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Preventive Medicine 40 (2005) 306–313

Preventive Medicine

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Does extended proactive telephone support increase smoking cessation among low-income women using nicotine patches?

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Available online 25 July 2004

Abstract

Background. It is unclear whether proactive telephone support enhances smoking cessation beyond the provision of nicotine replacement therapy alone.

Methods. We randomly assigned 330 low-income women smokers to receive either free nicotine patches (control condition) or free nicotine patches with up to 16 weeks of proactive telephone support (experimental condition). All participants were assessed by telephone at baseline and at 2 weeks, 3 months, and 6 months post-baseline to determine smoking status.

Results. Results revealed a significant effect for the telephone support at 3 months, with 43% of experimental versus 26% of control condition women reporting 30-day point prevalent abstinence ($P = 0.002$). The difference was no longer significant at 6 months. A metaanalysis conducted with five randomized studies revealed a slight but non-significant long-term benefit of proactive telephone support when added to the provision of free nicotine patches for smoking cessation.

Conclusions. This is the second study to demonstrate a short-term effect for proactive telephone support added to free nicotine replacement therapy; however, neither the current study, nor the metaanalysis including the four other published trials, confirmed a longer-term benefit.

Keywords: Smoking cessation; Nicotine replacement; Telephone support; Low-income women

Introduction

The provision of proactive support and problem-solving assistance delivered by telephone appears to be an efficacious intervention for cigarette smoking. In a metaanalysis by Lichtenstein et al. [1], proactive telephone counseling increased 3- to 8-month smoking abstinence rates by 30% above control conditions. Similarly, in a series of metaanalyses by Stead and Lancaster [2] for the Cochran Review, the authors found a modest effect for proactive telephone counseling at 6 months when it was the main component of an intervention. When proactive telephone support was combined with face-to-face counseling or pharmacotherapy, its contributions to abstinence were less robust.

To date, four randomized controlled trials have examined the impact of proactive telephone support as an adjunct to nicotine replacement therapy (NRT) [3–6]. The first three studies included a face-to-face physician intervention in both arms of the experimental design and found no 3- or 6-month effect for up to four proactive telephone counseling contacts. In contrast, Solomon et al. [6] had no face-to-face contact with participants, dispensed nicotine patches through the mail, and delivered a mean of seven support calls over 3 months. At a 3-month follow-up, they observed a significant effect for the proactive telephone support ($P =$

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doi:10.1016/j.ypmed.2004.06.005

0.03); however, the difference between conditions was lost by the 6-month follow-up. Relapse rates between 3 and 6 months were nearly twice as great in the experimental versus comparison condition, leading the authors to speculate that a longer period of availability to telephone support might extend abstinence.

The current study was designed to replicate the latter trial, but includes the provision of proactive telephone support for up to 12 calls over 4 months. This telephone contact schedule is more intensive than that used by any telephone-based smoking cessation trial to date and was designed to provide support up to 6 weeks past the point when access to free nicotine patches would end. The primary objective was to determine if this longer telephone support option, when added to the provision of free nicotine patches, would significantly enhance abstinence at 6 months over the provision of nicotine patches alone.

Additionally, we conducted a metaanalysis, incorporating the 6-month outcome data from the current study, to determine the combined effect of existing trials examining the benefit of proactive telephone support added to free NRT. This metaanalysis helps to place the current study findings in a broader context and strengthens the interpretation of the results.

Methods

Participants

To be in the study, participants had to be women smokers between the ages of 18 and 50 currently receiving Medicaid or Vermont Health Assistance Plan (VHAP) health care coverage for low-income Vermonters. They had to smoke greater than four cigarettes per day, have a home telephone, report that they intend to quit smoking in the next 2 weeks, have no plans to move in the next 6 months, and have no contraindications for use of over-the-counter NRT.

Procedure

We recruited participants throughout Vermont by posting flyers about the study in health care and human service agencies and on public bulletin boards. The flyers offered free nicotine patches to women smokers who met study guidelines. Interested smokers called a toll-free number to be screened for eligibility by a project interviewer. We mailed two copies of a study consent form to eligible women. When a woman returned her signed consent form, she was randomized to either the experimental or control condition and called by the interviewer to complete a baseline assessment. The Institutional Review Board of the University of Vermont approved this study.

