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A Randomized Controlled Trial of Multiple Tailored Messages for Smoking Cessation Among Callers to the Cancer Information Service

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Self-help materials computer-tailored to the specific needs of smokers have shown promise as a high-reach, low-cost intervention for smoking cessation. Adding tailored cessation materials to telephone-based cessation counseling may be a way of generating greater efficacy in promoting and maintaining cessation. The objective of this study is to assess the efficacy of adding different types of behavioral smoking cessation materials to brief telephone-based cessation counseling.

A total of 1,978 smokers calling the National Cancer Institute's (NCI's) Cancer Information Service (CIS) for help in quitting smoking initially received brief cognitive–behavioral cessation counseling from a CIS information specialist. Following a baseline interview administered by the information specialist, subjects were randomly assigned to one of four conditions, each delivered by U.S. mail: a single, untailored smoking cessation guide (SU); a single, tailored smoking cessation guide (ST); a series of four (multiple) printed materials tailored only to baseline data (MT); and a series of four (multiple) printed materials tailored to baseline as well as retailedored using 5-month interim progress data (MRT). The primary outcome measure was 7-day point prevalence abstinence rates assessed using a computer-assisted telephone interview (CATI) at 12-month follow-up.

At 12-month follow-up, using intent-to-treat, imputed, and per-protocol analyses, no differences were found among the four experimental conditions (linear trend), or when the ST, MT, and MRT groups were compared with the control (SU) group. Participants in the two multiple message group conditions combined (MT + MRT), however, had significantly higher abstinence rates than participants in the two single message group conditions combined (SU + ST). Moreover, among subjects who reported quitting at the 5-month follow-up, participants receiving the MRT...
materials reported higher abstinence rates at 12 months than the other three groups combined (SU + ST + MT).

The results of this study support the effectiveness, over and above a single tele-counseling interaction, of multiple tailored print material contacts on cessation. These effects, however, may be due to tailoring, or the longitudinal nature of the two multiple tailored conditions, or both. The strongest evidence for tailoring occurred in the MRT condition for relapse prevention, suggesting that print materials tailored to interim progress may be especially effective in this context. The qualities of specific psychosocial and communication elements in tailored materials should receive attention in future research.

Cigarette smoking remains the most preventable cause of premature death and disability in the United States, where 87% of lung cancer deaths, 30% of all cancer deaths, and 21% of all coronary heart disease deaths are attributed to smoking. Because of the lag between smoking onset and disease occurrence, cessation of smoking by current adult smokers is the primary approach that will yield reductions in mortality within the next 25 years (Doll, Peto, Wheatley, Gray, & Sutherland, 1994). To have an impact on the public’s health, smoking cessation programs must reach a large number of smokers while also maintaining efficacy. Two program modalities that have demonstrated impact on cessation are telephone-based and computer-tailored programs.

Telephone-based “quitlines” for tobacco cessation are employed in more than half the United States and in many other countries (Ossip-Klein & McIntosh, 2003). In a comprehensive meta-analysis of quitlines, Stead and colleagues (2003) found an average odds ratio for quitting smoking of 1.56 (CI: 1.38–1.77) when compared with “less intensive intervention.” Reviews and meta-analyses of print-based computer-tailored smoking cessation interventions also find generally positive results (Lancaster & Stead, 2002; Strecher, 1999). In contrast, nonsignificant results are generally found for untailored materials compared with brief personal advice (Lancaster & Stead, 2002).

Computer-based communication technologies offer the opportunity of tailoring a cessation program to the specific needs and interests of the smoker (Strecher, 1999). This technology has become increasingly more sophisticated and less expensive. Different from “targeting” or “market segmentation,” where an assessment is made at a group level (e.g., women, African Americans), tailored materials require assessment at an individual level (Kreuter, Stecher, & Glassman, 1999). A commonly used program consists of (a) an assessment of individual characteristics relevant to smoking cessation, (b) algorithms that use these data to generate interventions tailored to the specific needs of the user, and (c) a feedback protocol that delivers these messages to the smoker in a clear, vivid form.

Most quitline models include use of a computer by the telecounselor (or information specialist) to collect information from the user before, during, or after the counseling session. Data collection components of quitlines could be extended to incorporate data for use in tailored materials. A relevant question is therefore whether incorporating tailored print-based cessation materials into quitlines contributes added efficacy to cessation rates found from the quitline alone.

