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Nicotine Patch and Self-Help Video for Cigarette Smoking Cessation

Joel D. Killen, Stephen P. Fortmann, Laurie Davis, and Ann Varady
Stanford University School of Medicine

A total of 424 smokers were randomized in a 2 × 2 factorial experiment. A pharmacologic factor contained 2 levels: transdermal nicotine patch (TNP; 21 mg) and placebo. A self-help behavioral treatment factor contained 2 levels: video-enhanced self-help treatment manual and self-help treatment manual only. At 2 months, TNP produced a higher level of abstinence (36%) than placebo (20%), $p < .001$. No other comparison was significant. In secondary analyses, (at 2 months) and compliance with patch treatment regimen (at 2, 6, and 12 months) were associated with less relapse. Although nicotine replacement therapy has improved our ability to produce smoking cessation, the production of sustained, longer term abstinence remains an elusive goal.

Nicotine replacement therapy (NRT) is the state-of-the-art treatment for nicotine addiction. The growth in interest in the use of NRT stems from three observations: (a) Compulsive tobacco use involves physiological and behavioral dependence on nicotine, (b) nicotine need not be delivered by tobacco to produce its effects, and (c) NRT for nicotine addiction can be accomplished in a manner that permits therapeutic management of the dependence process and lessens the overall health risk to the user (Henningfield & Jasinski, 1988).

Nonetheless, the addition of behavioral treatment to NRT significantly increases long-term smoking cessation rates (Hughes, 1991). Indeed, NRT has been shown to be most effective when combined with intensive, clinic-based behavioral interventions designed to facilitate the development of self-regulator skills (Hall, Tunstall, Ginsberg, Benowitz, & Jones, 1987; Hall, Tunstall, Rugg, Jones, & Benowitz, 1985; Killen, Maccoby, & Taylor, 1984; Kozak & Fagerstrom, 1995; Schneider et al., 1983).

The evidence with respect to nicotine gum (NG) and clinic-based behavioral treatment combinations is conclusive. Both standard and meta-analytic reviews have concluded that NG is a useful pharmacological aid to smoking cessation when combined with behavioral treatment programs delivered through smoking cessation clinics (Hughes, 1991; Lam, Sacks, Sze, & Chalmers, 1987). However, abstinence rates are far less impressive when NG is delivered in general medical practice in conjunction with brief counseling interventions (British Thoracic Society, 1983; Hughes, Gust, Keenan, Fenwick, & Healey, 1989).

Nicotine patch (TNP) studies have not examined the efficacy of self-help or minimal-contact treatment combinations as thoroughly. For example, a recent meta-analytic review (Fiore, Smith, & Jorenby, 1994), concluded that 14 of 17 published TNP studies included a significant degree of counseling, either individual or group. However, in the Fiore et al. review, high-intensity behavioral treatment was associated with about two-fold higher abstinence rates at the end of treatment.

NG and TNP can now be purchased without prescription. As a result, psychologists and other health care professionals involved in smoking cessation treatment are likely to lose control over the way in which NRT products are used by consumers. In addition, the advent of managed care, with its heavy emphasis on cost containment, should further erode clinicians' ability to provide much specific instruction in the proper use of NRT or supervision in the application of behavior change skills. Thus, it may be prudent to focus resources on the development of cost-effective self-help behavioral interventions that can be provided as "stand-alone" adjuvants to NRT for the treatment of nicotine dependence (Benowitz, 1993).

To date, there are comparatively few published reports of controlled trials examining NRT combined with self-help treatment programs. In balance, the results of these studies do not support a strong case for the usefulness of NRT and self-help behavioral treatment combinations. For example, in one study, Lando and his colleagues found that smokers given NG along with self-help booklets did no better than those receiving NG coupled with an informational pamphlet (Lando, Kalb, & McGovern, 1988). Similarly, in two studies conducted by our own group, the combination of NG and self-help behavioral procedures was not superior to NG alone in preventing smoking relapse (Fortmann & Killen, 1995; Killen, Fortmann, Newman, & Varady, 1990). However, in a recent placebo-controlled investigation, smokers received either TNP or placebo, coupled with self-help materials, and telephone counseling. Active TNP produced an abstinence rate of 20.5% at 6-month follow-up; the

Joel D. Killen, Stephen P. Fortmann, Laurie Davis, and Ann Varady, Center for Research in Disease Prevention, Stanford University School of Medicine.

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Correspondence concerning this article should be addressed to Joel D. Killen, Center for Research in Disease Prevention, Stanford University School of Medicine, 1000 Welch Road, Palo Alto, California 94304-1885. Electronic mail may be sent via Internet to Killen@SCRDP.Stanford.EDU.

abstinence rate for the placebo condition was 2.5% (Westman, Levin, & Rose, 1993).

The core theoretical proposition underlying behavioral treatment for smoking cessation is that smokers require self-regulatory skills to cope with the nonpharmacological factors that maintain cigarette smoking and precipitate relapse (Lichtenstein & Glasgow, 1992). However, research indicates that smokers who attempt to quit with self-help treatment formats often fail to acquire and use skills effectively (Curry, 1993; Curry, Marlatt, Gordon, & Baer, 1988; Glasgow, Schafer, & O'Neill, 1981; Gritz et al., 1988).

Self-regulatory skills can be acquired most efficiently through modeling interventions that promote enactive mastery experiences (Bandura, 1986). Clinic-based behavioral treatments that are based on social learning principles promote skills acquisition through live modeling displays, therapist-guided rehearsal, and self-directed application of newly acquired skills (Bandura, 1986; Killen et al., 1984; Lichtenstein & Glasgow, 1992; Stevens & Hollis, 1989). In contrast, most self-help interventions, including our earlier efforts, have relied on print-based materials (i.e., manuals or quit kits) to facilitate training (Curry, 1993; Glynn, Boyd, & Gruman, 1990). The poor performance of self-help treatments in enabling acquisition of self-regulatory skills may reflect, in part, the weakness of the methods used to produce mastery.

Given the need for behavioral interventions that can be coupled to NRT products in an over-the-counter market, an aim in this study was to explore the use of video as an aid to skills training provided in the context of a self-help smoking cessation program. Our interest in the use of video derives from theory and evidence suggesting that visual media may be more effective than text-only formats for the delivery of interventions that are based on modeling principles (Rosenthal & Bandura, 1978; Rosenthal & Zimmerman, 1978; Salomon, 1979).

