, 95 (49.0%) were confirmed quitters (salivary cotinine ≤20 ng/ml). Given the rate of discrepancy between self-reported and cotinine verified quitting, logistic regression modeling was conducted to examine demographic and psychosocial

Table 2 Self-report and biochemically verified 7-day Abstinence rates.*

	Gum + HE (n = 189)	*Gum + MI (n = 189)*	*Placebo + HE (n = 188)*	*Placebo + MI (n = 189)*
Self-report imputed				
Quit at week 1 *n* (%)	48 (25.4%)	29 (15.3%)	41 (21.8%)	24 (12.7%)
Quit at week 8 *n* (%)	62 (32.8%)	45 (23.8%)	55 (29.3%)	33 (17.5%)
Quit at week 26 *n* (%)	67 (35.5%)	35 (18.5%)	60 (31.9%)	32 (16.9%)
Carbon monoxide verified (≤ 10 p.p.m.)				
Quit at week 1 *n* (%)	43 (22.8%)	29 (15.3%)	39 (20.7%)	24 (12.7%)
Quit at week 8 *n* (%)	58 (30.7%)	40 (21.1%)	47 (25%)	32 (16.9%)
Quit at week 26 *n* (%)	55 (29.1%)	29 (15.3%)	45 (23.9%)	28 (14.8%)
Saliva cotinine verified (≤ 20 ng/ml)				
Quit at week 26 *n* (%)	34 (18.0%)	19 (10.1%)	29 (15.4%)	13 (6.9%)

*Those lost to follow-up or outside scheduled visit window were treated as smokers.

Table 3 Joint and marginal salivary cotinine verified cessation rates for week 26 by counseling and nicotine replacement therapy (NRT) use.

	NRT		
Counseling	*Placebo Gum*	*Active Gum*	*Marginal*
HE	15.4%	18.0%	16.7%
MI	6.9%	10.1%	8.5%
Marginal	11.1%	14.2%	

factors related to misreporting. Results indicate that participants with higher baseline cotinine were less likely to report their smoking status accurately at week 26 (OR = 0.995, 95% CI = 0.993–0.998) than those with lower baseline cotinine. No other demographic (age, gender, baseline cpd, education, marital status, the presence of other smokers in the household, alcohol use, previous quit attempts in the past year, nicotine dependence) or psychosocial factors (motivation for quitting, depression, counselor–participant relationship) were related to misreporting of smoking status.

Table 3 shows the salivary cotinine-verified cessation rates for week 26 by counseling and gum, as well as at the margin. To examine the effect of gum, type of counseling and their interaction on cessation, a logistic regression for verified cessation at week 26 was performed (Table 4). Because the interaction between counseling and gum was not significant ($P = 0.6227$) it was dropped from the model, resulting in a model with only the main effects of gum and counseling. The results did not change when analyzing completers only and not imputing missing values as smokers.

We also utilized generalized estimating equations (GEE) to assess longitudinally the main effects of gum and counseling and their interaction on CO verified and self-reported 7-day abstinence. In both analyses, there was no significant gum × counseling interaction and there was no significant effect due to drug, but there remains a significant effect due to counseling.

Withdrawal symptoms

In order to evaluate whether withdrawal symptoms affected efficacy of nicotine gum or counseling, we assessed longitudinally withdrawal symptoms over time adjusting for baseline level and current smoking status. There were no main effects of gum or counseling, nor was there an interaction effect of these variables on withdrawal over time. As the mean withdrawal scores did not differ by either type of counseling or gum, we did not present the withdrawal scores by those who relapsed or remained abstinent.

Process evaluation of counseling and gum

Participants assigned to HE were more likely to return than those assigned to MI ($\chi^2 = 17.4$, $P = 0.004$). Overall, 68.8% of participants randomized to MI returned for five or more sessions, whereas 80.9% of participants randomized to HE returned for five or more sessions. Of those smoking 8–10 cpd at baseline ($n = 387$), participants reporting chewing a mean of 6.3 (SD = 4.8) and 4.4 (SD = 4.2) pieces of gum per day in the last 7 days of the recommended 10 and six pieces per day at weeks 1 and 8. Of those smoking 5–7 cpd at baseline ($n = 253$), participants reporting chewing a mean of 5.1 (SD = 3.6) and 3.3 (SD = 3.7) pieces of gum per day in the last 7 days of the recommended 8 and 4 pieces per day at weeks 1 and 8. Of those smoking < 5 cpd at baseline ($n = 115$), participants reporting chewing a mean of 4.1 (SD = 3.8) and 2.7 (SD = 3.0) pieces of gum per day in the last 7 days out of the recommended six and two pieces per day at weeks 1 and 8. No differences were found in gum usage between those randomized to active or placebo gum. Additionally,

Table 4 Logistic regression model for verified cessation rates at 26 weeks.

Variable	*Estimate (SE)*	*Odds ratio*	*95% CI for OR*	*P-value*
Intercept	– 2.00 (0.12)	–	–	< 0.0001
Counseling (HE = 1, MI = 0)	0.39 (0.12)	2.17	1.38–3.41	0.0008
NRT (gum = 1, placebo = 0)	0.12 (0.11)	1.31	0.84–2.02	0.2318

There was no significant interaction between NRT and counseling ($P = 0.6227$), thus it was dropped from the logistic regression model.

no differences were found in gum usage between those randomized to MI or HE.