Two options for follow-up materials are possible: (1) materials that are continually tailored to the originally baseline data provided, or (2) materials that are retailed according to new assessment data. Clearly, the second option seems optimal. Dijkstra and colleagues (1998) found an advantage of multiple messages over single
messages in moving smokers through stages of change. Countering these results, however, is a study by Velicer and colleagues (1999) who found no significant effect of dose (i.e., number of tailored materials sent out over time) on smoking cessation. This study, which was conducted as part of the CIS Research Consortium, evaluates the effectiveness of computer-tailored print material formats, varying in number and whether the materials are tailored. The tailored print interventions were evaluated over and above usual telecounseling for smoking cessation provided to callers of the NCI’s CIS (1-800-4-CANCER) telephone service.

**Methods**

**Setting**

Since 1976, the National Cancer Institute’s (NCI’s) Cancer Information Service (CIS) has been providing the public with information about cancer research, prevention, risk factors, symptoms, diagnosis, and treatment. The program has three parts: (1) an Information Service where CIS information specialists provide the latest, most accurate information in understandable language to the public through a toll-free telephone service in English and Spanish, reply to queries sent to the NCI’s LiveHelp instant messaging service offered at NCI’s website www.cancer.gov, and respond to e-mail inquiries sent to NCI’s web site; (2) a Partnership Program, in which CIS collaborates through an established network of 900 partners to reach those who traditionally do not seek health information or who have limited access because of educational, financial, cultural, or language barriers; and (3) a Research Program to advance the science of cancer-related health communications (Bright 2005).

This study was implemented in collaboration with seven CIS regional call center offices providing the 1-800-4-CANCER service. The regional offices were located in Birmingham, Alabama; Detroit, Michigan; Philadelphia, Pennsylvania; Colorado Springs, Colorado; Seattle, Washington; Los Angeles, California; and Honolulu, Hawaii. During the implementation period, the CIS entered a new contract period resulting in a reorganization so that all smoking calls were taken in four call centers (Detroit, Philadelphia, Colorado Springs, and Seattle). Although these changes occurred, they had little impact on the accrual and implementation of the study. In fact, the CIS telecommunications systems were updated so that all smoking calls from around the country were routed to the one of these four Smoking Call Centers.

Roughly 2% of the callers to the CIS list smoking cessation as the reason for their call. Given the large call volume to the CIS, this rate easily would supply the number of smokers required for the study. Approximately 18% of all CIS calls were from racial and ethnic minority populations (National Cancer Institute, 2005). In order to recruit a larger sample of African American and Hispanic smokers interested in quitting, a radio campaign was created targeting stations with predominantly African American or Hispanic listening audiences. Each station where radio time was purchased was asked to donate radio time in a 1:1 ratio in order to increase the frequency with which the messages were heard, while remaining within a limited budget. All participating radio stations agreed to this donation. The cities in which radio time was purchased included the following: Honolulu; Detroit; Birmingham; Jackson; Mississippi; Indianapolis; Philadelphia; New Orleans; Phoenix; Denver; Portland; San Diego; Los Angeles; Seattle; and Honolulu.
Subjects

During the enrollment period, callers to participating CIS offices who were inquiring about smoking cessation were asked some preliminary questions to determine study eligibility. To be considered a subject in the study, callers had to use English as a primary language, had to be 18 years of age or older, had to smoke at least five cigarettes per day, had to be interested in quitting smoking, could not currently (at the time of the call) be involved in another cessation program, and could not currently (at the time of the call) be undergoing or planning cancer treatment.

Measures and Follow-up Assessment

The baseline survey, conducted by CIS information specialists, included questions regarding the caller’s demographic characteristics, smoking history, current smoking characteristics, nicotine dependence (using the Fagerstrom Test for Nicotine Dependence (FTND) scale; Heatherton et al., 1991), motivation to quit smoking, perceived risks of continued smoking, specific motives for quitting, barriers to cessation, presence of smokers in the social environment, and perceived social support in quitting.

Both the 5- and 12-month follow-up assessment interviews were conducted by trained interviewers at the Survey Research Laboratory, University of Illinois, Chicago. The 5-month follow-up interviews consisted of questions comparable with those asked at baseline. Smoking cessation was assessed at the 5- and 12-month follow-up assessment. Cessation was assessed using point-prevalence abstinence, which was defined as self-report of no smoking at all for the previous 7 days. In addition, in both follow-up interviews subjects were asked several questions regarding their use and evaluation of the print materials, including whether they remembered receiving them; the extent to which these materials were read, saved, and provided new and useful information; and whether these materials motivated them to quit smoking.

