The Efficacy of Computer-Tailored Smoking Cessation Material as a Supplement to Nicotine Polacrilex Gum Therapy

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**Background:** Standard, generic self-help materials have been largely ineffective as behavioral treatments for smoking cessation. In contrast, self-help programs tailored to the needs of specific smokers have shown promise in facilitating quitting.

**Objective:** To evaluate the incremental efficacy of the Committed Quitters Program (CQP), a set of computer-tailored materials offered to purchasers of nicotine polacrilex gum, compared with a brief untailored user’s guide and audiotape, both as supplements to nicotine replacement therapy.

**Methods:** We conducted a randomized, open-label trial with 3 parallel arms. Subjects were smokers who purchased 2- or 4-mg nicotine polacrilex gum and called the CQP toll-free enrollment line. Three thousand six hundred twenty-seven subjects consented to participate in 1 of 3 study arms: (1) those receiving the CQP materials (CQP group, n = 1217), (2) those receiving CQP materials and an outbound telephone call (CQP + C group, n = 1207); and (3) those receiving no supplemental intervention beyond the user’s guide and audiotape that were prepackaged with the nicotine polacrilex gum (UG group, n = 1203). Twenty-eight-day continuous abstinence rates were assessed by telephone interviews at 6 weeks and 10-week continuous rates at 12 weeks into treatment.

**Results:** Abstinence rates among respondents at the 6- and 12-week assessments were significantly higher for the CQP (36.2% and 27.6%) and CQP + C (35.5% and 27.3%) groups compared with the UG group (24.7% and 17.7%) at both intervals. The quit rates for the CQP and CQP + C groups were almost identical.

**Conclusions:** The CQP proved to be an effective behavioral treatment, enhancing quit rates over and above nicotine replacement therapy and a brief untailored written guide and audiotape.

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Physicians are often called upon to provide smoking cessation treatment for their patients and are doing so in ever-greater numbers. The availability of medications for smoking cessation (nicotine replacement therapy [NRT] and, more recently, bupropion hydrochloride) has provided physicians with pharmacological tools to assist their smoking patients who want to quit. These medications are seeing increasing utilization, with the expectation that this will result in substantial public health benefits. However, some patients may need behavioral as well as pharmacological treatment, and many physicians do not have the time or the specific skills to provide detailed behavioral counseling on how patients should quit smoking. If physician intervention in smoking cessation is to have maximal public health impact, a method of delivering behavioral intervention on a mass scale is needed.

There have been few options available for patients seeking smoking cessation counseling. Intensive programs are hard to find, costly, and rejected by most patients. Consequently, written cessation guides have been a mainstay of smoking cessation guidance. Written guides have several advantages: they can embody the content of proven behavioral programs; they are inexpensive; they are unintrusive, allowing the smoker to get help in private; and they can be distributed to areas in which counseling is unavailable. Unfortunately, standard written cessation guides do not appear to be effective in helping people to quit smoking. A recent review concluded that the addition of standard self-help materials to NRT did not improve cessation rates. Thus, the challenge of providing effective, disseminable behavioral treatment remains.

Advances in self-help materials hold promise for enhancing the efficacy of printed materials. Standard self-help materials often lack focus or targeting. They are uniform for all recipients and are often encyclopedic and inaccessible in their attempt to cover all relevant content generically. In contrast, “tailored” materials can be custom-tailored to each individual's needs, allowing them to be more focused, brief, and...
SUBJECTS AND METHODS

SUBJECTS

The 3627 subjects who participated in the study were recruited from smokers who purchased nicotine polacrilex gum and called the toll-free CQP number (from July 18, 1996, through August 9, 1996). Participants were initially asked qualifying questions, as well as the questions needed to tailor the CQP materials (Table 1). Data were collected regarding demographic characteristics, smoking history, cessation history, and nicotine dependence (latency to first cigarette of the day). Participants were also asked about their current quit effort, including their target quit date (TQD), and motivation and confidence about quitting (for details, see variables listed in Table 2). Eligible callers met the following criteria: (1) current cigarette smoker, (2) age 18 years or older, (3) purchased 2- or 4-mg nicotine polacrilex gum, (4) had a TQD that was either the day they called in or within 7 days of the enrollment call date, (5) were attempting to quit smoking cigarettes (ie, not smokeless tobacco), and (6) agreed to be contacted for follow-up calls at 6 and 12 weeks. Participants were explicitly asked to consent to randomization and follow-up. The current study was approved by the Essex Institutional Review Board, an independent ethics review board located in Lebanon, NJ.