All study participants received prescriptions for free nicotine patches through the mail, along with a letter directing them to quit smoking the day after they filled their first prescription. Participants enrolled in Medicaid could fill the prescriptions with a $2.00 co-payment at any pharmacy in Vermont. Participants who obtained their health insurance through VHAP received a study voucher along with their prescription to cover the cost of their 50% co-payment. Women who smoked more than 10 cigarettes per day at baseline could receive prescriptions for 6 weeks of 21-mg patches, 2 weeks of 14-mg patches, and 2 weeks of 7-mg patches. Women who smoked between 5 and 10 cigarettes per day at baseline could receive prescriptions for 6 weeks of 14-mg patches and 2 weeks of 7-mg patches. We sent prescriptions in three separate mailings, with no greater than a 1-month supply prescribed in any one mailing. Women could get the second and third prescriptions only if they returned flyers indicating that they were no longer smoking. Women who did not return a flyer, or who reported smoking, did not receive further patch prescriptions, and in the latter case, they got a letter indicating that we could not prescribe more nicotine patches while they were continuing to smoke.

Smokers in the experimental condition received up to three prescriptions for free nicotine patches along with up to 4 months of proactive support by telephone from one of six women ex-smokers who were prepared to perform the support function through 8 h of training delivered by the first author. A participant was assigned to a support person immediately after the baseline assessment on the basis of the time of day that she wished to be contacted. The support person initiated all the calls, with the first call occurring before the quit date, the second on or shortly after the quit date, the third a few days later, and then subsequent calls occurring weekly and tapering to bi-weekly for up to 4 months. As in our prior studies utilizing proactive telephone peer support [6–9], the support person followed a semi-structured protocol to provide encouragement, guidance, and reinforcement for quitting smoking, and to assist the woman in problem-solving high-risk-for-smoking situations. Contact times were negotiated between the support person and the participant, and the participant was told that she could receive the calls for up to 4 months or terminate the calls at any time. During each call, the support person wrote down the date and length of the call, the woman's smoking status, her use of nicotine patches, key issues discussed, and plans for further contact. These support logs were submitted to the first author for review at the end of each month; she conducted quality control calls with a randomly selected 50% of participants to verify contact and to ensure that the calls were well received. She also conducted periodic refresher training sessions with support staff and maintained telephone contact with them to review and discuss the protocol.

Smokers randomized to the control condition received up to three prescriptions for free nicotine patches, but did not receive any support calls to address psychosocial issues associated with quitting.

Measures

All participants received assessment calls from trained project interviewers (separate from telephone support staff) at baseline, 2 weeks, and 3 and 6 months post-baseline. The baseline interview assessed smoking behavior and history (average cigarettes per day, nicotine dependence using the Fagerstrom Test for Nicotine Dependence (FTND) [10], age of smoking onset, prior quit attempts, prior use of nicotine patches), motivation to quit smoking, four items about confidence to resist smoking across several different situations, intentions to quit in the next month, number of other smokers in the household, smoking among close friends and family, and perceived support for quitting. Responses to the motivation, confidence, smoking among friends and family, and the perceived support questions were indicated along 4-point scales (1 = not at all or none; 4 = a lot). Confidence score was the mean of responses to the four confidence items (Cronbach's alpha = 0.61). The intention to quit question contained a 5-point scale (1 = definitely not; 5 = definitely). FTND scores could range from 0 to 10, with higher scores indicative of greater nicotine dependence. Other questions addressed demographic characteristics, experience feeling downhearted and blue in the past month, current use of antidepressants, stress level in the past month, and current concern about their weight. Depression item responses ranged from 1 (not at all) to 4 (a lot); stress and weight concern responses ranged from 0 (not at all) to 10 (extremely).

The 2-week post-baseline assessment was designed to check on nicotine patch acquisition, use and problems, to assess smoking status, and with participants in the experimental condition, to determine receipt of initial telephone support. Further process evaluations were conducted at the 3-month telephone interview when participants were asked about the number of days they used nicotine patches, their usefulness and the likelihood they would recommend them to a friend who smoked. These were assessed on 4-point scales (1 = not at all useful/not likely to recommend; 4 = extremely useful/likely to recommend). Similar questions were asked of experimental participants regarding the telephone peer support. At 4 months, we used the telephone support log data to determine the total number of support calls received by each participant and the mean duration of each call.

