# Cognitive—Behavioral Therapy to Reduce Weight Concerns Improves Smoking Cessation Outcome in Weight-Concerned Women

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Women smokers concerned about weight gain (N=219) were randomly assigned to 1 of 3 adjunct treatments accompanying group smoking cessation counseling: (a) behavioral weight control to prevent weight gain (weight control); (b) cognitive-behavioral therapy (CBT) to directly reduce weight concern, in which dieting was discouraged; and (c) standard counseling alone (standard), in which weight gain was not explicitly addressed. Ten sessions were conducted over 7 weeks, and no medication was provided. Continuous abstinence was significantly higher at posttreatment and at 6 and 12 months of follow-up for CBT (56%, 28%, and 21%, respectively), but not for weight control (44%, 18%, and 13%, respectively), relative to standard (31%, 12%, and 9%, respectively). However, weight control, and to a lesser extent CBT, was associated with attenuation of negative mood after quitting. Prequit body mass index, but not change in weight or in weight concerns postquit, predicted cessation outcome at 1 year. In sum, CBT to reduce weight concerns, but not behavioral weight control counseling to prevent weight gain, improves smoking cessation outcome in weight-concerned women.

In formal treatment programs, women often have less success than men in quitting smoking (e.g., Ockene, 1993; Perkins, 1996; Royce, Corbett, Sorensen, & Ockene, 1997; Wetter et al., 1999). That women may have greater difficulty than men in quitting exacerbates the overall health burden due to smoking because women may be at greater risk than men for many smoking-related illnesses, including heart disease and lung cancer (Prescott, Hippe, Schnohr, Hein, & Vestbo, 1998; Zang & Wynder, 1996).

Although several explanations are possible for the greater difficulty women have in quitting smoking, perhaps the clearest difference between women and men who smoke is their concern over the weight gain that typically accompanies a quit attempt (Meyers et al., 1997). Women are more than twice as likely as men to expect to gain a lot of weight if they quit (Pirie, Murray, & Luepker, 1991) and, in fact, often do gain more weight than men after quitting (Williamson et al., 1991). Young women are nearly four times as likely as men to report weight gain as a cause of smoking relapse (Swan, Ward, Carmelli, & Jack, 1993). Smokers concerned about cessation-induced weight gain express less intention to quit (Weekley, Klesges, & Relyea, 1992), report greater

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withdrawal severity on quitting (Pinto et al., 1999), are more likely to drop out of treatment (Mizes et al., 1998), and have poorer overall cessation outcome (Jeffery, Hennrikus, Lando, Murray, & Liu, 2000; Meyers et al., 1997), relative to smokers not concerned about weight gain. For example, Meyers et al. (1997) found that weight-concerned smokers, 80% of whom were women, were less than half as likely as those not weight-concerned to be continuously abstinent (no slips allowed) for 1 year (4.2% vs. 9.1%, respectively) in a trial of standard cessation counseling without any medication.

Because concerns about weight gain have been recognized as a significant obstacle to cessation, a few clinical trials have evaluated the efficacy of adding a behavioral weight control intervention (dieting and exercise) to standard counseling for smoking cessation (Hall, Tunstall, Vila, & Duffy, 1992; Pirie et al., 1992). The rationale for adding behavioral weight control to cessation treatment was that, by reducing weight gain after quitting, concerns about weight gain should be ameliorated, thereby enhancing cessation rates (see Perkins, Levine, Marcus, & Shiffman, 1997). However, adding weight control did not significantly improve cessation rates and, in one case (Hall et al., 1992), was associated with marginally poorer 1-year outcome, compared with results for standard counseling alone. Worsening of smoking cessation outcome due to the weight-related interventions in Hall et al. (1992) could have been due, in part, to the fact that it was offered to all participants, even those not particularly concerned about weight, and only after they had successfully quit. By contrast, Pirie et al. (1992) provided a weight intervention that was integrated within the standard smoking cessation counseling and offered it only to women who expressed concern over weight. Targeting only those for whom a weight-related intervention is relevant may explain their trend toward better abstinence at 1 year in women given weight control versus standard treatment only (23% vs. 15%, respectively) in the absence of nicotine replacement.

On the other hand, smokers who gain more weight after quitting are no more likely, and may even be less likely, to later relapse (e.g., Hall, Ginsberg, & Jones, 1986; McBride, French, Pirie, & Jeffery, 1996; see also Perkins, 1994), casting some doubt on the logic of intervening to attenuate weight gain. The critical factor influencing smoking relapse in weight-concerned women may be the women's overconcern about weight gain, rather than the experience of weight gain itself (Perkins, 1994; Perkins et al., 1997). Although general concern about weight may be unrelated to cessation outcome, concerns specific to weight gain due to smoking cessation may be associated with poorer outcome (French & Jeffery, 1995). Cognitive-behavioral interventions that focus on amelioration of maladaptive concerns about weight and shape have been developed and used successfully in the treatment of eating disorders (Fairburn, Marcus, & Wilson, 1993). However, no prior study has systematically examined the effectiveness of a cognitive-behavioral intervention for weight concerns as an adjunct to smoking cessation treatment in weight-concerned smokers.

Alternatively, it is possible that introduction of any adjunctive treatment related to weight may place too great a behavioral burden on those trying to quit smoking (Hall et al., 1992). The effort involved in following a dietary regimen, for example, may interfere with engaging in coping strategies useful in preventing smoking relapse. Thus, the optimal strategy for treating weight-concerned women smokers may be to refrain from directly addressing weight-related issues while providing smoking cessation counseling, so that participants can devote their full efforts to following cessation counseling advice during and after the quit attempt.