DISCUSSION

The current study tested the efficacy of 2 mg nicotine gum in conjunction with counseling for smoking cessation among African American light smokers. Contrary to expectation that those receiving active gum would have higher quit rates than those receiving placebo gum, the 2 mg nicotine gum was not effective for smoking cessation in our sample of African American light smokers. Although several studies in controlled research settings have shown that nicotine gum is effective for smoking cessation, a number of studies in primary care settings have failed to find significant effects for the gum over placebo [34–37]. Among the reasons given for the lack of effectiveness of gum in 'real world' versus controlled trial settings are poor adherence to dosing instructions and lower motivation to quit [35–37]. In the present study, our failure to find an effect of gum may have been due to inadequate usage or under-dosing. Specifically, because this was a sample of light smokers we chose to use 2 mg as opposed to 4 mg gum and prescribed a maximum of 10 pieces of gum per day. On average, participants chewed 5.5, 3.8 and 3.9 pieces of gum per day at weeks 1, 3 and 8, respectively, which probably did not provide adequate nicotine replacement, particularly when considered within the context of the relatively high mean baseline serum cotinine levels (244.2 ng/ml) found among participants in our sample. This compares to previous work with a sample of heavier African American smokers who had a mean cotinine level of 292 [38]. This suggests that our population of African American light smokers may have had better cessation outcomes if treated with pharmacotherapy dosages used for heavier smokers. It is also possible that our group of light smokers may have underreported their baseline cigarettes smoked per day. While participants reported smoking an average of 7.4 (SD = 2.4) cpd at baseline, their cotinine values are consistent with a significantly higher rate of smoking closer to the national average for African American smokers (12 cpd) [8]. Because we considered the possibility of under-reporting as a factor in the discrepancy between self-reported cigarettes smoked per day and cotinine levels, we explored factors associated with this discrepancy. The only statistically significant finding was that those with higher serum cotinine levels were less likely to report their smoking accurately. However, this difference (odds of 0.995, or 1 ng unit difference) does not seem to be clinically significant. Future studies might consider using other means of assessing smoking status, such as cigarette smart packs, timeline follow-back procedures or baseline cotinine levels as an adjunct to self-report.

This study also found that withdrawal symptoms were not affected by treatment. This finding is not surprising for two reasons. First, if lack of effect of nicotine gum on abstinence is due to under-dosing of the gum, then inadequate nicotine replacement may be a possible explanation for why withdrawal symptoms did not change over time. Secondly, some studies of a subset of light smokers called 'chippers' (who smoke five or fewer cigarettes a day) showed that that group of light smokers did not report withdrawal symptoms when abstinent from smoking. Findings from present study with respect to withdrawal symptoms are consistent with these earlier studies of chippers [4,39].

With regard to counseling, this study also found that African American light smokers randomized to HE were more likely to return for their counseling visits than those randomized to MI. Additionally, participants receiving the advice-oriented health education had higher quit rates that those who received motivational interviewing counseling. Differential return rates do not explain the higher effect of HE because results remained the same when analyzed for completers only. These findings suggest that HE counseling was perceived as more relevant among our sample of highly motivated smokers. Because of the common notion that light smokers would not be interested in quitting we had hypothesized that this group of smokers would do better with a counseling technique designed to enhance and reinforce their motivation. However, our baseline data showed that majority of participants in the study were already highly motivated to quit before receiving any intervention. Our finding of less favorable outcomes with MI is consistent with other studies that have shown that MI works better among people who are resistant, angry or demonstrate low motivation to change a particular health behavior [40], and therefore may be contraindicated for patients who are

ready for action. On the other hand, having more favorable outcomes with advice-oriented health education is an encouraging finding with practice implications for health care providers. Because health education does not require the type of specialized training as does MI, it approximates more closely the type of cessation advice that can be delivered in most health-care settings.

Our study has some limitations. First, although a wide variety of community-based recruitment strategies were used to reach potential participants from the entire Kansas City metropolitan area, randomization and follow-up activities occurred at a single community health center. Therefore, our findings may not be generalizable to all African American light smokers. Secondly, because of the nature of our intervention, participants were required to have both a home address and access to telephone. It is possible for results to be different among people without access to a telephone or who are homeless. Thirdly, similar to our previous studies in this population, about two-thirds of our sample were females. This may have resulted in lower quit rates in our sample because some studies have reported that women appear to have lower quit rates on NRT [41]. Fourthly, as is the case in most smoking cessation clinical trials, participants are a self-selected group who are motivated to quit smoking, which may limit generalizability, but actually reflects the group of smokers for whom pharmacotherapy may be most appropriate. Finally, as discussed earlier, our instructions on gum usage were incongruent with patient serum cotinine levels. This may have led to significant underdosing which, in turn, could have contributed to lack of efficacy for nicotine gum.

In sum, the current study found that advice-oriented health education was more effective than motivational interviewing counseling for smoking cessation among African American light smokers who were motivated to quit and that the 2 mg nicotine gum was not effective in this population. While it is encouraging to see a large number of African American light smokers enroll in a cessation clinical trial, contrary to the belief by many that it would be easier for light smokers to quit smoking, the quit rates for African American light smokers in this study are lower than expected. Given these low quit rates, the growing prevalence of light smoking, and its associated health risks, efforts must continue to develop and test interventions that would enhance smoking cessation among light smokers. Extending smoking cessation interventions to African American light smokers is an important contribution towards reducing tobacco-related health disparities in the United States.

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