For outcome evaluation, the 3- and 6-month follow-up assessments included most of the questions from the baseline interview, as well as questions to assess abstinence. We defined self-reported abstinence in three ways: no smoking in the past 7 days, no smoking in the past 30 days, and no smoking in the past 30 days at both the 3- and 6-month assessments (repeated point prevalence). We did not obtain biochemical verification for self-reported abstinence, as participants were recruited from all over Vermont making such data collection difficult, and because our prior study using similar interventions revealed high confirmation of self-reported abstinence when it was compared to carbon monoxide levels [6].

Statistical analysis

Experimental and control participants were compared at baseline and all follow-up assessments using chi-squares for dichotomous variables and *t* tests for continuous variables. An intention-to-treat model was applied for all self-reported abstinence outcomes, with losses to follow-up counted as smokers. Logistic regression was used to determine the impact of baseline variables and experimental condition on 3- and 6-month abstinence.

Metaanalysis

A metaanalysis was conducted to determine whether evidence from previous studies, when combined with the results of the current study, suggested that proactive telephone support improved smoking abstinence assessed 6 months after initiating use of NRT. We identified published articles using PsychLit and Medline databases. Results from studies were included in the pooled analysis if: (a) participants in the experimental condition received NRT plus proactive telephone support, and participants in the control condition received NRT but no telephone support, and (b) 7-day point prevalent abstinence was assessed 6 months after baseline. In the two studies with more than two comparison conditions [3,4], only data from the two conditions most similar to the above-defined experimental and control conditions were used for the pooled analysis.

Odds ratios (ORs) were computed for each study based on the number of participants in the experimental and control conditions who reported 7-day point prevalent abstinence from smoking at 6 months. The chi-square test for homogeneity of effect was used to assess between-study heterogeneity in the odds ratios from each study [11]. A pooled odds ratio was calculated using the Mantel–Haenszel method. The pooled odds ratio is a weighted average of study-specific odds ratios in which the weights are inversely proportional to the variance of each study.

Results

From October 2000 through January 2002, 662 women called our toll-free telephone number to inquire about the study. Of these, 330 were eligible and enrolled. Of the women not enrolled, 92% were excluded because they were not on Medicaid or VHAP, not aged 18–50, or were planning to move in the next 6 months. The remaining exclusions were due to no home telephone, contraindications for nicotine patch use, or because they smoked fewer than five cigarettes per day. Of those successfully recruited, 62% heard about the study at a health care facility, 14% at a human service agency, and the remaining 24% learned

about it through a publicly posted flyer or from a family member or friend.

Table 1 presents the baseline characteristics of experimental ($n = 171$) and control ($n = 159$) condition participants. No significant difference was observed for any baseline variable except percent living with another smoker, where 54% of experimental participants compared to 41% of controls reported having another smoker in their household ($P = 0.02$). Given this difference, living with another smoker was used as a co-variate in our logistic regression analyses.

Two-week post-baseline process data are presented in Table 2. As can be seen from that table, 99% of women in both conditions reported receiving their nicotine patch prescriptions. There was no significant difference in smoking abstinence at this early point in the trial; however, significantly more women in the experimental condition than controls had filled their prescriptions and had started using the nicotine patches ($P = 0.02$ for both comparisons). Ninety-five percent of the experimental group participants reported receiving at least one support call by this 2-week assessment.

Table 3 reveals process data from the 3-month follow-up assessment. Response rates were uniformly high in both conditions (93% and 94%), as were reported use of the nicotine patches and appraisal of the patches. Mean number of days of patch use was 37.7 and 35.8 days in the experimental and control conditions, respectively; this difference was not significant. Ninety-eight percent of the participants in the experimental condition reported receiving one or more support calls; they rated the calls high on usefulness and likelihood of recommending them to a friend who smokes.

Support log data at 4 months revealed that participants in the experimental condition received an average of 8.2 support calls (SD = 4.0). The number of calls ranged from 0 to 21, with 30% of participants receiving fewer than 6 calls, 68% receiving 6–14 calls, and 2% receiving greater than 14 support calls. Forty-four percent of the experimental participants received calls throughout the entire 4-month support window. Calls lasted an average of 10.1 min (SD = 5.6), with the first few calls typically slightly longer and later calls shorter in duration.

