

# Comparative effectiveness trial of family-supported smoking cessation intervention versus standard telephone counseling for chronically ill veterans using proactive recruitment

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**Objectives:** Smoking cessation among patients with chronic medical illnesses substantially decreases morbidity and mortality. Chronically ill veteran smokers may benefit from interventions that assist them in harnessing social support from family and friends.

**Methods:** We proactively recruited veteran smokers who had cancer, cardiovascular disease, or other chronic illnesses (diabetes, chronic obstructive pulmonary disease, hypertension) and randomized them to either standard telephone counseling or family-supported telephone counseling focused on increasing support for smoking cessation from family and friends. Participants each received a letter from a Veterans Affairs physician encouraging them to quit smoking, a self-help cessation kit, five telephone counseling sessions, and nicotine replacement therapy, if not contraindicated. The main outcome was 7-day point prevalent abstinence at 5 months.

**Results:** We enrolled 471 participants with mean age of 59.2 (standard deviation [SD] = 7.9) years. 53.0% were white, 8.5% were female, and 55.4% were married/living as married. Overall, 42.9% had cardiovascular disease, 34.2% had cancer, and 22.9% had other chronic illnesses. At baseline, participants were moderately dependent on cigarettes as measured by the Heaviness of Smoking Index (mean = 2.8, SD = 1.6), expressed significant depressive symptoms as measured by the Center for Epidemiological Studies Depression scale (54.8% > 10), and reported high self-efficacy for quitting (mean = 5.7; SD = 1.5). At 5-months follow-up, we found no differences in smoking cessation by arm: 19.8% in the family-supported intervention and 22.0% in the standard arm. The following factors were associated with smoking cessation at 5 months: having cardiovascular disease or other diagnosis compared to cancer, lower nicotine dependence, older age, and higher self-efficacy.

**Conclusions:** This comparative effectiveness trial among chronically ill veterans did not find differences in smoking cessation by type of intervention. Future studies should expand upon our findings and consider tailoring proactive telephone-based interventions based on age and type of disease.

**Keywords:** smoking cessation, veterans, social support, counseling, proactive, family

## Introduction

Smoking cessation among patients with chronic medical illnesses, such as coronary heart disease, cancer, hypertension (HTN), chronic obstructive pulmonary disease (COPD), and diabetes, can substantially decrease morbidity and mortality. For example, patients who quit smoking after a cancer diagnosis decrease the number and severity

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of complications as well as risk for tumor progression and the development of a second primary cancer.<sup>1</sup> Among patients with coronary heart disease, a meta-analysis found a 36% reduction in mortality for those who quit smoking compared with those who continued to smoke.<sup>2</sup> Among patients who have been smokers and who experience a cardiac event, quitting reduces the risk of a recurrent event by 50%.<sup>3,4</sup> In the first year of smoking cessation, patients with COPD can expect improvements in their forced expiratory volume as well as cough and sputum production.<sup>5-7</sup> These improvements continue over time after cessation.<sup>8</sup> Among diabetic patients, the risk for all-cause mortality declines in proportion to the length of time since smoking cessation.<sup>9</sup> Smoking is hazardous for hypertensive patients as well; it can significantly increase the risk of secondary cardiovascular complications.<sup>10</sup> When a hypertensive patient stops smoking, these risks diminish relatively quickly and continue to decrease as the length of cessation increases.<sup>5</sup> Moreover, smoking cessation also can improve quality of life for patients with chronic medical illnesses.<sup>1</sup> Despite these benefits, many patients with chronic medical illnesses continue to smoke.<sup>11</sup>

Telephone counseling is a cost-effective way to deliver a standardized, high-quality smoking cessation intervention to individuals who are geographically dispersed; it offers a convenient, flexible, private way to receive repeated tailored counseling contacts.<sup>12</sup> Effective telephone counseling interventions are those based on a skills-training approach derived from social learning theory and other cognitive-behavioral models of addiction.<sup>13</sup> In addition to skills training, intra- and extratreatment social support are essential elements of effective cessation counseling.<sup>14</sup> Other important elements of effective telephone counseling include encouraging quit attempts, conveying belief in the smoker's ability to quit, and having smokers practice requesting support from others. As few as one or two brief calls can achieve benefits, and effectiveness of telephone counseling increases with repeat contacts.<sup>15</sup> Three or more calls increases the odds of quitting compared with minimal intervention (eg, self-help, brief advice, pharmacotherapy only). Success has been achieved with scheduling calls to coincide with the peak time of relapse in a fixed schedule,<sup>16</sup> and with a series of brief proactive telephone counseling calls at times negotiated to suit the caller.<sup>17</sup> For veterans, the option of receiving smoking cessation services over the telephone increases the use of behavioral counseling and pharmacologic therapy because many patients live hundreds of miles from Veterans Affairs Medical Centers (VAMC).<sup>18</sup> Thus, telephone counseling has the potential to increase cessation among patients with chronic illness.