STUDY DESIGN

All callers to the CQP line who met the entry criteria were invited to participate in the study and offered up to $25 for completing the 6- and 12-week follow-up calls. Those who consented were equally randomized (by computer) to receive the CQP support materials (CQP group), to receive the CQP materials and a call 2 days after their TQD (CQP + C group), or to proceed only with the user’s guide and audiotape provided in each starter package of the nicotine polacrilex gum (UG group). After being informed of their group assignment, some callers chose to withdraw from the study and were asked if they would agree to participate in follow-up. Participants who withdrew from the UG group were sent the CQP materials.

At 6 and 12 weeks (+2 weeks) after each subject’s self-selected TQD, subjects were contacted by telephone to assess current smoking status, abstinence history, CQP usage (amount of treatment materials read, frequency of referring to materials, helpfulness and satisfaction with materials), and nicotine polacrilex gum use. Participants were called beginning at 6 weeks and 12 weeks after their TQD. At each time point, there was a 2-week window to contact participants; up to 6 call attempts were made. (All data were gathered by ICT Inc [Philadelphia, Pa], a national interview survey firm, using a computer-assisted telephone interviewing system that flagged eligible callers and enforced skip patterns and valid response ranges.) At both follow-up assessments, smoking abstinence was measured by self-report. Biochemical verification was not possible because of the telephone call follow-up. To increase the veracity of self-reports, the study used the bogus pipeline technique: participants were told that reported abstinence might be checked by a breath sample. At 6 weeks, following the Food and Drug Administration’s (FDA’s) standards for assessing efficacy, continuous abstinence was defined as no smoking at all for the prior 28 days. At 12 weeks, continuous abstinence was defined as no smoking for the preceding 10 weeks (ie, again allowing the FDA-mandated 2-week grace period). Participants who were contacted but refused to be interviewed were counted as failures (ie, smokers). Those who reported smoking at 6 weeks and were not reached at 12 weeks were considered treatment failures at 12 weeks.

PHARMACOLOGIC TREATMENT

All subjects participating in the study purchased nicotine polacrilex gum on their own and agreed to use it as directed by SmithKline Beecham Consumer Healthcare. The dose of nicotine polacrilex gum, either 2 or 4 mg, and the frequency of use were determined by subjects, based upon package labeling instructions. Subjects were asked about the dosage of nicotine polacrilex gum purchased and their use during the course of the study.

BEHAVIORAL TREATMENT

All subjects were randomly assigned to 1 of 3 behavioral intervention groups. Those assigned to the control or UG group received no treatment beyond that provided in the retail package, which included the user’s guide and an audiotape, both of which were reviewed and approved by the FDA. In addition to instructions on product use, the user’s guide and audiotape included brief sections on how to quit and maintain abstinence, based on cognitive-behavioral methods.

The CQP group received the user’s guide and audiotape at the time they purchased nicotine polacrilex gum. Information collected during the enrollment call was used to tailor the CQP behavioral materials for this group, including demographic characteristics, smoking history, motives for quitting, expected difficulties quitting, and situations that were expected to present challenges. This information was used to tailor the messages for each user; for example, the materials highlighted and reinforced the individual smoker’s motives for quitting and suggested coping responses for the particular situations that were expected to present challenges to that particular smoker. Program materials consisted of 6 mailings over a 12-week period (Table 1). Participants assigned to the CQP and CQP + C groups were sent the materials within 1 week of the enrollment call. Based on cognitive-behavioral models of smoking and the subject’s information, mailings incorporated information that was specifically designed to support each particular subject. In the initial package was a 6-week calendar containing weekly tips for quitting and maintaining abstinence, health information, testimonials from others who had quit, and prompts to comply with the NRT medication. The calendar included subject-specific information, such as each subject's TQD, the reasons for quitting, re- smoking at this time, and idiosyncratic challenges to quitting. Thus, specific content appeared in some booklets but not others (eg, based on whether a particular situation is deemed challenging) and in some cases was...
modified across smokers (eg, health information is made relevant to the enrollee's demographic characteristics). In subsequent mailings, content was also personalized for the subject and was aimed at supporting the quit effort at each stage of quitting. Sample materials are available on request from the authors.