Three- and 6-month outcome data are presented in Table 4. The 3-month results reveal comparably high 24-h quit attempts in the two conditions over the past 3 months (88% versus 84% in the experimental and control conditions, respectively, $P > 0.1$). There was a significant effect for the proactive telephone peer support when either 7-day or 30-day point prevalent abstinence is the dependent variable. Using the more conservative outcome, the 30-day point prevalent abstinence rates were 42.7% versus 26.4% in the experimental and control conditions, respectively ($P =$

Table 1
Baseline characteristics by condition

	Experimental ($n = 171$)	Control ($n = 159$)
Demographics		
Age (years) ($M \pm$ SD)	33.7 ± 8.9	34.8 ± 8.2
Education (years) ($M \pm$ SD)	12.6 ± 1.8	12.3 ± 1.8
Race [Caucasian, % (n)]	93% (159/171)	93% (147/159)
≥1 child in home, % (n)	74% (126/171)	79% (126/159)
Smoking history		
Age started (years) ($M \pm SD$)	14.7 ± 3.3	14.7 ± 3.3
Cigarettes/day ($M \pm$ SD)	23.6 ± 12.7	23.6 ± 11.5
Fagerstrom score ($M \pm$ SD)	5.5 ± 2.3	5.4 ± 2.3
Quit attempts past year ($M \pm$ SD)	1.4 ± 2.3	1.3 ± 1.9
Longest attempt (days) ($M \pm$ SD)	33.3 ± 65.2	28.6 ± 58.2
Ever used nicotine patches, % (n)	40% (68/171)	45% (71/159)
Smoking attitudes		
Motivation to quit ($M \pm$ SD)	3.9 ± 0.4	3.9 ± 0.3
Confidence to resist smoking ($M \pm$ SD)	3.0 ± 0.6	3.0 ± 0.6
Intentions to quit in month ($M \pm$ SD)	4.6 ± 0.6	4.6 ± 0.7
Smoking environment		
≥1 other smoker in home, % (n)	54% (91/170)	41% (65/159)*
Friends/family smoke ($M \pm$ SD)	3.0 ± 1.0	3.0 ± 1.0
Support for cessation ($M \pm$ SD)	3.6 ± 0.7	3.6 ± 0.8
Mental health		
Self-reported depression ever, % (n)	44% (74/170)	45% (72/159)
Down and blue past month ($M \pm$ SD)	2.3 ± 0.9	2.4 ± 1.0
Taking antidepressant medicines, % (n)	27% (46/171)	29% (46/159)
Stress level past month ($M \pm$ SD)	5.4 ± 2.7	5.5 ± 2.7
Weight concerns ($M \pm$ SD)	4.9 ± 3.7	5.5 ± 3.8

* $P = 0.02$.

Table 2
Two-week post-baseline process data

	Experimental ($n = 171$)	Control ($n = 159$)
Response rate, % (n)	98% (167/171)	99% (157/159)
Received prescription, % (n)	99% (165/167)	99% (157/159)
Filled prescription, % (n)	92% (152/165)	84% (131/156)*
Started using patches, % (n)	85% (129/152)	74% (97/131)*
Stopped all tobacco use, % (n)	63% (108/171)	55% (87/159)
Received ≥ support call, % (n)	95% (158/167)	–

* $P = 0.02$.

Table 3
Three-month follow-up process data

	Experimental ($n = 171$)	Control ($n = 159$)
Response rate, % (n)	94% (161/171)	93% (147/159)
Nicotine patches		
Reported use of patches, % (n)	98% (157/161)	95% (140/147)
Days used patches ($M \pm$ SD)	37.7 ± 25.3	35.8 ± 25.9
Usefulness of patches ($M \pm$ SD)	3.5 ± 0.8	3.5 ± 0.8
Likely to recommend patches ($M \pm$ SD)	3.8 ± 0.6	3.8 ± 0.6
Proactive telephone support		
Received ≥ support call, % (n)	98% (158/161)	–
Usefulness of support calls ($M \pm$ SD)	3.3 ± 1.0	–
Likely to recommend calls ($M \pm$ SD)	3.5 ± 0.8	–

