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Randomized Controlled Trial for Behavioral Smoking and Weight Control Treatment: Effect of Concurrent Versus Sequential Intervention

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The authors compared simultaneous versus sequential approaches to multiple health behavior change in diet, exercise, and cigarette smoking. Female regular smokers ($N = 315$) randomized to 3 conditions received 16 weeks of behavioral smoking treatment, quit smoking at Week 5, and were followed for 9 months after quit date. Weight management was omitted for control and was added to the 1st 8 weeks for early diet (ED) and the final 8 weeks for late diet (LD). ED lacked lasting effect on weight gain, whereas LD initially lacked but gradually acquired a weight-suppression effect that stabilized ($p = .004$). Behavioral weight control did not undermine smoking cessation and, when initiated after the smoking quit date, slowed the rate of weight gain, supporting a sequential approach.

Tobacco use, unhealthful diet, and physical inactivity lead the list of behavioral risk factors that heighten morbidity from chronic disease (Department of Health and Human Services [DHHS], 2002). The fact that behavioral pathogens tend to co-occur (Thompson & Warburton, 1992) creates the possibility of intervening broadly, comprehensively, and efficiently on more than one risk behavior simultaneously (cf. Bock, Marcus, Rossi, & Redding, 1998; Calfas et al., 2002; Emmons, Marcus, Linnan, Rossi, & Abrams, 1994). However, major questions remain unanswered about how best to accomplish multiple behavior change, including how to choose which behaviors to modify, whether to intervene on behaviors simultaneously or sequentially, and whether improvement on one behavior tends to be offset by deterioration of other behaviors (Kravitz et al., 1993; Ory, Jordan, & Bazzarre, 2002).

The decision to quit smoking potentially creates a teachable moment for intervention that also promotes healthful diet and activity change. Because a majority of smokers gain weight after quitting smoking (Klesges et al., 1997; Williamson et al., 1991), and because that prospect worries most women (Pirie, Murray, & Luepker, 1991), the average female smoker making a quit attempt may also be motivated to prevent gaining weight. Current guidelines recommend the use of behavioral treatment plus nicotine replacement and bupropion SR (sustained release) for smoking cessation (DHHS, 2000). Both of these pharmacotherapies (Hurt et al., 1997; Nordstrom, Kinnunen, Utman, & Garvey, 1999), as well as indirect serotonin agonists (Spring et al., 1995; Spring, Wurtman, Gleason, Wurtman, & Kessler, 1991), have been shown to inhibit postcessation weight gain without undermining abstinence. However, weight suppression is short lived because discontinuing pharmacotherapy leads to weight gain (Borrelli et al., 1999; Danielsson, Rossner, & Westin, 1999; Jorenby et al., 1999; Spring et al., 1995). We chose to examine a nondrug behavioral approach to attaining smoking cessation and weight control for two reasons. First, alternative nondrug treatments remain needed for the many smokers who prefer not to use pharmacotherapy to quit smoking and regulate body weight. Second, modifying diet and activity without introducing a new drug might offer better prospects for long-term weight maintenance because delayed postcessation weight gain need not be triggered by end-of-treatment withdrawal of a weight-suppressing drug.

Evidence has been mixed regarding whether behavioral weight control intervention combines efficaciously with behavioral smoking cessation treatment. Hall, Tuskell, Vila, and Duffy (1992) found that adding behavioral weight control (diet and exercise) to cessation treatment produced no significant weight suppression and heightened relapse to smoking. For Pirie et al. (1992) as well, adding diet and exercise to smoking treatment failed to suppress

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postcessation weight gain. In contrast to Hall et al., however, Pirie et al. found no adverse effect of behavioral weight control on abstinence. Differing from both Hall et al. and Pirie et al., Perkins et al. (2001) found successful suppression of postcessation weight gain by using both behavioral weight control and cognitive–behavioral treatment to address weight concerns (WCs). Moreover, unlike Hall et al. (1992), both of Perkins et al.'s (2001) weight-related modules tended to enhance abstinence compared with cessation treatment alone, with cognitive–behavioral treatment producing significant improvement. Increased exercise without dietary change has been associated with positive effects on abstinence in some studies (Marcus, Albrecht, King, & Parisi, 1999), though not all (Nishi, Jenicek, & Tatara, 1998; Ussher, Taylor, West, & McEwen, 2000), and exercise effects on postcessation weight gain have also been inconsistent (Jonsdottir & Jonsdottir, 2002; Kawachi, Troisi, Rotnitsky, Coakley, & Colditz, 1996; Marcus et al., 1999).

In view of these contradictory findings, the current study compared the effects of a single behavior change intervention versus two temporal variations of a multiple behavior change intervention on women's smoking cessation and weight gain. Both multiple behavior change interventions aimed to modify smoking, diet, and physical activity, whereas the single behavior change intervention aimed to modify solely smoking. In one multiple change condition, participants simultaneously initiated changes in smoking, eating, and activity. In the other, they changed the same behaviors sequentially, beginning with smoking. The aims were (a) to reexamine whether adding behavioral weight control to cessation treatment suppresses weight gain but undermines abstinence and (b) to determine whether outcomes differ depending on whether weight control intervention begins concurrently or after smoking cessation treatment.

To simplify the task of learning to manage food intake, we implemented a dietary intervention that initially supplied participants with all of their foods via a prepackaged meal plan. This enabled participants to take a learn-by-doing approach to acquiring new eating habits before mastering a knowledge base in nutrition. The meal plan included high-carbohydrate snacks because nicotine discontinuation has been shown to increase self-administration of such foods (Hall, McGee, Tunstall, Duffy, & Benowitz, 1989; Spring et al., 1991), possibly because snacks serve as positive reinforcers and substitute for cigarettes (Carroll, Carmona, & May, 1991; Spring, Pagoto, McChargue, Hedeker, & Werth, 2003).

Three treatment conditions were compared. In all conditions, participants received 16 weeks of behavioral smoking cessation treatment, quit smoking at Week 5, and were followed up for 9 months after the quit date. Early diet (ED) received a weight management module (diet and exercise) during the first 8 weeks of cessation treatment; late diet (LD) received weight management during the final 8 weeks. Control focused only on smoking cessation until they received weight loss counseling at Week 16. A treatment burden hypothesis posited that adding weight control to cessation treatment would impede abstinence relative to cessation treatment alone, with the rationale that changing several behaviors would be more difficult than changing a single behavior. Two competing treatment sequence hypotheses were specified. One hypothesis predicted superior outcomes for the ED condition. The rationale was that establishing healthy diet and activity patterns before quitting smoking would heighten self-efficacy and expectations that both smoking cessation and weight control could be attained, thereby facilitating both outcomes. The alternative hypothesis predicted superior outcomes for the LD condition. The rationale was that quitting smoking before beginning weight control would be less difficult than initiating both behaviors simultaneously and would reinforce healthy priorities that construe the health advantages of quitting smoking as more important than the cosmetic disadvantages of weight gain.