Study Design and Treatment Conditions

Figure 1 describes the experimental design of the study.

Baseline data were collected from eligible and consenting callers by a CIS information specialist using a computer-assisted telephone interview system. At this point in time, subjects also received a theoretically and empirically informed telecounseling intervention for smoking cessation (Fleisher & Thomsen, 2000). The CIS information specialist training includes an understanding of the transtheoretical model applied to cessation, the role of addiction and habit, and recognized methods of cessation. Information specialists are trained to assess stage of readiness, level of addiction using the FTND, and tobacco use and cessation history. For those ready to quit, assessment data are used to generate a personalized interaction that focuses on the setting of a quit date, addressing barriers and motives to quitting, reviewing established methods of quitting, and preparing for high-risk situations and the possibility of lapses. This treatment protocol is a standard component of the CIS’s response to smokers interested in quitting and was implemented as a component of each treatment arm of the trial. The typical telecounseling interaction takes approximately 15 minutes.
Over and above this telecounseling, subjects were randomly assigned to one of four print material conditions, each delivered by U.S. mail.

**Single Untailed (SU)**
A single, untailed smoking cessation publication published by the NCI (*Clearing the Air*) was sent 7–10 days after enrollment. This 24-page publication focuses on the following: (1) selection of cognitive and behavioral methods of quitting; (2) enlisting social support; (3) quitting activities just before quitting, on the quit date, and immediately after quitting; (4) expectation management; (5) advice for managing stress; (6) advice for tolerating and managing weight gain; and (7) activities to prevent relapse. While there is a brief section describing the benefits of quitting, the majority of the publication focuses on managing cessation and maintenance.
Single Tailored (ST)
An 8-page booklet, tailored to information collected during the baseline assessment, was sent 7–10 days after enrollment. The content of the tailored materials was based on cognitive–behavioral methods of smoking cessation and relapse prevention, including self-efficacy enhancement and suggestions for coping (Fiore et al., 1990). The tailored materials utilized baseline data regarding motives of quitting (e.g., health, monetary, physician, children), previous quit attempts and methods of cessation, nicotine dependence (using the FTND scale [1991]), barriers to quitting (e.g., nicotine dependence, concern with weight gain, habitual barriers, smoking and alcohol consumption, psychosocial stress), social support (including the presence of a supportive other, the degree of support provided, and the smoking status of the supportive other), age, and gender.

The tailoring process identified motives and barriers cited by the smoker, then generated text related to those specific motives and barriers. For example, a person citing health concerns as a motive would receive information related to smoking and health. A person citing stress as a barrier to quitting would receive information related to stress management. Motives and barriers not cited by the smoker were not addressed in the booklet.

Multiple Tailored (MT)
A series of four printed materials, including one booklet, two newsletters, and one letter, was mailed. The initial booklet was the same as the tailored guide of the ST condition, and was sent 7–10 days after enrollment. Follow-up materials were sent 7–10 days after the 5-month follow-up survey, 8 months postenrollment, and 12 months postenrollment. All materials were tailored using only the data collected during the baseline interview.

Multiple Retailored (MRT)
A series of four printed materials, including one booklet, two newsletters, and one letter was mailed. The initial booklet was the same as the tailored guide of the ST condition. Consistent with the MT group, follow-up materials were sent 7–10 days after the 5-month follow-up survey, 8 months postenrollment, and 12 months postenrollment. The follow-up materials, however, were tailored using both baseline and 5-month follow-up data. This allowed assessment of progress in cessation activity and an associated recalibration of messages. Subjects in the MRT condition received follow-up materials that also utilized smoking status, quit attempts over the previous 5 months, stage of change, motives, barriers, and social support at the 5-month follow-up. This retailored information provided an opportunity to refocus tailored materials to the progress (or lack of progress) made during this time period, and to set new goals for cessation.

Tailoring Logistics and Procedures
Information collected from CIS baseline interviews was transferred electronically twice a week from the CIS Central Support office to the AMC Cancer Research Center Biostatistics Core in Denver, Colorado. A data file containing variables used for tailoring messages in the print materials then was transferred electronically to the Health Media Research Laboratory (HMRL) at the University of Michigan in
Ann Arbor. A computer-based tailoring engine consisting of a software algorithm and database of message components were stored at the HMRL.