Table 4
Three- and 6-month outcome data

	Experimental (n = 171)	Control (n = 159)	P value
3-month follow-up			
≥1 quit attempt of at least 24 h, % (n)	88.3% (151/171)	83.7% (133/159)	ns
7-day point prevalent abstinence, % (n)	48.0% (82/171)	36.5% (58/159)	0.035
30-day point prevalent abstinence, % (n)	42.7% (73/171)	26.4% (42/159)	0.002
Cigarettes/day (smokers only) ($M \pm$ SD)	14.8 ± 8.1	14.9 ± 11.5	ns
Fagerstrom score ($M \pm$ SD)	3.9 ± 2.4	3.9 ± 2.7	ns
Motivation to quit ($M \pm$ SD)	3.7 ± 0.7	3.7 ± 0.6	ns
Confidence to resist smoking ($M \pm$ SD)	3.0 ± 0.9	2.9 ± 0.9	ns
≥1 other smoker in home, % (n)	52% (84/161)	37% (55/147)	0.01
Down and blue past month ($M \pm$ SD)	2.5 ± 1.1	2.5 ± 1.1	ns
Stress level past month ($M \pm$ SD)	6.0 ± 3.0	6.4 ± 3.0	ns
Weight concerns ($M \pm$ SD)	4.5 ± 3.8	5.4 ± 3.7	ns
6-month follow-up			
7-day point prevalent abstinence, % (n)	38.0% (65/171)	30.2% (48/159)	ns
30-day point prevalent abstinence, % (n)	32.8% (56/171)	25.8% (41/159)	ns
30-day abstinence at 3 and 6 months, and (n)	28.7% (49/171)	19.5% (31/159)	0.052
Cigarettes/day (smokers only) ($M \pm$ SD)	16.8 ± 10.0	16.8 ± 11.3	ns
Fagerstrom score ($M \pm$ SD)	3.9 ± 2.6	4.0 ± 2.6	ns
Motivation to quit ($M \pm$ SD)	3.7 ± 0.6	3.7 ± 0.7	ns
Confidence to resist smoking ($M \pm$ SD)	3.0 ± 1.0	2.8 ± 0.9	ns
≥1 other smoker in home, % (n)	48% (71/149)	40% (56/139)	ns
Down and blue past month ($M \pm$ SD)	2.6 ± 1.0	2.5 ± 1.0	ns
Stress level past month ($M \pm$ SD)	6.7 ± 2.9	6.6 ± 2.9	ns
Weight concerns ($M \pm$ SD)	4.5 ± 3.8	5.5 ± 4.0	0.03

0.002). The odds ratio was 2.07 (95% CI 1.30, 3.30), suggesting that adding the proactive telephone support to the provision of nicotine patches doubled the odds of being abstinent at 3 months. In a multivariate analysis including baseline variables, being in the experimental condition remained a significant predictor of 30-day point prevalent abstinence at 3 months (OR = 2.21; 95% CI 1.36, 3.58), along with having one or more children in the home (OR = 2.06; 95% CI 1.12, 3.78), and stress rating in the past month at baseline (OR = 0.90; 95% CI 0.82, 0.98). A one-unit decrease in baseline stress score was associated with a 10% increase in the odds of being abstinent at 3 months.

There were no significant differences between conditions on any attitudinal, support, or mental health indices at the 3-month follow-up, although as at baseline, significantly more participants in the experimental condition reported having another smoker in their household. Among participants who reported continuing to smoke at the 3-month assessment, we observed no significant differences by condition in mean cigarettes smoked per day (14.7 and 14.9 in experimentals and controls, respectively) nor in mean nicotine dependence scores (3.9 for both groups).

Six-month follow-up response rates were 87% in each condition. By this assessment, neither 7-day nor 30-day point prevalent abstinence rates were significantly different, with 32.8% of experimental participants and 25.8% of controls reporting not smoking in the past 30 days (P = 0.17). In a multivariate analysis including baseline variables, only baseline stress level was a significant predictor of 30-day abstinence at 6 months (OR = 0.89; 95% CI 0.82, 0.98). Repeated point prevalent abstinence for 30 days at both 3 and 6 months approached significance, with rates of 28.7% in experimentals and 19.5% in controls (P = 0.052). The odds ratio was 1.66 (95% CI 0.99, 2.77).

