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Nicotine Replacement: Effects on Postcessation Weight Gain

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The present study examined nicotine replacement effects on postcessation weight gain in smoking cessation clinic volunteers using objective indices of cigarette smoking, gum use, and body weight. After they achieved abstinence, subjects were randomly assigned to either active nicotine or placebo gum conditions for 10 weeks, during which smoking status was carefully monitored. Analyses revealed strong evidence for a gum effect on weight gain, with active gum users gaining a mean total of 3.8 lb compared with 7.8 lb for placebo gum users at the end of the 10-week trial. Evidence for a dose–response relation was found, suggesting that more gum use (≥6.5 pieces/day) resulted in greater weight suppression. Placebo gum subjects reported greater postcessation increases in eating and hunger compared with active gum subjects. The implications of the weight suppression effect of nicotine gum for smoking cessation treatments are discussed.

There is considerable evidence that smoking cessation results in weight gain for both men and women. Examples of the amount of weight gained can be derived from several long-term prospective studies of weight change following smoking cessation, which have found that smokers who remain abstinent for at least 1 year gain between 5 and 12 lb (Blitzer, Rimm, & Giefer, 1977; Coates & Li, 1983; Comstock & Stone, 1972; Hall, Ginsberg, & Jones, 1986; Khosla & Lowe, 1971). Several studies have reported that the amount of weight gain is related to precessation smoking level, as measured by self-reported consumption (Blitzer et al., 1977; Comstock & Stone, 1972; Hall et al., 1986; Emont & Cummings, 1987), although this finding is not universally supported. Furthermore, weight gain is a clinically important issue in the treatment of tobacco dependence because, insofar as weight gain is a concern of smokers, this concern can act as a deterrent to quit or to achieve successful long-term abstinence (Klesges & Klesges, 1988).

There are several hypothesized routes by which smoking cessation leads to weight gain (see Wack & Rodin, 1982, for a review). There is strong suggestive evidence, from both animal and human research, that nicotine is responsible for suppressing caloric consumption and altering metabolism, which results in the lower body weight commonly observed in smokers. Animal studies have shown that nicotine administration suppresses weight gain in growing rats (Grunberg, Winders, & Popp, 1987; McNair & Bryson, 1983; Wager-Srdar, Levine, Morley, Hoidal, & Niewoehner, 1984). Other data supporting the role of nicotine in altering metabolism or eating behavior come from human studies of the metabolic effects of nicotine, in which drug administration has been shown to chronically increase resting metabolic rate as assessed by indirect calorimetry (Glauser, Glauser, Reidenberg, Rusy, & Tallarida, 1970), whereas drug withdrawal has appeared to enhance appetite and eating (Stamford, Matter, Fell, & Papanek, 1986). However, chronic exposure to other constituents of cigarette smoke such as carbon monoxide (Koob, Annau, Rubin, & Montgomery, 1974; Reckzeh & Dontenwill, 1970) and nicotine (Wager-Srdar et al., 1984) produce weight loss in animals and may also contribute to the weight changes associated with cigarette smoking cessation. Clearly, further research is needed to fully understand the relation between cigarette smoking and weight gain.

If removal of nicotine from the body causes rebound weight gain, nicotine replacement after smoking cessation might be expected to reduce or prevent weight gain. Clinical studies have suggested that nicotine replacement via the use of Nicorette chewing gum may suppress postcessation weight gain in recently abstinent smokers. Emont and Cummings (1987) found a significant inverse correlation between weight gained and number of pieces of nicotine gum chewed per day over a 1-month period for heavier smokers. This study, however, relied on the self-report of weight, gum use, and smoking status over a fairly brief period of abstinence. Fagerstrom (1987) reported similar findings at the end of a 6-month study, suggesting a dose–response relation between gum use and weight gain: Infrequent nicotine gum users (≤263 pieces used during the trial) showed a 6.8-lb weight gain compared with frequent gum users (>263 pieces), who showed a 2.0-lb weight gain. This study, however, did not report the biological verification of abstinence or the duration of gum use.

The present study examined nicotine replacement effects on postcessation weight gain under tightly controlled conditions that included close monitoring and biological verification of gum use, objective weight measurements, and frequent smoking abstinence checks based on biological measures. We hypothesized that weight gain would be suppressed in the active as compared with the placebo gum condition. The study also provided an opportunity to examine self-reported changes in eating styles and patterns following smoking cessation.