This clinical trial was aimed at identifying the most effective approach to addressing weight gain concerns in women quitting smoking. Continuous smoking abstinence rates were determined over 1 year of follow-up in weight-concerned women receiving behavioral weight control for prevention of weight gain, versus cognitive—behavioral treatment (CBT) for direct reduction of weight concerns, as adjunct interventions accompanying standard, group-based cessation counseling (FreshStart; Shiffman & Cline, 1990). We compared these rates with abstinence among women receiving standard cessation counseling alone to determine which adjunct, if either, was superior to standard treatment. We also examined the influence of these interventions on mood after quitting and explored predictors of 1-year abstinence.

## Method

## **Participants**

Participants for this trial were women wanting to quit smoking but concerned about cessation-induced weight gain. Women eligible for participation were required to be 18-65 years of age, typically smoking at least 10 cigarettes per day, currently free of any major health problem or illicit drug use, significantly interested in quitting smoking, and endorsing concerns about weight gain after quitting (see the *Recruitment and Screening* section). Women who were trying to become pregnant or were following a medically prescribed diet that might conflict with the reduced-calorie diet of the weight control intervention were not eligible. A total of 219 women met these criteria and agreed to participate in the trial.

### Recruitment and Screening

Participants were recruited from the Allegheny County (Pennsylvania) area through a variety of recruitment methods—primarily newspaper advertisements, flyers distributed to health and community centers, and radio public service announcements. All announcements described the trial as not involving medication and designed for "women who want to quit smoking but are concerned about weight gain." Potential participants were first screened by telephone for eligibility and, after hearing a brief description of the program, their interest in participating. The telephone screening inquired about current health, including major medical or psychiatric problems and drug dependence. (Hospitalization for these problems within the previous year precluded participation in the trial.)

This screening also assessed degree of desire to quit smoking and severity of concern about cessation-related weight gain. Both interest in quitting smoking and weight gain concern were assessed with 100-mm visual analog scales ( $0 = not \ at \ all$ , 100 = extremely). Interest in quitting was assessed with the item, "How strong is your desire to quit smoking right now?" Weight gain concern was assessed by two items: (a) "How concerned are you about gaining weight after quitting?" and (b) "How concerned would you be if quitting smoking caused you to permanently gain 10 pounds?" The second item focused on a gain of 10 lb (4.5 kg) because this is the average weight gain in women smokers 1 year after quitting (e.g., Hudmon, Gritz, Clayton, & Nisenbaum, 1999) and is the median weight gain at which weight-concerned smokers indicate they would resume smoking after a quit attempt (Meyers et al., 1997). Those who responded at least "50" on the 100-mm scale assessing interest in quitting and on either of the two scales assessing weight gain concern were eligible. (Responses to either of the two items were used because of differing expectations about cessation-induced weight gain among women. Some women, particularly those who have never quit for very long and thus have not actually experienced weight gain, do not express much concern when generally asked about weight gain, that is, the first item. However, they are extremely concerned when asked about a 10-lb weight gain, that is, the second item, which as noted is the average gain typically experienced after cessation. Conversely, some women indicate that they have gained much more than 10 lb during previous quit attempts and express substantial concern when generally asked about weight gain, the first item, but are less concerned at the prospect of gaining 10 lb, the second item. Nevertheless, about 90% of eligible women endorsed 50 or higher on both items.)

Of the 905 callers, 299 were not eligible because they smoked fewer than 10 cigarettes/day (106); had current medical or psychiatric problems, including trying to become pregnant or on a medically prescribed diet (88); were not sufficiently concerned about weight gain (78); or other reasons (27). A total of 606 callers were eligible, but 387 declined to participate because of lack of availability for sessions, lack of interest in the intervention, desire for cessation medication, or other reasons, leaving 219 for randomization. Callers not eligible or interested were referred to other local treatment programs. Those eligible and interested were scheduled for an in-person information session to learn more about the requirements of the program and the general description of the three treatment approaches being compared. Written informed consent was obtained at this session from all participants after the potential risks and benefits of their participation were explained.

Recruitment was conducted in three waves per year (winter, spring, and fall) with one wave producing enough participants to form three treatment groups, one for each treatment condition. The order of treatment condition assignment was determined in advance and counterbalanced across recruitment waves. After a sufficient number of participants to form a group (approximately 10–12) had been recruited, the group was assigned whatever treatment condition had been previously determined. Participants did not learn of their treatment condition assignment until the first treatment session, after all baseline information had been received.

## Description of Counseling Treatments

All participants received standard cognitive-behavioral smoking cessation counseling modeled on the American Cancer Society's FreshStart program (Shiffman & Cline, 1990), in addition to one of three weightgain-related adjuncts: CBT to reduce concerns (CBT), behavioral weight control to prevent weight gain (weight control), or nonspecific social support (standard), which involved no discussion of weight. Each of the three interventions consisted of ten 90-min sessions provided over 7 weeks, with two sessions per week during the first 3 weeks and one session per week over the last 4 weeks. Participants were instructed to quit smoking after their group's fourth session and before the fifth session (i.e., 4 weeks prior to the end of treatment). Follow-up sessions were scheduled at 3, 6, and 12 months postquit for assessment purposes; no treatment was provided. We also asked participants to refrain from any use of nicotine replacement products (NRT), especially during the 7-week treatment period, in order to "give this program a chance to work on its own." However, we felt we could not practically or ethically prevent participants from using NRT, particularly because NRT became available over the counter in the middle of this study. Thus, we asked them to honestly inform us of any other assistance they received in quitting, including NRT, and indicated they would not be removed from the study if they did use other assistance. Outcome results were examined with and without these few participants (see the Results section).

