Benefits of Telephone Care Over Primary Care for Smoking Cessation

A Randomized Trial

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Background: Brief clinician intervention and telephone counseling are both effective aids for smoking cessation. However, the potential benefit of telephone care above and beyond routine clinician intervention has not been examined previously. The objective of this study is to determine if telephone care increases smoking cessation compared with brief clinician intervention as part of routine health care.

Methods: This 2-group, prospective, randomized controlled trial enrolled 837 daily smokers from 5 Veterans Affairs medical centers in the upper Midwest. The telephone care group (n=417) received behavioral counseling with mailing of smoking cessation medications as clinically indicated. The standard care group (n=420) received intervention as part of routine health care. The primary outcome was self-reported 6-month duration of abstinence 12 months after enrollment. Secondary outcomes were 7-day point prevalence abstinence at 3 and 12 months, participation in counseling programs, and use of smoking cessation medications.

Results: Using intention-to-treat procedures, we found that the rate of 6-month abstinence at the 12-month follow-up was 13.0% in the telephone care group and 4.1% in the standard care group (odds ratio [OR], 3.50; 95% confidence interval [CI], 1.99-6.15). The rate of 7-day point prevalence abstinence at 3 months was 39.6% in the telephone care group and 10.1% in the standard care group (OR, 5.84; 95% CI, 4.02-8.50). Telephone care compared with standard care increased the rates of participation in counseling programs (97.1% vs 24.0%; OR, 96.22; 95% CI, 52.57-176.11) and use of smoking cessation medications (89.6% vs 52.3%; OR, 7.85; 95% CI, 5.34-11.53).

Conclusion: Telephone care increases the use of behavioral and pharmacologic assistance and leads to higher smoking cessation rates compared with routine health care provider intervention.

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To assess the potential benefits of telephone care above and beyond routine intervention by health care providers, we conducted a 2-group prospective randomized controlled trial within the Veterans Health Administration system. Performance measures of tobacco treatment at Veterans Affairs medical centers (VAMCs) show high rates of documentation of tobacco use status (99%) and advice to quit (75%), and tobacco treatment medications are part of the national Veterans Affairs formulary. The objective of the present study was to determine if telephone care, consisting of counseling and provision of smoking cessation medications, increased abstinence from cigarette smoking compared with standard intervention as part of routine health care.

**METHODS**

**SETTING**

This study was conducted at 5 VAMCs (Black Hills, SD; Fargo, ND; Minneapolis, Minn; Sioux Falls, SD; and St Cloud, Minn). All study staff were located at the Minneapolis VAMC.

**PARTICIPANTS AND RECRUITMENT**

Patients who had visited a primary care clinic at a participating VAMC in the year prior to study initiation were eligible to receive an invitation letter that included a toll-free telephone number at the Minneapolis VAMC. Callers were screened for eligibility criteria of daily smoking and willingness to set a quit date within the next 30 days. Individuals were excluded if they were not willing to receive telephone counseling, did not have a telephone number, were difficult to communicate with over the telephone (ie, had speech or hearing problems), or were currently using smoking cessation medications.

**RANDOMIZATION**

Participants were randomly assigned to telephone or standard care using a computer-generated randomization scheme stratified by primary care facility and blocked within sites. At the time of enrollment and entry into the study database, participants were permanently assigned to treatment condition as determined by the randomization sequence.

**INTERVENTION**

Subjects randomized to the standard care group were mailed self-help materials ("You Can Quit Smoking" Consumer Guide) and had continued access to clinical smoking cessation services through their VAMC. In addition to primary care–based interventions, all VAMCs have referral-based smoking cessation programs. Program structure varies by site (eg, number of sessions and group or individual therapy). Nicotine patches, nicotine gum, and slow-release bupropion hydrochloride were available at all sites.

Subjects randomized to telephone care received counseling using a protocol adapted from the California Smokers' Helpline. Counselors received 3 days of training. Study staff, including a study physician, met weekly to review participants progress. The telephone care protocol consisted of 7 calls scheduled over a 2-month period in a relapse-sensitive fashion. Additional courtesy calls were scheduled at the discretion of the counselor to reinforce motivation to quit or to follow up after relapse. Subjects received counseling for up to 3 quit attempts during the 12 months after enrolling in the study.

Telephone counselors encouraged use of pharmacologic therapy. Nicotine patch was recommended as the initial agent. Slow-release bupropion, nicotine gum, or a combination was recommended if the subjects had prior unsuccessful use of the nicotine patch. Medications were prescribed by study physicians (L.C.A. and A.M.J.). In the case of slow-release bupropion, counseling staff screened for contraindications and requested approval from the subjects’ primary care providers. All medications were mailed directly to subjects from VAMC pharmacies.