The CQP + C group received the user's guide and audiotape at the time they purchased nicotine polacrilex gum as well as the tailored CQP materials. In addition, participants in the CQP + C group received a brief telephone call approximately 2 days after their TQD. The purpose of this call was to encourage participants and to provide some tangible support prior to the arrival of the CQP materials in the mail. The caller, who was not an experienced counselor, provided a standard list of behavioral techniques that are thought to be useful early in abstinence.

**SUBJECT RETENTION/DISPOSITION**

During open enrollment for the CQP, 6894 smokers called the toll-free number to enroll (out of approximately 95000 purchasers of nicotine polacrilex gum during this period; ie, approximately 7% of nicotine polacrilex gum users enrolled in the CQP). All callers were screened on inclusion/exclusion criteria, and 4944 qualified and were asked to enroll in the study. Of these, 3807 callers (77.0%) accepted, consented to the study procedures, and were randomized to 1 of the 3 treatment groups (1218 to the CQP group, 1213 to the CQP + C group, and 1376 to the UG group). Treatment assignment was disclosed to the caller. After being informed about their group assignment, 180 subjects (173 of whom were assigned to the UG group) decided to withdraw; they were asked if they would continue to participate in follow-up, but their data were not included in analyses. The 180 subjects were replaced in the sample. (An analysis that counted them by their assignment on outcome (ie, to see whether nicotine polacrilex gum use accounted for all the treatment effects). Usage of medication could have mediated the treatment outcome. We examined whether enhanced compliance with medication could have mediated the treatment effects. We examined reported nicotine polacrilex gum use at 2 weeks into the program (ie, the “grace period” for assessing outcome). Logistic regressions were used to test the association of nicotine polacrilex gum use and outcome and then to simultaneously evaluate the effects of treatment assignment on outcome (ie, to see whether nicotine polacrilex gum use accounted for all the treatment effects). Using logistic regression to test the interaction between subject characteristics and treatment on outcome, we also tested whether the CQP materials were differentially effective among particular subgroups of smokers (men and women, light and heavy smokers, and those with high and low self-efficacy). We examined these effects within the sample of respondents who reported using their assigned (UG or CQP) materials. Therefore, in addition to analyses including all participants enrolling in the study, we conducted secondary efficacy analyses focused on those participants who reported that they referred to the treatment materials—either the CQP or UG materials. Participants were considered to not have used the materials only if they reported that they “never” referred to them (the response options were “never,” “rarely,” “sometimes,” “often,” or “very often”). We used subjects’ reports of use at 6 weeks to classify utilization (almost all of the CQP materials were sent within the first 6 weeks).

We assessed the influence of several variables on treatment outcome. We examined whether enhanced compliance with medication could have mediated the treatment effects. We examined reported nicotine polacrilex gum use at 2 weeks into the program (ie, the “grace period” for assessing outcome). Logistic regressions were used to test the association of nicotine polacrilex gum use and outcome and then to simultaneously evaluate the effects of treatment assignment on outcome (ie, to see whether nicotine polacrilex gum use accounted for all the treatment effects). Using logistic regression to test the interaction between subject characteristics and treatment on outcome, we also tested whether the CQP materials were differentially effective among particular subgroups of smokers (men and women, light and heavy smokers, and those with high and low self-efficacy). We examined these effects within the sample of respondents who reported using their treatment materials to ensure that the tests of other moderators were independent of treatment utilization, which is thought to moderate treatment effects.