Specific characteristics of the three interventions are briefly described below, and detailed description of each intervention and its rationale is provided elsewhere (Perkins et al., 1997).

Weight control. The goal of the weight control condition was to attenuate weight gain after quitting smoking, largely by reducing betweenmeal snacking, the primary source of excess caloric intake after quitting smoking (Perkins, 1993; Perkins, Epstein, & Pastor, 1990). This program provided specific behavioral instructions designed to maintain participants' prequit baseline weight using behavioral weight control techniques common in the treatment of obesity (e.g., Brownell & Wadden, 1986). Participants were given daily calorie goals (typically 500 kcals less than would be required to maintain baseline weight if still smoking) and were instructed to self-monitor daily food intake in a diary, which was reviewed weekly by the group therapist and returned with constructive feedback. Participants also graphed their weight (obtained by research assistants at each session) on a chart containing a solid horizontal line across time at their prequit baseline weight. After smoking cessation, if participants' weight had increased by 2 lb (0.9 kg) above this line at any session, their calorie goals were reevaluated and problems related to their compliance with the calorie goals were addressed. In addition to the calorie goals and self-monitoring, stimulus control techniques to decrease exposure to food cues, particularly snacking-related cues, and to emotional cues that trigger eating were taught. Women also were provided with lessons on general nutrition, portion control, and healthful food choices.

CBT for weight concerns. The goal of this adjunct was to promote the acceptance of modest weight gain and reduce concerns about cessationrelated weight gain. Treatment was based on the assumption that chronic efforts to control body weight and maladaptive thoughts and beliefs about diet, shape, and weight prevent women from accepting the possibility of a modest weight gain. Thus, therapy focused on the reduction of dietary restraint and on restructuring maladaptive thoughts and beliefs about the importance of low weight and perfect shape (Fairburn et al., 1993). Women were educated about the average amount of weight individuals gain after quitting smoking, the health benefits of quitting superseding the health risks of even large amounts of weight gain, and the evidence against trying to diet while quitting smoking (Perkins, 1994). Women were instructed and encouraged to self-monitor negative thoughts that were then used as examples in lessons on cognitive restructuring. Groups also explored their dysfunctional beliefs about body shape (e.g., "I must be very thin to be attractive and successful" or "self-indulgence is a sign of a weak character") and learned to challenge these beliefs and reduce the rigidity with which they held to such unrealistic, maladaptive convictions. Lessons also covered topics such as reducing dietary restraint (i.e., the avoidance of eating for long periods or avoiding specific "bad" foods) and improving body image. Finally, moderate consumption of healthy foods during between-meal snacking was encouraged, and dieting per se was discouraged.

Standard. No additional didactic information was presented in the nonspecific treatment (standard). However, to equate the three conditions for therapy contact time, women were encouraged to discuss other aspects of their smoking cessation, and discussion about weight gain concerns was discouraged. Specifically, women talked in more detail about their smoking histories, the effects of quitting smoking on their families and friends, and other hobbies or life events. Group leaders facilitated these discussions but otherwise did not provide any specific information about cessation that was not provided to the other two groups.

To determine any initial biases in favor or against one of the three treatment approaches, all participants were given a brief description of each approach at the initial introductory session, prior to treatment assignment. They then were instructed to indicate the degree to which each treatment was acceptable to them on a 0 (not at all) to 100 (extremely) scale, and cautioned that their responses to this measure would have no bearing on which treatment they received. Results indicated that the mean ( $\pm$  SEM) rating of the weight control intervention was significantly (p < .01) higher (77.2  $\pm$  1.9) than the ratings for the CBT (64.1  $\pm$  2.0) and standard (68.4  $\pm$  2.0) groups, which did not differ.

To test treatment fidelity, we assessed whether participants in each group learned the relevant information from their particular treatment condition and did not receive information specific to the other conditions. A written quiz of 10 questions assessed their knowledge of information relevant to behavioral weight control (3 questions), cognitive treatment of attitudes (3 questions), and smoking (4 questions) upon entry into the study (but before assignment to group) and again at posttreatment (Session 10). Mean (± SEM) group improvement from pre- to posttreatment in the number of correctly answered items relevant to weight control, cognitive treatment, and smoking, respectively, were  $1.1 \pm 0.1$ ,  $0.5 \pm 0.1$ , and  $0.5 \pm 0.1$  for those in the weight control group;  $0.0 \pm 0.1$ ,  $1.6 \pm 0.1$ , and  $0.8 \pm 0.1$  for the CBT group; and  $0.1 \pm 0.1$ ,  $0.4 \pm 0.1$ , and  $0.5 \pm 0.1$  for the standard group. Thus, the weight control and CBT groups increased their knowledge of information specific to their treatment condition more than they increased their knowledge of any other information. This result indicated that each treatment was successful in disseminating information specific to its goal and that there was no contamination of information between treatments.

The therapists were women with Master's degrees in clinical or counseling psychology who received intensive didactic training, including modeling and role-playing, in each of the specific treatments compared in this clinical trial. They also received ongoing weekly supervision to ensure adherence to the content of each particular treatment. Each of the treatments adhered to a manual developed to assist in training and for reference by therapists while conducting treatment sessions. Assignment of therapists to treatment condition was counterbalanced across recruitment waves, such that each therapist conducted each of the three treatments with equal frequency.