Method

Recruitment, Screening, and Randomization

Participants were recruited from the community via newspaper and radio stories, paid advertisements, posted flyers, and pay-slip announcements distributed by local employers. Announcements offered a free quit-smoking program for women interested in quitting smoking and minimizing weight gain. Enrollment criteria required women to (a) be between ages 20 and 75 years, (b) have smoked 10 or more cigarettes per day for the past year, (c) be willing and able to participate in smoking cessation treatment, (d) follow a prepackaged meal plan and a physical activity program, and (e) be willing to accept assignment into any of the three treatment conditions. Exclusion criteria ruled out participants who were current substance abusers, pregnant, lactating, or current users of nicotine replacement therapy, appetite suppressants, or beta-blockers. Also excluded were candidates with a history of diabetes, hypoglycemia, eating disorder, psychosis, or surgery for obesity. Participants who were currently dieting or had strong biases against or prior experience with the Nutri/System meal plan were also excluded.

Three cohorts were enrolled yearly at the University of Illinois at Chicago, Finch University of Health Sciences–Chicago Medical School, and the Hines Veterans Affairs Medical Center. Each cohort involved all three treatment conditions. The first cohort's treatment extended from January to April, the next cohort's lasted from May to August, and the last cohort's treatment went from September to December. Cohorts treated during Year 1 ($n = 72$) attended only 16 weekly study visits; 6 monthly follow-up visits were added to the protocol during Year 2 ($n = 243$). Intervention delivery and assessment of outcome variables were conducted in the same fashion across all years of the study.

Candidates who inquired about the program were screened via a standardized telephone interview. Those who met eligibility criteria were scheduled for in-person screening and were mailed questionnaires that assessed demographics, medical history, tobacco and alcohol use, depression (Beck Depression Inventory [BDI]; Beck, Ward, Mendelson, & Erbaugh, 1961), diet history, and weight cycling. During the screening visit, participants provided informed consent and completed the Fagerström Tolerance Questionnaire (FTQ; Fagerström, 1978), Smoking Self-Efficacy Scale (Colletti, Supnick, & Payne, 1985), and Why Do You Smoke? questionnaire (Ikard, Green, & Horn, 1969). They were also administered the nonpatient version of the Structured Clinical Interview for *DSM–III–R* (Spitzer, Williams, Gibbon, & First, 1992), an alcohol screening interview, and the Hamilton Depression Rating Scale (Hamilton, 1960). Baseline waist–hip ratio, weight, and height were measured, with the latter two variables converted to body mass index (BMI) with the formula weight in kilograms divided by the square of height in meters (kg/m^2; Keys, Fidanza, Karvonen, Kimura, & Taylor, 1972). Participants were then trained to record 4-day food diaries, which were used to determine baseline caloric intake.

After completing food diaries, participants indicated their availability and preferences for three different time slots (noon, late afternoon, evening) and locations available to hold treatment groups. After three time slots had been filled with 8–15 participants, groups were assigned to treatment conditions (ED, LD, control) via blocked randomization. Each group was scheduled for an orientation session 1 week before treatment began, at which participants were introduced, encouraged to exchange names and telephone numbers, informed of their treatment assignment, and given an overview of their respective programs. At the orientation session for ED, a nutrition assistant explained how to follow the meal plan and participants sampled Nutri/System foods. Participants then placed food orders so that a 1-week supply of prepackaged foods could be distributed at the first treatment session. Orientation to the meal plan occurred at Week 8 for LD.

Participants

Of the 824 women screened, 315 were randomized to treatment. Study candidates were excluded for the following reasons: (a) unable to contact (n = 179, 35.2%); (b) logistical problems with day, time, or location (n = 97, 19.1%); (c) already quit smoking (n = 66, 13.0%); (d) exclusionary psychiatric or medical condition (n = 49, 9.6%); (e) taking exclusionary medications (n = 48, 9.4%); (f) not interested (n = 36, 7.1%); (g) smoking less than 10 cigarettes per day (n = 15, 2.9%); (h) outside age range (n = 15, 2.9%); (i) using nicotine replacement (n = 3, 0.6%); and (j) previously used meal plan (n = 1, 0.2%). The flowchart in Figure 1 shows the number of participants from each treatment group who remained enrolled at the smoking quit date, through a 2-week grace period, through end of treatment, and follow-up.

The randomization sample was 66% Caucasian, 31% African American, and 3% other. Table 1 presents demographic data for each treatment group. The overall sample was comprised of middle-age, mildly depressed, moderately overweight, mildly weight-concerned women who were moderately heavy smokers and mildly to moderately nicotine dependent. Participants