Most human behavior is learned by observation through modeling (Bandura, 1986). Live demonstrations, text, video and film displays, and a variety of other media can be used to model information, rules of behavior, and behavior change instructions. However, all have their effects through the process of observational learning (Bandura, 1986). Visual media may be more effective than text-only formats for the delivery of modeling interventions because visual media more effectively activate the subprocesses that govern observational learning (Rosenthal & Bandura, 1978; Rosenthal & Zimmerman, 1978; Salomon, 1979). For example, video can enhance both attentional and motivational processes by modeling behavior with functional value to viewers and by portraying models of interest to them. Retention of modeled information is related both to the characteristics of the modeled performance and to information-processing strategies used by the viewer. Retention is enhanced when models explain the rules used to guide their behavior, when complex behaviors are divided into their component parts, and when diverse and creative coping behavior is modeled in a variety of situations. With respect to both the retention of information and the production of modeled behavior, video modeling displays can effectively prompt viewers to engage in active information processing that enhances both retention of modeled information and the ability to reproduce behavior (Maibach & Flora, 1993). Thus, in electing to test a video-enhanced self-help intervention in this study, we hoped to operationalize social learning principles more effectively than may be possible with print-based self-help approaches.

This study was designed to explore two primary hypotheses. The first hypothesis was that TNP would produce significantly higher abstinence rates than placebo at each follow-up. The second hypothesis was that a video-enhanced self-help treatment manual would produce higher abstinence rates at each follow-up than a print-based manual. With respect to the second hypothesis, our goal was to develop a self-help intervention that (a) could be coupled to NRT, (b) could be comparatively easy to disseminate, and (c) would include several theoretically important components that may be difficult to implement in print-based self-help interventions. To examine treatment efficacy, we randomized 424 participants in a placebo-controlled 2 × 2 factorial design that included both NRT and self-help behavioral treatment factors.

Method

Design

A total of 424 smokers (214 men, 210 women) were randomized in a 2 × 2 fully crossed factorial experiment. A pharmacologic factor contained two levels: TNP (21 mg) and placebo patch. A self-help treatment factor contained two levels: video-enhanced self-help manual and self-help manual only. Assignment to the patch condition was double-blind. All participants received the print-based self-help treatment manual because there is general consensus that NRT should be coupled with behavioral interventions and that over-the-counter marketing will include such interventions.

Recruitment of Participants

Program announcements were placed in local newspapers. Interested smokers at least 18 years old were instructed to telephone the program office located in San Jose, California. A baseline interview was conducted at the time of the initial telephone contact to collect background information and determine eligibility. After completion of the baseline telephone interview, callers who wanted to participate were scheduled for an initial office visit. At the first visit, participants were randomized to treatment condition, and they signed written consent forms, completed a questionnaire assessment battery, and received instructions on use of TNP.

Exclusionary Criteria

During the baseline telephone interview, potential participants were also asked a series of medical questions to assess their eligibility for TNP treatment. Individuals who were pregnant, lactating, or receiving active treatment for cancer or peptic ulcer disease were excluded from the study. Those who reported a history of heart disease, recent chest pain, diabetes, or thyroid disease were asked to obtain written permission to participate from their physicians. We provided a detailed letter to each physician explaining the nature of the study and the Food and Drug Administration's cautions on the use of transdermal nicotine.

Variables Measured at the Initial Baseline Telephone Interview

In addition to basic demographics and medical status questions, the following information was obtained during the initial telephone contact:

Smoking history. Various aspects of current and past smoking behavior were assessed (i.e., cigarettes smoked per day, prior quit attempts, number of years smoked, age began smoking, cigarette brand).

Modified Fagerstrom Tolerance Questionnaire. The Fagerstrom Tolerance Questionnaire (FTQ; Fagerstrom, 1978) and a recent revision (Fagerstrom Test for Nicotine Dependence; FTND; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) were developed to help researchers and clinicians categorize smokers according to their degree of nicotine dependence (see also Fagerstrom & Schneider, 1989). Our modification of the FTQ entailed rescaling the items to provide more response choices and analyzing daily cigarette consumption separately (Killen et al., 1990). The five questions included in our modification refer to the following aspects of an individual's cigarette consumption pattern: (a) difficulty in refraining from smoking where it is forbidden, (b) smoking more in the morning, (c) smoking when bedridden with illness, (d) depth of inhalation, and (e) time after awakening before smoking one's first cigarette. Scores on the modified FTQ range from 5–25. Good test–retest reliability was established before use of this modified instrument in the study. Test–retest correlations for the five questions were .78, .71, .83, .79, and .90, respectively.

Previously, we documented the validity of this measure by demonstrating that it predicted craving over an 8-week period. The magnitude of the relationship was comparable with that reported for several biochemical indices of tobacco smoke intake (Killen, Fortmann, Newman, & Varady, 1991).

Personal characteristics. The following personal characteristics were assessed: age, gender, race, marital status, employment status, and education.

Reliability of Telephone Interview

Test–retest reliability for each of the telephone interview questions (medical history, smoking history, modified FTQ, personal characteristics) was previously established in a pilot study with 57 smokers (Killen et al., 1990). Pearson correlations were calculated between smokers' response to each item at Time 1 and Time 2 (mean interval between assessments was 15.5 days). Adequate stability of survey responses ($r > .70$) was observed on all but two of the questions, which were subsequently dropped from the interview.

Variables Measured at the Initial Office Visit

The following variables were assessed at the initial office visit.

Craving. NRT is designed to promote smoking cessation and relapse prevention by preventing or reducing craving and other abstinence effects associated with nicotine withdrawal. Therefore, to examine the relationship between craving and TNP, we measured craving at baseline and at several points during the course of treatment.

We obtained a craving score based on two items (Have you felt cravings for a cigarette? and Have you felt strong urges to smoke?) by averaging the two items. For each item, participants rated on a 6-point scale how upsetting cravings and urges had been.

Depression symptoms. Depression symptoms were measured with the 20-item Center for Epidemiological Studies Depression Scale (CES-D). The instrument was developed for use in studies of the epidemiology of depressive symptomatology in the general population. The scale has high internal consistency (Radloff, 1977).

Body mass index (BMI). BMI is generally considered to be the preferred index of relative body weight as a reflection of adiposity (Kraemer, Berkowitz, & Hammer, 1990). BMI was computed as kilograms divided by square meters. Height and weight were recorded on a standard balance beam scale. Participants removed shoes, jackets, and any additional heavy clothing before they were measured.