## Assessment of Abstinence

Continuous abstinence, defined as no relapse since the quit day, was the primary outcome measure at each follow-up point (end of treatment 4 weeks postquit, and 3, 6, and 12-months postquit). Relapse was defined as self-report of 7 consecutive days of any smoking at all or an expired-air carbon monoxide (CO) greater than 8 ppm, as widely recommended (Ossip-Klein et al., 1986). In addition, for consistency, continuously abstinent participants also had to meet the criteria for point-prevalence abstinence at each follow-up point. Point-prevalence was defined as self-

report of no smoking at all during the 7 days prior to the follow-up point, confirmed by CO ≤ 8 ppm, as also commonly used (e.g., Kenford et al., 1994). Thus, for continuous abstinence, lapses (or slips, i.e., any smoking at all, even a puff) short of relapse were allowed except during the 7 days prior to each follow up. CO was assessed by a commonly used hand-held monitor (BreathCO model, Vitalograph Inc., Lenexa, Kansas). Those who dropped out or were otherwise lost to follow up at any point were presumed to have relapsed to smoking and coded as such in all outcome analyses (i.e., intention to treat analysis). In addition, days to relapse was assessed by determining the number of days between each participant's quit day and the first day of smoking at the point of relapse (7 consecutive days of any smoking, CO > 8 ppm, etc.). Days to relapse was used in the survival analysis (see the *Statistical Analysis* section).

## Secondary Outcome Measures

Tobacco withdrawal symptoms were assessed with the widely used scale developed by Hughes and colleagues (Hughes, Gust, Skoog, Keenan, & Fenwick, 1991). Each symptom was rated by participants on a 0 (not at all) to 100 (extremely) scale. Total withdrawal was the mean of these symptom ratings. Cigarette craving ("desire to smoke") was rated on a similar 0–100 scale. The Beck Depression Inventory (BDI; Beck, Ward, Mendelsohn, Mock, & Erbaugh, 1961) was administered to assess depressive symptoms. Mood was also assessed with the Profile of Mood States (POMS; McNair, Loor, & Droppelman, 1971), which contains scales assessing tension, depression, anger, confusion, and vigor. Postcessation concern about a 10-lb weight gain over the next year was assessed using a 0 (not at all) to 100 (extremely) scale. Finally, body weight was measured at each session fully clothed on an electronic scale (Seca, Model 882; Hanover, MD).

#### Predictors of Cessation Outcome

Information on smoking, health, and weight was obtained upon entry into the study but before participants knew of their assignment to treatment (to avoid biasing responses to questionnaires). Smoking information included saliva cotinine levels, smoking history (e.g., age at first cigarette, current number of cigarettes/day), and scores on the Fagerstrom Test of Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). Saliva cotinine samples were frozen and sent to LabStat, Inc. (Kitchener, Ontario, Canada) for analysis. Health information included typical alcohol and caffeine intake, and past history of mood disorder (Inventory to Diagnose Depression-Lifetime, IDD-L; Zimmerman & Coryell, 1987). Weight-related information included weight-control smoking (Weight Control Smoking Scale; Pomerleau et al., 1993), restrained eating (Three-Factor Questionnaire [TFQ]; Stunkard & Messick, 1985), and specific questions about dieting in the past year, maximum amount of weight gain during a previous quit attempt, amount of gain expected during this quit attempt, and concern (on a 0-100 scale) about a 10-lb weight gain over the next year after quitting. Much of this information initially was compared across groups to determine success of randomization, but variables also were used as potential predictors of smoking cessation outcome. Body mass index (BMI) was determined by assessing weight in kilograms and dividing by height in meters squared. Other predictors of outcome included responses to smoking cessation, such as change in craving, withdrawal, BDI, and POMS scores from prequit baseline to the first week after quitting, when withdrawal typically peaks (Hughes et al., 1991). In addition, change in weight and change in concern about weight gain from baseline to end of treatment (4 weeks postquit) were used to predict cessation outcome at later follow-up points.

### Statistical Analysis

Differences in baseline characteristics among the three groups were evaluated using analyses of variance (ANOVAs) for continuous variables and chi square tests for categorical variables. Continuous abstinence was compared among the groups using a series of chi square tests. Kaplan-Meier survival curves were estimated using the number of days to relapse, and the log rank test for the equality of the survival curves was used to compare the three treatment groups. ANOVAs and follow-up t tests were used to compare weight gain differences among groups. A series of logistic regressions were used to examine the predictors of abstinence, with treatment group entered as a covariate in each equation. In all logistic regressions, the likelihood ratio test was used to evaluate the significance of adding the variable to the model that included treatment group.

#### Results

#### Characteristics of Participants

The characteristics of participants in each group are presented in Table 1. Chi square comparisons indicated no significant group differences, except for the proportion of participants having dieted in the last 12 months (greater in CBT vs. weight control),  $\chi^2(1, N = 141) = 5.9$ , p < .05.

## Treatment Session Attendance, Attrition, and Satisfaction

Mean attendance at the 10 treatment sessions was 76%, 81%, and 77% for the CBT, weight control, and standard groups, respectively (ns). Attrition by the end of the 7 weeks of treatment (4 weeks postquit) was 19%, 10%, and 21% for CBT, weight control, and standard, respectively, and the difference between weight control and standard was significant,  $\chi^2(1, N = 145) = 3.75, p =$ .05. This rate of attrition is similar to or less than that typically observed in other trials (e.g., 29% during 6 weeks of patch treatment in Study 2 of Kenford et al., 1994), even though weightconcerned smokers are more likely to drop out of treatment (Mizes et al., 1998). Mean attendance at the 3 follow-up sessions was 62% and did not differ between groups. As noted previously, all participants lost to follow-up were assumed to have relapsed to smoking. In addition, groups did not differ at the end of treatment in participant ratings of how satisfied they were with treatment  $(Ms \pm SEs = 80.6 \pm 2.9, 81.8 \pm 2.7, \text{ and } 79.3 \pm 2.9 \text{ on a } 0-100)$ scale for CBT, weight control, and standard, respectively) and in "how much the treatment helped" them quit (76.4  $\pm$  3.6, 75.0  $\pm$ 3.3, and  $76.5 \pm 4.1$ , respectively).