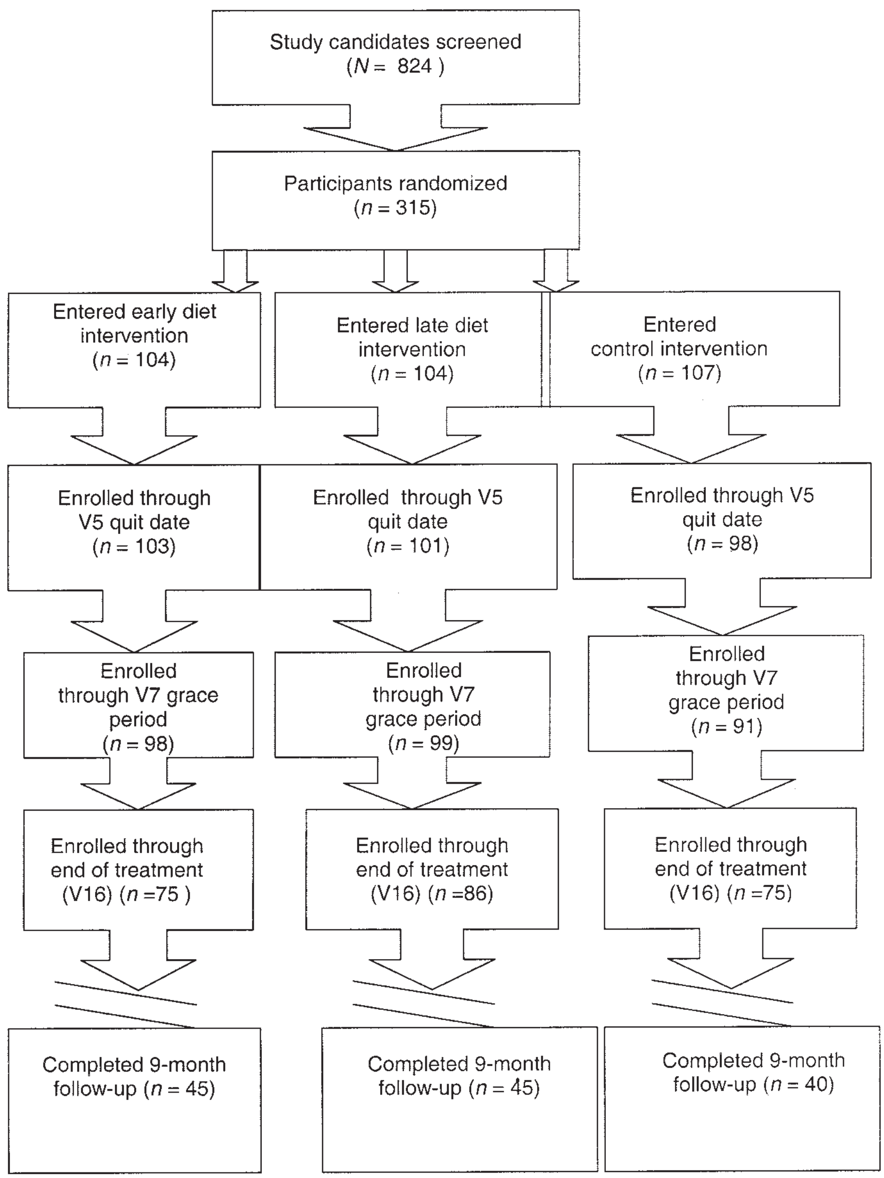

Figure 1. Flowchart showing progression of participants through the study. Hatched lines between end of treatment and follow-up indicate that participants in the first cohort were not asked to attend follow-up. V5 = Visit 5; V7 = Visit 7; V16 = Visit 16.

Table 1
Demographic and Clinical Characteristics

Characteristic	Control (n = 107) *M*	Control *SD*	Early diet (n = 104) *M*	Early diet *SD*	Late diet (n = 104) *M*	Late diet *SD*
Age (years)	43.39	11.28	41.45	9.80	43.20	9.81
Body weight	162.36	33.85	162.21	31.61	167.75	39.00
Body mass index	26.80	5.44	27.23	4.99	28.26	5.95
Cigarettes per day	19.75	8.88	20.24	8.64	21.02	10.90
FTQ	5.88	1.95	6.04	1.97	5.94	2.00
Weight concerns	8.84	2.88	8.47	2.35	8.68	2.79
BDI	9.48	7.74	8.91	7.00	8.94	6.70

Note. FTQ = Fagerström Tolerance Questionnaire; BDI = Beck Depression Inventory.

in the Year 1 cohort smoked significantly more cigarettes per day ($n = 72$; $M = 23.00$, $SD = 12.11$) than full-study-phase participants ($n = 243$; $M = 19.00$, $SD = 8.40$; $p = .001$) but did not differ on ethnicity, age, WC, FTQ, BDI, or BMI. No significant baseline differences were evident between the three treatment groups on age, ethnicity, WC, FTQ, number of cigarettes smoked per day, BDI, or BMI (see Table 1).

Procedure

Candidates for the study were informed that, although weight gain is a likely consequence of quitting smoking, it is unknown how weight gain can best be minimized without jeopardizing abstinence from smoking. Therefore, the goal of the study was to test three different interventions, each of which involved a smoking cessation and a weight management component. Study participants were scheduled for 16 weekly sessions of group cognitive–behavioral smoking cessation treatment plus 6 monthly follow-up sessions. The scheduled quit date was Week 5. ED received the weight management module (i.e., prepackaged meals and physical activity plan) during Weeks 1–8 of treatment, whereas LD received the weight management module during Weeks 9–16 of treatment. Control did not receive the weight management module. However, to equalize treatment desirability and credibility, they were informed that their final treatment group session (Visit 16) would be devoted to weight loss strategies, and they would be offered individual weight loss counseling after treatment ended. (In fact, though, no control participant accepted the offer of weight loss counseling after the end of treatment.)

Weight Management Module

The weight management module offered to ED and LD included both a prepackaged meal plan and a moderate-intensity physical activity plan.

Meal Plan

Participants' daily calorie intake was evaluated from diet records to develop a meal plan that supplied a high-carbohydrate, low-fat, balanced diet at a level sufficient to preserve baseline precessation energy intake minus 150 kcal per day. A 150 kcal per day decrease was implemented to compensate for metabolic slowing due to nicotine withdrawal (Perkins, Epstein, Marks, Stiller, & Jacob, 1989). The meal plan involved supplying participants with prepackaged Nutri/System foods. Food provision reduced the complexity, burden, and knowledge needed to implement a diet. The regimen also minimized feelings of deprivation because the fat content of the prepackaged foods was sufficiently low so that participants could be supplied with large quantities of food that they could feel free to eat while still maintaining energy balance. In addition, the meal plan incorporated high-carbohydrate, low-fat snacks that were to be eaten in the late afternoon and evening, which enabled participants to indulge in what may be a biologically driven urge for carbohydrate snacks during nicotine deprivation (Spring, Chiodo, & Bowen, 1987; Spring et al., 1991, 2003).

Weight management groups underwent meal plan training during which they learned what Nutri/System foods were available, sampled the foods in their prepared versions, were advised on food preparation, and learned what supplemental foods they needed to eat (fresh fruits and vegetables). Each week they received food for three meals plus two snacks per day. To conduct meal plan training in a group format without embarrassing group members by disclosing their caloric intake, we color coded paper materials. A different color was used for each meal plan and tandem order form for daily dietary intakes of 1,200 kcal, 1,500 kcal, and progressive 150 kcal increments up to 2,400 kcal per day. Before starting the meal plan, each participant met individually with a nutrition assistant who explained how to distribute the food allowance across the day. After participants began the meal plan, they placed a weekly food order at each group session and received their foods at the next treatment session. During weight management treatment, group sessions incorporated discussion of (a) how to integrate changes in eating into daily life, (b) successes and failures with the meal plan, and, eventually, (c) how to identify healthy, low-fat grocery store foods and develop meal planning and recipe redesign strategies. During a transitional week before finishing weight management treatment, participants interspersed 4 days of eating low-fat grocery store meals with 3 days of eating Nutri/System meals. Nutrition assistants remained available to counsel participants throughout weight management, transition, and follow-up.

Physical Activity

The physical activity regimen was modeled after Centers for Disease Control and Prevention–American College of Sports Medicine guidelines, which recommend 30 min of moderate-intensity activity at least 5 days per week (Pate et al., 1995). At the beginning of the weight management module, the current Centers for Disease Control and Prevention–American College of Sports Medicine guidelines were explained. Participants were given a list of activities that qualified as moderate intensity and were encouraged to progress toward the standard by incorporating any enjoyable forms of activity into their daily lives. To help participants initiate the activity regimen, we trained them to self-monitor heart rate and led them on a 30-min walk after each treatment session. Only ED and LD were led on group walks, and these discontinued at the end of the 8-week weight management module, although participants were encouraged to continue organizing their own group walks.

Smoking Cessation

All three groups received the same smoking cessation intervention, which consisted of 16 weekly sessions of cognitive–behaviorally oriented group therapy, led by a licensed clinical psychologist and a clinical psychology graduate student. In the four sessions preceding the quit date, participants discussed their reasons for smoking, physical dependence on nicotine, and self-efficacy for quitting. They self-monitored their smoking via pack wraps, identified smoking triggers, developed behavioral contracts for the quit date, and practiced stimulus control and coping strategies to manage withdrawal symptoms and cravings. The remaining sessions were devoted to relapse prevention or, if the quit attempt was unsuccessful, recycling toward a new quit date. In addition to group support, participants were offered telephone support as needed. They were also given a 24-hr pager number that they were urged to use to contact their group leader to cope with temptations to smoke.