Smoking behavior and quitting are strongly influenced by the smoker's social network. Perceptions of support for quitting from spouse, family and friends are related to quit attempts and cessation. Positive support, such as expressing pleasure at the smoker's efforts to quit, has been found to predict cessation.<sup>19-21</sup> The absence of negative support, such as nagging or complaining about smoking, has also been found to be related to quitting.<sup>22</sup> Review of intervention studies suggests that helping individual smokers understand what type of support might be most helpful and teaching smokers how to ask for that type of support from both family and close friends are important elements of smoking cessation interventions.<sup>23</sup> An essential next step is to conduct a comparative effectiveness trial to test whether the addition of a family-support component (to assist veterans in harnessing social support from their family and close friends) to standard telephone counseling improves smoking cessation among chronically ill smokers, compared with standard telephone counseling.

## Methods

### Study participants

A total of 471 patients were recruited from the VAMC in Durham, North Carolina and followed up for 12 months. The target sample size ( $n = 470$ ) was designed to provide 80% power to detect a 14% difference in 7-day point prevalence cessation rates at 5 months post randomization between arms (30% standard counseling vs 44% family-supported intervention). To be eligible for this study, patients met all these criteria: enrolled in Durham VAMC and receiving treatment for chronic illnesses (ie, cancer, cardiovascular disease, HTN, diabetes, COPD), currently smoking and planning to quit smoking in the next 30 days, and ability to identify a support person (defined as a relative or a friend that the subject felt would support them the most if they decided to quit smoking). Patients who meet any one of these exclusion criteria were excluded: active diagnosis of psychosis documented in the medical record, no access to a telephone, refusal to provide informed consent, and severely impaired hearing or speech that would make them unable to respond to telephone counseling.

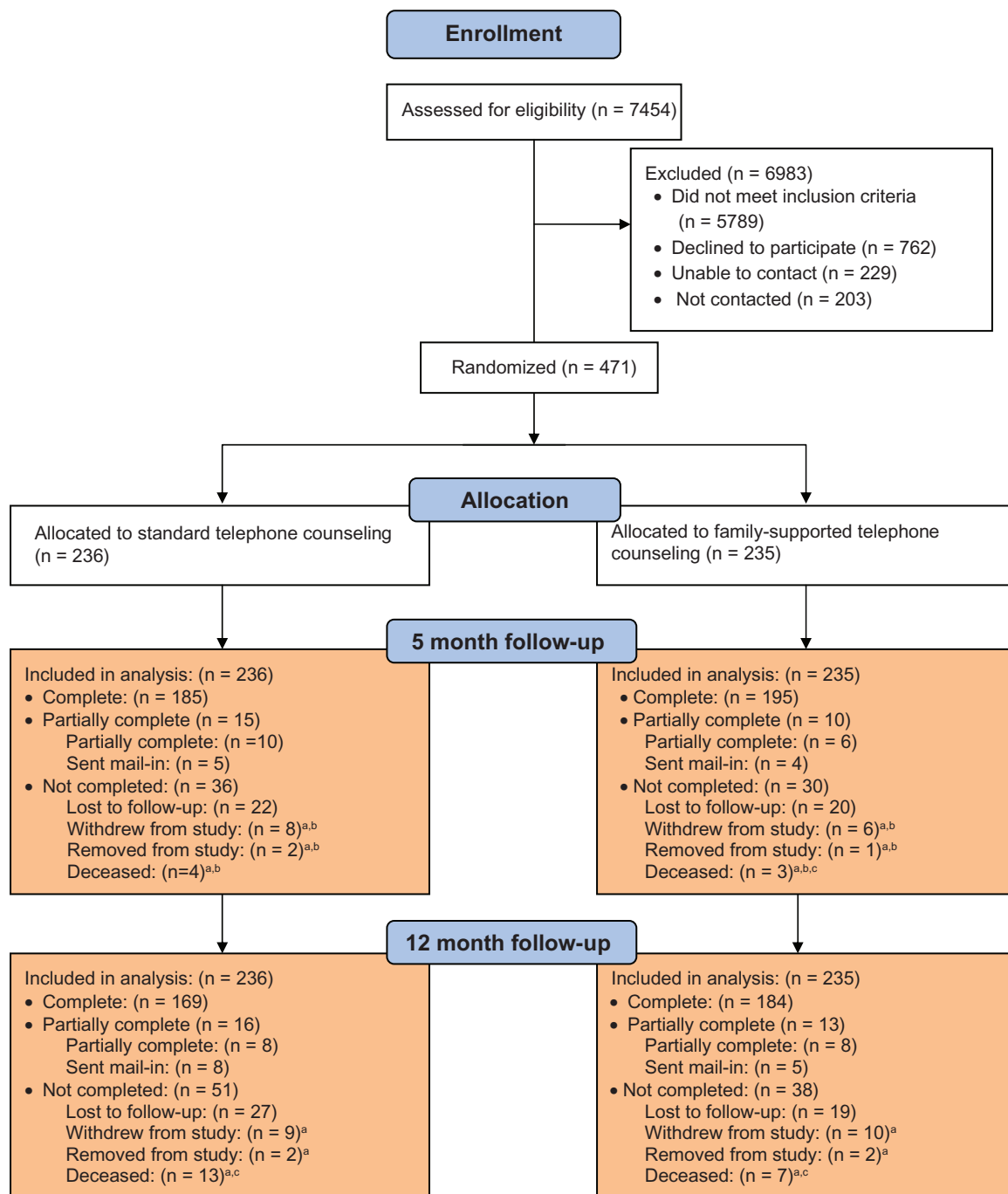
### Procedures

Patients treated for chronic diseases including cancer, cardiovascular disease, diabetes, COPD, and HTN were identified from Durham VAMC computerized medical records. We screened medical records for smoking, and mailed smokers an introductory letter from the Chief of