Whereas depression symptoms and BMI were included in response to treatment analyses presented in this article, other hypotheses concerning these variables are secondary to the primary hypotheses and, therefore, will be examined in future reports.

Variables Measured at 2-, 6-, and 12-Month Follow-Ups

Participants returned to the study center for follow-up at 2 months. They provided expired-air samples for the analysis of carbon monoxide (CO) levels and saliva samples for cotinine determination. In addition, they estimated the number of times that they watched the video and referred to the treatment manual during the course of the intervention.

We contacted participants by telephone at 6- and 12-month follow-ups to determine smoking status. Those who said that they had not had even a puff of a cigarette for the 7 consecutive days preceding the phone contact were asked to visit a survey center to provide a saliva sample for cotinine determination.

Variables Measured During Treatment

Research staff contacted participants by telephone at 24 hr, 1 week, and 1 month into treatment to assess smoking status, side effects, craving, and patch use.

Biochemical Assessment

Nonsmoking status at follow-up was assessed by examination of saliva cotinine concentrations or, at the 2-month assessment, by expired-air CO measurement for those still wearing patches. CO measurements were performed with the Ecolyzer (Energetics Science Inc., New York). We collected saliva samples by having participants hold a dental roll in their mouths until it was saturated, as described by Luepker, Pechacek, and Murray (1981). Cotinine concentrations were measured for this study according to the method of Jacob, Wilson, and Benowitz (1981).

Definition of Abstinence

Abstinence was defined as a report of nonsmoking (not even a puff) for 7 consecutive days before contact and a saliva cotinine level below 20 ng/ml or a CO level below 9 parts per million (ppm).

Definition of Relapse

Participants reported the date on which they relapsed and returned to smoking. The relapse date was defined as the first day on which a participant smoked for 7 consecutive days (Ossip-Klein, Bigelow, Curry, Hall, & Kirkland, 1986).

Reclassification Procedures

Except for participants who were outside the area at the time of assessment, all those who reported abstinence but who failed to provide breath or saliva samples for the relevant biochemical confirmation were classified as smokers.

Treatments

Self-help treatment. All participants received a manual designed to help them develop self-regulatory skills to resist urges to smoke. The manual described seven different "high-risk" situations typically encountered by ex-smokers, coupled with one or more strategies to be used to cope successfully with urges to smoke in each risky situation. The manual provided space for participants to record their own coping strategies for the situations depicted and for high-risk situations specific to them.

Participants were instructed to complete the manual before quitting smoking, to review it during the course of treatment, and to practice their coping strategies. Before leaving the study center, all participants were asked to complete a "plan of action" detailing at least three situations that they expected to be risky for them and at least one coping strategy for each.

In addition to the self-help treatment manual, half of the participants also received a 20-min video designed to enhance the efficacy of the manual by (a) presenting viewers with characters who modeled the use of specific, concrete self-regulatory skills for coping with risky situations without resorting to smoking and (b) giving viewers an opportunity to cognitively rehearse the skills modeled by video characters.

The video follows two fictional, but realistic, characters as they experience a day in which they struggle to manage without cigarettes. Because the success of modeling interventions may depend, in part, on the use of models who are similar to the target audience, we were careful to select representative characters and to place them in realistic settings and situations. Viewers observed the characters as they confronted situations that many smokers identify as risky and watched as characters coped in these situations without resorting to smoking. Viewers were instructed to place themselves in these, or similar, situations and to plan their own approach to managing in the situations successfully without smoking. Freeze framing was used so that viewers are able to develop personal scenarios before learning how the characters themselves have chosen to react. Interspersed throughout the program are testimonials from former smokers presenting tips on what coping strategies worked for them.

Participants viewed the video in groups of 8–10 during the initial office visit. Each participant assigned to the video groups was then given a copy of the video with instructions to use it in conjunction with the manual throughout the remainder of the study.

TNP: Primary treatment phase. Half of the participants in the trial received an 8-week supply of TNP (21 mg) for the primary treatment phase, and half received placebo. Participants were instructed to apply new patches every 24 hr. The transdermal systems were provided without cost. Participants who reported irregular or intermittent smoking after their quit day were allowed to continue using the medication, provided that they continued to try to quit smoking. Those who did return to regular smoking during treatment were instructed to discontinue and return the patches. These participants remained in the study, and they were followed for ascertainment of response variables and analyzed according to intention to treat.

TNP: Down-titration phase. A down-titration phase was introduced beginning in Week 9. Participants on TNP received 14 mg for Weeks 9–12 and 7 mg for Weeks 13–16. Participants in the placebo condition wore placebo patches throughout the down-titration phase.

Concomitant Medication

The use of chronic medication other than the study drug was permitted. However, all such drug use was documented with name, dose, indication, and dates of initiation and discontinuation. Changes in dose were recorded as appropriate.

Safety–Side Effects

Side effects were assessed by telephone on a weekly basis. Those reporting difficulty were reminded of proper TNP application. Skin responses other than mild irritation or erythema prompted withdrawal of patches and referral to personal physicians.

Primary Statistical Analysis

The primary statistical analysis was directed at testing the main hypotheses of the study: that both TNP and the video-enhanced self-help behavioral treatment manual would improve abstinence rates and result in lower relapse rates. We used logistic analysis to test the statistical significance of differences in abstinence among the four treatment groups at 2-, 6-, and 12-month follow-ups. Separate models were fitted for each follow-up point, with biochemically confirmed smoking status as the dependent variable and patch (TNP or placebo) and video status (video plus manual or manual only) as independent variables. We analyzed 12-month relapse curves with survival analysis using the Cox proportional hazards model, with time to relapse as the dependent variable and treatment condition as the independent variable. Wald chi-square values are reported for the logistic analyses (SAS LOGISTIC) and for the Cox proportional hazards analyses (SAS PHREG). Log-rank chi-square values are given for survival curve analyses (SAS Lifetest).

The reader should note that the rates for survival analysis are somewhat higher than the abstinence rates because, to have been designated as abstinent, a participant must have reported no smoking for 7 consecutive days. In the survival analysis, participants were not considered to have relapsed unless they reported smoking for 7 consecutive days.

Results

Comparability of Study Groups

Table 1 compares the four treatment conditions on a number of baseline variables and shows no important differences, although participants in the placebo-only group were slightly younger than those in other treatment conditions.