By the 6-month assessment, the difference in percent of participants having another smoker in their household was no longer significant. However, there was a significant difference by condition in mean concern about weight, with control participants expressing greater concern than experimentals (5.5 versus 4.5, respectively; P = 0.03). As at 3 months, there were no significant differences among remaining smokers in mean cigarettes smoked per day (16.8 in both conditions) nor in mean nicotine dependence scores (3.9 versus 4.0 in experimental and control conditions, respectively) at the 6-month assessment.

Because the significant difference in abstinence between conditions was lost from 3- to 6-month follow-up, we examined the relapse rates by condition and predictors of relapse among participants who were abstinent at the 3-month assessment. This analysis revealed a non-significant difference in relapse between 3- and 6-month assessments, with 33% of women in the experimental condition and 26% in the control condition returning to smoking after the 3-month assessment. We entered all baseline and 3-month assessment variables into a series of logistic regressions and found that only confidence to resist smoking at 3 months was a significant predictor of abstinence at 6 months (OR = 3.43; 95% CI 1.37, 8.64). Thus, for every unit increase in confidence score at 3 months, the odds of being abstinent at 6 months increased 3.4 times.

Within the experimental condition, we examined the relationship between support call dose and 30-day point prevalent smoking status by comparing participants who were and were not abstinent at 6 months on the number of support calls received. Participants who were abstinent received significantly more calls (M = 9.5, SD = 3.0) than did participants who were still smoking at 6 months (M = 7.1, SD = 4.4) (P < 0.001). We also examined the relationship between 6-month smoking status and receipt of the complete versus incomplete sequence of 4-month support calls. Chi-

square results revealed a significant association ($P < 0.001$), with 54% abstinence among experimental participants who received support calls throughout the 4-month support window and 15% abstinence among those who terminated calls or could not be reached before the end of the 4-month support period.

Metaanalysis

Four published studies, in addition to the current study, satisfied the inclusion criteria for the metaanalysis [3–6]. As can been seen in Table 5, study size and participant age were similar across studies. Although the inclusion criteria for smokers differed among studies, the mean number of cigarettes smoked per day at baseline was similar. All but one study [3] included only smokers motivated to quit; one study in addition to the current study included only women [6]. In three of the studies [3–5], participants in both the experimental and control conditions also received smoking cessation advice, counseling, or an orientation session from a physician.

Abstinence from smoking, assessed at 6 months using a 7-day point prevalence measure, ranged from 18% to 38% among those who received proactive telephone counseling and from 15% to 30% among those who received no telephone support (Table 6). Odds ratios computed for the five studies ranged from 0.85 to 1.42. Although the ORs in four of the five studies were above 1.0 (1.14 to 1.42), all 95% confidence intervals included 1.0. Individual study data, therefore, do not support a conclusion of a statistically significant difference in quit rates between the experimental and control conditions at 6-month follow-up.

The test for homogeneity of effect provided no evidence for heterogeneity between study odds ratios ($Q = 2.82$, $P = 0.59$), indicating that the between-study differences in results are no greater than would be expected by chance. Therefore, a fixed-effects model was deemed appropriate to calculate a pooled odds ratio [11]. The pooled estimate was consistent with a slight but non-statistically significant increase in the odds of being abstinent at 6 months among those receiving proactive telephone support compared to those not receiving telephone support (OR = 1.14; 95% CI 0.91, 1.43) (Fig. 1). Only one of the five studies [5] reported a lower quit rate among participants who received proactive telephone support. When this study was excluded, the pooled odds ratio was 1.27 (95% CI 0.97, 1.66) of borderline significance.