**STATISTICAL ANALYSIS**

Demographic characteristics and smoking history variables were compared across the 3 treatment groups; χ² analyses were used to compare categorical variables and t tests were used for continuous variables. To assess potential bias resulting from study procedures, we also compared demographic characteristics and smoking history variables for those who agreed to participate vs those who refused to participate, and for those who remained in the UG group vs those who withdrew after being assigned to the UG group. We also evaluated procedural bias by comparing the follow-up rates between groups at 6 and 12 weeks.

For the primary efficacy analyses, the 6- and 12-week outcomes for the 3 treatment groups were compared with χ² analyses for those who were contacted for follow-up. We expected that group differences would emerge most strongly among those subjects reporting that they actually used their assigned (UG or CQP) materials. Therefore, in addition to analyses including all participants enrolling in the study, we conducted secondary efficacy analyses focused on those participants who reported that they referred to the treatment materials—either the CQP or UG materials. Participants were considered to not have used the materials only if they reported that they “never” referred to them (the response options were “never,” “rarely,” “sometimes,” “often,” or “very often”). We used subjects’ reports of use at 6 weeks to classify utilization (almost all of the CQP materials were sent within the first 6 weeks).

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appealing. Individual tailoring requires collecting information about the individual's relevant characteristics and must have the capability of embodying that information in the resulting materials. The outcomes of tailored programs were the one bright spot in the meta-analysis on written quitting aids by Lancaster and Stead. For example, Strecher et al compared tailored and untailored guides and found an advantage in tailored guides (among light smokers), while Curry et al suggest that adding brief counseling telephone calls, in addition to tailored materials, may further enhance the efficacy of broad-reach behavioral treatment.

Given the success of NRT and the promise of tailored, written self-help treatments, we have paired the 2 treatment approaches. The present study tested the incremental efficacy of a tailored self-help program, referred to as Committed Quitters, a free supplement with any purchase of nicotine polacrilex gum (Nicorette; SmithKline Beecham, Pittsburgh, Pa). This was the first study evaluating the combination of NRT and tailored support. (A subsequent study combining the Committed Quitters Program [CQP] and nicotine patch therapy suggested that the program increased quit rates, but only among the smokers who reported using their assigned treatment materials.) Behavioral materials might be particularly important to support therapy with nicotine polacrilex gum because of the challenge of maintaining compliance with the medication. Based upon previous interventions that included counseling telephone calls, we also tested the addition of a supportive telephone call early in the quit process.

SUBJECT DEMOGRAPHIC CHARACTERISTICS

The average participant was about 41 years old, had been smoking for over 22 years, smoked about 26 cigarettes per day, and showed signs of significant nicotine dependence (smoking an average of 15 minutes from time of waking). Thus, the sample included heavy, relatively dependent smokers. There were no group differences in baseline characteristics (Table 2).

Table 1. Timeline and Description of Committed Quitters Program Materials

<table>
<thead>
<tr>
<th>Interval</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 0</td>
<td>Participants call in to enroll in study.</td>
</tr>
<tr>
<td>Week 1</td>
<td>Six-week stop smoking plan centered around a 6-week calendar. Each week's 2-page spread contains health information, information about what to expect, and tips for dealing with specific challenges to abstinence.</td>
</tr>
<tr>
<td>Week 2</td>
<td>A social support trifold brochure emphasizes the usefulness of social support and includes stories from successful quitters.</td>
</tr>
<tr>
<td>Week 4</td>
<td>A tailored trifold brochure prepares participants to gradually cut back nicotine polacrilex gum use in the near future and encourages participants to maintain abstinence.</td>
</tr>
<tr>
<td>Week 6</td>
<td>A personalized newsletter supports changes in nicotine polacrilex gum use, encourages participants, and solicits information from relapsers in order to provide further tailored materials.</td>
</tr>
<tr>
<td>Week 12</td>
<td>An award certificate is sent to participants (unless they have reported a relapse). Participants who initially expressed concern about weight gain receive a weight control tip sheet.</td>
</tr>
</tbody>
</table>

Table 2. Demographic Baseline Characteristics, Smoking History, and Initial Motivation and Confidence of Those Offered Study Participation

