Integrating smoking cessation treatment into primary care: an effectiveness study

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Abstract

Background. Lack of interest has been cited as a reason not to offer cessation assistance to smokers, but research suggests that smokers accept treatments offered proactively. This study assessed acceptability, utilization, and effectiveness of free smoking cessation treatment among diverse primary care patients.

Method. Medical assistants invited 4,174 adult smokers to participate. Enrollees (1,869) self-selected or were assigned to receive free nicotine patch therapy alone or in combination with the Committed Quitters® program, and for some, individual counseling.

Results. In nearly 68% of cases, patients accepted a treatment invitation; 77% of eligible smokers enrolled; 85% of these picked up free patches. Given a choice of treatments, 75% of participants elected a psychosocial treatment in addition to patch therapy. Thirteen percent of treatment initiators achieved biochemically confirmed 7-day point-prevalence abstinence at 1 year, with no significant treatment effects. Minority patients showed greater initial interest but less utilization than did White patients.

Conclusions. Free, readily accessible smoking cessation treatment offered in primary care settings was accepted and used by the majority of unselected smokers of diverse racial/ethnic origins. Psychosocial treatment components did not significantly increase abstinence rates. Barriers, rather than lack of interest, may keep minority smokers from using cessation treatments.
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Introduction

Among the most confounding paradoxes surrounding tobacco dependence in the United States is the reluctance of clinicians and health care delivery systems to address this cause of illness and death despite its high prevalence (23% among American adults) [1] and staggering costs. Over 440,000 tobacco-attributable deaths occur per year [2] and more than US$100 billion in added health care and other costs accrue annually [2]. Currently, primary care providers are not capitalizing on the many opportunities to treat this chronic disorder, although 70% of smokers visit a primary care clinician annually [3], 70% of smokers report being interested in quitting [1], and 40% of smokers make an attempt to quit each year [4]. Although empirically supported counseling and pharmacotherapeutic interventions exist [5], along with a clinical practice guideline for intervention in health care settings [6], only a minority of smokers use evidence-based treatments to quit under the care of a clinician [7]. Mobilizing the primary care delivery system to identify and intervene universally with tobacco users is a critical preventive health care challenge.

In the present study, we sought to assess acceptability, utilization, and effectiveness of free nicotine patch and psychosocial smoking cessation treatments in a diverse

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sample of primary care patients. Past research has suggested that only 5–14% of medical patients act on referrals for formal treatment programs [8–10]. However, patients referred to these programs still faced many barriers to accessing treatment (e.g., cost, inconvenience). We sought, therefore, to reduce barriers to utilization by using proactive recruitment [11,12] during vital sign assessment at primary care clinics and providing free, convenient treatment.

In this study, we recruited a diverse sample of smokers. To date, most of the research on smoking cessation has been conducted with White, middle-class participants. Past research has demonstrated both gender [5,7,12,13] and racial/ethnic differences [14] in smoking and cessation behavior (including use of nicotine patches [5,15] and other formal treatments [1,13,16]). As argued elsewhere [17], these differences in smoking and quitting make it important to explore treatment willingness and effectiveness among smokers of both genders and diverse racial/ethnic backgrounds.

The current study was designed to assess utilization and effectiveness of free nicotine replacement therapy (NRT) and two psychosocial treatments differing in intensity. Numerous studies have shown that intensive psychosocial treatments are efficacious among "treatment seekers," patients who seek treatment by volunteering for randomized clinical trials [6]. It is unclear, however, what proportion of smokers in a primary care population will accept such treatments (i.e., will be "treatment acceptors"). Moreover, it is unclear if intensive psychosocial treatments are effective among treatment acceptors. To determine treatment acceptance, some patients in this study were allowed to select their preferred treatment. Thus, unselected patients in primary care clinics were invited by medical assistants to participate in a treatment program involving free NRT and possible psychosocial treatment. Outcomes of clinic invitations were tracked, along with self-selected treatment intensity, use of patch and psychosocial treatment components, and smoking status over 1-year post-cessation. We addressed five key questions in this study:

1. Are primary care patients who smoke willing to enter a free smoking cessation treatment program involving nicotine patches and possible counseling?
2. What is the preferred intensity of psychosocial treatment among smokers?
3. Do smokers adhere to the treatment regimen once enrolled?
4. How effective are the combined pharmacological and psychological tobacco dependence treatments offered in this study, and does their effectiveness differ as a function of random assignment vs. self-selection of treatment?
5. Do smokers of different genders and races/ethnicities respond differently to the treatments offered in this study in terms of acceptability, utilization, and benefit?