Measurement

Primary Outcomes

Smoking status. Abstinence from smoking was assessed beginning at Visit 7, which is consistent with Society for Research on Nicotine and Tobacco guidelines (Hughes et al., 2003) that recommend allowing a 2-week grace period after the designated (Visit 5) quit date. Seven-day point prevalence smoking status was evaluated via self-report and ecolyzer measurement of expired carbon monoxide (CO). Participants who reported any smoking since the last visit (even a puff) were coded as smoking, regardless of ecolyzer results. Similarly, participants with ecolyzer values of equal to or greater than 10 ppm of carbon monoxide were coded as smoking, regardless of self-report. Of the 315 randomized participants, there were 183 (58.1%) who, on at least one occasion, reported smoking that escaped detection by the ecolyzer. In comparison, there were only 31 (9.8%; 10 control, 7 ED, 14 LD) who reported abstinence when ecolyzer data suggested smoking, and these numbers did not differ significantly by group. Thus, the data pattern suggests that participants were disproportionately more honest than dishonest in reporting smoking status. For the 71 participants who on at least one occasion self-reported abstinence but lacked ecolyzer data (i.e., when equipment malfunctioned or participants were unable to attend a session), we accepted self-reports of abstinence from those whose self-report and ecolyzer data were concordant on all visits when both were collected. However, for the 19 participants whose self-report of abstinence was invalidated at least once by ecolyzer data and who had another self-reported incidence of abstinence when ecolyzer data were missing, we recoded all unbioverified self-reports as smoking. The average number of visits recoded as smoking for these 19 participants did not differ among groups (control $M = 1.90$, $SD = 1.12$; ED $M = 2.14$, $SD = 1.41$; LD $M = 0.93$, $SD = 0.75$).

Weight change. So that smoking status could be controlled when assessing weight change, evaluation of weight change also began at Visit 7. Participants were weighed weekly with a balance beam scale throughout the treatment portion of the study and monthly throughout the follow-up period. Weight change at each visit was calculated by subtracting out participants' baseline weight.

Baseline Characteristics

Nicotine dependence. Physical dependence on nicotine was measured at baseline via the eight-item FTQ (Fagerström, 1978). FTQ scores range from 0 to 11, with values of 7 and higher suggesting significant nicotine dependence (Fagerström & Schneider, 1989; Gilbert et al., 1998; Killen, Fortmann, Newman, & Varady, 1991). Previous research has shown an association between FTQ scores and other measures of nicotine dependence (e.g., plasma nicotine and cotinine), supporting the construct validity of the FTQ (Heatherington, Kozlowski, Frecker, & Fagerström, 1991).

Smoking-specific weight concern. Attitudes about smoking as an appetite or weight control strategy were measured by a weight-concern scale developed by Weekley, Klesges, and Reylea (1992) as an adjunct to the Why Do You Smoke? questionnaire (Ikard et al., 1969). Scores range from 3 to 15, and the scale shows evidence of predictive validity (Weekley et al., 1992). A score of 7 or below indicates a low level of WC, whereas a score of 11 or greater indicates a high level of smoking-specific WC.

Missing Data

Dropout

A time-to-dropout variable reflected how long participants remained in treatment. Participants were considered to have dropped out of the study when they missed two or more consecutive visits and did not attend further visits. Time to dropout was operationalized as the number of weeks from baseline to the final visit attended.

Intermittent Missing Data

A percentage-of-missing data variable reflected the completeness of the smoking outcome data that each individual participant provided until the point of dropout. Percentage of intermittent missing data was calculated by determining the percentage of visits prior to dropout for which no smoking status data (self-report or ecolyzer) were available.

Treatment Process Measures

Session Attendance

During the 16-week intervention phase, attendance at smoking cessation treatment sessions was recorded weekly by group leaders. Percentage of attendance at treatment visits conveyed somewhat different information than percentage of missing smoking data because it was possible for participants to miss a group treatment session but still provide ecolyzer or self-report data on smoking status.

Outcome Expectations

At Weeks 1, 4, 8, 12, and 16 of the intervention phase, participants used single-item 10-point scales to rate their expectations about the degree to which treatment would (a) help them quit smoking, (b) minimize weight gain, and (c) be effective overall. One-month test–retest reliabilities for these single-item scales ranged as follows: $r = .36–.71$ for outcome expectations about quitting smoking, $r = .42–.59$ for expectations about minimizing weight gain, and $r = .34–.74$ for expectations about the program overall, with ratings showing increased reliability later in treatment.

Self-Efficacy

Participants rated self-efficacy for smoking cessation weekly using the Self-Performance Survey short form (Smith, Dobbins, & Wallston, 1991). In the current study, this four-item scale exhibited internal consistency reliability of $\alpha = .44–.55$ for Visits 1 and 2, which increased to $\alpha = .61–.83$ for subsequent visits. One-week test–retest reliabilities ranged from $r = .41$ to .78. Test–retest reliability of $r = .71$ has previously been reported over a 6-month interval, and the scale has shown evidence of validity as a longitudinal predictor of coping behavior (Smith et al., 1991).

Treatment Priorities

The manner in which participants prioritized their goals regarding weight control and smoking cessation was measured by having participants provide weekly ratings of their treatment priorities. Using 10-point scales, in which 1 = *not important* and 10 = *extremely important*, they rated the importance they presently assigned to preventing weight gain and to quitting smoking. One-week test–retest reliabilities for these one-item scales ranged from $r = .82$ to .96 for priority given to weight gain prevention and from $r = .41$ to .89 for priority given to smoking cessation.

Treatment Burden

To compare the three treatment conditions on demand or felt burden, participants rated the difficulty of following the smoking cessation program weekly using 10-point rating scales. One-week test–retest reliabilities ranged from $r = .17$ to .73.

Preliminary Analyses

Treatment groups were examined for evidence of differential dropout and differential missing data to determine whether the analytic plan needed to control for these sources of variation. There were no significant differences between the first and remaining cohorts or between any of the three groups in the percentage of the study completed prior to dropout. Across all cohorts, the average percentage of study completed prior to dropout was 78.3% for control, 80.9% for ED, and 86.2% for LD. Smoking status was missing intermittently at 11.4% visits prior to dropout for control and 8.6% for LD, which was a nonsignificant difference, though ED tended to have less missing data ($M = 7.8\%$) than control, $F(1, 185) = 3.85$, $p = .051$. Differences between the treatment groups in time to dropout and percentage of missing data did not reach conventional levels of significance but, nevertheless, showed some evidence of differentiation between groups. Therefore, we controlled for both sources of variation in the primary analyses by treating time to dropout and percentage of missing data as covariates.

Analytic Plan

To preserve the trial's internal validity, we analyzed outcomes on an intent to treat basis, including available data from all randomized cases, regardless of treatment adherence, intercurrent events, or missing data (Friedman, Furberg, & DeMets, 1998).