Reclassification

Of self-reported nonsmokers, 75% and 69% provided biochemical confirmation at 6 and 12 months, respectively; these rates did not differ by treatment group. As noted, those failing to provide confirmation were reclassified as smokers. At 12 months, the exact numbers of unverified reports in each group were as follows: TNP + Video + Manual = 14; TNP + Manual = 17; Placebo + Video + Manual = 14; Placebo + Manual = 14.

At the 6-month follow-up, only 6 self-reported nonsmokers were outside the San Francisco Bay Area and were unable to be assessed in person. At the 12 month follow-up, only 4 self-reported nonsmokers were outside the Bay Area.

Logistic Analysis

We used logistic analysis with patch and video factors as covariates to examine abstinence rates at 2-, 6-, and 12-month follow-ups. Abstinence rates for each treatment condition are presented in Table 2. At 2 months, TNP produced a higher level of abstinence (36%) than placebo (20%), $\chi^2(1, N = 424) = 13.57$, $p < .001$; odds ratio (OR) = 2.26; 95% confidence interval (CI) = 1.45, 3.50. No other comparison was significant. The video did not enhance the efficacy of the treatment manual at any follow-up. Indeed, the video produced a somewhat lower abstinence rate at 6 months, $\chi^2(1, N = 424) = 3.95$, $p < .05$; OR = 0.60; 95% CI = 0.36, 0.99.

Survival Analysis

We used Cox proportional hazards analysis to examine time to relapse (first day on which a participant smoked for 7 consec-

Table 1
Comparison of Baseline Variables Among Treatment Conditions

Variable	Placebo	TNP	Placebo + video	TNP + video	*p*
M (and *SD*)					
Cigarettes smoked per day	22.52 (7.78)	23.05 (8.33)	23.69 (9.71)	24.84 (10.23)	.27
Modified FTQ	17.14 (3.50)	16.63 (3.95)	16.68 (3.37)	16.70 (3.66)	.71
Depression (CES-D)	13.59 (9.66)	11.87 (8.61)	12.30 (9.67)	13.62 (9.44)	.41
BMI (kg/m^2)	26.14 (4.48)	25.85 (5.03)	26.22 (5.30)	27.33 (6.10)	.18
Age (years)	42.21 (10.36)	44.84 (10.87)	46.89 (12.34)	47.47 (11.21)	.002
Education (years)	13.66 (2.28)	14.46 (2.35)	14.45 (2.74)	14.10 (2.24)	.06
%					
Gender (male)	48	50	51	52	.94
Married	41	42	44	50	.51
White	80	83	81	84	.81
Sample size	104	103	108	109	

Note. TNP = nicotine patch; FTQ = Fagerstrom Tolerance Questionnaire; CES-D = Center for Epidemiological Studies Depression Scale; BMI = body mass index.

utive days) over 12 months, with patch condition and video condition as the independent variables.

In the short term, those receiving TNP were significantly less likely to relapse than those receiving placebo, $\chi^2(1, N = 424) = 11.56, p < .001$; hazard ratio = 1.45; 95% CI = 1.17, 1.80. As shown in Figure 1. TNP groups separate from the placebo groups early on, but survival curves converge before the 6-month follow-up, log-rank $\chi^2(1, N = 424) = 12.03, p < .001$. In contrast, the relapse rates for the video-plus-manual group and manual-only group were not significantly different, log-rank $\chi^2(1, N = 424) = 3.26, p < .10$. As a result, survival curves for these groups are not presented.

Analysis of Compliance With Treatment Instructions

We conducted secondary analysis to examine the effects of treatment protocol compliance on relapse. To assess compliance with the patch treatment protocol, at 24 hr, 1 week, 1 month, and 2 months, research assistants queried participants by telephone about patch use. Participants were considered to be fully compliant if, at all assessments, they responded yes to the question "Are you wearing a patch now?" By this definition, only 44% of participants in the TNP condition and 22% of participants in the placebo patch condition were fully compliant, $\chi^2(1, N = 424) = 23.47, p < .001$.

At the 2-month follow-up, participants were asked how many times they had watched the video and referred to the treatment manual. The mean number of manual referrals was 5.08 (SD = 6.43), and the mean number of additional tape viewings was 2.64 (SD = 4.99). There was no significant difference in mean use of manual or video across groups. Because these variables were highly correlated ($r = .54, p < .001$), the mean number of manual referrals was used to index compliance with manual–video treatment instructions in the compliance analysis.

We used stepwise Cox proportional hazards analysis to examine time to relapse, with treatment condition and treatment protocol (patch, manual) compliance status included as independent variables. At 2 months, patch compliance status, $\chi^2(1, N = 410) = 37.0, p < .001$, and patch treatment condition, $\chi^2(1, N = 410) = 13.68, p < .001$, entered the model. At 6 months, patch compliance status entered the model, $\chi^2(1, N = 410) = 39.40, p < .001$. At 12 months, patch compliance status entered the model, $\chi^2(1, N = 410) = 33.64, p < .001$.

Survival curves displaying the effects of patch condition and patch compliance status are presented in Figure 2. The curves are significantly different, $\chi^2(3, N = 424) = 40.84, p < .001$. It is evident that compliance, independent of patch treatment condition, has an important effect on relapse.

Table 2
Percentage of Participants Reporting Not Smoking for at Least 7 Days, Biochemically Confirmed at 2-, 6-, and 12-Month Follow-Ups by Treatment Condition

Condition	2 months[a]	6 months[b]	12 months	6 & 12 months[c]
TNP + manual	41	25	20	15
TNP + manual + video	31	16	14	7
Placebo + manual	18	18	14	10
Placebo + manual + video	21	12	10	10

Note. TNP = nicotine patch.
[a] At 2 months, the logistic model showed significant main effects for TNP, $\chi^2(1, N = 424) = 13.27, p < .001$. [b] At 6 months, the logistic model showed significant main effects for the no-video condition, $\chi^2(1, N = 424) = 3.95, p < .05$. [c] Percent abstinent at both 6 and 12 months.

Effect of TNP on Craving

Participants who said that they were not smoking during telephone calls conducted at 24 hr, 1 week, and 1 month were asked to report their current level of craving. Craving levels are presented in Figure 3. At each of these assessments, we compared craving levels of those in TNP and placebo conditions. Craving levels at 24 hr ($p < .001$) and 1 week ($p < .05$) were significantly lower for those assigned to receive TNP. There was no significant difference in reported craving level between groups at the 1-month assessment.