Method

Study design

The study used a 2 (condition-assignment arm) × 3 (treatment condition) factorial design. Participants were randomly assigned to a condition-assignment arm in which they were either assigned randomly to a treatment condition (*Random Arm*), or able to select their own treatment condition (*Selection Arm*). (See Fig. 1) In each arm, the lowest intensity condition, *Patch Only*, included an 8-week course of free nicotine patches (supplied by SmithKline Beecham), the intermediate intensity condition, *Patch + CQ*, included free patches plus the opportunity to enroll in the Committed Quitters® (CQ) program (SmithKline Beecham), and the highest intensity condition *Patch + CQ + Counseling*, included free patches, access to CQ, and individual counseling. The CQ program involved an initial telephone interview and counseling session followed by a 10-week course of supportive, tailored mailings. Participant information was faxed to CQ staffers who then called participants up to five times to enroll them. The counseling entailed four 15–25 min face-to-face meetings at patients' clinics with trained University of Wisconsin smoking cessation counselors who provided education regarding cessation, motivational enhancement, problem solving assistance, and coping skill training. Sessions occurred pre-cessation, on or around the quit date, and during the first 2 weeks post-cessation.

Study sponsorship

This study was funded by a grant from the National Cancer Institute (NCI 1 RO1 CA71377) and was initiated and analyzed by the authors. SmithKline Beecham provided nicotine patches and access to the CQ program, but did not participate in any aspect of study design or data analysis.

Participants

Participants were patients attending four primary care clinics in the Madison, WI, and 12 primary care clinics in the Milwaukee, WI areas between 1997 and 2000. In Madison, WI, primary care departments in four clinics from two Health Maintenance Organizations (HMOs) served as recruitment sites. Diverse clinics served as recruitment sites in Milwaukee, WI, including five faculty practices, three of which were hospital based or owned, one of which was a family medicine practice, and one of which was a city-owned community health center. Five additional federally funded community health centers served as sites, along with two clinics owned by a nonprofit provider network. All of the clinics in Milwaukee were mixed-payment clinics, receiving funds from HMOs, Preferred Provider Organization, Medicare, Medicaid, and other insurance programs. Participating clinics ranged in size from 1 to 31 primary care
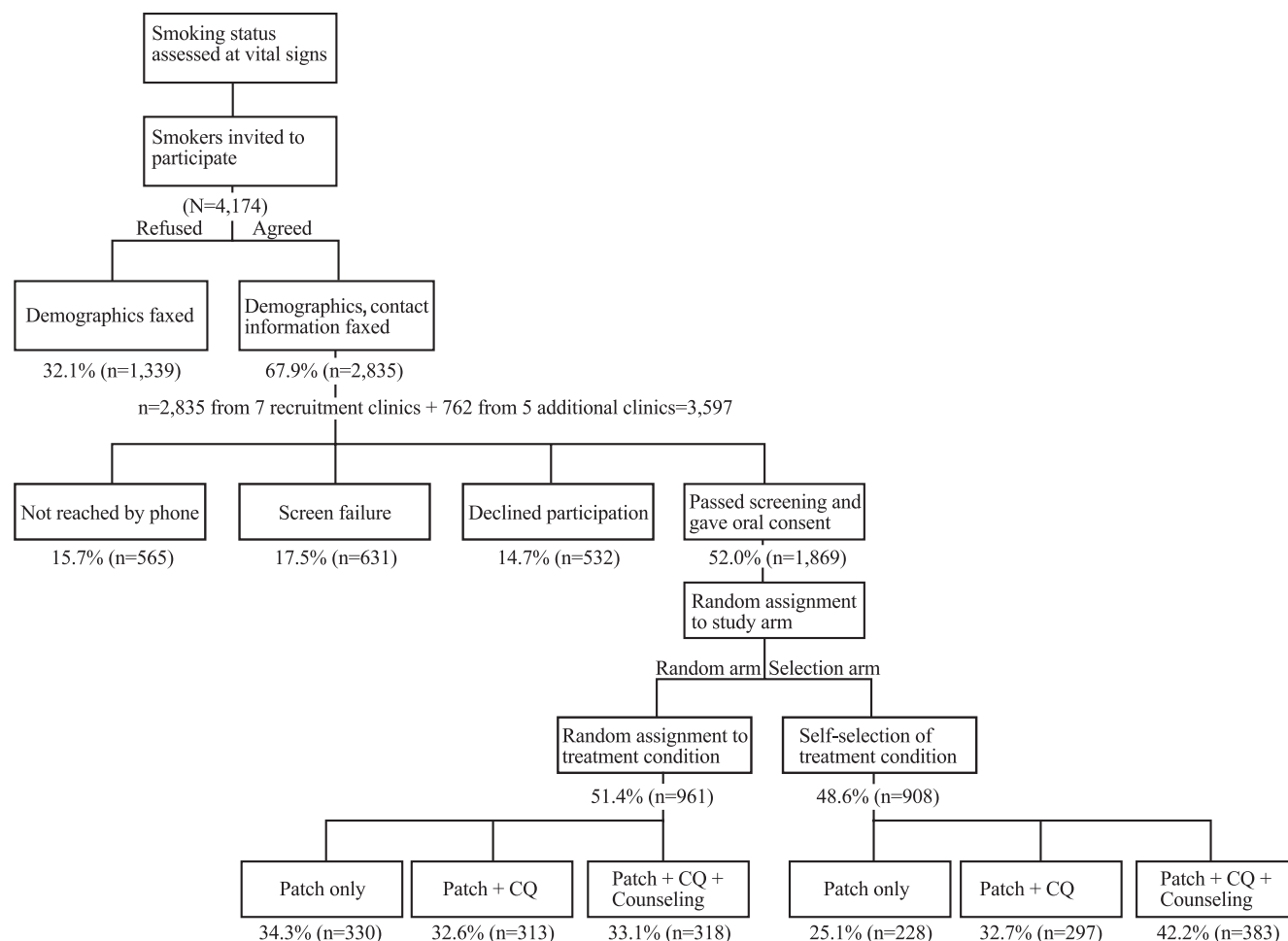
Fig. 1. Study procedures. The denominators used in calculating outcomes varied based upon the number of clinics included in screening and enrollment vs. recruitment.