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Method

Subjects

Subjects were recruited from the community through local media to participate in a smoking cessation program involving nicotine gum, behavioral counseling, and group support. Interested smokers who responded to advertisements were screened in brief telephone interviews and were required to be 18–70 years old, to smoke at least 10 cigarettes/day, to be motivated to quit smoking, to be free from psychiatric diagnosis, to reside within 15 miles of the hospital, and to be medically approved to chew nicotine gum. Of the 127 adults who attended the introductory meeting, 87 (68.5%) attended the requisite three prequit meetings and were assigned to a gum condition. Depending on their compliance from this point on, subjects were categorized as dropouts, exclusions, or completers. Over the course of the 10-week trial, there were 44 (50.6%) dropouts for reasons including initial failure to quit smoking (30%), failure to keep appointments after quitting (9%), self-reported relapse to smoking (57%), hospitalization (2%), and failure to use gum (2%). Subjects were not dropped for isolated smoking slips that were followed by abstinence. Of the remaining 43 subjects who completed the 10-week trial, there were 3 exclusions following detection of noncompliance with smoking abstinence ($n = 2$) and/or gum use ($n = 1$) based on biochemical analyses that were performed after the end of the study. Thus, 40 study completers remained for all subsequent analyses.

Study completers ($n = 40$), when compared with dropouts ($n = 44$), were of higher socioeconomic status (SES) based on Hollingshead's Index of Social Status ($p < .002$) and were lighter smokers based on reported cigarettes smoked per day: For completers, $M = 29.7$, $SD = 9.9$; for dropouts, $M = 36.0$, $SD = 13.8$ ($p < .03$). Placebo gum subjects were also overrepresented among study dropouts (67% of dropouts had been assigned to placebo). Exclusions did not differ from completers on any of the baseline measures.

Procedure

Subjects attended three smoking cessation classes over a 2-week period prior to receiving gum. Classes consisted of small group discussions about addiction and the hardships of quitting smoking, instruction on nicotine gum use, behavioral instruction in smoking cutdown, stimulus control of smoking cues, alternative behaviors for smoking, and relapse prevention. All subjects received "Freedom From Smoking in 20 Days," a booklet published by the American Lung Association as a behavior change guide. A battery of self-report measures, objective indices of cigarette smoke exposure, and body weight were obtained at the first meeting. The prequit smoking goal was to reduce cigarettes to five per day in preparation for 10 weeks of complete abstinence and daily gum use. At the third prequit meeting, subjects received a 1-week supply of gum under double-blind conditions and were told to quit smoking completely and to begin chewing between 5–15 pieces of gum daily.

Assignment to gum condition was random, with stratification on sex, baseline weight, and baseline carbon monoxide (CO) level. Subjects were deliberately overassigned to the placebo condition (1.4:1) in anticipation of greater dropout in this condition.

During the 10 weeks of abstinence, subjects reported to the laboratory twice weekly for biological and self-report data collection, replenishment of gum supply (105 pieces/week), and brief smoking cessation counseling with the experimenter. At each lab visit, subjects were weighed on a standard balance beam scale, provided a breath sample for analysis, returned used gum from the previous week, and completed questionnaires. For the CO analysis, subjects expired breath into a 1-L bag following a 20-s breath hold. The contents were analyzed for CO with a MiniCo Carbon Monoxide Indicator (Catalyst Research Corporation, Model 1000).

Carbon monoxide was used throughout the study to provide objective feedback to subjects about their progress in cutting down and to provide an objective confirmatory variable to researchers for assessing abstinence later in the study (8 ppm or less was coded as abstinent). Saliva from the first baseline meeting and from postcessation Weeks 1, 2, 6, and 10 were sent to an outside laboratory on completion of the study for gas chromatography analysis of cotinine and thiocynate. Thiocyanate, a biochemical index of smoke exposure, is not influenced by nicotine gum exposure and was used to confirm smoking abstinence. Cotinine, a nicotine metabolite, was used to verify adequate levels of nicotine exposure in the active gum condition and to corroborate abstinence in the placebo gum condition. We used a further procedure for abstinence verification: Subjects were visited in their homes 2–3 times per week on weekday evenings and on weekend days for unannounced breath sample collections, which were later subjected to CO analysis. Each day of the week was selected with an equal probability for the home visits according to a predetermined random schedule. As an additional incentive for remaining abstinent, each abstinence level CO score earned the subject a token toward a weekly cash lottery, with prizes ranging from $10 in postquit Week 1 to $75 in Week 10. At follow-up Week 23, subjects attended the lab to be weighed and to provide CO verification.