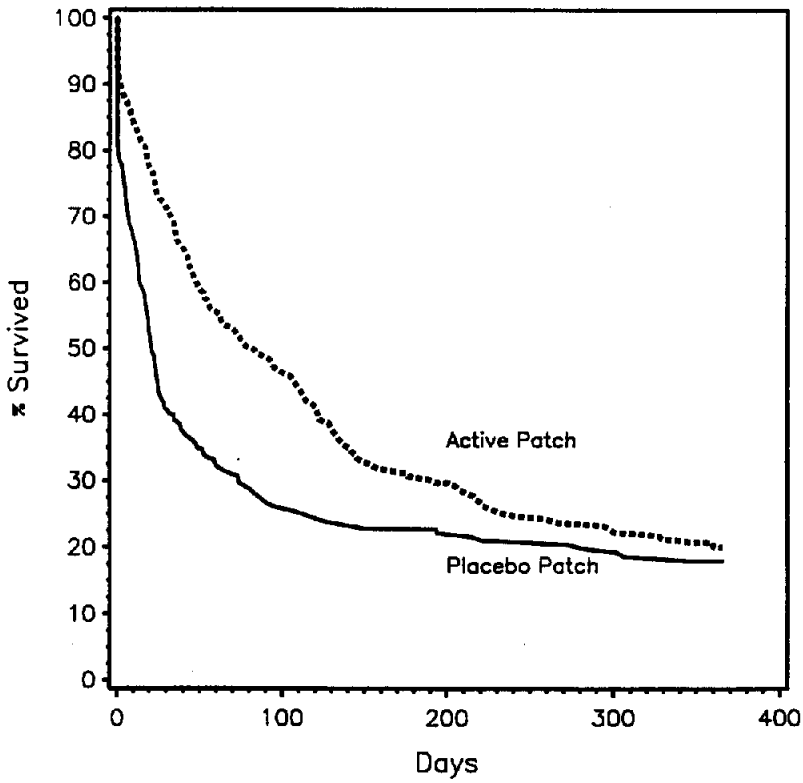

Figure 1. Relapse to regular smoking (daily use for at least 1 week) over 1 year after randomization comparing those in active nicotine patch and placebo patch treatment groups.

Response to Treatment Analysis

To examine variables that might predict response to treatment, we repeated the relapse analysis using data only from participants assigned to the TNP groups. Because there was no main effect for the video enhancement, we did not examine response to treatment in those groups.

We investigated response to treatment with a stepwise multivariate Cox proportional hazards model using $p < .01$ as the criterion for entry. The independent variables were those listed in Table 1. Only level of nicotine dependence, as measured by the modified FTQ, was associated with relapse. Those with higher nicotine dependence scores at baseline relapsed at significantly higher rates from baseline to 12-month follow-up, $\chi^2(1, N = 209) = 7.32, p < .01$; hazard ratio = 1.05; 95% CI = 1.01, 1.10. For illustration, survival curves for each modified FTQ quartile are presented in Figure 4. By the 12-month follow-up, survival (nonrelapse) rates for each quartile were as follows: Quartile 1 = 35%; Quartile 2 = 21%; Quartile 3 = 18%; Quartile 4 = 13%.

Efficacy of the Blind

At the 6-month follow-up, participants were asked to guess their treatment assignment. Seventy-five percent of those receiving TNP guessed correctly, compared with 64% of those assigned to placebo conditions, $\chi^2(1, N = 384) = 60.26, p < .001$.

Discussion

This study was designed to explore two primary hypotheses. The first hypothesis was that TNP would produce significantly higher abstinence rates than placebo at each follow-up. This hypothesis was partially confirmed. At the 2-month follow-up, the overall abstinence rate for groups receiving TNP was 36%, compared with 20% for those assigned to placebo conditions. This result was statistically significant. However, the abstinence rates produced by TNP and placebo at 6- and 12-month follow-ups were not significantly different.

Survival analysis revealed a now-common pattern of relapse. Survival curves separate early on with relapse occurring less precipitously in the TNP groups. Indeed, the superiority of TNP over placebo in promoting smoking cessation is very striking during the early course of treatment. For example, 14% of the participants in the TNP groups relapsed by the end of the first week, compared with 30% in the placebo conditions. However, unlike our earlier work with NG, the survival curves converged near the 6-month mark instead of maintaining a degree of separation.

How do these results compare with other TNP studies? In fact, the performance of smokers in our TNP groups was somewhat better at the end of treatment than the performance of smokers in a number of other TNP trials and very similar at 6-month follow-up. For example, Fiore et al. (1994) pooled data from 17 double-blind, placebo-controlled TNP studies published

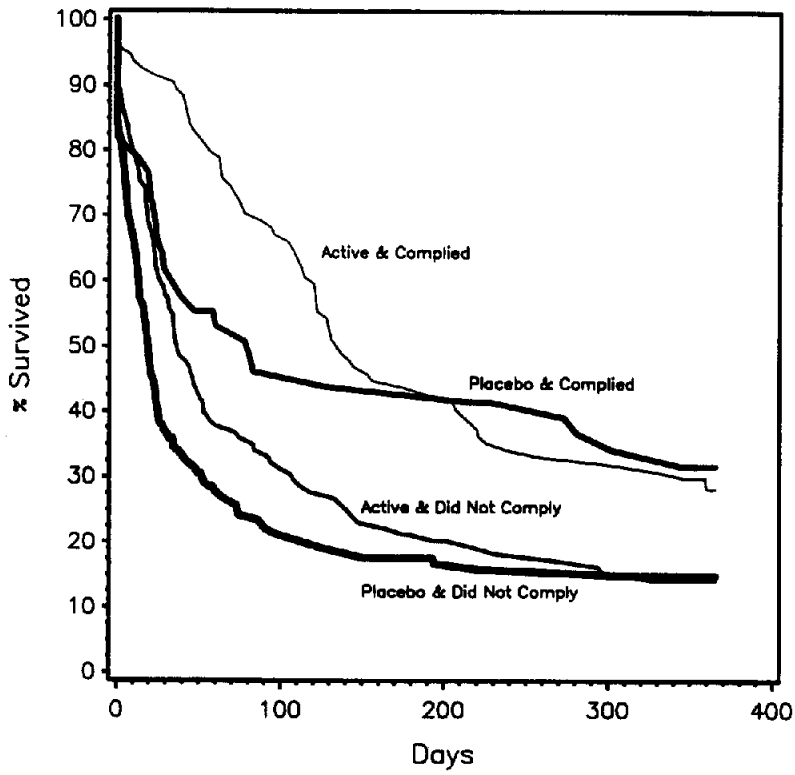

Figure 2. Relapse to regular smoking (daily use for at least 1 week) over 1 year after randomization comparing those who complied and those who did not comply with active or placebo patch treatment instructions.