<table>
<thead>
<tr>
<th>Item</th>
<th>Enrolled</th>
<th>Not Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UG Group (n = 1203)</td>
<td>CQP Group (n = 1217)</td>
</tr>
<tr>
<td>Demographic Characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, %</td>
<td>54.9</td>
<td>53.4</td>
</tr>
<tr>
<td>Age (mean ± SD), y</td>
<td>41.7 ± 13.0</td>
<td>41.0 ± 12.7</td>
</tr>
<tr>
<td>Level of education (mean ± SD), y</td>
<td>13.5 ± 2.1</td>
<td>13.6 ± 2.2</td>
</tr>
<tr>
<td>Gross household income (mean ± SD), $</td>
<td>38 800 ± 22 300</td>
<td>39 800 ± 22 300</td>
</tr>
<tr>
<td>Previous Cessation and Nicotine Replacement Therapy Experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous quit attempt, %</td>
<td>91.6</td>
<td>91.8</td>
</tr>
<tr>
<td>Prior nicotine patch use, %</td>
<td>38.7</td>
<td>34.9</td>
</tr>
<tr>
<td>Prior nicotine gum use, %</td>
<td>20.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Smoking History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cigarettes per day (mean ± SD)</td>
<td>26.9 ± 12.2</td>
<td>26.1 ± 12.1</td>
</tr>
<tr>
<td>Years of smoking (mean ± SD)</td>
<td>23.1 ± 12.6</td>
<td>22.3 ± 12.4</td>
</tr>
<tr>
<td>Time of first cigarette (mean ± SD), min</td>
<td>14.6 ± 31.7</td>
<td>16.8 ± 27.1</td>
</tr>
<tr>
<td>No. of lifetime cessation attempts (mean ± SD)</td>
<td>4.5 ± 7.3</td>
<td>5.5 ± 17.7</td>
</tr>
<tr>
<td>Initial Motivation and Confidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level of motivation (mean ± SD) (range, 1-5)</td>
<td>4.3 ± 0.7</td>
<td>4.3 ± 0.8</td>
</tr>
<tr>
<td>Confidence of success (mean ± SD) (range, 1-5)</td>
<td>3.9 ± 1.0</td>
<td>4.0 ± 1.0</td>
</tr>
</tbody>
</table>

*Statistical comparisons refer to those who accepted enrollment in the study (ie, those in the enrolled UG, CQP, and CQP + C groups) vs those who either declined or refused. UG indicates user's guide; CQP, Committed Quitters Program; and CQP + C, Committed Quitters Program plus follow-up telephone call. 
†P < .01.
‡P < .001.
We compared those who refused to participate (n = 1137) with those who agreed to participate and remained in the study (n = 3627 by treatment group). Those who refused participation seemed to be of slightly higher socioeconomic status, given their higher education, higher income, and age; they also were less likely to have previously attempted to quit, were less motivated, and were less confident in the quit attempt, suggesting less commitment to quit (Table 2). These analyses suggested that the study sample was similar to the general population of CQP callers, but with a somewhat greater motivation to quit and lower socioeconomic resources.

We compared those who withdrew from the UG group after learning about their randomization group with those who remained in the UG group and found very few differences; those who withdrew were more educated and less motivated to quit smoking (Table 2), much like those who declined initial consent.

### FOLLOW-UP RATES

Contact rates for the 6-week follow-up were similar among the 3 groups (χ² = 4.18 [n = 3627]; P = .12); 751 (61.7%) in the CQP, 778 (64.5%) in the CQP + C, and 789 (65.6%) in the UG groups were contacted at 6 weeks. The refusal rates were different across the 3 groups (χ² = 8.97 [n = 2318]; P = .01), with the CQP group (3.7%) showing a lower refusal rate than the UG group (7.2%; χ² = 9.02 [n = 1540]; P = .003) and a trend toward differential refusal rates compared with the UG + C group (5.7%; χ² = 3.16 [n = 1529]; P = .08). No differences were found between the UG and the CQP + C groups (χ² = 1.60 [n = 1567]; P = .21).