The tailored engine employed in this study was developed at the HMRL using a multidisciplinary team of behavioral scientists, computer programmers, and graphic artists. The behavioral scientists wrote message elements that were linked together in a printed format. For each message section, elements were written in response to all possible responses provided in the baseline (for all treatment conditions) and 5-month follow-up survey (for the MRT treatment condition only). The message database for this project included more than 2,000 text and graphic elements. Several graphic styles were tested in each of the participating regions through intercept interviewing in order to find a style that was acceptable to most people who viewed it. On the basis of these tailoring factors, more than five billion variations of the tailored booklets could be created.

The software algorithm used data from baseline (for all treatment conditions) and 5-month survey (for the MRT treatment condition only) to select a combination of message and graphic elements from the database. These elements automatically were assembled into individually tailored guides by the tailoring engine, which were then printed on the HMRL’s high-speed color printers. A research assistant was responsible for checking printed materials, which were subsequently trimmed, folded, and stapled. To assure that the tailored materials always reached the correct subject, the individual’s name and address were printed directly on the booklet and inserted into a window envelope for mailing.

Data Analysis

The primary outcome of 12-month differences in abstinence between treatment conditions was assessed using logistic regression. Since both age and the FTND were significant predictors of cessation, these two variables were entered as covariates. These outcomes were analyzed using three approaches to treating subjects who were not reached at the 12-month follow-up survey:

1. Intent-to-treat (ITT) analysis: subjects who were not reached at 12-month follow-up were considered as failures (that they did smoke).
2. Imputation (IMP) analysis: subjects who were not reached at 12-month follow-up but who were reached and had reported abstinence at the 5-month follow-up survey were considered as abstinent at 12-month follow-up.
3. Per-protocol (PP) analysis: subjects who were not reached at 12-month follow-up were removed from the analysis.

In secondary analyses, we were interested in whether the interventions for the two groups receiving multiple printed materials (MT and MRT combined) were more effective than the interventions for the two groups receiving a single set of materials (SU and ST combined). In another secondary analysis, we were interested in whether subjects who had quit smoking at the 5-month follow-up responded differently to the MRT condition, which longitudinally tailored messages based on progress from baseline to 5 months. Finally, we were interested in exploring why the tailored booklets worked or did not work. To better understand this issue we examined the evaluations of the printed materials by respondents at both 5- and 12-month follow-up periods.
Results

Subject Accrual and Retention

A total of 2,999 smokers called between March 8, 1999, and June 8, 2000. Of the smokers who called the CIS for assistance in quitting, 2,464 met initial enrollment criteria. Of this sample, 164 callers were not ready to quit smoking within the next 30 days, 81 callers were currently using other smoking cessation programs, and 241 failed to provide baseline data (age and FTND) essential to the analyses. These callers were removed from the sample, leaving 1,978 smokers who became subjects in the study. Sixty-six percent (1,299) of the 1,978 baseline subjects completed the 5-month follow-up survey. This survey, administered to subjects in all four treatment groups, was required for retailoring information in one of the treatment conditions. Therefore, only those subjects who received the 5-month survey were eligible to receive the 12-month survey. Sixty-seven percent (869) of the 1,299 subject surveyed at 5 months completed the 12-month survey. This final sample of subjects completing both follow-up surveys represents 44% of the original 1,978 subjects of the trial. Response rates to the 5- and 12-month follow-up survey did not differ between the treatment conditions.

Baseline Characteristics

There were no significant differences in demographic or smoking history characteristics between subjects randomized to the four conditions. The average age of subjects was 41 years (s.d. = 12.4); the majority of subjects were female (70%). The majority of subjects (71%) were White, 17% were African American, and 4% were Hispanic. Half of the subjects had at least some college. Subjects had smoked for an average of 22.7 years (s.d. = 12.1). Forty-six percent of subjects smoked more than a pack of cigarettes per day. The large majority of subjects (81%) smoked their first cigarette of the day within the first 30 minutes after waking, and the average FTND score was 5.9 (s.d. = 2.4).

Process Analysis

To better understand the reasons for the failure of the initial tailored booklet in achieving a higher abstinence rate than the untailored booklet (Clearing the Air), we examined subjects’ responses to the printed materials at both 5- and 12-month follow-up periods. At both follow-up periods, respondents were asked questions regarding the intervention materials they received as part of the experimental manipulation. Table 1 presents the responses to the intervention materials. By the 5-month follow-up respondents in the ST = MT = MRT groups had received only the tailored booklet and thus could be collapsed into one group contrasted against the SU group.