Discussion

Results from this study replicated our prior findings [6], demonstrating a significant effect for proactive telephone support as an adjunct to free NRT at 3 months post-baseline. Although the proportions of participants reporting quit

Table 5
Study design and participant characteristics in studies comparing the effect of proactive telephone support to no proactive telephone support on smoking abstinence rates among participants using nicotine patches or gum

First author	Year	Participants included if smoked more than:	Age	Mean no. cigarettes/day baseline (experimental/control)	Included only those motivated to quit?	% Female (experimental/control)	Study no.	Mean no. calls in experimental group	Description of control group*	Description of experimental intervention*
Lando [4]	1997	>20 cigarettes/day	18–65	27.6/27.4	yes	60.5/46.6	336	4	Orientation session	Orientation session plus 4 telephone calls
Ockene [3]	1991	≥1 puff in last week	18–75	23.3**	no	56.8**	380	3	Physician counseling	Physician counseling plus 3 telephone calls
Reid [5]	1999	≥15 cigarettes/day	18+	24.2/22.8	yes	47.2/47.7	396	3	Physician advice	Physician advice plus 3 telephone calls
Solomon [6]	2000	>4 cigarettes/day	18–50	23.0/24.3	yes	100/100	214	7	Baseline assessment	Baseline assessment plus telephone calls
Current study		>4 cigarettes/day	18–50	23.6/23.6	yes	100/100	330	8	Baseline assessment	Baseline assessment plus telephone calls

* Both control and experimental groups received nicotine patches or gum.
** Mean cigarettes/day and % female for control and experimental groups combined.

Table 6
Seven-day point-prevalence abstinence assessed at 6 months, comparing the effect of proactive telephone support (experimental condition) to no telephone support (control condition) among participants using nicotine patches or gum

First author	Year	Study no.	Percent quit		Quit/total		Odds ratio	95% CI
			Experimentals (%)	Controls (%)	Experimentals	Controls		
Lando [4]	1997	336	25	23	41/162	40/174	1.14	(0.69, 1.87)
Ockene [3]	1991	380	18.3	15.4	48/263	18/117	1.23	(0.68, 2.22)
Reid [5]	1999	396	26.9	30.2	53/197	60/199	0.85	(0.55, 1.32)
Solomon [6]	2000	214	23	19	24/106	20/108	1.29	(0.66, 2.50)
Current study		330	38	30	65/171	48/159	1.42	(0.90, 2.24)

attempts and the numbers of days of NRT use were comparable between conditions, the telephone support doubled the odds of being abstinent at 3 months, suggesting that the support and/or problem-solving assistance provided over the telephone strengthened efforts to quit smoking with nicotine patches.

The primary purpose of this study, however, was to test the impact of the availability of extended proactive telephone support, when added to the provision of free nicotine patches, on 6-month smoking abstinence rates. Results failed to demonstrate a significant effect, although the odds ratio of 1.42 was greater than that observed in comparable studies and was larger than the pooled odds ratios found in prior metaanalyses of proactive telephone support [1,2]. Substantial relapse occurred in both conditions between 3- and 6-month follow-up (33% and 26% in the experimental and control conditions, respectively). The availability of proactive telephone support extended beyond the end of nicotine patch delivery did not appear to impact these later relapse rates.

In multivariate analyses, the only variables found to predict 6-month abstinence were baseline stress level (lower stress was associated with greater abstinence) and confidence to resist smoking assessed at 3 months. Unlike our prior study where confidence scores were significantly higher at 3 months among women receiving telephone support, we found no relationship at 3 months between confidence scores and experimental condition in the current study, indicating that the mechanism by which the proactive telephone support exerted its influence was not replicated. We explored the possibility that the telephone support may have disproportionately helped those women who had lower confidence to resist smoking at baseline; however, these analyses (not presented) did not reveal such a relationship. Thus, although confidence to resist smoking is a predictor of later abstinence, our extended telephone support did not appear to enhance that confidence.