## Smoking Cessation Outcome

Continuous abstinence rates were significantly higher at the end of treatment (4 weeks postquit) for CBT, relative to standard, as shown in Table 2. During follow-up, CBT remained superior at 6 and 12 months, but not at 3 months,  $\chi^{2}(1, N = 145) = 2.67, p =$ .10. In contrast, weight control was no better than standard treatment at 4 weeks or any follow-up point. Differences in outcome were not significant between CBT and weight control. The 1-year survival analysis of days to relapse was also significantly different between groups, as shown in Figure 1. Point-prevalence abstinence showed a similar pattern across groups, with rates for CBT, weight control, and standard of 28%, 24%, and 16%, respectively, at 6 months, and 29%, 21%, and 16%, respectively, at 1 year. The difference in point-prevalence between CBT and standard was marginally significant, both at 6 months,  $\chi^2(1, N = 145) = 2.99$ , p < .09, and 1 year,  $\chi^2(1, N = 145) = 3.66$ , p < .06. Groups also differed significantly in the proportion of participants able to avoid

Table 1
Participant Characteristics by Treatment Group

|                                    | Treatment group         |      |              |      |                     |      |  |
|------------------------------------|-------------------------|------|--------------|------|---------------------|------|--|
|                                    | Weight control (n = 72) |      | CBT (n = 72) |      | Standard $(n = 75)$ |      |  |
| Characteristic                     | M                       | SD   | М            | SD   | М                   | SD   |  |
| Age                                | 45.7                    | 10.4 | 44.3         | 9.5  | 43.6                | 10.0 |  |
| Education (% college graduate)     | 51.4                    |      | 43.0         |      | 46.7                |      |  |
| Body weight (kg)                   | 69.1                    | 14.9 | 69.3         | 12.0 | 68.7                | 12.1 |  |
| Body Mass Index                    | 25.6                    | 5.4  | 25.8         | 4.7  | 25.5                | 4.7  |  |
| Cigarettes/day                     | 22.3                    | 9.2  | 20.8         | 9.6  | 22.0                | 9.5  |  |
| Cotinine level                     | 206.6                   | 81.7 | 190.8        | 90.2 | 194.1               | 87.7 |  |
| Smoking duration (years)           | 27.4                    | 10.4 | 24.7         | 10.9 | 24.9                | 10.1 |  |
| Previous quit attempts             | 3.2                     | 3.4  | 3.4          | 2.7  | 3.0                 | 2.0  |  |
| Fagerstrom score (0-10)            | 5.2                     | 1.9  | 4.8          | 2.5  | 5.1                 | 1.9  |  |
| Weight Control Smoking Scale (0-9) | 4.5                     | 2.5  | 5.3          | 2.5  | 5.0                 | 2.8  |  |
| Concern about weight gain (0-100)  | 81.6                    | 19.6 | 82.9         | 19.1 | 88.6                | 18.0 |  |
| Dieted in past 12 months* (%)      | 45.1                    |      | 65.3         |      | 60.0                |      |  |
| Depression history (%)             | 58.3                    |      | 55.6         |      | 42.7                |      |  |

Note. CBT = cognitive-behavioral therapy.

lapsing (any smoking at all, even a puff) before the end of treatment (43%, 31%, and 21% for CBT, weight control, and standard, respectively);  $\chi^2(2, N=217)=8.08, p<.02$ . Subsequent rates of lapsing during follow up did not differ among groups, suggesting the influence of CBT was primarily in preventing early lapses during the treatment period. A total of 14 participants used NRT on their own at some time prior to the end of treatment (ns=3 in CBT, 9 in weight control, and 2 in standard; only 7 of the 14 were abstinent), and 13 used NRT at some time during the 12-month follow up (ns of 4, 3, and 6, respectively). Outcome results were not changed when analyses were repeated without these participants.

## Weight Gain

Weight gain was examined only in women who had been continuously abstinent up to the follow-up point of interest, because differential resumption of smoking between groups would confound differences in weight gain (Klesges et al., 1997). As expected, ANOVAs indicated that weight gain from prequit base-

line to the end of treatment was significantly different between groups, F(2, 88) = 6.94, p < .005. In follow-up t-test comparisons, weight gain 4 weeks postquit was significantly less in the weight control group compared with standard, as shown in Table 3. Thus, as designed, the weight control intervention was successful in attenuating postcessation weight gain. Unexpectedly, weight gain in the CBT group also was less than weight gain in the standard group, but not different from that in the weight control group. Notably, weight gain also was significantly less in the CBT group versus the standard group at 6 and 12 months, while weight gain in the weight control group was no longer different from that in the standard group at any follow-up point, as also shown in Table 3.

## Weight Concern

Weight concern was examined separately in women who were continuously abstinent versus not abstinent at the end of treatment, because there is evidence that, as with weight gain, concerns about weight may be affected by resumption of smoking (McBride et al., 1996). T-test results showed that concern about a 10-lb weight gain

Table 2
Participants Continuously Abstinent From Quit Date to Posttreatment and Through 1-Year Follow-Up

|                           | Follow-up        |    |     |      |     | w-up |      |      |
|---------------------------|------------------|----|-----|------|-----|------|------|------|
|                           | Posttrea<br>4 we |    | 3 m | onth | 6 m | onth | 12 m | onth |
| Treatment group           | n                | %  | n   | %    | n   | %    | n    | %    |
| CBT $(n = 72)$            | 40**             | 56 | 24  | 33   | 20* | 28   | 15*  | 21   |
| Weight control $(n = 72)$ | 32               | 44 | 17  | 24   | 13  | 18   | 9    | 13   |
| Standard $(n = 75)$       | 23               | 31 | 16  | 21   | 9   | 12   | 7    | 9    |

Note. CBT = cognitive-behavioral therapy.