At 12 weeks, contact rates were again similar among the 3 groups (χ² = 5.057; P = .08): 870 (71.5%) in the CQP, 858 (71.1%) in the CQP + C, and 900 (74.8%) in the UG groups. Refusal rates were different across the 3 groups (χ² = 12.14 [n = 2628]; P = .002), with the CQP group (3.8%) showing a lower refusal rate than both the UG group (7.7%; χ² = 12.22 [n = 1770]; P = .001) and the CQP + C group (6.2%; χ² = 5.19 [n = 1728]; P = .02). No differences were shown between the UG and the CQP + C groups (χ² = 1.51 [n = 1758]; P = .22).

### EFFICACY ANALYSES

At both the 6- and 12-week follow-up, the CQP and CQP + C groups had virtually identical quit rates. The 28-day continuous abstinence rates at 6 weeks were 36.2% and 35.5% for the CQP and CQP + C groups, respectively (χ² = 0.05 [n = 1003]; P = .82), and the 10-week continuous abstinence rates at 12 weeks were 27.6% for the CQP group and 27.3% for the CQP + C group (χ² = 0.02 [n = 1336]; P = .90). Since there was no observable effect on quit rates in the CQP + C group, the analyses reported in the remainder of this report focus on differences between the CQP and UG groups.

Analyses of all respondents revealed that the CQP group had significantly higher abstinence rates than the UG group at both the 6- and 12-week follow-up. Table 3 summarizes the findings for those subjects meeting the protocol criteria. We also conducted intent-to-treat analyses, counting subjects who were not reached at the 6- and 12-week follow-up as treatment failures; although the absolute quit rates were lower, the CQP group quit rates were significantly higher than those for the UG group. We also conducted sensitivity analyses to evaluate potential bias introduced by the methods. First, we examined the influence on the analysis of those participants who withdrew from the UG group and were subsequently sent CQP materials. When we included these smokers in the UG group (ie, by original randomization, rather than actual treatment), the CQP group quit rates were still higher than the UG group quit rates. Second, we examined the effect of differential refusal rates among the groups at the 6- and 12-week follow-up. Even when we control for the refusal rates, the effect was unchanged: the CQP group still showed significantly higher quit rates.

We had hypothesized that treatment effects would be most prominent among those who used their respectively assigned materials. Most of the sample (75.1%) was classified as having used the assigned materials. Utilization rates were different among the 3 groups (χ² = 31.76 [n = 1675]; P = .001), with both the CQP (77.7%) and CQP + C (82.6%) groups exhibiting more use than the UG group (68.2%) (χ² = 14.04 [n = 1251]; P = .001 and χ² = 27.65 [n = 1097]; P = .001, respectively).

As expected, among those subjects who reported using their respective materials, the CQP group continued to demonstrate significantly higher abstinence rates than the UG group at both the 6- and 12-week follow-up (Table 3). At 6 weeks, the CQP group quit rates were 45% higher than those of the UG group, and at 12 weeks, the CQP group reported 71% higher abstinence rates. Further analyses revealed a trend toward utilization having a differential effect on outcome for the groups (group × utilization interaction: χ² = 2.858 [n = 1186]; P = .09). Com-

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**Table 3. Comparison of Abstinence Rates Between User’s Guide (UG) and Committed Quiters Program (CQP) Groups**

<table>
<thead>
<tr>
<th>Abstinence Rates at Follow-up Interviews</th>
<th>CQP Group</th>
<th>UG Group</th>
<th>χ² Value</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All subjects</td>
<td>572 (36.2)</td>
<td>750 (24.7)</td>
<td>20.653*</td>
<td>1.732 (1.367-2.195)</td>
</tr>
<tr>
<td>28-Day abstinence at 6 weeks</td>
<td>768 (27.6)</td>
<td>963 (17.7)</td>
<td>24.600*</td>
<td>1.779 (1.417-2.233)</td>
</tr>
<tr>
<td>10-Week abstinence at 12 weeks</td>
<td>418 (41.6)</td>
<td>444 (28.6)</td>
<td>16.068*</td>
<td>1.780 (1.342-2.360)</td>
</tr>
<tr>
<td>10-Week abstinence at 12 weeks</td>
<td>396 (32.3)</td>
<td>433 (18.9)</td>
<td>19.593*</td>
<td>2.044 (1.489-2.807)</td>
</tr>
</tbody>
</table>

*P ≤ .001.
parisons of utilization vs nonutilization of assigned materials showed that use of materials significantly affected treatment outcome only for those subjects receiving the CQP materials (use, 41.6%; vs no use, 23.8%; $\chi^2_1=10.16$ [n=542]; $P=.001$) but not for those in the UG group (use, 28.6%; vs no use, 24.5%; $\chi^2_1=1.17$ [n=644]; $P=.28$). Among those who reported making any use of their materials, reported quantity of use did not affect outcome ($\chi^2_1=0.441$ [n=862]; $P=.51$).