Cardiology, Chief of Oncology, or a primary care physician (the Principal Investigator (PI)) informing them of the study and encouraging smoking cessation. The letter included a toll free number patients could call to opt out of the study. Those who did not opt out were called to obtain informed consent and assess eligibility. Eligibility criteria included smoking at least seven cigarettes in the previous 7 days,

wanting to quit in the next 30 days, and the ability to identify a support person.

All participants completed baseline surveys which collected demographics, smoking history and characteristics (eg, nicotine dependence), and key psychosocial variables (eg, social support). We conducted recruitment from February 2008 to February 2010. Figure 1 displays study recruitment



**Figure 1** Study recruitment.

**Notes:** <sup>a</sup>Cumulative number of participants; <sup>b</sup>includes participants who terminated study procedures during the intervention window or first follow-up window; <sup>c</sup>deceased participants are removed from analyses at the follow-up assessments.

in detail. The Durham VAMC Institutional Review Board approved the study.

### Randomization

Smokers who enrolled in the study were randomly assigned to receive either standard telephone counseling or family-support focused telephone counseling that would assist the veterans to harness social support from their family and close friends. We used blocked randomization, stratified by sex and disease type (cancer, cardiovascular disease, and other). Participants randomized to the standard telephone counseling control arm received a letter from a VA physician encouraging smoking cessation, nicotine replacement therapy (NRT), if not contraindicated, a self-help cessation kit, and five telephone-counseling calls. Participants randomized to the family-supported intervention arm received all components of the standard telephone-counseling arm plus an enhanced family-supported intervention that included a support skills booklet and additional telephone counseling content focusing on social support skills.

The main distinction between the two arms of this comparative effectiveness study was the family-supported intervention that aimed to help increase positive interactions between the participant and their designated support person, to facilitate smoking cessation. Specifically, the family-supported intervention was designed to assist the patient to (1) identify how people in their social environment influenced their desire and ability to quit smoking; (2) learn how to enlist and harness social support to reduce distress and facilitate progress towards cessation; and (3) plan for problem-focused steps associated with successful cessation.

### Intervention description

We conducted the intervention from February 2008 to June 2010. All participants received up to five telephone counseling sessions designed to enhance motivation and develop skills needed to quit smoking. The counseling protocol was informed by Motivational Interviewing techniques, the Transtheoretical Model, and Social Cognitive Theory.<sup>24–26</sup> Counseling sessions were scheduled every 3 to 4 weeks and were approximately 20 minutes in length. Each session followed a standard cognitive-behavioral therapy format including checking in at the beginning of the session, reviewing the agenda and getting patient input, and goal setting. At the end of each session, participants worked with the counselor to review progress towards goals and to set new goals to work for the next session.

Each counseling session included standard content related to smoking cessation (eg, getting ready for your quit date, how to handle slips) tailored to each participants' needs. Participants randomized to family support-based intervention also received an 8-page disease-specific family support booklet describing activities focused on (1) identifying and enlisting positive support for quitting, (2) identifying and minimizing negative support for quitting, and (3) plans for enlisting support for potential smoking cessation slips. During each session, counselors focused on one activity. At the end of each session, participants worked with counselors to review progress towards goals and to set new work goals for the next session. Participants in the family-supported counseling group were encouraged to set at least one additional support-related goal, in addition to other goals.

All participants also received a quit kit that included a letter congratulating the participant for his/her decision to try to quit smoking, a guide to the telephone counseling sessions, the American Lung Association's "Freedom From Smoking" booklet,<sup>27</sup> a list of disease-specific resources, and an envelope filled with items (such as straws, sugar-free candy, and rubber bands) they could use to occupy their hands when they felt the urge to pick up a cigarette.

At the first telephone counseling session (in both standard and family-support arms), counselors discussed types and side effects of each type of NRT available. For interested participants, counselors tailored the NRT amount and delivery type based on number of cigarettes smoked per day, using an established protocol.<sup>28</sup> The PI for the study wrote NRT prescriptions, and NRT was provided by the Durham VAMC pharmacy. Patients who reported contraindications at baseline (ie, high blood pressure not controlled by medication or taking prescription medication for depression) had to obtain VA physician authorization prior to receiving NRT.

### Intervention integrity

We developed written counseling protocols for both treatment conditions. Masters-level counselors attended 30-hour trainings that included didactic instruction, discussion of smoking cessation strategies, and role playing counseling sessions. Counseling sessions were audio recorded. The investigators listened to the first 10 sessions for each of the counselors, and provided individual feedback to the counselors; for the remaining sessions, investigators listened to a 15% sample of the audio recordings, and again provided individual feedback to counselors. Throughout the study, investigators met with counselors on a weekly basis to discuss cases and practice skills.