<sup>\*</sup> p < .05.

<sup>\*</sup>  $p \le .05$  for difference from standard. \*\* p < .01.

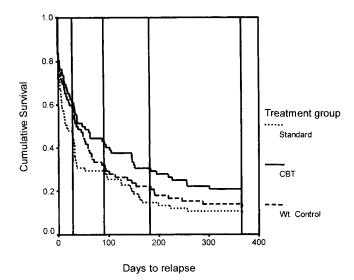


Figure 1. Survival curves (days to relapse) by treatment group. Vertical lines indicate the end of treatment (4 weeks postquit) and follow-up sessions (3, 6, and 12 months postquit). Log Rank = 6.22, p < .05. CBT = cognitive-behavioral therapy; Wt. = weight.

over the next year among all abstinent women did not decrease from pretreatment baseline to end of treatment ( $Ms \pm SDs$ ) of  $72 \pm 26$  and  $72 \pm 24$ , respectively, on 100-point scale), and there were no differences between groups. Thus, the clinical efficacy of CBT in aiding smoking abstinence at the end of treatment cannot be attributed to a specific effect on reducing weight concern, at least as measured in this study. However, weight concern did significantly decrease from baseline to end of treatment in women who had relapsed by the end of treatment ( $75 \pm 24$  and  $69 \pm 29$ , respectively), r(79) = 2.47, p < .02.

## Craving, Withdrawal, and Negative Mood

Subjective responses during the first week after quitting were examined only in women who were abstinent during the first week. T-test comparisons between groups indicated that, relative to those in the standard group, women in the weight control group reported marginally smaller increases in total withdrawal, t(98) = 1.77, p < .10, and significantly smaller increases in BDI, t(98) = 1.97, p = .05; POMS-depression, t(98) = 2.06, p < .05; and POMS-tension, t(98) = 2.26, p < .05, after quitting smoking, as shown in

Figure 2. There were no differences between CBT and weight control or between CBT and standard, except for a significantly smaller increase in POMS-tension in CBT versus standard, t(99) = 2.34, p < .05. No group differences in desire to smoke (craving) were significant.

#### Predictors of Smoking Cessation Outcome

Predictors of 1-year outcome from logistic regression analyses were presented in Table 4. None of these predictors interacted with treatment group. Prequit (baseline) weight-related characteristics significantly associated with continuous smoking abstinence at 1 year included a higher BMI, a higher score on the TFQ-disinhibition scale, and answering "no" to "want to be as thin as possible." Prequit smoking characteristics associated with abstinence included greater number of prior quit attempts and older age at first cigarette. Among responses to cessation, only greater decrease in desire to smoke from prequit baseline to each subsequent follow-up point (1 week, 4 weeks, 3 months, and 6 months) was associated with 1-year abstinence.

Finally, any smoking at all within the first 2 weeks of the quit day (i.e., "lapse"), particularly on the quit day itself, was strongly associated with a very low likelihood of continuous abstinence at all subsequent time points. For example, of the 38 women (18% of entire sample) who smoked at all on their quit day, 0% had quit by the end of treatment 4 weeks later, compared with 53% of those who did not smoke at all on their quit day. Similarly, of the 130 women (59% of entire sample) who lapsed any time within the first 2 weeks of their quit day, only 3% were continuously abstinent by the 1-year follow-up, compared with 30% of those who did not smoke at all during the first 2 weeks, a 10-fold difference, as shown in Figure 3.

#### Discussion

Better strategies for addressing weight concerns in conjunction with smoking cessation are needed to improve the particularly poor cessation rates of weight-concerned women smokers (Meyers et al., 1997; Perkins, 1994). The results of this clinical trial indicate that a CBT adjunct designed to reduce weight concerns, but not a behavioral weight control adjunct aimed directly at attenuation of weight gain, will improve smoking cessation outcome in weight-concerned women beyond that produced by standard cessation counseling.

Closer examination of the outcome results in Table 2 and Figure 1 indicates that the efficacy of CBT over standard coun-

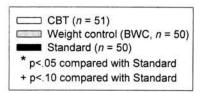
Table 3

Mean (± SD) Weight Gain (in kg) for CBT, Weight Control, and Standard Treatment Conditions at Posttreatment and Follow-Up Among All Those Continuously Abstinent Up to Each Point

|                 | _                         | Follow-up     |               |               |  |  |
|-----------------|---------------------------|---------------|---------------|---------------|--|--|
| Treatment group | Posttreatment<br>(4 week) | 3 month       | 6 month       | 12 month      |  |  |
| CBT             | 1.1 ± 1.4**               | $2.6 \pm 2.5$ | 2.9 ± 2.6**   | 2.5 ± 4.2*    |  |  |
| Weight control  | $0.6 \pm 1.6***$          | $2.6 \pm 3.4$ | $4.1 \pm 4.8$ | $5.4 \pm 3.3$ |  |  |
| Standard        | $2.2 \pm 1.4$             | $3.7 \pm 3.0$ | $6.4 \pm 3.5$ | $7.7 \pm 4.7$ |  |  |

Note. CBT = cognitive-behavioral therapy.