**OUTCOME MEASURES**

Smoking status was determined by telephone survey 3 and 12 months after study enrollment. Data collection was conducted independently of counseling by evaluation staff blinded to participants’ intervention group. The primary outcome was self-reported 6-month sustained abstinence at the 12-month follow-up. Secondary outcomes were self-reported 7-day point prevalent abstinence and the number of quit attempts. Process measures included the receipt of behavioral counseling and use of pharmacologic therapy based on telephone counseling records and self-report on follow-up surveys.

Recruitment occurred from June 2001 to December 2002. The intervention occurred from June 2001 to November 2003. The evaluation occurred from September 2001 to December 2003. The study was reviewed and approved by the institutional review boards at all sites.

**STATISTICAL ANALYSIS**

A likelihood ratio χ² test was used to compare rates of 6-month sustained abstinence and 7-day point prevalence abstinence for the treatment groups using intention-to-treat with nonrespondents at follow-up considered to be continuing smokers. Among those who completed follow-up assessments, likelihood ratio χ² tests were used to compare treatment groups with respect to the number of quit attempts and the reported use of counseling and medications.

Sample size requirements were calculated for the primary outcome. Assuming a 2-sided significance level of .05, the study sample size provided 80% power or greater to detect a change in the smoking abstinence rate of 7.5% given an abstinence rate in the standard care group of 14% or less.

**RESULTS**

The flowchart for evaluation of study participants is shown in the Figure. Mailing of invitation letters (n=68 903) led to 1831 calls. Of callers, 1288 were current smokers. Among current smokers, 995 (77%) were eligible for the study. Reasons for ineligibility included occasional or non-daily smoking (n=138), no interest in telephone counseling (n=69), current use of smoking cessation medications (n=28), difficulty communicating over the telephone (n=26), not having a telephone number (n=16), and not being willing to set a quit date (n=15). Among eligible smokers, 838 (84%) agreed to participate, with 420 subjects randomized to standard care and 418 subjects randomized to telephone care.

A total of 38 individuals voluntarily withdrew from the study (13 telephone care, 25 standard care). The most
common reasons for withdrawal were loss of interest in the study (7 telephone care, 13 standard care) and dissatisfaction with services (1 telephone care, 9 standard care). One subject in the telephone care group withdrew and requested that no information be used for research purposes. Ten individuals in the telephone care group and 6 individuals in the standard care group died during the course of the study. Excluding deaths and the 1 individual who requested information be removed, 407 participants in the telephone care group and 414 participants in the standard care group were included in the analysis of the 12-month outcomes. The response rates for the 3- and 12-month follow-up surveys were 91% (755/830) and 87% (715/821), respectively, with no significant difference in response rate between study groups at either time point.

### BASELINE CHARACTERISTICS

At baseline, there were no significant differences between treatment groups (Table 1 and Table 2). Nearly half of the participants reported a history of heart or vascular disease, and approximately one third reported having lung disease (emphysema, chronic bronchitis, or asthma). Prior assistance in quitting was common, with 82% (688/837) having tried smoking cessation medications previously.

### TELEPHONE CARE

Among the 417 subjects in the telephone care group, 94% (392) completed the initial counseling call that lasted a mean (SD) of 44.9 (14.5) minutes. Seventy-two percent of participants (299) completed 3 or more counseling calls. Owing to courtesy calls, relapses, and counseling associated with repeated attempts to quit, subjects completed a mean (SD) of 7.7 (4.1) calls. The median time from study enrollment to participants’ last call was 77 days (mean [SD] time, 103.3 [76.3] days). Eighty-four percent of subjects (352/417) completed their final call within 180 days of study enrollment. The mean (SD) total duration of telephone contact was 123.1 (71.3) minutes.

### STANDARD CARE

All 420 subjects in the standard care group were mailed self-help materials. Additional assistance in quitting was available from health care professionals. In the first 3 months after study enrollment, 64% of standard care subjects (239/372) reported making 1 or more visits to a health care professional. By 12 months after study enrollment, 90% of standard care subjects (344/384) reported visiting a health care professional. Ninety-six percent (329/344) reported being a smoker at the time of...
their visit. Of these smokers, 98% (324/329) reported some discussion of smoking cessation. Discussions tended to be brief, with 75% (244/324) reporting that discussion of smoking lasted 5 or fewer minutes. Of those who discussed smoking, 95% (308/324) reported being advised to quit, and 50% (162/324) reported being offered smoking cessation medications.