through September 1993. To provide information about the magnitude of the effect of TNP, they combined abstinence rates for active groups and placebo groups and compared the groups at both end of treatment and 6-month follow-up. Overall, mean biochemically confirmed abstinence rates for TNP users were 27% at end of treatment and 22% at 6 months, compared with 13% and 9%, respectively, for placebo (Fiore et al., 1994); the corresponding figures for our study are 36% and 21% for TNP versus 20% and 15% for placebo. In general, then, the abstinence rates achieved by TNP in our study are very similar to the rates produced by TNP in other studies. However, it appears that participants in the placebo groups in our study did somewhat better than their counterparts in other investigations.

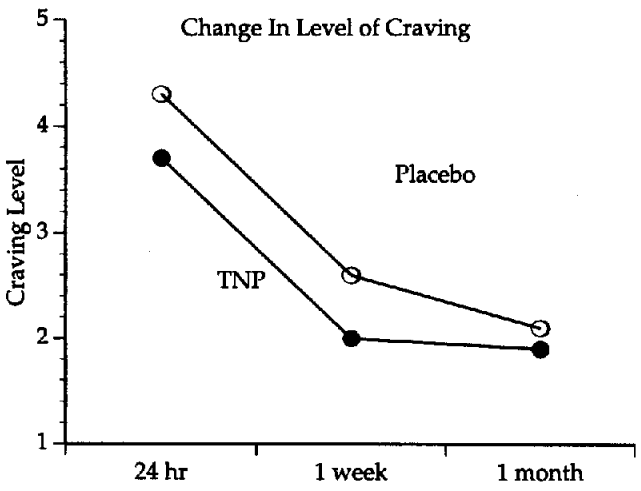

Figure 3. Mean craving level assessed at telephone calls completed at 24 hr, 1 week, and 1 month postrandomization. TNP = nicotine patch.

Compliance with treatment instructions is an important mediator of treatment outcome. One obstacle to successful nicotine replacement through NG is that many smokers fail to comply with instructions to chew gum. The advent of TNP promised higher compliance due, in part, to ease of use. However, although compliance analyses are frequently missing from reports of efficacy studies, there is evidence that compliance to TNP protocols is far from complete. For example, in one large trial with over 1,600 smokers, more than half discontinued patch use before the end of the 12-week intervention (Imperial Cancer Research Fund General Practice Group, 1993). Other investigators have also reported substantial deviations from TNP treatment protocols (Kozak & Fagerstrom, 1995; Westman et al., 1993). In this study as well, compliance to the protocol governing patch use was, at best, incomplete. Full compliance was 44% and 22% in TNP and placebo conditions, respectively.

Our secondary analysis of the relationship of compliance and relapse produced interesting results. Full compliance to the TNP

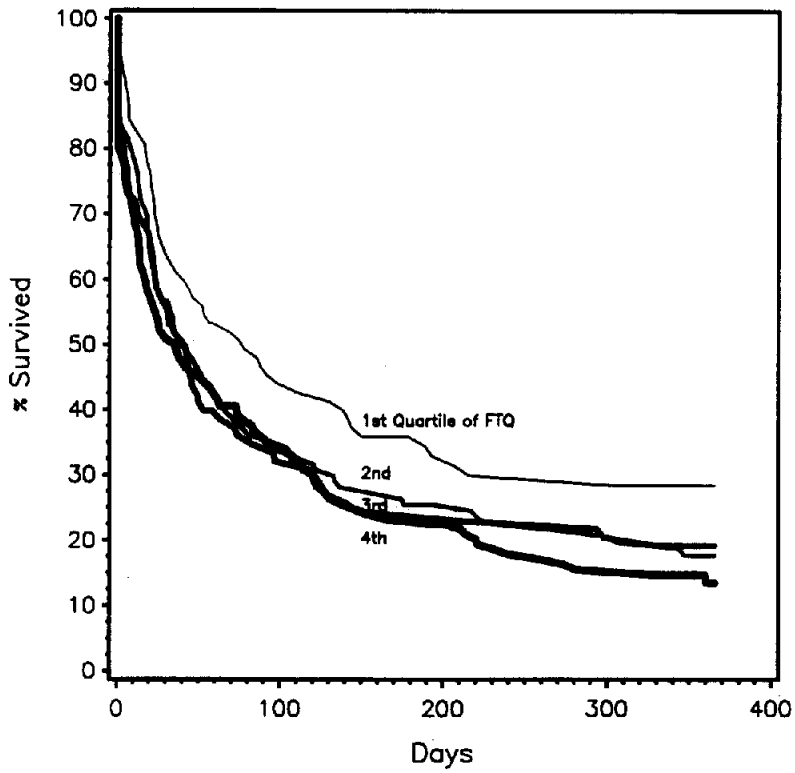

Figure 4. Relapse to regular smoking (daily use for at least 1 week) by quartiled modified Fagerstrom Tolerance Questionnaire (FTQ) score.

protocol produced lower short-term relapse rates. This result leads to the reasonable conclusion that proper use of the medication will produce a treatment effect. However, by the 6-month mark, the performance of participants who used placebo patches as instructed matched the performance of fully compliant active patch users. This finding, by no means surprising, reminds us that psychological factors such as effort, commitment, and perhaps, expectancy have an important role to play even in efforts to alter behavior that may be governed by both psychological and biological factors (Gottlieb, Killen, Marlatt, & Taylor, 1987).

Several other questions concerning TNP were addressed by our analyses. One analysis focused on the effect of nicotine replacement on craving. As a scientific term, craving has come under fire primarily because of its common language origins. Some addiction researchers deem craving an unsuitable term for scientific theory because of its highly subjective nature (Wise, 1988). Others would not banish craving entirely but make a strong case for using the word only to describe "strong desires to take drugs" (Kozlowski & Wilkinson, 1987).