At the 5-month follow-up, respondents in the tailored booklet groups were more likely to report having read the materials. These respondents also were more likely to report that the materials seemed to be written for them. At the 12-month follow-up, respondents in the MT and MRT conditions were more likely to report that they saved the materials. Respondents in the MRT condition at 12-month follow-up were more likely to report that the materials were written for them.
Table 1. Process evaluation of intervention print materials

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>5 months SU N (%)</th>
<th>12 months ST/MT/MRT N (%)</th>
<th>5 months SU N (%)</th>
<th>12 months ST N (%)</th>
<th>12 months MT N (%)</th>
<th>12 months MRT N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much of the booklet (materials) did you read?</td>
<td>ALL</td>
<td>170 (61)</td>
<td>620 (72)</td>
<td>117 (56)</td>
<td>139 (67)</td>
<td>174 (70)</td>
<td>166 (72)</td>
</tr>
<tr>
<td></td>
<td>MOST</td>
<td>53 (19)</td>
<td>120 (14)</td>
<td>60 (29)</td>
<td>44 (21)</td>
<td>46 (18)</td>
<td>41 (18)</td>
</tr>
<tr>
<td></td>
<td>SOME</td>
<td>30 (11)</td>
<td>56 (7)</td>
<td>18 (9)</td>
<td>14 (7)</td>
<td>17 (7)</td>
<td>11 (5)</td>
</tr>
<tr>
<td></td>
<td>LITTLE</td>
<td>17 (6)</td>
<td>32 (4)</td>
<td>8 (4)</td>
<td>9 (4)</td>
<td>9 (4)</td>
<td>9 (4)</td>
</tr>
<tr>
<td></td>
<td>NONE</td>
<td>10 (4)</td>
<td>28 (3)</td>
<td>5 (2)</td>
<td>3 (1)</td>
<td>3 (1)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Did you save the booklet (materials)?</td>
<td>YES</td>
<td>231 (85)</td>
<td>704 (84)</td>
<td>121 (58)</td>
<td>136 (66)</td>
<td>182 (74)</td>
<td>166 (72)</td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>40 (15)</td>
<td>131 (16)</td>
<td>86 (42)</td>
<td>71 (34)</td>
<td>64 (26)</td>
<td>65 (28)</td>
</tr>
<tr>
<td>Did the booklet (materials) seem to be written especially for you?</td>
<td>YES</td>
<td>154 (57)</td>
<td>548 (67)</td>
<td>117 (59)</td>
<td>138 (68)</td>
<td>164 (68)</td>
<td>170 (76)</td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>114 (43)</td>
<td>276 (34)</td>
<td>81 (41)</td>
<td>64 (32)</td>
<td>78 (32)</td>
<td>53 (24)</td>
</tr>
<tr>
<td>How easy was the information in the booklet (materials) to understand?</td>
<td>VERY</td>
<td>239 (88)</td>
<td>764 (92)</td>
<td>165 (82)</td>
<td>185 (89)</td>
<td>214 (87)</td>
<td>212 (93)</td>
</tr>
<tr>
<td></td>
<td>SOMEWHAT</td>
<td>29 (11)</td>
<td>65 (8)</td>
<td>32 (16)</td>
<td>22 (11)</td>
<td>29 (12)</td>
<td>15 (7)</td>
</tr>
<tr>
<td></td>
<td>NOT TOO</td>
<td>2 (1)</td>
<td>3 (0)</td>
<td>2 (1)</td>
<td>2 (1)</td>
<td>2 (1)</td>
<td>1 (0)</td>
</tr>
<tr>
<td></td>
<td>NOT AT ALL</td>
<td>1 (0)</td>
<td>1 (0)</td>
<td>2 (1)</td>
<td>0 (0)</td>
<td>1 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>How effective was the booklet (materials) at addressing your specific questions and concerns?</td>
<td>ALL</td>
<td>82 (30)</td>
<td>240 (29)</td>
<td>55 (27)</td>
<td>46 (22)</td>
<td>58 (24)</td>
<td>54 (24)</td>
</tr>
<tr>
<td></td>
<td>MOST</td>
<td>120 (44)</td>
<td>368 (44)</td>
<td>94 (47)</td>
<td>96 (47)</td>
<td>112 (46)</td>
<td>106 (47)</td>
</tr>
<tr>
<td></td>
<td>SOME</td>
<td>51 (19)</td>
<td>131 (16)</td>
<td>37 (18)</td>
<td>40 (20)</td>
<td>39 (16)</td>
<td>38 (17)</td>
</tr>
<tr>
<td></td>
<td>FEW</td>
<td>17 (6)</td>
<td>67 (8)</td>
<td>11 (5)</td>
<td>20 (10)</td>
<td>23 (10)</td>
<td>24 (11)</td>
</tr>
<tr>
<td></td>
<td>NONE</td>
<td>2 (1)</td>
<td>28 (3)</td>
<td>4 (2)</td>
<td>3 (1)</td>
<td>10 (4)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>How much of the information regarding quitting smoking was new to you?</td>
<td>ALL</td>
<td>20 (7)</td>
<td>43 (5)</td>
<td>15 (7)</td>
<td>11 (5)</td>
<td>16 (7)</td>
<td>13 (6)</td>
</tr>
<tr>
<td></td>
<td>MOST SOME</td>
<td>43 (16)</td>
<td>109 (13)</td>
<td>23 (11)</td>
<td>28 (14)</td>
<td>39 (16)</td>
<td>35 (15)</td>
</tr>
<tr>
<td></td>
<td>VERY LITTLE</td>
<td>108 (40)</td>
<td>312 (37)</td>
<td>75 (37)</td>
<td>73 (35)</td>
<td>84 (34)</td>
<td>76 (33)</td>
</tr>
<tr>
<td></td>
<td>NONE</td>
<td>60 (22)</td>
<td>215 (26)</td>
<td>55 (27)</td>
<td>48 (23)</td>
<td>59 (24)</td>
<td>67 (29)</td>
</tr>
<tr>
<td></td>
<td>42 (15)</td>
<td>158 (19)</td>
<td>35 (17)</td>
<td>46 (20)</td>
<td>48 (20)</td>
<td>37 (16)</td>
<td></td>
</tr>
<tr>
<td>Did the booklet (materials) increase your motivation to quit smoking?</td>
<td>YES</td>
<td>168 (61)</td>
<td>500 (59)</td>
<td>124 (61)</td>
<td>120 (58)</td>
<td>149 (61)</td>
<td>152 (67)</td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>106 (39)</td>
<td>341 (41)</td>
<td>78 (39)</td>
<td>88 (42)</td>
<td>95 (39)</td>
<td>76 (33)</td>
</tr>
</tbody>
</table>