### SMOKING OUTCOMES

Results for self-reported 6-month sustained abstinence and point-prevalence abstinence are summarized in Table 3. At the 12-month follow-up, 13.0% of individuals in the telephone care group (53/407) were abstinent for 6 or more months. This compares with 4.1% in the standard care group (17/414) (odds ratio [OR], 3.50; 95% confidence interval [CI], 1.99-6.15). At the 3-month follow-up, the rate of 7-day abstinence in the telephone care group was 39.6% (164/414) compared with 10.1% (42/416) in the standard care group (OR, 5.84; 95% CI, 4.02-8.50). Owing to relapse in the telephone care group and new quit attempts in the standard care group, the absolute difference in 7-day abstinence at 12 months between the groups was smaller but still significant.

Subjects in the telephone care group made more quit attempts compared with those in the standard care group. In the telephone care group, 8.4% (29/344) did not make a quit attempt, 24.1% (83/344) made 1 quit attempt, 11.6%...
PARTICIPATION IN COUNSELING PROGRAMS AND USE OF MEDICATIONS

Participation in smoking cessation counseling programs was substantially higher in the telephone care group than in the standard care group (Table 4). At 3 months, 82.4% of individuals in the telephone care group (313/380) and 11.4% of individuals in the standard care group (42/368) participated in any smoking cessation counseling program (telephone, individual, or group counseling program; OR, 36.26; 95% CI, 23.93-54.95). A large difference persisted at the 12-month follow-up. Fewer individuals in the telephone care group used in-person individual and group counseling services. The absolute rates of use of in-person programs were quite low overall.

Use of smoking cessation medications was significantly higher in the telephone care group than in the standard care group. At 3 months, 86.3% of subjects in the telephone care group (327/379) and 30.1% of subjects in the standard care group (112/372) reported any use of smoking cessation medications (OR, 14.60; 95% CI, 10.11-21.07). While a greater number of subjects in the standard care group began using medications more than 3 months after study enrollment, the difference in rates of medication use persisted at the 12-month follow-up.

Over the course of the study in the standard care group, 43% of participants (149/348) used neither a medication nor a counseling program, 33% (116/348) used 1 or more smoking cessation medications but no counseling program, 6% (20/348) used a counseling program but no medications, and 18% (63/348) used both medications and a counseling program. The 6-month abstinence rates for these groups were 2.7% (4/149), 2.6% (3/116), 10.0% (2/20), and 12.7% (8/63), respectively. This compares with the telephone care group in which 88.0% of participants (345/392) used both medications and a counseling program and had a 6-month abstinence rate of 11.9% (41/345). These findings suggest that the overall difference in abstinence between the 2 treatment groups is due mainly to the greater number of participants in the telephone care group that used both smoking cessation medications and a counseling program.

COMMENT

Among smokers who are interested in quitting, the option of receiving services over the telephone dramatically increases the use of behavioral counseling and pharmacologic therapy. Even compared with very high rates of brief health care provider intervention in the standard care group, smokers receiving telephone care were more successful in achieving abstinence.

The increase in smoking cessation observed in this study is consistent with delivery of a combined behavioral and pharmacologic intervention. A recent review

Table 4. Participation in Smoking Cessation Counseling Programs and Use of Smoking Cessation Medications in the First 3 Months and by 12 Months