## Outcome measures

The primary outcome measure was self-reported 7-day point prevalent cessation at 5 months post randomization. At the 5-month follow-up surveys, patients were asked whether they have smoked a cigarette or taken even a puff, in the preceding 7 days. Postcards were mailed to subjects not completing telephone surveys to ask about smoking status. Nonrespondents to follow-up interviews and postcards, excluding deaths, were treated as smokers in analyses. Secondary outcomes included 7-day point prevalent smoking cessation at 12 months post randomization.

Although our main outcome measure was self-reported abstinence, we attempted to verify self-reported abstinence by mailing saliva-sampling kits to test for cotinine (a biomarker of nicotine) to those participants who reported not smoking. We asked participants to inform us if they were using NRT at the time that they provided saliva samples. Return rates (via mail) for saliva samples were low (50.5%) at both the 5- and 12-month follow-up surveys.

## Other measures used in main analysis

### Demographics

Race was dichotomized as white and other. Age, sex, marital status, highest level of education, and current employment status were also recorded.

### Disease classification

Primary patient diagnosis was categorized as heart disease, cancer or other (ie, HTN, COPD, diabetes). If a patient had more than one disease, priority ranking was cancer, then heart disease, and then other conditions.

### Smoking history

Serious quit attempts since disease diagnosis were categorized as at least one or none. Nicotine dependence was assessed using the Heaviness of Smoking Index, a two item measure of number of cigarettes smoked per day, and time to first cigarette (range: 0–6).<sup>29</sup> During baseline surveys, patients were asked to identify one relative or friend they felt would be most supportive of their decision to quit smoking. Patients were asked to classify the smoking status of the named support person according to the following categories: (1) currently smokes, trying to quit; (2) smokes, not planning to quit; (3) ex-smoker; and (4) never smoked. Support person smoking status was dichotomized as current smoker versus not currently smoking. Frequency of communication with the named support person was categorized as daily, weekly, monthly, live with support person, and other, and then

dichotomized as lives with/has daily contact with support person versus does not live with/no daily contact with support person.

### Depression

Depression symptoms were measured using the 10-item Center for Epidemiological Studies Depression scale, which is a general measure of depressive symptoms that has been used extensively in epidemiologic studies.<sup>30</sup> A score of 10 or higher indicated clinically significant depressive symptoms.

### Self-rated health

Patients were asked to rate their current health as excellent, very good, good, fair, or poor, and this was dichotomized as fair/poor and excellent/very good/good.

### Support for quitting

We measured expected smoking-related support at baseline via the Partner Interaction Questionnaire (PIQ).<sup>22</sup> The PIQ is a validated measure of positive and negative support with sound psychometric properties (positive support Cronbach's alpha ( $\alpha$ ) = 0.89; negative support  $\alpha$  = 0.82).<sup>22</sup> The PIQ lists 10 positive behaviors (eg, "compliment you on not smoking") and 10 negative behaviors (eg, "refuse to clean up your cigarette butts") that smokers may experience when trying to quit. For each item, patients were asked to rate how often they would expect the named support person to exhibit each behavior on a scale from 0 = almost never to 4 = very often. Following previous research with the PIQ,<sup>31,32</sup> we used the ratio of positive to negative support.<sup>22</sup>

### Worry

Patients were asked how concerned they were about cigarette smoking making their disease worse. The response set was not at all, a little, somewhat, and a lot, and this was dichotomized as a lot or not at all/a little/somewhat.

### Desire to quit

Patients were asked to rate how much they wanted to quit smoking in the next 6 months on a 7-point scale where 1 meant not at all and 7 meant very much.

### Self-efficacy for quitting

Patients were asked to rate their confidence in quitting smoking completely in the next 6 months on a scale from 1 meaning not at all confident to 7 meaning completely confident.



## Statistical analysis

Differences between intervention arms in baseline variables were tested by Pearson chi-squared statistics, *t*-tests, and Wilcoxon rank-sum statistics, depending upon the distribution of the data. The primary analysis compared cessation rates at 5 months post randomization between intervention arms, using a multivariable logistic regression model based on intention-to-treat principles. The model included intervention arm and the stratification variables (disease type, sex) used in randomization. We conducted a sensitivity analysis including baseline variables that differed between randomization arms. The difference in cessation rates at 12 months post randomization (secondary outcome) was analyzed using a similar approach. Formal tests of potential subgroup effects of baseline variables at 5 and 12 months were conducted using logistic regression models that included intervention arm, the subgroup variable of interest, and an intervention arm by subgroup interaction term. Potential associations between baseline variables and the 5-month cessation outcome were individually examined in a series of logistic regression models that included the baseline variable and intervention arm. To adjust for potential confounding, those variables with a moderate association with the 5-month outcome ( $P$ -value  $< 0.20$ ) were then included in a multivariable logistic regression model that also included intervention arm and the stratification variables used in randomization. The same multivariable model was fit for both the 5- and 12-month cessation outcomes. The linearity in the logit assumption for continuous variables in models was assessed using the Box–Tidwell method.<sup>33</sup> The c-statistic was used to summarize model discrimination. Analyses were conducted using SAS 9.2 (SAS Institute, Cary, NC).