\(^a^p < .05\) for chi-square test for independence of rows and columns at 5 months.  
\(^b^p < .05\) for chi-square test for independence of rows and columns at 12 months.  
\(^c^p < .05\) for chi-square test for contrast between MT and MRT at 12 months.
Outcome Analysis

Table 2 presents 12-month outcomes by treatment condition using three approaches for the analysis of missing data (see Methods section). An omnibus test of all four treatment conditions was not significant using ITT, IMP, or PP analysis approaches. This omnibus test examined whether there was an overall trend across experimental conditions at 12-month follow-up that would conform to the increasing intensity and tailoring of the experimental conditions (i.e., SU < ST < MT < MRT). This finding of no difference also extended to a series of pairwise comparisons with the usual care control condition at 12 months (i.e., SU vs. ST, SU vs. MT, and SU vs. MRT), as well as analyses conducted at 5-month follow-up that compared SU vs. ST, MT, and MRT combined (at 5-month follow-up, the ST, MT, and MRT groups received the same intervention, representing one tailored mailout). This latter analysis represents a direct test of the tailored booklet versus the untailored booklet (Clearing the Air).

Given the lack of significant overall differences reported above, additional secondary analyses examined differences between the two multiple materials groups (MT and MRT combined) and the single materials groups (SU and ST combined) at 12 months. In all three analytic approaches, the 12-month 7-day point prevalence rates were higher in the two conditions receiving multiple tailored materials over the two conditions receiving a single set of materials. The odds ratios found between the two multiple materials groups and the two single materials groups were statistically significant (p < 0.05) and similar across the intent-to-treat, imputation, and per protocol analyses (O.R. = 1.41, 1.49, 1.44, respectively). These outcomes did not change when age and FTND were removed from the logistic model.

