

## Short- and Long-Term Smoking Cessation for Three Levels of Intensity of Behavioral Treatment

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Efficacy and costs of 3 levels of medical-behavioral treatment intensity in conjunction with nicotine replacement therapy (NRT) were compared in 240 one-pack-a-day smokers: (a) a low-intensity (LI) group that received 8 weeks of NRT ( $n = 80$ ) and 1 advice and education (A&E) session with a nurse practitioner (NP); (b) a moderate-intensity (MI) group that was provided NRT and 4 A&E sessions with an NP ( $n = 80$ ); and (c) a high-intensity (HI) group that received treatment combining NRT, 4 A&E sessions, and 12 weeks of individualized cognitive-behavioral therapy ( $n = 80$ ). Biochemically confirmed abstinence rates at 9, 26, and 52 weeks posttreatment initiation were highest for the HI (45%, 37%, 35%) group, followed by the LI (35%, 30%, and 27%) and MI (27%, 12%, 12%) groups. Group differences approached statistical significance at 9 weeks and were statistically significant at both 26 and 52 weeks. The cost of LI treatment was \$308, that of MI was \$338, and the HI treatment cost was \$582.

Nicotine replacement therapy (NRT) in conjunction with behavioral treatment has shown promise for initiating smoking cessation (Hughes, Goldstein, Hurt, & Shiffman, 1999; Jorenby et al., 1999). NRT tends to double quit rates compared to placebo, yet poorer outcomes with minimal therapeutic contact suggest possible benefits of more intensive treatments (Hughes et al., 1999; Lifrak et al., 1997). Because rates of resumed smoking tend to be quite high at long-term follow-up ( $\approx 70\%$ – $85\%$ ), there continues to be a need for defining optimal treatment strategies for maintaining abstinence.

The primary goal of this study was to determine the efficacy and costs of three levels of intensity of medical-behavioral treatment used in conjunction with NRT in smokers who smoked one or more packs of cigarettes a day. Three groups were compared: (a) a low-intensity (LI) group, which received NRT for 8 weeks, instructional videotapes, and one advice and education (A&E) session with a nurse practitioner (NP); (b) a moderate-intensity (MI) group, which received these treatments plus three brief NP-delivered A&E sessions; and (c) a high-intensity (HI) group, whose treatment consisted of the foregoing treatments plus 12 weeks of individualized, manual-driven cognitive-behavioral therapy. We hypothesized that increased intensity of treatment would result in higher abstinence rates.

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### Method

#### Participants

Participants were 240 male and nonpregnant female members of the community between the ages of 21 and 65 who smoked at least one pack of cigarettes daily, met *Diagnostic and Statistical Manual of Mental Disorders* (4th ed. [*DSM-IV*]; American Psychiatric Association, 1994) criteria for nicotine dependence, and reported at least one previous failed attempt at smoking cessation.

Candidates were excluded if they had any medical condition that would preclude the use of NRT (e.g., unstable cardiovascular disease, hyperthyroidism, etc.). Psychiatric exclusionary criteria included current *DSM-IV* nonsubstance use diagnosis of greater than moderate severity, *DSM-IV* substance abuse/dependence disorder in remission less than 6 months, current use of cocaine or nonprescribed amphetamine, organic mental disorder, current psychosis, or expressed homicidal/suicidal ideation.

#### General Procedure

Screening and evaluation included a medical history and examination and structured and unstructured psychiatric examinations (see Alterman, Gariti, Cook, & Cnaan, 1999).

Treatment randomization was implemented after the first A&E session in Week 1 when all evaluations and assessments had been completed. We used urn randomization (Wei, 1978) to balance groups for gender, level of nicotine dependence (Fagerström, 1978), and psychiatric pathology.

Research assessments were done during intake/baseline; during study week visits 1, 3, and 6 by trained technicians to obtain information on smoking, withdrawal, attendance, patch adherence, and so on; and at Weeks 9, 26, and 52 to determine smoking status.

#### Measures of Smoking

##### Self-Report Measures

Timeline followback (Ehrman & Robbins, 1994) was administered by a research technician to delineate amount of daily cigarette use during the prior week at the seven aforementioned data collection points.