## Results

### Study response and participant characteristics

Of the 7454 patients assessed for eligibility, 5789 did not meet inclusion criteria, 229 were unable to be contacted, 762 declined to participate, and 203 were not contacted because we had reached our target sample size (see Figure 1). Thirty-eight percent of contacted, eligible patients were randomized into the study ( $n = 471$ ). Overall, intervention participation was excellent and comparable in both arms. Follow-up rates were 86.0% and 81.1% at 5 months and 12 months, respectively. Loss to follow up was similar in both arms. For the 5-month follow up, we examined whether there were differential dropout rates and found nonmarried subjects were

less likely ( $P = 0.05$ ) to complete the follow-up interview compared with married subjects.

The overall mean age of participants was 59.2 years ( $SD = 7.9$ ); 91.5% were male; and 67.7% had attained some college education or more. With regards to race, 53.0% were white and 47.0% were in the “other” race category. Of the 221 subjects classified as nonwhite/other, 89.1% were African American (41.9% of total), 8.6% were Native American, and 2.2% were of other race. Nearly half of the subjects (46.9%) named a spouse or significant other as their support person. Participants were moderately dependent on cigarettes (Heaviness of Smoking Index mean = 2.8,  $SD = 1.6$ ). Overall, 42.9% of participants had heart disease, 34.2% had cancer, and 22.9% had other chronic diseases. The majority of participants (59.3%) rated their overall health as fair or poor. Overall, 54.8% expressed significant depressive symptoms as measured by the Center for Epidemiological Studies Depression scale, and 53.8% reported they worried a lot about the impact of their smoking on their disease. Participants reported high self-efficacy for smoking cessation (mean = 5.7;  $SD = 1.5$ ). More participants in the family-support arm were married or living as married compared with the standard telephone counseling arm ( $P < 0.05$ ) (Table 1).

### Comparative effectiveness

Results of primary and secondary analyses indicated no significant differences in smoking cessation rates between standard and family-supported interventions at the 5- and 12-month follow-up interviews (Table 2). Rates of smoking cessation were high across both arms. Smoking cessation rates were 19.8% versus 22.0% at 5 months, and 22.4% versus 22.4% at 12 months, for the family support and standard telephone counseling arms, respectively. Similar results were found in the sensitivity analyses that adjusted for marital status, which was the baseline variable that was different between randomization arms.

### Counseling calls and smoking cessation

The mean number of telephone sessions completed was 3.5 ( $SD = 1.8$ ) and half of the participants completed all five counseling calls. Counseling completion rates were similar between the randomization arms (Table 3). We examined the association between intervention “dose” (number of telephone counseling sessions completed) and cessation at 5 months. Cessation rates were higher (30.3%) for those completing five calls compared with participants completing no calls (12.5%), and those completing one to four calls (10.7%). At 12 months, cessation rates remained higher

**Table 1** Baseline characteristics of chronically ill smokers randomized to standard telephone counseling versus family-supported telephone counseling

	<b>Overall N = 471 n (%)</b>	<b>Family-supported telephone counseling N = 235 n (%)</b>	<b>Standard telephone counseling N = 236 n (%)</b>	<b>P-value<sup>c</sup></b>
Age, mean (SD)	59.2 (7.9)	59.1 (8.0)	59.2 (7.7)	0.90
Sex <sup>a</sup>				0.74
Male	431 (91.5)	214 (91.1)	217 (91.9)	
Female	40 (8.5)	21 (8.9)	19 (8.1)	
Race				0.46
White	249 (53.0)	129 (54.9)	120 (51.1)	
Other	221 (47.0)	106 (45.1)	115 (48.9)	
Married/living as married				0.02
Yes	261 (55.4)	143 (60.9)	118 (50.0)	
No	210 (44.6)	92 (39.1)	118 (50.0)	
Education				0.36
Less than high school graduate	57 (12.1)	31 (13.2)	26 (11.1)	
High school graduate	95 (20.2)	47 (20.0)	48 (20.4)	
Trade school or some college	255 (54.3)	120 (51.1)	135 (57.4)	
College graduate	63 (13.4)	37 (15.7)	26 (11.1)	
Employment status				0.10
Full time	38 (8.1)	14 (6.0)	24 (10.2)	
Part time	59 (12.6)	35 (14.9)	24 (10.2)	
Not employed	373 (79.4)	186 (79.1)	187 (79.6)	
Disease classification <sup>b</sup>				0.91
Cancer	161 (34.2)	78 (33.2)	83 (35.2)	
Cardiovascular	202 (42.9)	102 (43.4)	100 (42.4)	
Other <sup>b</sup>	108 (22.9)	55 (23.4)	53 (22.5)	
CESD score $\geq 10$				0.52
Yes	258 (54.8)	125 (53.2)	133 (56.4)	
No	213 (45.2)	110 (46.8)	103 (43.6)	
Self-rated health				0.85
Fair/Poor	278 (59.3)	137 (58.8)	141 (59.7)	
Excellent/very good/good	191 (40.7)	96 (41.2)	95 (40.3)	
Worry smoking will make disease worse				1.00
A lot	253 (53.8)	127 (54.0)	126 (53.6)	
<A lot	217 (46.2)	108 (46.0)	109 (46.4)	
HSI, mean (SD)	2.8 (1.6)	2.8 (1.7)	2.8 (1.6)	0.89
Desire to quit smoking				1.00
Value of 7	388 (82.4)	194 (82.6)	194 (82.2)	
<7	83 (17.6)	41 (17.4)	42 (17.8)	
Global self-efficacy for quitting, mean (SD)	5.7 (1.5)	5.8 (1.6)	5.7 (1.5)	0.86
At least one serious quit attempt since disease diagnosis				0.83
Yes	342 (75.0)	169 (74.4)	173 (75.5)	
No	114 (25.0)	58 (25.6)	56 (24.5)	
Live with a smoker				0.18
Yes	164 (34.8)	89 (37.9)	75 (31.8)	
No	307 (65.2)	146 (62.1)	161 (68.2)	
Support person is a spouse or significant other				0.12
Yes	221 (46.9)	119 (50.6)	102 (43.2)	
No	250 (53.1)	116 (49.4)	134 (56.8)	
Support person is a current smoker				0.06
Yes	130 (27.8)	55 (23.7)	75 (31.8)	
No	338 (72.2)	177 (76.3)	161 (68.2)	