<sup>\*</sup> p < .05 for difference from standard treatment. \*\* p < .01. \*\*\* p < .001.



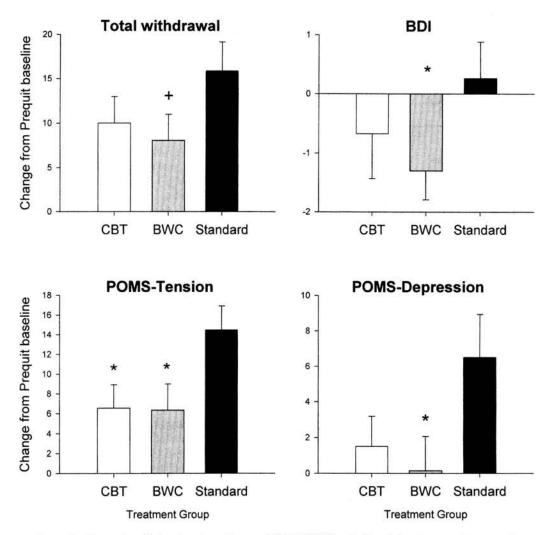


Figure 2. Change in withdrawal and negative mood (BDI, POMS scales) in abstinent women from prequit baseline to the first week of smoking cessation, by treatment group. CBT = cognitive-behavioral therapy; BWC = behavioral weight control; BDI = Beck Depression Inventory; POMS = Profile of Mood States.

seling was achieved during the period of active treatment. Declines in abstinence rates during the follow-up period, after the end of treatment, were roughly parallel across conditions. CBT also reduced rates of lapsing during treatment. Given the strong relationship between early lapse and subsequent relapse (see Figure 3), CBT may have been particularly effective in reducing relapse by discouraging lapses during the treatment period. Although CBT did not improve prevention of relapse after treatment ended, the superior outcome with CBT was maintained at 6-month and 1-year follow-ups, showing durability in the efficacy of CBT apparent by the end of the treatment period.

In contrast to the outcome results, however, the weight control intervention was successful in its objective of attenuating weight gain by the posttreatment period, whereas CBT was not successful in reducing weight concerns. Weight gain at posttreatment was significantly less in the weight control group than in the standard group, whereas weight concerns did not change in the CBT group or the other groups. Therefore, the superiority of the CBT intervention cannot be attributed specifically to reduction in weight concerns as measured in this study. In fact, because weight gain was significantly less and outcome better in CBT at most points, relative to standard treatment, the efficacy of CBT may have been

Table 4
Predictors of Abstinence at 1 Year

| Variable  | β      |
|---|--------|
| Baseline weight-related characteristics               |        |
| BMI   | .1299* |
| Wish to be thin                                       | 8180*  |
| TFQ-Disinhibition                                     | .2661* |
| Baseline smoking characteristics                      |        |
| Number of prior serious quit attempts                 | .1152* |
| Age at first cigarette                                | .1274* |
| Change in desire to smoke after quitting <sup>a</sup> |        |
| l week  | 0231** |
| 1 month   | 0215** |
| 3 months  | 0426*  |
| 6 months  | 0406*  |

*Note.* BMI = Body Mass Index; TFQ = Three-Factor Questionnaire. <sup>a</sup> Change from prequit baseline to postquit.

due (at least in part) to its unexpected effect in reducing weight gain. On the other hand, this possibility is lessened by the fact that weight gain from prequit baseline to the end of treatment generally was not significantly related to smoking cessation outcome at follow up.

A possible explanation for the lack of effect of CBT on weight concerns may be that our measure of weight concern was flawed or not sensitive enough to detect a change in concern, a problem common to this clinical research area (Jeffery et al., 2000). Our measure of concern at posttreatment assessed concern about a "10-pound weight gain over the next year." Because most abstinent women had already gained several pounds (see Table 3), their continuing high level of concern may have reflected their attitudes about an additional 10 lb weight gain, which would result in a cumulative gain due to cessation larger than 10 lb. Thus, CBT actually may have reduced weight concerns, but our measure may not have been adequate for assessing change in concern after a quit attempt. However, this same measure was sensitive to a reduction in concern in women who relapsed by the end of treatment (and therefore did not gain weight).

Another possible explanation for the efficacy of CBT involves nonspecific therapeutic influences, such as attenuation of stress and negative mood after quitting or greater expectations of participants or therapists that CBT would be more effective. CBT, and to an even greater extent the weight control intervention, attenuated negative mood responses during the first week of cessation, relative to the standard group (see Figure 1). Arguing against this influence being key to CBT's efficacy is the observation that weight control did not produce better cessation outcome at any point, even though it also attenuated negative mood after quitting smoking. Because participants initially rated weight control as most preferred and CBT as least preferred prior to their randomized assignment to groups, participants' expectation of success with CBT is unlikely to account for its efficacy. This is further supported by the equal ratings of treatment "satisfaction" and "helped with quitting" across conditions at the end of treatment. Finally, therapists' expectations of success may have been greatest with CBT, perhaps inadvertently biasing their performance in providing the three treatments. We did not formally assess therapists' attitudes about the treatments prior to the beginning of the study. However, anecdotal reports from the therapists suggested that they least preferred delivering CBT because of its complexity and their perception of resistance of some participants to its message (i.e., encouraging weight acceptance among weight-concerned women). In any case, further research with better measures of concern and of process variables is needed to ascertain the mechanism by which CBT improved cessation outcome.