Despite such criticism, many tobacco researchers have asserted the importance of craving in the maintenance of the smoking habit. For example, West and Schneider (1987) suggested that craving "is also potentially the most important feature of cigarette withdrawal" (p. 407). Russell (1988) referred to craving or the urge to smoke as "the most fundamental and difficult problem for smokers who are trying to quit" (p. 68). Our own work has shown that initial craving after cessation may be an important and useful predictor of smoking relapse (Killen, Fortmann, Kraemer, Varady, & Newman, 1992; Killen et al., 1991).

Because the rationale for NRT is the alleviation of craving and other abstinence effects that may influence relapse, we examined the effects of TNP on craving in this study. We compared self-reported craving, obtained during periodic telephone calls, of those participants reporting abstinence at the time of a telephone contact. As in previous work, craving was observed to diminish over the course of the trial for those able to refrain from smoking. Those assigned to receive TNP reported significantly lower levels of craving during calls made at 24 hr and 1 week postrandomization. Craving levels of TNP and placebo groups converged by the 1-month contact.

Because TNP produced a significant short-term effect, we conducted an analysis to determine which variables might influence response to treatment in the TNP groups. The modified FTQ was the best predictor of relapse over the course of the study; 35% of those scoring in the lowest quartile survived to Month 12, compared with only 13% scoring in the highest quartile.

The FTQ and the FTND were developed to help researchers and clinicians categorize smokers according to their degree of nicotine dependence (Fagerstrom & Schneider, 1989; Heatherton et al., 1991). The instrument assumes that nicotine dependence should be related to (a) how often the drug is used (number of cigarettes per day), (b) nicotine yield of the brand, (c) effective use of the drug, (d) how soon one smokes after awakening from sleep (because plasma nicotine levels are mini-

mal), (e) the degree to which the first cigarette of the day is judged most satisfying (as a result of craving relief), and (f) more internal stimulus control relative to external control (Fagerstrom & Schneider, 1989). The finding of a strong association between FTQ score and relapse adds to an increasing body of evidence revealing nicotine dependence as an important mediator of treatment response and raises the question of how dependence might be better accounted for in the next generation of smoking cessation treatments.

The second hypothesis guiding this research was that a video-enhanced self-help intervention would produce higher abstinence rates at each follow-up than a print-based self-help treatment manual. This hypothesis was not confirmed.

How are we to account for the failure of the video intervention to enhance the self-help manual? A variety of secondary analyses examining compliance data and reported that helpfulness of these materials failed to provide a conclusive answer to this question. Rather, over the course of our work, it seems increasingly clear to us that skills training interventions may not be well suited to intervention formats that eliminate or minimize the opportunity for guided problem identification and training. Skills mastery is achieved most thoroughly through interventions that use modeling, guided rehearsal, and self-directed application of newly acquired skills (Bandura, 1986). The accurate identification of problematic situations, the specific skills chosen for training, the time alloted to training and practice, and the individual's perceived level of personal mastery and adjustments in training schedule required to match individuals' performance accomplishments are just some of the variables that influence skill acquisition and performance. Although video can be a powerful medium for providing modeling demonstrations, clearly, the supervision and guidance afforded by more intensive, clinic-based skills training interventions are unavailable with self-help treatment formats.

From a social learning perspective an analysis of treatment efficacy should ask three questions: (a) whether a treatment method can induce behavior change, (b) whether changes generalize across situations and response systems, and (c) whether the changes are maintained over time (Bandura, 1969). This analysis applied to the field of smoking cessation indicates that, although NRT has improved our ability to produce smoking cessation, the production of sustained, longer term abstinence remains an elusive goal. Smoking cessation treatment programs that combine NRT with intensive, clinic-based behavioral interventions have achieved some measure of success in this regard, but access to such intensive programs is limited. In any case, most smokers appear unwilling to commit to such treatment efforts. Continued creative research effort will be needed if we are to develop a new generation of interventions capable of producing more generalizable and durable treatment effects.

References

Bandura, A. (1969). *Principles of behavior modification.* New York: Holt, Rinehart, Winston.

Bandura, A. (1986). *Social foundations of thought and action.* Englewood Cliffs, NJ: Prentice Hall.

Benowitz, N. L. (1993). Nicotine replacement therapy: What has been accomplished—Can we do better? *Drugs, 45,* 150–157.

British Thoracic Society. (1983). Comparison of four methods of smoking withdrawal in patients with smoking-related diseases: Report by a subcommittee of the Research Committee of the British Thoracic Society. *British Medical Journal, 286,* 595–597.

Curry, S. J. (1993). Self-help interventions for smoking cessation. *Journal of Consulting and Clinical Psychology, 61,* 790–803.

Curry, S. J., Marlatt, G. A., Gordon, J., & Baer, J. S. (1988). A comparison of alternative theoretical approaches to smoking cessation and relapse. *Health Psychology, 7,* 545–556.

Fagerstrom, K. O. (1978). Measuring degree of physical dependence to tobacco smoking with reference to individualization of treatment. *Addictive Behaviors, 3,* 235–241.

Fagerstrom, K. O., & Schneider, N. G. (1989). Measuring nicotine dependence: A review of the Fagerstrom Tolerance Questionnaire. *Journal of Behavioral Medicine, 12,* 159–181.

Fortmann, S. P., & Killen, J. D. (1995). Nicotine gum and self-help behavioral treatment for smoking relapse prevention: Results from a trial using population-based recruitment. *Journal of Consulting and Clinical Psychology, 63,* 460–468.

Fiore, M. C., Smith, S. S., & Jorenby, D. E. (1994). The effectiveness of the nicotine patch for smoking cessation. *JAMA: Journal of the American Medical Association, 271,* 1940–1947.

Glasgow, R. E., Schafer, L., & O'Neill, H. K. (1981). Self-help books and amount of therapist contact in smoking cessation programs. *Journal of Consulting and Clinical Psychology, 49,* 659–667.

Glynn, T. J., Boyd, G. M., & Gruman, J. C. (1990). Essential elements of self-help/minimal intervention strategies for smoking cessation. *Health Education Quarterly, 17,* 329–345.

Gottlieb, A., Killen, J. D., Marlatt, G. A., & Taylor, C. B. (1987). Psychological and pharmacological influences on cigarette smoking: The effects of nicotine gum and expectancy on smoking withdrawal symptoms and relapse. *Journal of Consulting and Clinical Psychology, 55,* 606–608.

Gritz, E. R., Marcus, A. C., Berman, B. A., Read, L. L., Kanim, L. E., & Reeder, S. J. (1988). Evaluation of a work-site self-help smoking cessation program for registered nurses. *American Journal of Health Promotion, 3,* 26–35.