(Continued)

**Table 1** (Continued)

	Overall N = 471 n (%)	Family-supported telephone counseling N = 235 n (%)	Standard telephone counseling N = 236 n (%)	P-value
Lives with or has daily contact with support person				0.90
Yes	399 (84.7)	200 (85.1)	199 (84.3)	
No	72 (15.3)	35 (14.9)	37 (15.7)	
PIQ ratio, median (1st quartile, 3rd quartile)	1.2 (1.0, 1.7)	1.2 (1.1, 1.7)	1.2 (1.0, 1.7)	0.82

**Notes:** <sup>a</sup>One female subject was randomized to the male strata due to incorrect documentation of sex in the medical record; <sup>b</sup>disease type: Other refers to diabetes, HTN or COPD. Disease stratification variable differs slightly from actual disease due to re-classification post randomization. <sup>c</sup>Characteristics missing at baseline were analyzed using case-wise deletion.

**Abbreviations:** CESD, Center for Epidemiological Studies Depression scale; HSI, Heaviness of Smoking index; HTN, hypertension; COPD, chronic obstructive pulmonary disease; PIQ, Partner Interaction Questionnaire.

(28.9%) for those completing five calls compared with participants completing no calls (6.5%), and those completing one to four calls (17.9%).

## Request of nicotine replacement therapy and smoking cessation

We examined requests for NRT by study arm and found no difference (74.9% in the family-supported arm and 78.8% in the standard counseling arm). Those participants who requested NRT had similar smoking cessation rates at 5 months compared with those not requesting NRT (21.8% vs 17.9%, respectively).

## Subgroup analyses and association of baseline factors with smoking cessation

Examination of subgroup effects of baseline variables at 5 and 12 months found no differential cessation rates among baseline subgroups. The following baseline factors were associated with smoking cessation at the 5-month follow up: older age, cardiovascular disease or other diagnosis (HTN, COPD, and diabetes) compared to cancer, lower nicotine dependence, and higher self-efficacy for quitting (Table 4).

The following factors were associated with smoking cessation at the 12-month follow up: older age, and lower nicotine dependence. The c-statistics for the 5- and 12-month follow-up models were 0.74 and 0.68, respectively.

## Discussion

This is the first comparative effectiveness trial comparing a family-supported smoking cessation intervention with a standard telephone counseling intervention for chronically ill veteran smokers. Although we did not find differences in smoking cessation by study arm, overall cessation rate in both arms (>20%) were high compared with rates achieved in most self-directed interventions utilizing proactive recruitment,<sup>34</sup> and were similar to results from a recently published trial utilizing a national telephone “quitline” in England.<sup>35</sup>

We expected a larger differential effect in the family-supported intervention compared with standard telephone counseling but we recognize that the support intervention may not have been strong enough. The support component of our intervention focused on helping smokers elicit helpful support, and developing skills for asking for more positive or less negative support. It is possible that the support received from the support person may not have been intense

**Table 2** Comparative effectiveness of standard counseling intervention versus family-supported intervention with family support at 5-months and 12-months follow-up surveys

	Overall: N = 471 n (%)	Family-supported telephone counseling N = 235 n (%)	Standard telephone counseling N = 236 n (%)	Odds ratio <sup>b</sup> (95% confidence interval)
<b>Smoking status at 5 months</b>				
Abstinent	97 (20.9)	46 (19.8)	51 (22.0)	0.87 (0.55, 1.36)
Smoker <sup>a</sup>	367 (79.1)	186 (80.2)	181 (78.0)	1.00
<b>Smoking status at 12 months</b>				
Abstinent	101 (22.4)	51 (22.4)	50 (22.4)	1.00 (0.64, 1.56)
Smoker <sup>a</sup>	350 (77.6)	177 (77.6)	173 (77.6)	1.00

**Notes:** <sup>a</sup>Surviving subjects with missing data either at the 5-month assessment (n = 59) or at the 12-month assessment (n = 69) are considered to be smokers at the respective assessment. Deceased subjects, n = 7 at the 5-month assessment and n = 20 at the 12-month assessment, are removed from the respective analysis; <sup>b</sup>odds ratios from multivariable logistic regression models adjusting for stratification variables of disease type and sex.