### Biochemical Measurements

*Exhaled carbon monoxide concentration of expired air.* Carbon monoxide (CO) breath samples were collected at all scheduled study visits using a Vitalograph CO monitor. A CO level greater than 9 parts per million was considered objective evidence of recent smoking.

*Cotinine analysis of urine samples.* Urine samples for cotinine analysis, using immunoassay technology (enzyme linked immunosorbent assay; ELISA), confirmed by gas chromatography/mass spectrometry for all positive results, were obtained at the 9-, 26-, and 52-week assessments. Because nicotine's prime metabolite, cotinine, is detectable in urine for approximately 4 days (range = 2–7 days), this measure provided a much wider detection window than can be determined by CO. An ELISA reading of 200 ng/ml or a gas chromatography/mass spectrometry score of 50 ng/ml or greater were taken as evidence of smoking.

### Other Predictor Variables

Sociodemographic and smoking history information were obtained at baseline, and the Fagerström Tolerance Questionnaire (Fagerström, 1978) measure of severity of nicotine dependence was administered.

### Treatment Cost Determination

Direct costs of treatment services were ascertained by recording amount of time of therapeutic visits and related services for all patients and multiplying these by hourly costs per service provider, using averaged salary costs for these personnel during the year 1996. A standard university plant cost of 25% was added to these figures. Costs of patches dispensed were also included at a weekly cost of \$25. Costs for specialized medical examinations or for research activities were not included.

### Medical–Behavioral Treatments

#### Dispensing the Nicotine Patch and Initial A&E Session (All Patients)

One of three master's-level substance abuse trained NPs met for about 30 min with each participant at the beginning of Week 1 to advise about proper use of the patch immediately after three instructional–educational videotapes were viewed.<sup>1</sup> The NP explored reasons for the smoking cessation effort, confirmed the participant's quit date, and provided instruction on how to use the patch and on possible side effects and adverse reactions.

The Nicoderm brand nicotine patch was used. It was prescribed at the nicotine weaning dosing schedule of 21 mg/day for 4 successive weeks, followed by 14 mg/day for the next 2 weeks and 7 mg/day for the final 2 weeks. A 1-week supply was given at the end of the first visit with the NP, and an additional 2-week supply was dispensed on a Day 4 checkup visit. A 3-week supply was given in Week 3, and the final 2-week supply was given at the end of the Week 6 visit.<sup>2</sup> NRT had to be completed within 8 weeks.

The LI group received no further treatment. During Weeks 3 and 6, group members obtained additional patches from a different study nurse having no other interaction with them.

#### Three Additional A&E Sessions (Weeks 3, 6, and 9)

Participants in the MI and HI groups met with their Session 1 NP during study weeks 3, 6, and 9 for additional A&E sessions of about 15–20 min each. This treatment was mainly educational in orientation and is a close approximation of the National Cancer Institute's manual for physicians (U.S. Department of Health and Human Services, 1991).

### Cognitive–Behavioral Treatment

This treatment was provided to HI group participants beginning in the first study week by one of four master's-level or greater therapists. The 12 weekly sessions were 45–50 min in duration and could extend through Week 15. A slightly modified version of the Individual Cognitive/Behavioral Relapse Prevention Counseling Manual for Smoking Cessation (Lifrak et al., 1997) provided the foundation for this treatment.

### Data Analysis

Abstinence and smoking determinations were based on a combination of self-report, CO, and COT data. We compared rates for each of the three follow-up evaluations using hierarchical logistic analysis. The group treatment variable was entered in the first step. Several participant background variables of interest—gender, race–ethnicity, and the Fagerström score (a cutoff of 8 was used)—were added in the second step. This second analysis step therefore determined whether these latter variables contributed to the explanation of outcomes over and above any group effect.

### Results

#### Background Characteristics of the Three Treatment Groups

Sociodemographic and smoking-related characteristics of the three treatment groups are described in Table 1. These data revealed that urn randomization was quite effective in equalizing group characteristics.