Subjective Report Measures

A battery of subjective report measures was administered at the lab visits. A face-valid food groups questionnaire was created by the experimenters to provide general information about food consumption patterns over the course of the study. This questionnaire asked subjects to rate the perceived extent of change in their dietary consumption during a given study week compared with their food consumption levels when they were smoking. The food groups questionnaire inquired about subjects' overall appetite; meal size; and consumption of sweets and desserts, fruits and vegetables, and dairy products. This measure allowed us to gather preliminary data on the self-perception of changes in diet patterns as a function of quitting smoking and gum condition. The exercise questionnaire, another face-valid measure created for the purpose of this study, asked subjects to recollect the amount of exercise they had done each day of the previous week, whether or not they had dieted that week to lose weight, and what methods of dieting were used. The Three-Factor Eating Questionnaire (Stunkard & Messick, 1985), administered at baseline and at Week 10, was used as an index of eating patterns. The 51-item measure was scored according to the format described by Stunkard and Messick. Originally designed to measure dimensions of human eating behavior, this questionnaire is composed of three factor-analytically derived subscales: Factor 1, Cognitive Restraint of Eating and Nutritional Knowledge; Factor 2, Disinhibition; and Factor 3, Hunger. Factors 1 and 2 were conceptualized as relatively stable trait variables and were not expected to change from baseline to Week 10 as a result of smoking cessation. However, Factor 3, Hunger, might be mediated by cigarette use if appetite is in fact curbed by smoking. Thus, hunger was predicted to increase from baseline to postcessation Week 10 and was expected to increase more for placebo than for active gum subjects.

Results

Data were collected weekly or summarized for weekly intervals and were analyzed in repeated-measures analyses of variance (ANOVAs) and covariance (ANCOVAs) for effects of active versus placebo gum condition (group), postcessation time (week), and Group × Week interaction. The unit of measurement for weight analyses was the change in pounds from baseline at each postcessation week. Baseline weight was the mean value of three precessation measurements. The results for all

Table 1
Baseline Subject Characteristics

Variable	Active (n = 20) M	Active (n = 20) SE_M	Placebo (n = 20) M	Placebo (n = 20) SE_M
Demographic				
Female (%)	55.00		50.00	
Age (years)	41.80	2.16	43.55	2.10
Smoking history (years)	24.00	2.09	24.35	2.15
Previous quit attempts (no.)	2.10	0.40	2.90	0.67
Baseline weight (lb)	158.10	6.11	158.20	6.56
Group average				
Men	171.11	5.59	178.30	4.84
Women	147.45	9.71	138.10	8.88
Smoking				
Cigarettes per day	25.50	1.52	33.95	2.61
Cigarette nicotine yield (mg)	0.78	0.07	0.81	0.07
Carbon monoxide (ppm)	28.37	1.75	31.56	3.01
Salivary cotinine (ng/ml)	336.90	24.40	303.80	31.20
Salivary thiocyanate (μM/L)	3454.45	286.90	2977.45	255.80
Diet and exercise				
TFEQ				
Factor 1	7.60	1.04	7.05	1.09
Factor 2	4.00	0.59	6.05	0.99
Factor 3	3.35	0.60	4.75	0.69
Exercise per week (hr)	1.0	0.56	.34	0.31
Dieting to lose weight (%)	15		20	

Note. TFEQ = Three-Factor Eating Questionnaire.

repeated-measures ANOVAs are reported as Huynh-Feldt-corrected p values (Jaccard & Ackerman, 1985).

Subject Characteristics

Table 1 shows baseline demographic, smoking behavior, and questionnaire means for the 40 study completers by gum condition. Baseline comparisons between the two gum conditions revealed that placebo subjects reported smoking significantly more cigarettes per day compared with active subjects, $t(38) = 2.80$, $p < .008$. Groups did not differ at baseline on biological exposure to tobacco constituents; body weight; or self-report measures of eating, dieting, and exercise behavior.