Longitudinal analysis of smoking status at the 16 time points (Visits 7–16 of treatment and Visits 1–6 of follow-up) was performed with a logistic regression model for correlated dichotomous responses estimated by the generalized estimating equations (GEE) method (Liang & Zeger, 1986), as implemented in SAS PROC GEE. This model characterized the repeated dichotomous classifications in terms of an initial cessation level and time-related changes in the cessation level. Both time and time squared terms were included in all analyses. Covariates were baseline weight, nicotine dependence, time to dropout, percentage of attendance, percentage of smoking status data missing prior to dropout, and weight change. Weight change was a time-varying covariate, whereas all others were time-invariant covariates. Controlling for these covariates, specific tests were conducted to determine the effect of condition on initial cessation (an initial effect of group) and time-related changes in cessation (a Group × Time interaction). Each condition contrast was also tested in interaction with session attendance to determine whether smoking outcome differed depending on the dose of treatment received. Nonsignificant interaction terms were removed from the model in a backwards manner (i.e., Group × Time Squared first, and then Group × Time) and the model was refit. If both Group × Time and Group × Time Squared terms were nonsignificant, the model was refit including only the main effect of group (i.e., group difference averaged over all time points). In terms of the group comparisons, two a priori contrasts were estimated: ED = ED versus control and LD = LD versus control. The GEE model provides statistical tests that are robust to misspecification of the dependency structure that results from the repeated assessments of an individual over time (Diggle, Liang, & Zeger, 1994). For this analysis, an m-dependent (or Toeplitz) correlation structure was chosen on the basis of the pattern of observed correlations of smoking status across time.

Weight change, determined by subtracting baseline weight from weight at each visit, was analyzed across the 16 time points. The analytic approach used mixed effects regression modeling, implemented via SAS PROC MIXED that incorporated a random intercepts, linear and quadratic trend model with autoregressive errors. As recommended by Verbeke and Molenberghs (2000), this variance covariance structure for the longitudinal data was selected after comparisons with several other potential structures. Model covariates were as follows: (a) baseline weight, (b) nicotine dependence, (c) percentage of attendance, (d) percentage of smoking status data missing prior to dropout, (e) percentage of visits at which participants were abstinent, and (f) weekly smoking status (a time-varying covariate). Both time and time squared terms were included in all analyses. Specific tests were conducted to determine the effect of condition on initial weight change (an effect of group at Week 7) and time-related changes in weight change (Group × Time interaction). The same a priori group contrasts were specified as in the smoking analysis: ED = ED versus control and LD = LD versus control. Again, each contrast was interacted with attendance to test whether effects varied by amount of treatment received. In addition, if both Group × Time and Group × Time Squared terms were nonsignificant, the model was refit excluding the nonsignificant Group × Time interaction terms in a backward manner.

In addition to the primary outcomes, several treatment process variables were analyzed: (a) treatment priorities (i.e., importance of quitting smoking, importance of not gaining weight), (b) treatment outcome expectations (for overall treatment, for cessation, for weight control), (c) treatment burden, and (d) smoking-specific self-efficacy. Session attendance (a dichotomous time-varying variable) was analyzed using a GEE logistic regression model, as described above for analyzing smoking status. Treatment priorities, treatment expectations, treatment burden, and smoking-specific self-efficacy were analyzed with a mixed effects regression model, as described above for analyzing weight change. All analyses included terms for both time and time squared, and each model included the same a priori ED and LD contrasts described above, as well as their interactions with both time variables. Again, if interaction terms were nonsignificant, the model was refit excluding the nonsignificant terms in a backward manner.

It is important to note that neither GEE nor MIXED places restrictions on the number of observations per individual; thus, participants with missing data were not excluded from the analysis. Instead, model parameters were estimated with all available data (rather than assuming that missing is equal to smoking, for example). These two complementary statistical models were developed for the longitudinal analysis of dichotomous and continuous variables (i.e., smoking and weight change), respectively (Diggle et al., 1994).

Results

Smoking Outcome

Table 2 presents the results of the GEE analysis with available data to predict smoking status. Because none of the Group × Time or Group × Attendance interaction terms was statistically significant, Table 2 presents results of the GEE model with only covariates plus main effects for group and time. As shown in Table 2, higher FTQ and greater percentage of missing data prior to dropout negatively predicted abstinence, whereas greater weight gain and longer time to dropout positively predicted abstinence. There were no significant differences in smoking status between ED and control ($z = -1.19$, $p = .282$) or between LD and control ($z = -0.96$, $p = .611$), and post hoc testing did not detect differences between ED and LD combined versus control ($z = -0.74$, $p = .462$). Figure 2 shows the predicted probability of smoking for each treatment group across time after controlling for covariates. As Table 2's significant linear and quadratic time trends indicate, the probability of smoking increased and gradually stabilized over time. There was no evidence that either ED or LD had worse smoking cessation outcomes than control; indeed, the data fell in

Table 2
Predictors of Smoking Status From Visit 7 To 9-Month Follow-Up Determined by GEE Logistic Regression With Available Data

Variable	Regression coefficient	*SE*	*z*
Covariates			
Baseline weight	0.003	.003	1.07
Weight change	−0.060	.012	−5.08**
FTQ	0.236	.063	3.73**
Time to dropout	−0.037	.009	−4.03**
% missing	2.296	.950	2.42*
Time effects			
Time	0.096	.018	5.40*
Time squared	−0.001	.001	−2.95**
Group effects			
ED	−0.317	.267	−1.19
LD	−0.259	.270	−0.96

Note. Weight change is time varying. Percentage missing reflects smoking status data missing before droupout. Smoking status coded as 0 = abstinent and 1 = smoking. There were no significant Group × Time interactions. GEE = generalized estimating equations; FTQ = Fagerström Tolerance Questionnaire; ED = early diet versus control; LD = late diet versus control.
* $p < .05$. ** $p < .01$.

the opposite direction. Reanalyzing the data treating missing as equal to smoking did not alter conclusions regarding the nonsignificant main effects of group (ED $z = -0.16$, $p = .870$; LD $z = -0.68$, $p = .494$) and its nonsignificant interactions with time (ED × Time $z = -0.25$, $p = .799$; ED × Time Squared $z = 0.31$, $p = .755$; LD × Time $z = 0.16$, $p = .876$; LD × Time Squared $z = 0.16$, $p = .874$).

Making no assumptions about missing data (i.e., not coding missing as smoking) and examining only available data without adjustment for covariates yielded end-of-treatment (3 months postquit) abstinence rates of control = 37.5%, ED = 52.4%, and LD = 45.0% and 9-month abstinence rates of control = 41.2%, ED = 45.0%, and LD = 39.5%. Coding missing data as smoking yielded end-of-treatment abstinence rates of control = 29.9%, ED = 38.5%, and LD = 39.4% and 9-month abstinence rates of control = 18.2%, ED = 21.4%, and LD = 19.5%.