**MEDIATORS AND MODERATORS OF TREATMENT EFFECTS**

We assessed whether enhanced compliance with medication could have mediated the treatment effects. Compared with subjects in the UG group, subjects in the CQP group reported using significantly more pieces of nicotine polacrilex gum per day during the first 2 weeks (4.9 vs. 4.1; t=2.979 [n=1187]; $P=.003$). A logistic regression model with 28-day continuous abstinence as the dependent variable showed that greater use of nicotine polacrilex gum was significantly related to abstinence ($\chi^2_1=98.36$ [n=1128]; $P<.001$). However, when we controlled for nicotine polacrilex gum use at 2 weeks in a logistic regression analysis, the relationship between treatment group and outcome was still significant ($\chi^2_1=7.05$ [n=1128]; $P=.008$).

To explore whether the CQP might have differential benefit for different kinds of smokers, we used logistic regression to test interactions between treatment (UG group vs CQP group) and subject characteristics. We found no moderators of the CQP treatment effect; the CQP provided equal benefit to men and women, light and heavy smokers, subjects using 2- or 4-mg nicotine polacrilex gum, and subjects with high and low nicotine dependence, confidence, and motivation. The CQP group quit rates were consistently higher than UG group quit rates.

**COMMENT**

The study demonstrated the efficacy of the CQP-tailored behavioral materials in promoting smoking cessation when used in conjunction with nicotine polacrilex gum. Those who received the CQP materials reported a 47% higher quit rate at 6 weeks and a 56% higher quit rate at 12 weeks. As expected, the effect was stronger among those who referred to their assigned materials (45% higher at 6 weeks and 71% higher at 12 weeks). This demonstrates the potential for tailored smoking cessation materials to supplement over-the-counter NRT in helping smokers to quit. Particularly because it is often difficult to provide smoking cessation counseling in a time-constrained medical setting, programs such as the CQP may be important supplements to physician advice to quit smoking.

This is the second study that demonstrates the incremental efficacy of tailored behavioral materials as a supplement to NRT and the first to show the effect among all respondents. The findings are consistent with the trend demonstrating that tailored materials are more effective than untailored programs, but remarkable for showing an incremental effect in a sample of smokers who already were using an effective smoking cessation medication and a standard booklet and audiotaape. Lancaster and Stead report that written materials have generally provided no benefit when added to NRT or to other materials or treatments.

In contrast to the positive findings on the CQP, we did not find that adding a single, brief, supportive telephone call to the CQP was effective in increasing quit rates. Several studies have previously reported that the addition of telephone counseling increases quit rates \(^7,9\) (see also Lancaster and Stead \(^3\)). However, those studies involved multiple telephone contacts by skilled counselors that were tested as supplements to less intensive (compared with those of the CQP) self-help materials. Thus, against a background of weaker intervention, multiple skilled-counseling contacts may help. In our study, adding a single, simple contact to a multicomponent intervention failed to produce any incremental benefit. It may be difficult to achieve an incremental benefit over the base intervention, which combined NRT, an untailored user’s guide and audiotaape, and a tailored program involving several mailings.

As expected, the effect of the tailored CQP was most robust among those who reported using the materials; materials need to be used if they are to help. We did not see additional increments in quit rates with increasing use of the materials, perhaps because more intensive use of materials may also reflect greater need for materials (eg, experiencing more difficulty quitting). We observed a similar pattern in evaluating another version of the CQP for users of nicotine patches. In that instance, only a subanalysis of those who used supplemental materials proved significant, but the pattern was similar. Thus, the results appear to replicate across samples, programs, and forms of NRT. In any case, the findings suggest the importance of urging patients to use the materials they receive.