Gum Use

In a repeated-measures ANOVA of gum chewed per day, there was a significant Group × Week interaction, $F(9, 342) = 2.10$, $p < .03$, reflecting relatively steady gum use by active gum subjects compared with a gradual decline in gum use over the weeks by placebo subjects. However, the overall mean gum use for the two groups did not differ (for the active group, $M = 6.9$, $SE_M = .50$; for the placebo group, $M = 5.7$, $SE_M = .52$). Cotinine analysis was used to verify compliance with gum use. Active gum subjects achieved steady average cotinine levels of 166.5 ng/ml ($SE_M = 15.9$) from Weeks 2–10, whereas no significant salivary cotinine could be detected for placebo subjects ($M = 3.0$ ng/ml, $SE_M = 1.4$), $F(1, 38) = 88.18$, $p < .001$.

Abstinence Verification

Self-reported smoking abstinence was verified by frequent breath sample carbon monoxide analysis and by periodic analysis of saliva samples for thiocyanate. Only 5% of the 1,487 CO readings obtained (lab visits plus home visits) exceeded the abstinence cutoff of 8 ppm, with no difference shown between the gum conditions. Average salivary thiocyanate levels, which did not differ between groups, decreased from a mean level of 3,216 μM/L ($SE_M = 196$) during postcessation Week 1 to a mean of 1,108 μM/L ($SE_M = 85$) by postcessation Week 10. Nonsmoking salivary thiocynate levels generally fall below 1,200 μM/L (Bliss & O'Connell, 1984). Given the assurance of smoking abstinence concurrent with appropriate nicotine and placebo gum use, the analysis of weight change was undertaken.

Weight Gain

Active versus placebo gum effects. The study provided strong evidence for a gum effect on postcessation weight gain, with group main effect $F(1, 39) = 10.6$, $p < .002$, as illustrated in Figure 1. For the placebo group, weight gain began immediately after cessation and continued at a steady rate through Week 10. By Week 10, placebo gum subjects had gained an average of 7.8 lb. Body weight also increased steadily for active gum subjects to postcessation Week 7, after which no further weight gain was observed: Group × Week interaction, $F(9, 342) = 4.0$, $p < .001$. Active gum subjects gained only 3.8 lb, on average, by the end of Week 10. These data suggest that using active gum resulted in a 50% reduction in cessation-related weight gain.

A more conservative confirmatory analysis of the gum effect on weight gain was performed by using a repeated-measures ANCOVA with two baseline measures, cigarettes per day and

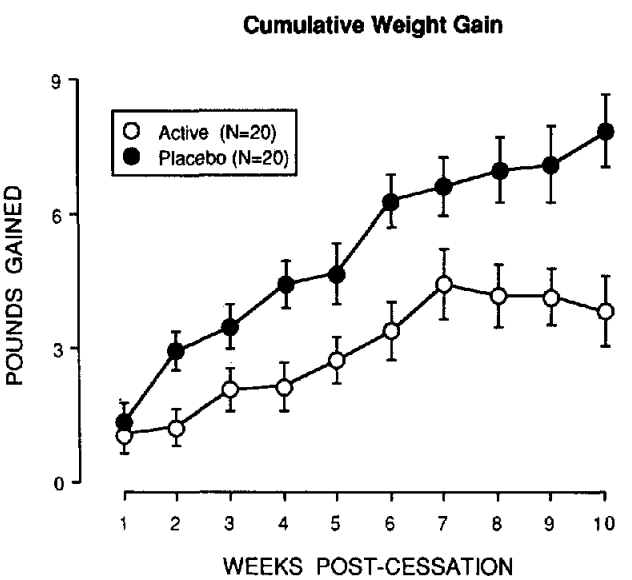

Figure 1. Cumulative weight gain in pounds ($M \pm SE_M$) is shown for active gum (open circles) and placebo gum (closed circles) subjects over 10 postcessation weeks. (Weight change is assessed in relation to baseline body weight, which was averaged over three precessation measurements.)

body weight, as covariates. Cigarettes per day was chosen as a covariate because the groups reported using significantly different numbers of cigarettes per day at baseline ($p < .05$; see Table 1). Although precessation body weight did not differ between the groups at baseline, it was selected as a covariate because baseline weight was correlated with weight gain in the placebo condition, $r(18) = .42$. In the ANCOVA, the group effect remained significant, $F(1, 36) = 10.21$, $p < .003$. Baseline weight (but not baseline cigarettes per day) emerged as a significant covariate, $F(1, 36) = 8.47$, $p < .006$. Adjusted and unadjusted mean pounds differed by no more than .05 lb at any given weekly time point.