Weight Change Outcome

Longitudinal analysis of available weight change data showed significant Group × Time interactions between LD and both linear and quadratic time trends, as well as a nonsignificant interaction between ED and the linear time trend (see Table 3). Figure 3 displays mean weight change over time for the three treatment groups with available data, and Figure 4 displays estimated weight change after controlling for covariates. ED showed significantly less weight gain than control at Visit 7, but their weight suppression advantage was lost over time. The figures suggest that by the end of follow-up, ED's weight gain exceeded control's, although the difference was not significant. Statistical power was, however, low for this comparison (standardized $d = 0.18$, power = 0.11) because 9-month data were available for only 37% of the sample. In contrast, at Visit 7 weight gain was comparable for LD and control, but over time the rate of weight gain became progressively slower for LD than control (see Figures 3 and 4). Thus, LD gradually acquired a weight control advantage that persisted in that LD's trajectory of weight gain was flattened. Again, the difference from control at the final follow-up was nonsignificant, although the previously mentioned concern about power also applies (standardized $d = 0.19$, power = 0.12). Over time, therefore, the rate of weight gain slowed significantly for LD compared with control, whereas the rate of weight gain for ED did not differ from control.

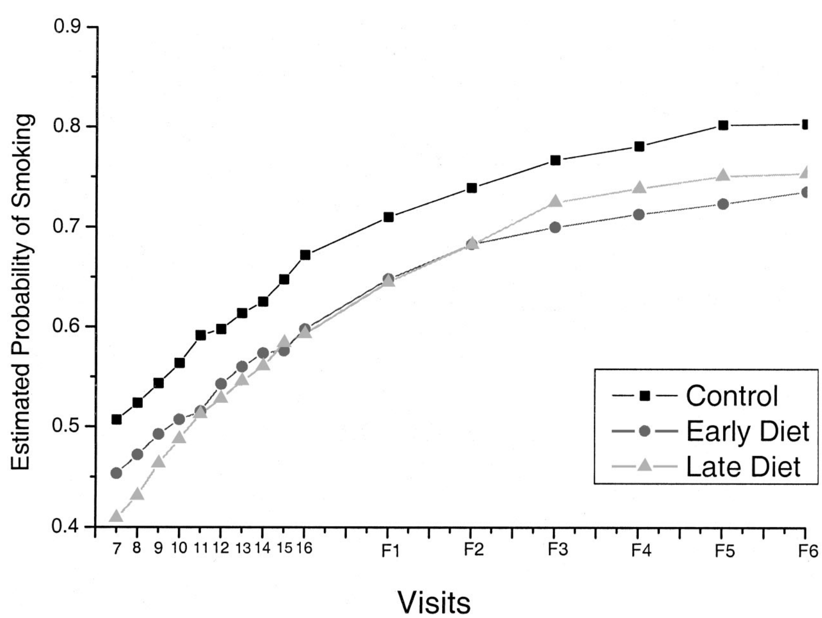

Figure 2. Estimated probability of smoking by each group over time. F = posttreatment follow-up.

Table 3
Predictors of Weight Change (Minus Baseline) From Visit 7 To 9-Month Follow-Up, Determined by Mixed Effects Regression With Available Data

Variable	Regression coefficient	*SE*	*t*
Covariates			
Baseline weight	−0.114	.046	−2.47*
Smoking status	−0.414	.154	−2.68**
FTQ	−0.099	.132	−0.73
% attendance	1.121	1.722	0.65
% abstinence	0.023	.007	3.23*
% missing	−0.042	1.933	−0.02
Time effects			
Time	0.198	.048	4.10**
Time squared	−0.003	.001	−3.22**
Group effects			
ED	−1.338	.620	−2.16*
LD	0.017	.635	0.03
ED × Time	0.094	.055	1.71†
LD × Time	−0.174	.072	−2.42*
LD × Time Squared	0.005	.002	2.92**

Note. Smoking status is time varying. Percentage abstinence reflects cumulative visits abstinent before dropout. Percentage missing reflects smoking status data missing before dropout. Smoking status coded as 0 = abstinent and 1 = smoking. For all *t* statistics, $df = 2114$. FTQ = Fagerström Tolerance Questionnaire; ED = early diet versus control; LD = late diet versus control.
† $p < .10$. * $p < .05$. ** $p < .01$.

Examining raw available data without adjustment for covariates yielded end-of-treatment weight change in pounds of control $M = 3.08$, $SD = 5.68$; ED $M = 3.35$, $SD = 5.44$; and LD $M = 2.57$, $SD = 7.73$ and 9-month weight change of control $M = 6.20$, $SD = 6.65$; ED $M = 7.57$, $SD = 8.24$; and LD $M = 4.88$, $SD = 7.06$. Controlling for covariates yielded estimated end-of-treatment weight change in pounds of control $M = 3.41$, ED $M = 3.05$, and LD $M = 2.29$ and 9-month weight change of control $M = 4.14$, ED $M = 6.22$, and LD $M = 5.26$.

To assess whether treatment effects on weight gain were moderated by the amount of treatment received, we interacted treatment attendance with both ED and LD contrasts and their linear and quadratic time trends. Session attendance did not significantly influence the effect of ED, $t(2112) = -0.66$, $p = .508$, or its interaction with time, $t(2112) = -0.45$, $p = .655$. In contrast, session attendance significantly moderated interactions between the LD contrast and both linear, $t(2124) = -2.75$, $p = .006$, and quadratic, $t(2124) = 2.67$, $p = .008$, time trends. To interpret how session attendance altered the LD treatment effect, we split the sample into high attenders (attended at least 80% of possible visits, $n = 181$) and low attenders (attended less than 80% of visits, $n = 134$) and examined the model's simple effects. Among low attenders, no significant treatment effects were found. LD did not differ from control at Visit 7, $t(333) = 0.53$, $p = .596$, nor were there significant interactions between LD and either linear, $t(333) = 0.74$, $p = .460$, or quadratic, $t(333) = -0.03$, $p = .976$, time trends. However, the weight gain pattern differed among high attenders. After an absence of difference between LD and control at Visit 7, $t(1810) = -0.84$, $p = .401$, significant linear, $t(1810) = -2.82$, $p = .005$, and quadratic, $t(1810) = 3.00$, $p = .003$, time trends indicated that LD gained weight thereafter at a slower rate than control. In summary, LD was more effective in suppressing the rate of weight gain among participants who attended a majority of treatment sessions; the LD treatment effect was nonsignificant among women whose attendance was less than 80%.