#### Smoking Outcomes

The analysis for abstinence rate 1 week after NRT conclusion (study week 9) was based on 202 of the 240 (84.2%) participants. Week 26 analysis was based on 204 of the 240 (85.0%) participants, and the Week 52 analysis included 224 of the 240 (93.3%) participants.<sup>3</sup> Rates of data loss didn't differ significantly for the three treatment groups.

<sup>1</sup> The three videotapes were the Nicoderm Patient Instructional videotape on the use of the patch (11 min), "The Committed Quitter" (15 min), and the "Smart Move" video distributed by the American Cancer Society (18 min).

<sup>2</sup> Although these conditions for dispensing medication may not appear to be the same as those for private-practice physicians who provide the patient with a prescription for a fixed period, that is, 8 weeks, in practice patients often decide to obtain their medication at fixed intervals because of the attendant costs of an up-front purchase of all patch materials. It should also be noted that this study began several years before the patch could be purchased over the counter.

<sup>3</sup> At Week 9, follow-up data could not be obtained on 23 (9.6%) participants, cotinine verification was not available for another 10 (4.2%) cases, and an additional 5 patients (2.1%) determined to have worn the patch during the past 7 days were excluded. At Week 26, follow-up data could not be obtained on 30 (12.5%) participants, cotinine verification was not available for another 5 cases (2.1%), and 1 case of nicotine replacement medication use within 7 days of the assessment was excluded. At Week 52, follow-up data could not be obtained on 12 (5%) participants, cotinine verification was not available for 2 (0.83%) additional cases, and 2 (0.83%) patients had died of causes apparently unrelated to smoking in the prior 6-month period.

Table 1  
Background Characteristics of Participants in Three Treatment Groups

Variable	Low intensity (n = 80)	Middle intensity (n = 80)	High intensity (n = 80)	p
Age	40.9 ± 9.2	40.1 ± 10.6	39.6 ± 8.9	ns
Years of schooling	14.7 ± 3.1	14.5 ± 2.9	15.1 ± 3.0	ns
% Women	48.8	45.0	53.8	ns
% Married	31.3	28.8	27.5	ns
% Caucasian	60.0	63.8	62.5	ns
% Working/student	82.5	83.8	88.8	ns
% Lifetime substance dependence diagnosis	58.8	45.0	57.5	ns
No. cigarettes smoked daily	27.3 ± 10.6	27.2 ± 9.5	26.3 ± 9.8	ns
No. years smoking	22.6 ± 9.7	22.0 ± 10.4	20.9 ± 8.9	ns
No. prior quit attempts	6.3 ± 8.5	4.5 ± 5.7	5.9 ± 7.0	ns
% With prior formal treatment	25.0	21.3	17.5	ns
Fagerström scores <sup>a</sup>	6.8 ± 1.5	6.9 ± 1.6	6.9 ± 1.4	ns
Baseline serum cotinine <sup>b</sup>	341 ± 155	364 ± 180	358 ± 166	ns

<sup>a</sup> High dependence is defined by a score of 6 or more. <sup>b</sup> 250 or more ng/ml is considered a high score.

**Week 9 smoking outcomes.** Biochemically confirmed abstinence rates achieved by the three groups are shown in Table 2. Abstinence was highest for the HI group (45.1%), contrasted with 26.9% of the MI group and 35.4% for members of the LI group. These group differences failed to achieve statistical significance,  $\chi^2(2, N = 202) = 5.00, p = .082$ . In the second analysis step, patients with higher Fagerström scores, Wald statistic(1) = 7.87,  $p = .005$ , were found to have lower abstinence rates. None of the main effects of the other predictor variables were statistically significant.

**Week 26 smoking outcomes.** Abstinence rates at 6 months posttreatment initiation were 36.8% for the HI group, 11.6% for the MI group, and 29.9% for the LI group (see Table 2), indicating relatively small declines in abstinence from 9 weeks for the HI and LI group but a marked decline for the MI group. Overall, the groups differed significantly in abstinence rates,  $\chi^2(2, N = 204) = 13.08, p = .0014$ . We also performed two ad hoc contrasts suggested by the findings. The abstinence rate of the MI group was compared with those of both the HI and LI groups and was found to be significantly lower, Wald statistic(1) = 10.84,  $p = .001$ . The abstinence rate for the HI and LI groups were compared and were not found to differ significantly, Wald statistic(1) = 0.72, *ns*. None of the pretreatment measures were significantly predictive of outcome after the effects of treatment group were removed.