The efficacy of the CQP was general; the program was equally effective among men and women, those with high or low self-efficacy, heavy and light smokers, and those with high or low nicotine dependence. This was also true for the CQP offered in combination with nicotine patches. These findings contrast with those of Strecher et al, who found that the tailored program was most effective among light smokers. The key difference may be the combination of tailored materials with NRT. Nicotine replacement therapy may be the perfect complement to the tailored program, especially for heavier smokers; NRT addresses craving and withdrawal and allows the smoker to make use of the behavioral prescriptions contained in the CQP materials. Receiving the CQP materials increased NRT use, which is known to increase success, but this did not account for the efficacy of the CQP.

It seems likely that the efficacy of the CQP is attributable to its tailoring. However, the current study did not strictly compare tailored and untailored versions of the same program, but rather the incremental efficacy of adding the tailored CQP materials to an untailored guide. However, Curry et al compared tailored and untailored versions of the same material and concluded that tailored feedback was superior. The review of Lancaster and Stead indicates that tailored materials are superior. This suggests that efforts should be made to use tailored rather than generic interventions for smoking cessation.

Our study has several limitations. Reports of abstinence were not verified biochemically because of logisti-
The ability of over-the-counter NRT and the mail-in intervention materials to assist in quitting smoking represent a model for the delivery of smoking cessation to the multitude of patients who are motivated to make an attempt to quit by their physician contact. We also used a bogus pipeline manipulation (telling subjects their reports would be subject to verification), which is known to encourage truthful reporting. We also based our analysis on those subjects who could be contacted by telephone. Many subjects were lost to follow-up, often because the telephone number had been misrecorded or changed. In many smoking studies, failure to appear at the study site for follow-up is thought to reflect avoidance of being confronted with failure. In this instance, however, it seems unlikely that failure to answer the telephone was biased by participants’ smoking status; thus, participants who were not contacted were not counted in the denominator for outcome analyses. However, those who were contacted and refused to be interviewed were counted as treatment failures.

This study was conducted on smokers who called to enroll in the CQP. In the absence of promotion for the program, this was approximately 5% to 10% of all purchasers of nicotine polacrilex gum. Presumably, those who elect to take advantage of an added program are among the more motivated quitters, but also the most in need of help. Indeed, the samples in this and our other CQP evaluation study consisted of relatively heavy and nicotine-dependent smokers. In any case, the CQP was tested on the program’s natural constituency, ie, those who elected to enroll. Enrollees were likely to agree to take part in the study, and those who refused differed little from those who agreed to participate. Treatment assignment was not blinded in the study, ie, participants knew whether they received CQP materials or not. This is unlikely to account for the observed superiority of the CQP materials. Numerous prior studies with unblinded treatment failure showed a benefit of untailored materials. These limitations notwithstanding, our study also had important strengths. It evaluated a novel program that combines a sound behavioral approach with high-technology individualized tailoring. Furthermore, it evaluated a program that is actually available to millions of smokers; therefore, the results have immediate applicability in practice.

The CQP offers the combination of behavioral and pharmacological treatment for smoking cessation in an easily accessible, broadly disseminable package. Currently, nearly 50 million Americans smoke, and approximately 17 million try to quit annually, many on the advice of their physicians. Traditional clinical channels cannot hope to provide treatment to even a small fraction of this needy population. The ability of over-the-counter NRT and the mailing of tailored behavioral materials to assist in quitting represents a model for the delivery of smoking cessation interventions on a mass scale. Physicians are often urged to counsel their patients to quit smoking, and they are doing so in increasing numbers. However, physicians often have neither the time nor the specific training to provide detailed counseling on behavioral methods for quitting smoking. The CQP can provide efficacious behavioral smoking cessation counseling to the multitude of patients who are motivated to make an attempt to quit by their physicians. With the aggressive marketing of smoking cessation medications through over-the-counter sales or direct-to-consumer advertising, the utilization of such medications has been dramatically increased. Making effective behavioral treatment similarly available on a mass scale may have a significant public health impact.

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