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Telephone Care</th>
<th>Standard Care</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any counseling program</td>
<td>313/380 (82.4)</td>
<td>42/368 (11.4)</td>
<td>36.26 (23.93-54.95)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Telephone program</td>
<td>310/380 (81.6)</td>
<td>22/371 (5.9)</td>
<td>70.25 (42.49-116.16)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Group program</td>
<td>5/379 (1.3)</td>
<td>13/371 (3.5)</td>
<td>0.37 (0.13-1.04)</td>
<td>.05</td>
</tr>
<tr>
<td>Individual program</td>
<td>2/379 (0.5)</td>
<td>13/370 (3.5)</td>
<td>0.15 (0.03-0.65)</td>
<td>.004</td>
</tr>
<tr>
<td>Any medications</td>
<td>327/379 (86.3)</td>
<td>112/372 (30.1)</td>
<td>14.60 (10.11-21.07)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nicotine patch</td>
<td>240/378 (63.5)</td>
<td>65/372 (17.5)</td>
<td>8.21 (5.85-11.54)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nicotine gum</td>
<td>78/378 (20.6)</td>
<td>27/372 (7.3)</td>
<td>3.32 (2.09-5.28)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Slow-release bupropion</td>
<td>150/380 (39.5)</td>
<td>35/372 (9.4)</td>
<td>6.28 (4.19-9.41)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Combination medications</td>
<td>113/377 (30.0)</td>
<td>14/372 (3.8)</td>
<td>10.95 (6.14-19.50)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>By 12 Months‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any counseling program</td>
<td>395/407 (97.1)</td>
</tr>
<tr>
<td>Telephone program</td>
<td>394/407 (96.8)</td>
</tr>
<tr>
<td>Group program</td>
<td>12/356 (3.4)</td>
</tr>
<tr>
<td>Individual program</td>
<td>7/356 (2.0)</td>
</tr>
<tr>
<td>Any medications</td>
<td>352/393 (89.6)</td>
</tr>
<tr>
<td>Nicotine patch</td>
<td>259/384 (67.5)</td>
</tr>
<tr>
<td>Nicotine gum</td>
<td>88/356 (24.3)</td>
</tr>
<tr>
<td>Slow-release bupropion</td>
<td>173/368 (47.0)</td>
</tr>
<tr>
<td>Combination medications</td>
<td>124/361 (34.4)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; OR, odds ratio.
*Unless otherwise indicated, data are reported as number/total responders (percentage) of subjects.
†Denominators vary owing to item nonresponses.
‡At 12 months, participants were considered to have used counseling programs or medications if they answered affirmatively for use of these drugs or services at either 3- or 12-month follow-up. A participant who indicated receiving a specific service or using a drug at the 3-month evaluation but who was not reached for the 12-month evaluation was classified as having received this service or drug by 12-month follow-up. A participant who indicated they had not used a specific service or drug at 3 months and was not reached at the 12-month evaluation was classified as “missing” for analysis of that service by 12 months.

(40/344) made 2 quit attempts, and 55.8% (192/344) made 3 or more quit attempts. This compares with 23.0% (78/339), 15.0% (51/339), 13.6% (46/339), and 48.5% (164/339) of subjects who made 0, 1, 2, and 3 or more attempts, respectively, in the standard care group (P<.001).
suggests that telephone counseling alone increases the odds of quitting by 1.56 (95% CI, 1.38-1.77). Reviews of pharmacologic agents commonly prescribed in this study suggest that they increase the odds of quitting by 1.66 for nicotine gum (95% CI, 1.52-1.81), 1.74 for the nicotine patch (95% CI, 1.57-1.93), and 1.97 for slow-release bupropion (95% CI, 1.67-2.34). The odds of smoking cessation in our telephone care group were higher than might be expected for either telephone counseling or pharmacologic therapy alone, and this finding reinforces the recommendations of the national guidelines that combined behavioral and pharmacologic treatments for tobacco use is optimal.

Telephone care resulted in larger increases in sustained abstinence (of 6 months or more) than in short-term (7-day) abstinence at 12 months. Proactive telephone counseling has been shown in prior studies to reduce relapse rates. The telephone care group in the present study also had more immediate access to services than participants in the standard care group (who needed to visit or contact their health care provider to initiate treatment). More immediate assistance in the telephone care group may have accelerated progress toward smoking cessation compared with the standard care group and contributed to the finding of a greater increase in sustained abstinence.

An important lesson from this study is that large differences in provision of services are needed to produce meaningful differences in smoking cessation rates. Many attempts to improve delivery of tobacco treatment result in modest increases in use of services with little or no measurable increase in cessation. This does not necessarily mean that smoking cessation treatments are not effective, but rather that the magnitude of the change in services delivery is often not sufficient to lead to measurable increases in cessation. These findings highlight the need for major structural changes in the delivery of tobacco treatment services such as those tested herein and proposed in the national action plan.

This study has several limitations. First, because there was no in-person contact between study staff and participants, it was not logistically feasible to perform biochemical validation of smoking status. Prior analyses suggest that underreporting of smoking in field trials, such as this one, is very low. This does not necessarily mean that smoking cessation treatments are not effective, but rather that the magnitude of the change in services delivery is often not sufficient to lead to measurable increases in cessation.

Another limitation is that we tested the intervention in a select population. Participants were predominantly male, elderly, and had multiple medical problems as well as extensive smoking histories with past unsuccessful quit attempts. The 4% abstinence rate at 6 months in the standard care group may be somewhat lower than expected among daily smokers in the general population. Past unsuccessful attempts to quit despite use of pharmacologic therapy and continued smoking despite diagnosis of smoking-related diseases may indicate that participants in this study had particularly substantial barriers to quitting. Of note, the use of pharmacologic therapy (without counseling) did not seem to offer substantial benefits in the standard care group. The relative lack of efficacy of the nicotine patch in patients with a history of cardiovascular disease has been noted previously. Given these issues, it is possible that the magnitude of the treatment effect of telephone care compared with standard care would be different in a more general population of smokers.

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REFERENCES