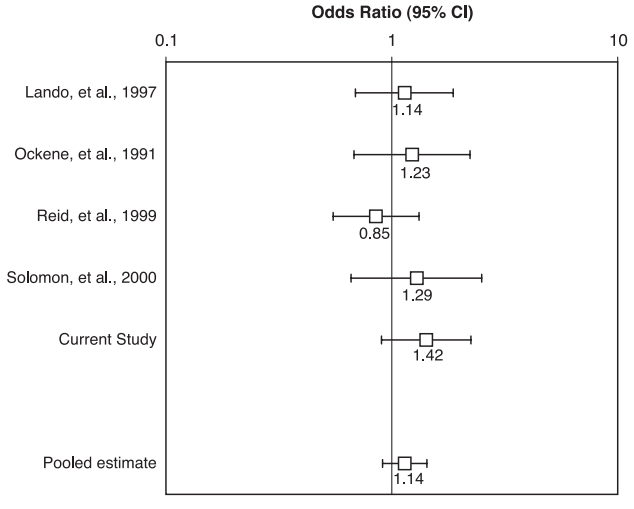

Fig. 1. Odds ratios and 95% confidence intervals for 7-day point-prevalence abstinence from smoking, assessed at 6 months, comparing subjects receiving nicotine replacement without proactive telephone support. The pooled odds ratio estimate is shown at this figure.

The only variable that differed significantly between experimental and control participants at 6 months was weight concerns; women in the control condition expressed greater concerns about their weight than did their experimental counterparts (5.5 versus 4.5, respectively). It is unlikely that this statistical difference is clinically meaningful, however, because non-significant differences in this same direction were already present at baseline and at 3 months.

Our data suggest no other mechanisms by which the proactive telephone support may be operating. This failure could reflect the need for more sensitive measurement of the self-efficacy and support constructs thought to underlie the intervention. It is unlikely that the failure is due to inadequate dosing on the independent variable, as women in the experimental condition received a mean of over 80 min of support divided across an average of 8.2 calls over up to 4 months. This represents over 2.5 times the total contact time for an intensive intervention recommended by the clinical practice guidelines [12], so we feel confident we delivered extended support. Furthermore, process data indicated that the telephone support calls were judged by participants to be useful and worthy of recommendation to a friend. Thus, the participants were heavily dosed on the telephone support and viewed it favorably.

Within the experimental condition, there was a dose–response relationship, such that women who received the full 4-month support call regimen were more likely to be abstinent at 6 months than were women who terminated the calls earlier. Additionally, the mean number of calls was significantly greater among experimental participants who were abstinent at 6 months compared to experimental

participants who were still smoking. However, these findings must be interpreted cautiously due to participant self-selection in call reception (i.e., women who relapsed may have terminated the support calls early while women who were doing well may have continued the calls).

Given our sample size, the study had power of only 0.40 (one-sided) to detect a difference of the magnitude we observed at 6 months. Even though we found a 27% increase in abstinence at 6 months among experimental participants compared to controls, this difference was too small to be statistically significant. For that reason, we conducted a metaanalysis pooling the odds ratios from the four prior studies plus this one to determine the combined impact of proactive telephone support with NRT on 6-month abstinence rates. The pooled estimate revealed a slight but non-significant increase in the odds of being abstinent among those who received proactive telephone support compared to those who did not. Thus, the empirical evidence to date does not indicate a statistically significant long-term benefit for adding proactive telephone support to the provision of free NRT.

These findings do not imply that investigations of proactive telephone support as an adjunct to NRT should end. In fact, the evidence of shorter-term (3 months), but not longer-term (6 months) efficacy suggests that a more careful examination of telephone support parameters may be needed. Although we chose to extend the amount of available support beyond prior limits, it is possible that the content of the calls is a more critical factor in determining longer term outcomes. For example, Mermelstein et al. [13] observed an interaction between telephone counseling content and gender, such that abstinence was greater among women exposed to non-directive support, and among men exposed to stage-based tailoring and barrier-specific problem-solving. Similar content variations in telephone counseling could govern short versus long-term abstinence.

We now have one earlier study [6] and the current study demonstrating a significant short-term effect for the addition of proactive telephone peer support to NRT, with each study obtaining the effect in low-income women smokers who received no face-to-face contact with clinical staff. The public health dilemma now lies with finding ways to maintain the effect over a longer period of time. Our simple extension of the telephone peer support that conveyed the short-term advantage did not maintain long-term abstinence. It is possible that the type of intervention required to sustain long-term abstinence is different from what works to achieve short-term success. Future studies might explore the possibility of combining successful short-term intervention strategies with, for example, contingency management approaches that reward continued abstinence over time. Regardless of which intervention innovations are pursued, it is important to assess carefully the possible mechanisms that might account for improved behavioral outcomes.

Acknowledgments

This research was funded by the Vermont Department of Health. We are very grateful to the interviewers and telephone support staff who contributed to this study.

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