**Table 3** Intervention components with telephone counseling and nicotine replacement therapy uptake

Standard intervention components	Family-supported intervention components
<ul style="list-style-type: none"> <li>✓ Letter from physician advising participants to quit smoking</li> <li>✓ "Freedom from Smoking" self-help materials</li> <li>✓ Nicotine replacement therapy 78.8% requested medication</li> <li>✓ Five sessions of standard telephone counseling</li> </ul>	<ul style="list-style-type: none"> <li>✓ Letter from physician advising participants to quit smoking</li> <li>✓ "Freedom from Smoking" self-help materials</li> <li>✓ Nicotine replacement therapy 74.9% requested medication</li> <li>✓ Five sessions of family-supported telephone counseling included all aspects of standard counseling plus:</li> </ul>
<b>Session 1</b> <ul style="list-style-type: none"> <li>▪ Explore motivation to quit.</li> <li>▪ Review stage appropriate information in <i>Freedom from Smoking</i> self-help guide.</li> <li>▪ Set quit date if appropriate.</li> <li>▪ Discuss NRT options for those setting a quit date. Completion rate: 90.7%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Review support skills materials and encourage patient to share support skills materials.</li> <li>▪ Role play on asking someone to help with quitting. Completion rate: 88.1%</li> </ul>
<b>Session 2</b> <ul style="list-style-type: none"> <li>▪ Discuss ways to manage cravings and difficult situations. Completion rate: 82.2%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Discuss the positive support.</li> <li>▪ Rehearse how to get positive support-write down statements that feel positive to patient. Completion rate: 80.4%</li> </ul>
<b>Session 3</b> <ul style="list-style-type: none"> <li>▪ Discuss how to handle slips. Completion rate: 71.2%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Focus on how to respond to and decrease negative support. Completion rate: 71.9%</li> </ul>
<b>Session 4</b> <ul style="list-style-type: none"> <li>▪ Discuss rewards. Completion rate: 62.7%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Focus on relapse prevention and how the support person can be helpful if the patient relapses. Completion rate: 60.4%</li> </ul>
<b>Session 5</b> <ul style="list-style-type: none"> <li>▪ Discuss ways that positive thinking can help with quitting or staying quit.</li> <li>▪ Develop a postcounseling action plan. Completion rate: 51.3%</li> </ul>	<ul style="list-style-type: none"> <li>▪ Review support skills discussed in previous counseling sessions.</li> <li>▪ Postcounseling action plan includes one goal related to support. Completion rate: 50.2%</li> </ul>

enough to influence quitting, over and above that of the telephone counseling.<sup>36</sup> One way to increase the intensity of the support intervention is to intervene with the support person directly. Studies that have intervened directly with the support person have yielded mixed results.<sup>19,37–39</sup> It is also possible that the smokers received adequate support from the intervention and did not require more from their support person. As others have found, support from the counselor may have adequately met the smokers' needs.<sup>40</sup> Similar to other support-based interventions studies, we were unable to isolate the effects of the support components from the effect of the total intervention.<sup>40</sup> Because the ability of a smoker to quit is clearly influenced by their social network, more research is needed to determine the optimal methods to assist smokers in harnessing this potential powerful element to aid the quitting process. Future research would benefit from research designs that would allow for the isolation of the effects of the support-based components of interventions.

Consistent with what others have found with telephone counseling,<sup>18</sup> participants in both arms who completed all five calls were more likely to quit smoking than those completing

no calls (OR = 3.0). The majority of participants requested NRT (76.9%) and those who requested NRT had similar rates of smoking cessation compared with those who did not request NRT. Our results show that chronically ill veterans who were more dependent on nicotine were less likely to quit than those who were less dependent. These results are consistent with other cessation studies that have identified nicotine dependence as a strong predictor of continued smoking.<sup>29,41–45</sup> Future interventions with chronically ill veterans may benefit from possible adjuncts that could be incorporated into a more intensive intervention including additional counseling sessions, in-person counseling, group counseling, non-nicotine pharmacological treatment, and scheduled gradual reduction of cigarettes smoked per day.