Active gum dose effect. The study also provided suggestive evidence for a nicotine dose effect on weight gain. Active gum subjects were categorized into high and low nicotine gum use based on a cutoff of 6.5 pieces per day. The high-use group ($n = 8$) used an average of 9.2 pieces per day throughout the trial, whereas the low-use group ($n = 12$) used an average of 5.4 pieces per day. The high- and low-use groups did not differ on baseline levels of reported cigarette consumption, cotinine, body weight, or any of the other baseline self-report measures. Low-use subjects, however, did have significantly greater baseline thiocyanate levels ($M = 3{,}989$ μM/L) compared with high-use subjects ($M = 2652$ μM/L), $t(18) = 2.61$, $p < .02$. Low-use subjects gained an average of 5 lb compared with high use subjects, who gained only 1.5 lb. In contrast, placebo gum subjects gained 7.8 lb. The difference in weight gain among the three nicotine dosages (i.e., placebo, low-use active, and high-use active) was significant, $F(2, 38) = 10.92$, $p < .0002$. Post hoc Tukey tests revealed that weight gain for the high-use group was significantly less than weight gain for both the low-use group ($p < .05$) and the placebo group ($p < .01$), whereas weight gain for the low-use group was not significantly different from that for the placebo group.

Three-month follow-up. All subjects were contacted 13 weeks after completion of the nicotine gum trial. At the lab visit, 25 subjects (11 active and 14 placebo) had CO-verified abstinence. No subjects were using nicotine gum. Follow-up weight gain (Weeks 11–23) ranged from −3 lb to 11.3 lb for abstinent active subjects ($M = 3.1$, $SE_M = 1.4$) and from −6.0 lb to 9.0 lb for abstinent placebo subjects ($M = 1.8$, $SE_M = 1.1$). At Week 23, the cumulative weight gains for the abstinent subjects from each of the gum conditions were not different: for abstinent active subjects, $M = 6.8$ ($SE_M = 1.7$); for abstinent placebo subjects, $M = 8.7$ ($SE_M = 1.6$). Post hoc analyses showed that weight at Week 10 did not predict follow-up smoking status; subjects who were abstinent at follow-up did not differ in weight at Week 10 from subjects who had relapsed by follow-up. Additionally, at Week 10, abstainers had weight gains that were similar to their respective group means: For abstinent active subjects, $M = 3.7$ ($SE_M = 1.2$); for abstinent placebo subjects, $M = 6.9$ ($SE_M = 1.0$).

Eating Patterns

Although the food groups questionnaire was developed solely for this study and was not subjected to tests of external validity, it provided preliminary evidence for the effect of gum use and smoking cessation on eating patterns. A repeated-measures ANOVA for each of the food groups was performed from assessments at postcessation Weeks 1 and 10. After 10 weeks of smoking cessation, placebo more than active gum subjects reported increases from precessation levels in meal size ($p < .02$), appetite ($p < .003$) and consumption of both salty ($p < .05$) and sweet ($p < .01$) snacks.

A further indication of change in self-reported hunger and eating patterns came from comparison of the individual factors of the Three-Factor Eating Questionnaire at baseline and postcessation Week 10. A repeated-measures ANOVA of Factor 1 showed no difference between gum conditions or change over time. Analysis of Factor 2 revealed a significant group main effect ($p < .017$), reflecting higher Factor 2 scores for placebo subjects but no interaction with time. Analysis of Factor 3 revealed a significant group main effect ($p < .003$), with placebo subjects having greater overall scores and a significant interaction ($p < .008$), which showed that placebo subjects had an increase in hunger over time compared with active subjects who showed a slight decrease.

Finally, a similar analysis of data from the self-report exercise questionnaire (Weeks 1 and 10) revealed no significant group differences or Group × Week interactions on either the percent of subjects who claimed that they were trying to diet or on average hours of exercise per week.