In another secondary analysis, we were interested in treatment effects at 12 months among subjects who reported abstinence at the 5-month follow-up (Table 3). We were particularly interested in the impact of the multiple tailored messages on relapse prevention and examined two comparisons: (1) the two multiple tailored

<table>
<thead>
<tr>
<th>Group</th>
<th>Intent-to-treat analysis** 12-mo 7-day point prevalence (n = 1,978)</th>
<th>Imputed analysis*** 12-mo 7-day point prevalence (n = 1,978)</th>
<th>Per protocol analysis**** 12-mo 7-day point prevalence (n = 869)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SU</td>
<td>8.1 (%)</td>
<td>10.4 (%)</td>
<td>16.5%</td>
</tr>
<tr>
<td>2. ST</td>
<td>7.2 (%)</td>
<td>10.0 (%)</td>
<td>15.9%</td>
</tr>
<tr>
<td>3. MT</td>
<td>10.3 (%)</td>
<td>13.4 (%)</td>
<td>20.6%</td>
</tr>
<tr>
<td>4. MRT</td>
<td>10.5 (%)</td>
<td>13.4 (%)</td>
<td>20.4%</td>
</tr>
</tbody>
</table>

*Rates adjusted for baseline Fagerstrom score and age.
**Intent-to-treat abstinence difference between groups 3 + 4 and groups 1 + 2 (Wald $X^2 = 4.7$, p < .05; OR = 1.41, 1.04–1.99).
***Imputed abstinence (using 4-mo abstinence to impute 12-mo missing data) difference between groups 3 + 4 and groups 1 + 2 (Wald $X^2 = 4.9$, p < .05; OR = 1.49, 1.04–1.81).
****Per protocol abstinence difference between groups 3 + 4 and groups 1 + 2 (Wald $X^2 = 4.2$, p < .05; OR = 1.44, 1.02–2.05).
groups (MT + MRT) against the two single material groups (SU + ST), and (2) the multiple retailored group (MRT) against the other three groups (SU + ST + MT). Using a per protocol analysis, a significant effect on relapse prevention was found in both comparisons. The relapse prevention effect of the MRT intervention was highest among the four treatment conditions and reduced relapse by nearly 50% when compared with the SU condition (24% vs. 43%). The relapse prevention effect of the MT condition alone was not significantly higher than the effect of the single materials groups (MT versus SU + ST). Using an intent-to-treat analysis, we found that relapse prevention in the MRT group was marginally higher than in the other three groups. Relapse prevention in the MT + MRT groups was not significantly higher than in the SU + ST groups, nor was it in the MT group versus the SU + ST groups.

Discussion

Adding tailored print-based materials to telecounseling for smoking cessation is now a feasible strategy for most computer-assisted telephone counseling formats that involve standardized data collection and storage. Data from these interactions can be fed to tailoring algorithms that automatically print guides for the user, potentially creating greater durability of the cessation messages provided to the smoker. This study sought to determine the impact of different formats of computer-tailored print materials over and above effective telephone counseling for smoking cessation.

The primary outcome analysis using an overall test of experimental group differences failed to demonstrate a significant effect at 12-month follow-up. Secondary analyses, however, demonstrated a significant difference in cessation rates between subjects receiving multiple tailored materials (MT + MRT) and those receiving only a single set of materials, whether tailored or untailored (SU + ST).

### Table 3. Comparison of 12-month abstinence rates between treatment conditions among subjects who were abstinent at 5 months using intent-to-treat (ITT) and per protocol (PP) assumptions

<table>
<thead>
<tr>
<th>Group</th>
<th>Intent-to-treat analysis** 12-mo 7-day point prevalence (n = 188)</th>
<th>Per protocol analysis*** 12-mo 7-day point prevalence (n = 133)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SU</td>
<td>41.9</td>
<td>57.1</td>
</tr>
<tr>
<td>2. ST</td>
<td>37.4</td>
<td>51.4</td>
</tr>
<tr>
<td>3. MT</td>
<td>41.7</td>
<td>63.3</td>
</tr>
<tr>
<td>4. MRT</td>
<td>53.6</td>
<td>75.8</td>
</tr>
</tbody>
</table>

**Rates adjusted for baseline FTND and age.

**Intent-to-treat difference between groups 3 + 4 and groups 1 + 2 (Wald $X^2 = 1.4, p = .2$; OR = 1.44, 0.78–2.68). Per protocol difference between group 4 and groups 1–3 (Wald $X^2 = 2.7, p = .10$; OR = 1.79; 0.89–3.61).