Other studies have found the age of the smoker to be an important predictor of smoking cessation in proactive telephone counseling interventions. In our study, the mean age was 59 years, and older age was associated with smoking cessation. In prior studies, older age defined as >50 years<sup>46,47</sup> and >55 years,<sup>48</sup> was associated with higher quit rates than younger smokers. Older smokers may be more responsive

**Table 4** Results from multivariable logistic regression models examining the effect of baseline patient and clinical characteristics on 5- and 12-month follow up smoking cessation rates<sup>a</sup>

	5-month follow up		12-month follow up	
	Adjusted odds ratio (95% confidence interval)	P-value	Adjusted odds ratio (95% confidence interval)	P-value
Family-supported telephone counseling arm	0.79 (0.49, 1.27)	0.33	0.99 (0.62, 1.58)	0.96
Age	1.04 (1.01, 1.08)	0.03	1.05 (1.02, 1.09)	0.002
Male sex	1.23 (0.46, 3.29)	0.68	1.66 (0.59, 4.67)	0.33
White race	0.78 (0.47, 1.31)	0.35	0.80 (0.48, 1.32)	0.38
Disease type		0.03 <sup>b</sup>		0.08 <sup>b</sup>
Cancer	1.00		1.00	
Cardiovascular	1.98 (1.11, 3.51)	0.02	1.45 (0.83, 2.52)	
Other <sup>c</sup>	2.24 (1.11, 4.51)	0.02	2.13 (1.09, 4.16)	
CESD score $\geq 10$	0.66 (0.41, 1.08)	0.10	0.90 (0.56, 1.45)	0.66
HSI	0.78 (0.66, 0.91)	0.002	0.75 (0.64, 0.88)	<0.001
Global self-efficacy for quitting	1.59 (1.27, 1.98)	<0.001	1.15 (0.97, 1.37)	0.11

**Notes:** <sup>a</sup>Variables considered, but not meeting model selection criteria included: married, education, employment status, living with a smoker, desire to quit, PIQ ratio, and having at least one serious quit attempt since disease diagnosis. There were 9 and 22 participants in the 5- and 12-month models, respectively, that were not included due to missing data (either missing outcome data due to death or missing on a factor included in the model); <sup>b</sup>Wald chi-square, degrees of freedom = 2, assessing overall association of disease type with smoking cessation; <sup>c</sup>other disease includes diabetes, HTN, and COPD.

**Abbreviations:** CESD, Center for Epidemiological Studies Depression scale; HSI, Heaviness of Smoking index; PIQ, Partner Interaction Questionnaire; HTN, hypertension; COPD, chronic obstructive pulmonary disease.

to telephone counseling because they may have elevated concerns about the effects of smoking on their health as they age, and have more frequent medical visits which offer opportunities for smoking cessation prompts.<sup>46</sup>

We also found self-efficacy was significantly associated with abstinence at 5 months, which is consistent with previous findings identifying self-efficacy as a strong predictor of abstinence and relapse.<sup>49,50</sup> Recent research has suggested that self-efficacy may be both a causal factor in quitting, as suggested by Social Learning Theory,<sup>51</sup> as well as a reflection of recent behavior change.<sup>52</sup> This sample of chronically ill veterans were experienced smokers with the majority (75.0%) reporting at least one previous quit attempt since their disease diagnosis. These findings suggest that a stepped-care approach may be effective; as such, smokers with low self-efficacy at the beginning of a quit attempt would receive more intensive intervention than those with high self-efficacy.

We found lower cessation rates for patients with cancer compared with patients with heart disease or other chronic conditions. Whereas patients with heart disease and other chronic illnesses may be receiving advice from their provider that quitting smoking is the most important step they can take to improve their health, patients with cancer may not receive this message.<sup>53</sup> Patients with cancer may have had more comorbidities. Additionally, the cancer experience may serve as a significant life stressor that may undermine efforts to quit smoking. In a previous smoking cessation intervention

for patients with head and neck cancer, a stepped-care approach was recommended that addressed the 30%–40% of patients who were unable to quit immediately after their diagnosis.<sup>54</sup> This stepped care approach might include additional pharmacotherapy, along with advice to stop smoking delivered repeatedly by the Primary care physician and members of the cancer treatment team.

There are some limitations to consider in evaluating this study. First, we conducted this trial among veterans with chronic physical illness at one site and our findings may not generalize to other populations of smokers. Second, although we found high participation rates with telephone counseling, we were unable to determine the reasons behind subjects not completing their telephone sessions. Third, we were unable to measure the additional burden of mental health comorbidities in this population. Depression, posttraumatic stress, and other mental health issues have been significantly associated with smoking rates and chronic illness. Finally, although we attempted biochemical confirmation of smoking abstinence for all self-reported quitters, return rates for saliva kits were less than optimal in both arms.

An additional limitation of this research is that we measured expected positive and negative support at baseline rather than actual support at baseline. Thus, we are unable to determine whether there was no added benefit from the family supported intervention because it failed to produce more support, or because increased support was produced but did not produce increased quitting. Generally, high posi-

tive support is considered optimal for quitting, while high negative support has been identified as a barrier to quitting.<sup>22</sup> At baseline, this sample of chronically ill veterans expected that their designated support person would provide relatively high levels of both positive and negative support for quitting. The majority of participants in the sample were experienced quitters, with 75% having made at least one attempt since diagnosis. Thus, expectations for both positive and negative support were likely influenced by experiences during previous quit attempts.

## Conclusion

Proactive telephone counseling for chronically ill veterans is feasible. However, telephone counseling focusing on family support was no more effective for smoking cessation than standard telephone counseling. Future studies should expand upon our findings and consider tailoring proactive telephone-based interventions based on age and type of disease.

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## Disclaimer

The views expressed in this manuscript are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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