Weight Concern

Individual differences in WC were not predictive of either smoking status ($z = -0.11$, $p = .915$) or weight change ($t =$

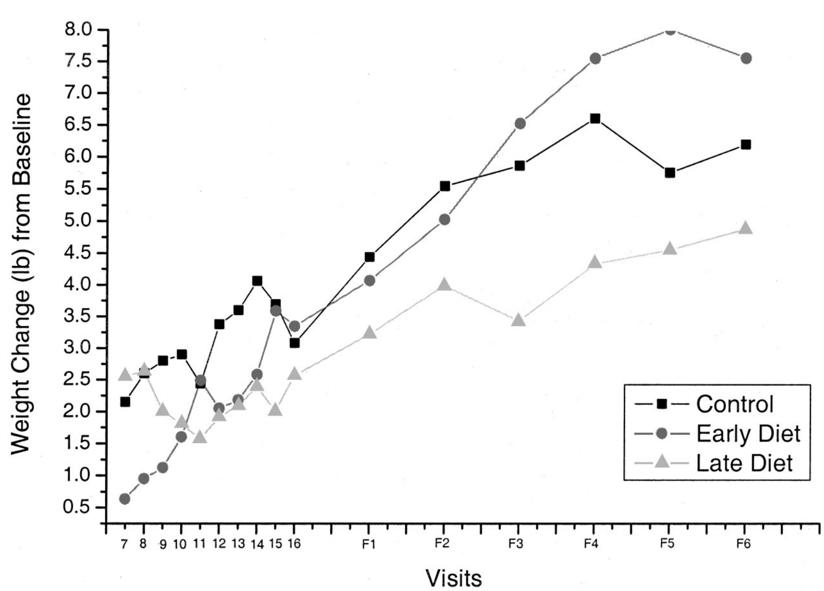

Figure 3. Mean weight change (in pounds) by group across treatment and follow-up periods showing all available data. F = posttreatment follow-up.

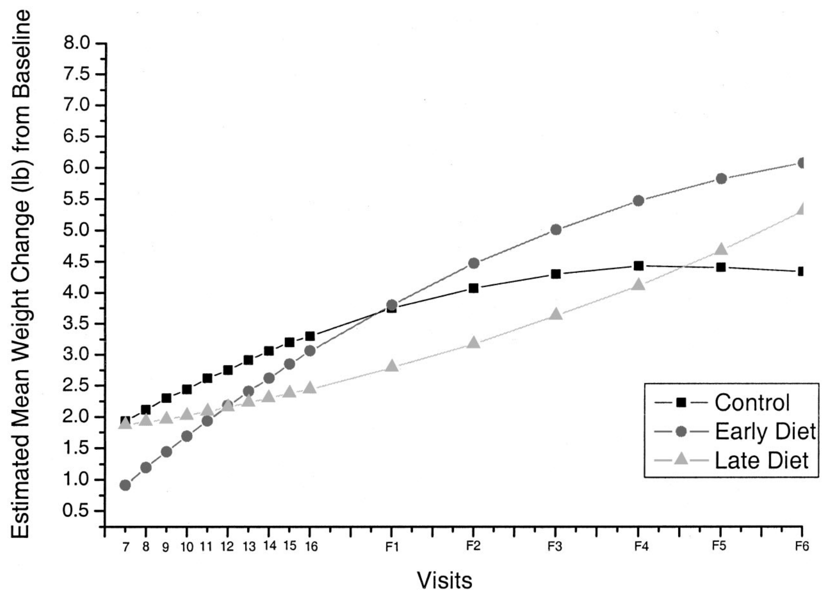

Figure 4. Estimated weight change (in pounds) by groups across time. F = posttreatment follow-up.

−0.31, p = .755). In addition, WC did not interact with treatment or time to predict either smoking status (WC × ED z = −0.76, p = .445; WC × LD z = −0.60, p = .549; WC × Time z = 0.71, p = .476; WC × Time Squared z = −0.28, p = .776) or weight change (WC × ED t = 0.45, p = .656; WC × LD t = −0.18, p = .861; WC × Time t = 0.99, p = .321; WC × Time Squared t = −1.44, p = .151).

Treatment Processes

Session Attendance

The average percentage of missed sessions was 13.2% for LD, 15.9% for control, and 20.4% for ED. LD and control did not differ significantly in absence rate, but ED missed significantly more sessions than did control (z = 2.48, p = .013). Attendance was significantly predicted by time (z = −4.03, p < .001), which indicated that participants' attendance rates decreased over time, and there was no interaction between time and group.

Outcome Expectations

The groups differed significantly in their expectations regarding treatment (see Table 4). LD had higher expectations than control about how well treatment would help them quit smoking, $t(470)$ = 2.54, p = .011, minimize weight gain, $t(469)$ = 7.12, p < .001, and be effective overall, $t(472)$ = 2.58, p = .010. Similarly, ED had higher expectations than control about the likelihood that treatment would help them quit smoking, $t(470)$ = 2.11, p = .036, and minimize weight gain, $t(470)$ = 2.54, p < .001, and marginally greater expectations that treatment would be effective overall, $t(472)$ = 1.69, p = .092. There were no significant changes in expectations over time or interactions between time and group.

Treatment Priorities

Mean treatment priority ratings are shown in Table 4. ED rated both quitting smoking, $t(2812)$ = 2.26, p = .024, and not gaining

Table 4
Means And Standard Deviations for Treatment Process Measures Aggregated Across Time

	Control		Early diet		Late diet	
Process measure	*M*	*SD*	*M*	*SD*	*M*	*SD*
General treatment expectations[a,d]	8.42	1.86	8.72	1.67	8.86	1.63
Cessation treatment expectations[a,c,d]	8.46	1.86	8.85	1.65	8.97	1.64
Weight control treatment expectations[a,c,d]	6.09	2.48	7.60	1.94	8.10	2.10
Importance of quitting smoking[b,c]	9.40	0.97	9.64	0.74	9.51	0.94
Importance of not gaining weight[b,c]	8.48	2.13	9.18	1.36	8.97	1.78
Difficulty of following the program[b]	6.05	1.85	6.39	1.76	6.10	1.89
Smoking-specific self-efficacy[b]	17.71	4.28	19.03	4.38	18.74	4.09

[a] Measure assessed at Visits 1, 4, 8, 12, and 16. [b] Measure assessed at each of Visits 1–16. [c] Indicates early diet differs significantly from control. [d] Indicates late diet differs significantly from control.

weight, $t(2813) = 2.57$, $p = .010$, as more important than control. Conversely, there were no significant differences between LD and control on their rated importance of quitting smoking or not gaining weight. Throughout the study and across all groups, participants rated quitting smoking as significantly more important than not gaining weight, $t(244) = 4.86$, $p < .001$. Neither the rated importance of quitting smoking nor the rated importance of not gaining weight changed significantly over the 16-week time course of treatment. However, the difference between the two importance ratings was significantly and negatively related to time, $t(244) = -2.23$, $p = .027$, indicating that participants gradually came to place a similar emphasis on quitting smoking and not gaining weight.

Treatment Burden

The rated difficulty of following the smoking cessation program did not change significantly over time or differ between groups. Group means averaged across the treatment phase of the study are shown in Table 4.

Smoking-Specific Self-Efficacy

Participants' self-efficacy regarding smoking cessation did not vary across time and did not differ by group. Treatment phase means by group are shown in Table 4.

Discussion

Concern that weight control efforts will undermine tobacco abstinence is reflected in current clinical practice guidelines, which discourage dieting until abstinence from smoking has become well-established (DHHS, 2000). However, the worries that behavioral weight control efforts will undermine abstinence or be ineffective at suppressing weight gain are unsupported by the present findings. In fact, cessation outcomes were somewhat better for groups that received combined treatments for smoking and weight, although differences from control participants treated only for cessation were nonsignificant.