***Per protocol difference between groups 3 + 4 and groups 1 + 2 (Wald $X^2 = 4.1, p < .05$; OR = 2.16, 1.03–4.65). Per protocol difference between group 4 and groups 1–3 (Wald $X^2 = 4.1, p < .05$; OR = 2.58, 1.06–6.85).
Given the known impact of telecounseling, we considered the test of tailored materials added to such counseling to be a rather stringent test. Through the telecounseling, subjects in all four conditions received a tailored interaction with the CIS information specialist. Adding tailored print materials, at least in the short term, could have been redundant. Use of the high-quality, 24-page, *Clearing the Air* guide in the control condition further added to the stringent nature of this test. This guide contained a large amount of information on the major aspects of smoking cessation.

We found no impact of a single set of tailored cessation materials (ST group) over the *Clearing the Air* materials (SU group) materials at 12-month follow-up, nor did we find an effect of multiple retailoring (MRT group) of print materials on cessation. We cannot, therefore, state that tailoring per se had an impact on cessation. The finding that multiple mailings of materials (MT + MRT) had a larger influence than a single mailing (SU + ST) may have been the result of multiple contacts provided in the MT and MRT conditions. These findings run counter to the results of Velicer and colleagues (1999), who found no relationship between number of materials mailed and cessation outcomes but a clear advantage of tailored over stage-matched materials.

Lack of a more substantial effect from the tailored materials may be due to weaknesses in the tailored materials created for this study. Contrary to other studies finding significant differences in how tailored versus untailored materials are perceived and used (e.g., Brug, Oenema, & Campbell, 2003; Strecher, 1999; Strecher, Shiffman, & West, 2005), this study found few differences between tailored and untailored materials. Tailored materials in this study were more likely to be read and perceived to be written specifically for the subject. The tailored materials, however, were not perceived to be more effective or useful, or to contain new information.

The tailored materials of this study focused on the smoker’s self-reported motives and barriers. Particularly among this cohort of generally well-educated smokers, arguments developed in the tailored materials to capitalize on motives already may have been understood. Moreover, the information provided for addressing barriers might have been insufficient. Among many smokers calling a help line for cessation assistance, the significantly greater amount of information available in the 24-page *Clearing the Air* booklet as compared with the 8-page tailored guide may have been an advantage.

The significant odds ratios found in this intervention are comparable with those found in other print-based tailored materials studies. In a Cochrane meta-analysis of print-based tailored versus nontailed self-help smoking cessation materials, Lancaster and Stead (2002) found an average odds ratio of 1.36 (CI: 1.13–1.64) for computer-tailored materials compared with nontailored or stage-matched materials. As another point of comparison, Stead and colleagues (2003), in another Cochrane meta-analysis, found an average odds ratio of 1.56 (CI: 1.38–1.77) for telephone counseling compared with “less intensive intervention.”

In addition to the findings involving smoking cessation for the full sample at 12 months, relapse prevention effects were found for the MRT group, which received materials retailed to their 5-month smoking status, quit attempts over the previous 5 months, stage of change, motives, barriers, and social support. This effect particularly was noteworthy, reflecting a substantial reduction in relapse compared with the SU control condition (from 43% to 24%). This finding suggests that the
investment of resources to update and revise tailored print messages may be most beneficial in this context.

Finally, we note several limitations of this trial. The study could not verify claims of abstinence biochemically because of the geographical spread of the sample. False reporting of cessation, however, is considered to be minimal when there is no personal contact with a therapist (Glasgow et al., 1992; Patrick et al., 1994; Strecher et al., 1989; Velicer, Prochaska, Rossi, & Snow, 1992). Missing data due to loss of subjects to follow-up is also a limitation. In our ITT analysis all subjects lost to follow-up were considered to be smokers, possibly making the ITT success rates unduly low. Analysis using both a missing data imputation strategy and a per protocol strategy raised average cessation rates but did not significantly alter odds ratios of effect magnitude. Regardless, the observed difference between the treatment conditions could not be explained by drop out, as there was no difference in drop-out rates.

Another potential limitation is that the sample of CIS callers enrolled in this study tended to be educated smokers who already were motivated to quit by virtue of their call to the CIS. In addition, all participants (as noted above) received standard CIS service for smoking cessation, which included a well-developed telephone counseling protocol, while the control group received well-accepted standard service print materials. It is conceivable that in usual service environments where smoking cessation protocols are less developed, where smokers are less educated or less motivated to quit, or all of these, the efficacy of tailored print materials may be further enhanced. This possibility underscores the need for additional research, particularly involving more diverse populations of smokers.

References