**Week 52 smoking outcomes.** Abstinence rates at 52 weeks posttreatment entry were similar to those found at 6 months. The rate was 34.7% for the HI group, 12.0% for the MI group, and 27.0% for the LI group,  $\chi^2(2, N = 224) = 11.50, p = .0032$ . The abstinence rate for the MI group was significantly lower than that of the other two groups, Wald statistic(1) = 9.97,  $p = .0016$ . Abstinence rates for the HI and LI groups did not differ significantly, Wald statistic(1) = 1.01, *ns*. Again, none of the baseline predictors significantly predicted abstinence rates at 12 months after effects of treatment group were removed.

**Results of intent-to-treat analysis.** We also analyzed the data using an intent-to-treat analysis (see Table 2). Abstinence rates were reduced by several percentage points for each of the groups; however, the findings concerning overall group differences and between-group differences at the three follow-up points remained unchanged.

**Treatment costs.** Direct LI treatment service costs were only \$138. The average cost of the nicodermal patches for this group was \$170, resulting in a total treatment cost of \$308. Service costs for the MI treatment were \$174, and the costs of services plus patches was \$338. Finally, service costs were \$402 for the HI treatment, and total treatment costs were \$582.

Table 2  
Abstinence Rates for Each of Three Treatments at Three Follow-Up Time Points

Follow-up week	LI group	MI group	HI group	p
Week 9 abstinence, n = 202	35.4 (n = 64)	26.9 (n = 67)	45.1 (n = 71)	.082
Week 9 abstinence, n = 225 <sup>a</sup>	31.9 (n = 72)	23.7 (n = 76)	41.6 (n = 77)	.06
Week 26 abstinence, n = 204	29.9 (n = 67)	11.6 (n = 69)	36.8 (n = 68)	.0014
Week 26 abstinence, n = 234 <sup>a</sup>	26.3 (n = 76)	10.0 (n = 80)	32.1 (n = 78)	.0016
Week 52 abstinence, n = 224	27.0 (n = 74)	12.0 (n = 750)	34.7 (n = 75)	.0032
Week 52 abstinence, n = 236 <sup>a</sup>	26.0 (n = 77)	11.3 (n = 80)	32.9 (n = 79)	.0029

*Note.* Group sample sizes are in parentheses. LI = low-intensity treatment; MI = middle-intensity treatment; HI = high-intensity treatment.

<sup>a</sup> Figures in lower rows at each time point are based on intent-to-treat analyses.

### Discussion

The results revealed excellent biochemically confirmed abstinence rates through 1 year for the HI and LI groups. Given that the MI group did not differ in background characteristics from the other two groups, and that a prior pilot study (Lifrak et al., 1997) had obtained abstinence rates of 25% and 28% at 6 and 12 months for this condition, the disappointing outcomes for this group are difficult to understand. Post hoc analyses of treatment satisfaction and adverse side effects in the three groups did not clarify the basis for the poor outcomes of the MI group.

The LI condition achieved an abstinence rate at 1 year of 26% (intent-to-treat analysis) at a cost of \$308/participant. Abstinence rates for this group were relatively consistent at all three follow-up points, supporting the stability of these findings. Because abstinence rates typically achieved for NRT without additional treatment are reported to be about 5% (Hughes et al., 1999), the findings for the LI condition are particularly encouraging, because this treatment is relatively easy to deliver and potentially applicable to a variety of treatment clinics.

The HI condition yielded abstinence rates about 7%–8% higher (although not statistically different) at a total cost of \$582/patient. These gains in abstinence over that of the LI condition are noteworthy within the general context of abstinence rates generally obtained. Thus, HI treatment might be considered when available funding is not a critical issue or for use with certain problematic populations.

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