Compared with the 1-year weight gain typically reported in smoking cessation studies with unselected women (e.g., 4.5 kg in Hudmon et al., 1999), mean ( $\pm$  SD) weight gain in the CBT group was smaller (2.5  $\pm$  4.2 kg), weight gain in the weight control group similar (5.4  $\pm$  3.3 kg), and weight gain in the standard group (i.e., those not receiving any weight-related intervention) was greater (7.7  $\pm$  4.7 kg). The weight gain in the standard group was very comparable with the largest gain these women reported experiencing during a prior quit attempt  $(8.1 \pm 5.7 \text{ kg})$  and to that initially expected by these women during this quit attempt  $(6.9 \pm 3.1 \text{ kg})$ . Thus, weight-concerned women appear to gain more weight after quitting than do other women smokers. By comparison, women in the CBT group were far more successful in attenuating weight gain during this quit attempt than they had expected to be and than they had been in the past. Because weight gain after quitting was not significantly related to subsequent long-term abstinence, the modest level of weight gain among those in CBT likely is not biased by any selectivity of the women able to stay abstinent for a year.

On the basis of our results, this CBT intervention may be the most effective to date for weight-concerned smokers, who, as noted, tend to have very poor outcome after a quit attempt. In a study of sedentary women smokers (with or without weight con-

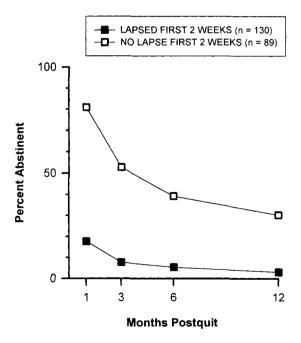


Figure 3. Rates of continuous abstinence (lapses allowed) across 12-month follow-up as a function of any smoking at all (lapse) during the first 2 weeks after the quit day.

<sup>\*</sup> p < .05. \*\* p < .01.

cerns), Marcus and colleagues (Marcus et al., 1999) reported that an aerobic exercise intervention plus 12 weeks of standard cessation counseling produced a point-prevalence rate at 1 year of 19%, compared with 14% in those receiving standard counseling alone. These rates are somewhat lower than the corresponding rate for CBT (29%) in the current study but comparable to that for weight control (21%) and for standard treatment (16%). Furthermore, our results are comparable to, or perhaps better than, those of smoking cessation trials involving medications. For example, in an outcome study of those wanting to quit smoking but avoid weight gain (two thirds of whom were women), 1-year continuous abstinence rates (slips allowed) were 17% for ephedrine plus caffeine, compared to 16% for placebo (Norregaard et al., 1996). These rates are slightly lower than our rate for CBT (21%) but greater than our rates for weight control (13%) and standard (9%). Even nicotine replacement, the current standard pharmacological treatment (Hughes, 1996), often does not produce better rates of abstinence (e.g., 6-month point-prevalence of approximately 15% for women receiving nicotine patch plus counseling; Wetter et al., 1999). Nevertheless, the fact that nearly 80% or more of women smokers relapse following all of these treatments, including our CBT intervention, highlights the intractability of smoking among weightconcerned smokers and signals the need to develop better interventions with this large subgroup of women smokers. In particular, the very strong relationship between lapses within the first 2 weeks of quitting and subsequent relapse (see Figure 3), also noted by others (Kenford et al., 1994), points to the need for greater intensity of treatment early in the quit attempt.

This trial demonstrates that improving smoking-cessation outcome in weight-concerned women is possible using a specific type of counseling alone, without medication. Treatment developers should pay greater attention to similar cognitive-behavioral approaches, which have taken a back seat to new medications over the past few decades (Shiffman, 1993). A direction for future research would be to distill the key elements of the CBT intervention so that it could be delivered in more concise fashion, as part of the counseling typically provided in community settings. Our results also suggest that dieting to prevent weight gain, the strategy most often attempted by weight-concerned women trying to quit and that rated by our sample as most acceptable of the three treatments, will be no more effective than doing nothing to specifically address weight concerns. Health care providers, therefore, probably should not encourage these women to engage in substantial efforts to diet while attempting to quit smoking.

Combining the CBT intervention with medication for smoking cessation may further improve outcome. Bupropion (Zyban, Glaxo Wellcome), originally developed as an antidepressant (Welbutrin), may be useful to examine in weight-concerned women for several reasons. First, bupropion attenuates weight gain after cessation (Hurt et al., 1997), perhaps complementary to the effects of CBT. Second, bupropion may relieve negative affect and other depressive symptoms after quitting (Shiffman et al., 2000). These adverse effects of cessation may be particularly important determinants of relapse for weight-concerned women, who are more likely than other smokers to have histories of mood disorder (Levine, Perkins, & Marcus, in press). Similar to bupropion, other antidepressant medications with specific effects in preventing cessation-related weight gain, such as fluoxetine (Spring et al., 1995), also may be effective in weight-concerned women smokers when combined

with CBT (Hitsman et al., 1999). However, the likely influence of nicotine replacement combined with a weight-related counseling intervention is not clear. One study found somewhat poorer 1-year outcome (continuous abstinence), as well as greater weight gain, in weight-concerned women given behavioral weight control plus nicotine gum versus groups of women given either weight control or nicotine gum alone (Pirie et al., 1992).

In conclusion, CBT to reduce weight concerns, but not a behavioral weight control intervention to attenuate cessation-related weight gain, improves smoking cessation outcome in weight-concerned women for as long as 1 year. The mechanism by which CBT enhances abstinence remains unclear, although future research with better measures of concern may clarify how it is effective. Further clinical research is also needed to determine the key effective ingredients of the CBT intervention to maximize its dissemination and to evaluate its efficacy when combined with medications for smoking cessation. Such research is likely to substantially improve the poor cessation rates in the large subgroup of weight-concerned women smokers.

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