For postcessation weight control, the findings suggest superiority for a sequential approach that addresses smoking cessation before initiating weight control treatment. Compared with those treated chiefly for smoking, smokers treated first for cessation and subsequently for weight control showed a reduction in their rate of weight gain. No difference from control was evident at the time of the quit, but, thereafter, LD's rate of weight gain slowed significantly and progressively, which suppressed the group's overall trajectory of weight gain. In contrast, smokers whose early treatment simultaneously addressed smoking and weight control initially showed weight suppression compared with control. However, their subsequent weight control advantage diminished, disappeared, and even tended to reverse. In summary, LD's long-term weight gain trajectory was suppressed relative to control's trajectory, whereas ED's overall trajectory was not. The interpretation that LD suppressed weight gain is tempered somewhat by the lack of a significant difference between LD versus control weight gain at the 9-month follow-up. However, the very low statistical power for that cross-section has already been highlighted. It should be noted also that the rationale for comparing the treatment groups on their longitudinal trajectories of weight gain is that time trends can be measured more reliably than can data points at any single slice of time. In that same vein, overemphasis on the single time slice afforded by the final follow-up is particularly unsound in the current case because only 37% of the sample was represented then.

The present findings are at variance with the suggestion that the benefits of addressing weight control during smoking cessation are confined to very weight-concerned women (Perkins et al., 2001). In the current study, women's response to the intervention conditions was independent of their level of WC. The absence of an interaction between treatment condition and WC is probably not attributable to a restricted range of scores because the observed distribution of WC scores covered the full range of possible scale values. The current sample does not appear to have overrepresented women with the highest levels of WC. Overall, the women showed an average level of smoking-specific WC, falling in between the cutpoints for either low or high concern. We suggest that worry about weight may be sufficiently normative for American women (Johnsen, Spring, Pingitore, Sommerfeld, & McKirnan, 2002; Rodin, Silberstein, & Striegel-Moore, 1984) to make a weight gain prevention module appealing to the average female smoker. That the modal participant had sufficient WC to find weight control treatment meaningful is also suggested by the trends for those in the weight control groups to remain in treatment longer and have less missing data than control participants assigned solely to cessation treatment.

We find it surprising that participants' ratings suggest that they found it no more difficult to make changes in diet, activity, and smoking than they did to make changes in smoking alone. In fact, undergoing an intervention that addressed both smoking and weight control heightened participants' expectations that treatment would succeed in improving all study outcomes. Being randomized to combined treatment not only enhanced expectancies about how well the intervention would prevent weight gain, but it also increased expectations about how well the intervention would promote smoking cessation.

Those in all three treatment conditions assigned greater importance to quitting smoking than to preventing weight gain, which mirrored the health priorities conveyed by project staff. We find it interesting that unlike the difficulty ratings, participants' treatment priority ratings convey some suggestion that the ED group may have felt overwhelmed by being asked to change eating, activity, and smoking simultaneously at the outset of treatment. ED participants were unique in exceeding control in the importance they ascribed both to quitting smoking and to not gaining weight. LD participants, in contrast, assigned both outcomes no greater priority than control. The pattern of results suggests that ED participants self-imposed higher and more pervasive standards for behavioral accomplishment than the other groups, which may have proved challenging to attain. In addition, the suggestion that ED participants may have felt overwhelmed is further supported by the finding that they failed to attend more treatment sessions than the other groups, even though they self-reportedly valued the treatment goals more highly.

The present findings are at variance with Hall et al.'s (1992) study and consistent with Pirie et al.'s (1992) study and Perkins et al.'s (2001) study in showing modestly enhanced abstinence among smokers treated behaviorally for combined cessation plus weight control, versus cessation only. To our knowledge, Hall et al.'s study has been the only trial to find evidence that combining smoking and weight control treatment undermines abstinence from tobacco. Hall et al.'s study was unique in that (a) the sample included males, (b) cessation treatment involved aversive conditioning, (c) the weight control module began after participants had successfully quit smoking, and (d) discussion of smoking was discouraged during weight gain prevention sessions. Although the explanation for these discrepant findings remains unclear, the fact that Hall et al.'s (1992) protocol required participants to shift their focus away from smoking and toward weight control, rather than integrating the two goals, might help to explain why weight control treatment undermined abstinence.

The current results resemble Perkins et al.'s (2001) findings and differ from Pirie et al.'s (1992) findings and Hall et al.'s (1992) findings in that both of our behavioral weight control conditions suppressed weight gain relative to cessation treatment alone. Women in the current study achieved weight suppression even though they were not preselected for having prominent smoking-specific WC. These discrepant findings regarding prevention of weight gain are difficult to explain. It may be important that the dietary interventions that have most successfully prevented weight gain (Perkins et al.'s [2001] weight-concern treatment and our weight control interventions) shared the characteristic that they discouraged restraint and encouraged self-administration of snacks.

The limitations of the study are important to consider. First, participants were sufficiently highly motivated to enroll at their own initiative in a time- and effort-intensive treatment. Results may not be generalizable to smokers in the community who are less motivated to seek treatment. Second, only women were included in the sample on the premise that they would be more motivated than men to prevent postcessation weight gain. However, in view of the evidence that it is men rather than women for whom weight gain predicts smoking relapse (Borrelli, Spring, Niaura, Hitsman, & Papandonatos, 2001), weight gain prevention interventions warrant investigation for male smokers as well. Third, our use of a dietary intervention approach involving food provision was apparently successful in minimizing the perceived burden of implementing weight control conjointly with smoking cessation. However, food provision is an expensive approach to promoting weight regulation. It is possible that different approaches to modifying diet and activity might be as effective and less costly. Similarly, telephone support and clinician access via a 24-hr pager may be difficult to replicate in many treatment settings. (It should be noted, however, that pager use was infrequent.) Fourth, our ability to determine whether the LD intervention prevented or only delayed postcessation weight gain is impeded by lack of longer term follow-up data.

These results support cautious optimism that multiple behavior change in smoking, eating, and activity in particular, may be more feasible than has previously been believed (DHHS, 2000). The results suggest that intervention success is greater when behavior changes are initiated sequentially rather than simultaneously, which is consistent with some, though not all, findings for changing several drug-use behaviors (Joseph, Willenbring, Nugent, & Nelson, 2003). For treatment to be effective, it may also be important that behavior changes promoted in the earlier phase of intervention continue to be retained as a treatment focus. An unknown that warrants further investigation is whether it matters which behavior change is initiated first. In the current study, the most successful intervention overall was LD treatment, which prompted changes in smoking before promoting changes in eating and activity. It remains unclear whether an alternative sequence that requested changes in eating and activity before beginning to address smoking behavior might have been as effective. We suspect that this is not the case in our context because participants who self-referred to treat the primary problem of tobacco use might have found it difficult to justify devoting 2 preliminary months to changing different behaviors, but that interpretation remains speculative and in need of empirical investigation.

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