Discussion

This study showed that postcessation weight gain was suppressed by approximately 50% in subjects who used active 2-mg Nicorette gum after quitting smoking as compared with subjects who used placebo gum, with total weight gains averaging 3.8 lb and 7.8 lb during the 10-week study for active and placebo gum subjects. Only 40% of active gum users gained 5 lb or more over 10 weeks, compared with 75% of placebo gum users. The weight suppression effect began by Week 2 of cessation and continued throughout the 10-week trial. The effect of active gum on weight suppression was very robust, as evidenced by significantly greater weight gain among placebo gum subjects in an analysis of covariance that controlled for baseline body weight and precessation cigarettes smoked per day. Finally, the trial was carried out under conditions of close subject monitoring that allowed us to verify both gum use and continued abstinence, conditions that lend scientific credibility to the results. The results of the present study are consistent with previous reports from nicotine gum clinical trials (e.g., Emont & Cummings, 1987; Fagerstrom, 1987), and the present study provides further experimental evidence for the role of nicotine in postcessation weight gain.

Subjects in the present study were highly motivated individuals who adhered to the rigors of an experimental protocol for 10 weeks. In addition, study completers were lighter smokers and of higher SES compared with dropouts. These factors could limit the generalizability of the findings to smokers in the general population. However, neither baseline cigarettes per day nor SES were significantly correlated with weight gain in study completers, suggesting that these were not important determinants of the nicotine gum effect. Furthermore, the amount of weight gained by placebo subjects was quite consistent with previous reports. These observations suggest that the present study

findings do not, in fact, have any serious generalizability limitations.

When data were analyzed for active gum subjects in relation to the number of pieces chewed per day, it became apparent that most of the weight suppression effect was due to 8 subjects who used more than 6.5 pieces of gum daily (M = 9.2 pieces per day) and gained little or no weight (mean weight gain = 1.5 lb). In contrast, subjects who used fewer than 6.5 pieces per day (n = 12) gained nearly as much weight as placebo gum subjects (mean weight gain = 5.8 lb). These observations, which suggest a nicotine dose–response relation, are consistent with recent studies by Fagerstrom (1987) and Emont and Cummings (1987) in which weight gain was suppressed to a greater extent in subjects who chewed more active gum.

Consistent with nicotine gum effects on weight gain, there was suggestive evidence that active gum subjects as compared with placebo gum subjects reported less postcessation change in self-perceived hunger, appetite, and consumption of various food groups. Other reports have linked smoking cessation to an enhanced preference for and consumption of sweet-tasting food in humans (Grunberg, 1982; Rodin, 1987) and in experimental animals (Grunberg, Bowen, Maycock, & Nespor, 1985), although studies directly measuring eating have shown inconsistent results (Rodin, 1987; Stamford et al., 1986). Further studies of postcessation dietary changes controlling for nicotine exposure are needed to elucidate the contribution of this behavioral factor to weight gain following smoking cessation.

Does the therapeutic use of nicotine gum prevent or merely postpone weight gain after smoking abstinence? Although our study was not designed specifically to test this issue, our 23-week follow-up data offer suggestive evidence that 10-week use of nicotine gum delayed rather than prevented eventual weight gain. The similar amounts of total weight gain for active and placebo subjects who were abstinent at the 23-week follow-up (6.8 lb and 8.7 lb, respectively) suggest that nicotine replacement delayed but did not prevent typical postcessation weight gain, an outcome that is consistent with the physiological effects of nicotine on dietary intake, physical activity, and resting or basal metabolic rate.

The study provided interesting data regarding the effects of active nicotine on gum usage. By the end of the trial, active gum subjects were chewing significantly more pieces of gum per day than were placebo subjects (for active subjects, M = 6.8 pieces; for placebo subjects, M = 4.8 pieces). This difference between active and placebo gum self-administration is consistent with the notion that nicotine gum is a reinforcer for smokers under blind administration conditions (Hughes, Pickens, Spring, & Keenan, 1985). Interestingly, however, active gum subjects chewed far less than the recommended 10–15 pieces per day despite frequent encouragement to increase gum use.

Nicotine gum use has demonstrable benefits for reducing withdrawal symptoms (e.g., Hughes & Hatsukami, 1986) and improving smoking cessation rates, especially among heavy smokers (Jarvik & Schneider, 1984; West, Hajek, & Belcher, 1986). Thus, methods are needed to overcome the resistance of smokers to use nicotine gum during cessation attempts. Because weight control appears to be a concern for a least a subgroup of smokers (Klesges & Klesges, 1988), information about the weight suppression effects of nicotine replacement therapy may be usefully applied to improve acceptance rates for this type of therapy. Among those for whom weight gain is an ongoing concern, the use of nicotine gum during the first few postcessation months may allow time to promote an acceptance of later weight gain or to implement additional changes in dietary and exercise behaviors that might effectively control weight in the absence of nicotine.

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