Hall, S. M., Tunstall, C. D., Ginsberg, D., Benowitz, N. L., & Jones, R. T. (1987). Nicotine gum and behavioral treatment: A placebo controlled trial. *Journal of Consulting and Clinical Psychology, 55,* 603–605.

Hall, S. M., Tunstall, C. D., Rugg, D., Jones, R. T., & Benowitz, N. (1985). Nicotine gum and behavioral treatment in smoking cessation. *Journal of Consulting and Clinical Psychology, 53,* 256–258.

Heatherton, T. F., Kozlowski, L. T., Frecker, R. C., & Fagerstrom, K. O. (1991). The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. *British Journal of Addiction, 86,* 1119–1127.

Henningfield, J. E., & Jasinski, D. R. (1988). Pharmacologic basis for nicotine replacement. In O. F. Pomerleau & C. S. Pomerleau (Eds.), *Nicotine replacement: A critical evaluation* (pp. 35–62). New York: A. R. Liss.

Hughes, J. R. (1991). Combined psychological and nicotine gum treatment for smoking: A critical review. *Journal of Substance Use, 3,* 337–350.

Hughes, J. R., Gust, S. W., Keenan, R. M., Fenwick, J. W., & Healey, M. L. (1989). Nicotine vs. placebo gum in general medical practice. *JAMA: Journal of the American Medical Association, 261,* 1300–1305.

Imperical Research Fund General Practice Group. (1993). Effectiveness of a nicotine patch in helping people stop smoking: Results of a randomised trial in general practice. *British Medical Journal, 306,* 1304–1308.

Jacob, P., Wilson, M., & Benowitz, N. L. (1981). Improved gas chro-

matographic method for the determination of nicotine and cotinine in biological fluids. *Journal of Chromatography, 222,* 61–70.

Killen, J. D., Fortmann, S. P., Kraemer, H. C., Varady, A., & Newman, B. (1992). Who will relapse? Symptoms of nicotine dependence predict long-term relapse following smoking cessation. *Journal of Consulting and Clinical Psychology, 60,* 797–801.

Killen, J. D., Fortmann, S. P., Newman, B., & Varady, A. (1990). Evaluation of a treatment approach combining nicotine gum with self-guided behavioral treatments for smoking relapse prevention. *Journal of Consulting and Clinical Psychology, 58,* 85–92.

Killen, J. D., Fortmann, S. P., Newman, B., & Varady, A. (1991). Prospective study of factors influencing the development of craving associated with smoking cessation. *Psychopharmacology, 105,* 191–196.

Killen, J. D., Maccoby, N., & Taylor, C. B. (1984). Nicotine gum and self-regulation training in smoking relapse prevention. *Behavior Therapy, 15,* 234–248.

Kozak, J., & Fagerstrom, K. O. (1995). High-dose treatment with the nicotine patch. *International Journal of Smoking Cessation, 4,* 26–28.

Kozlowski, L. T., Wilkinson, A. (1987). Use and misuse of the concept of craving by alcohol tobacco and drug researchers. *British Journal of Addictions, 82,* 31–36.

Kraemer, H. C., Berkowitz, R. I., & Hammer, L. D. (1990). Methodological difficulties in studies of obesity. I: Measurement issues. *Annals of Behavioral Medicine, 12,* 112–118.

Lam, W., Sacks, H. S., Sze, P. C., & Chalmers, T. C. (1987). Meta-analysis of randomised controlled trials of nicotine chewing-gum. *Lancet, ii,* 27–30.

Lando, H. A., Kalb, E. A., & McGovern, P. G. (1988). Behavioral self-help materials as an adjunct to nicotine gum. *Addictive Behaviors, 13,* 181–184.

Leupker, R. V., Pechacek, T. F., & Murray, D. M. (1981). Saliva thiocyanate: A chemical indicator of cigarette smoking in adolescents. *American Journal of Public Health, 71,* 1320–1324.

Lichtenstein, E. & Glasgow, R. E. (1992). Smoking cessation: What have we learned over the past decade? *Journal of Consulting and Clinical Psychology, 60,* 518–527.

Maibach, E., & Flora, J. A. (1993). Symbolic modeling and cognitive rehearsal: Using video to promote AIDS prevention self-efficacy. *Communication Research, 20,* 517–545.

Ossip-Klein, D. J., Bigelow, G., Curry, S., Hall, S., & Kirkland, S. (1986). Task Force I: Classification and assessment of smoking behavior. Proceedings of the National Working Conference on Smoking Relapse, *Health Psychology, 5,* 3–11.

Radloff, L. S. (1977). The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1,* 385–401.

Rosenthal, T. L., & Bandura, A. (1978). Psychological modeling: Theory and practice. In S. L. Garfield & A. E. Bergin (Eds.), *Handbook of psychotherapy and behavior change: An empirical analysis* (2nd ed., pp. 621–658). New York: Wiley.

Rosenthal, T. L., & Zimmerman, B. J. (1978). *Social learning and cognition.* New York: Academic Press.

Russell, M. A. H. (1988). Nicotine replacement: The role of blood nicotine levels their rate of change and nicotine tolerance. In O. F. Pomerleau & C. S. Pomerleau (Eds.), *Nicotine replacement: A critical evaluation* (pp. 63–94). New York: A. R. Liss.

Salomon, G. (1979). *Interaction of media, cognition and learning.* San Francisco: Jossey-Bass.

Schneider, N. G., Jarvik, M. E., Forsythe, A. B., Read, L. L., Elliot, M. L., & Schweiger, A. (1983). Nicotine gum in smoking cessation: A placebo-controlled, double-blind trial. *Addictive Behaviors, 8,* 253–261.

Stevens, V. J., & Hollis, J. F. (1989). Preventing smoking relapse, using an individually tailored skills-training technique. *Journal of Consulting and Clinical Psychology, 57,* 420–424.

West, R. J., & Schneider, N. (1987). Craving for cigarettes. *British Journal of Addiction, 82,* 407–415.

Westman, F. C., Levin, E. D., & Rose, J. E. (1993). The nicotine patch in smoking cessation. *Archives of Internal Medicine, 153,* 1917–1923.

Wise, R. A. (1988). The neurobiology of craving: Implications for the understanding and treatment of addiction. *Journal of Abnormal Psychology, 97,* 118–132.

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