providers (excluding pediatricians). Some clinics had already integrated smoking assessment into the vital signs procedure and encouraged clinicians to advise and assist patients in quitting. Every clinic contacted agreed to participate in the study.

Procedures

Fig. 1 depicts the enrollment procedure. Study procedures were approved by appropriate institutional review boards. Every patient's smoking status was identified by medical assistants (MAs) during vital sign assessment. All identified smokers were then read a paragraph describing the study and asked if they were interested in receiving more information. Interested patients provided names and contact information and signed an interest form to release information to our staff and indicate they had been told the risks of participation. MAs faxed all interest forms to our research staff (minus identifying information for those declining participation). MAs completed a 1-h in-service training and received periodic written study protocol reminders. Study coordinators and cessation counselors had regular contact with MAs and staff. MAs were not reimbursed for recruitment efforts, although thank-you gifts (e.g., fruit baskets) were sent to clinics periodically. Feedback regarding recruitment was provided to clinics throughout the study.

Research staff screened interested patients by telephone. Patients were excluded from the study if they were under 18 years of age, had medical contraindications to patch use, were using other smoking cessation treatments, lived with someone who was participating in the study, or smoked fewer than 10 cigarettes per day. Patients were also excluded if they did not have a regular telephone number or planned to move away within 6 months. Women who were pregnant, breast-feeding, trying to become pregnant, or unwilling to use a reliable form of birth control were excluded. Excluded participants were offered information about cessation resources in their area.

Patients who passed the telephone screening and remained interested were then randomly assigned to one of two condition-assignment arms; in the *Random Arm*, they were randomly assigned to one of the three treatment conditions (*Patch Only, Patch + CQ, Patch + CQ +*

Counseling). In the *Self-Selected Arm*, patients were allowed to select one of the three treatment conditions described to them. The consent form was read to participants and they provided oral consent. All participants specified a quit date within the next 2 weeks and were informed that an 8-week supply of free patches (21-mg patches for 4 weeks, 14-mg patches for 2 weeks, and 7-mg patches for 2 weeks) was available at the pharmacy associated with their clinic.

At the pharmacy, participants read the consent form, or had it read to them, and signed it in the presence of a pharmacy staff-member. Staffers faxed a form to our research staff to indicate whether participants picked up their patches within 30 days. The CQ program attempted to enroll eligible participants by telephone and faxed the outcome of their efforts to our research staff. Trained smoking cessation counselors attempted to contact participants in the *Patch + CQ + Counseling* condition by telephone to schedule appointments. At least three attempts to reach participants were made initially and following missed appointments.

Brief follow-up telephone interviews were conducted with participants. Only participants who picked up patches were called 2 and 12 weeks post-quit. All enrollees were called at 6 months and 1 year post-cessation.

Assessments

At the initial recruitment clinic visit, participants' gender, race/ethnicity, age, clinic, and city of residence were recorded. At the telephone screening, highest grade completed and average number of cigarettes smoked per day were recorded. Additional items regarding smoking and quitting history were included. We assessed treatment utilization by asking pharmacists, CQ staffers, and counselors to note whether study participants were exposed to each treatment component.

At each of the follow-up interviews, participants were asked to report whether they had smoked in the last 7 days (to determine 7-day point-prevalence abstinence), whether they returned to smoking for seven consecutive days (to determine continuous abstinence), and if so, when (to determine latency to relapse). At the 6-month and 1-year follow-ups, participants reporting point-prevalence abstinence were asked to complete carbon monoxide (CO) testing at a convenient location. Duration of patch use and reasons for discontinuing use were also assessed.

Statistical analyses

Dependent variables of interest included the proportion of patients who: accepted the study invitation at the clinic, enrolled in the study, selected psychosocial treatments, reported using treatment components, and achieved point-prevalence abstinence at 1-year post-quit. Multivariate logistic regressions were conducted using clinic, age, education, and cigarettes smoked per day as control variables. Condition-assignment arm, study condition, and the inter-

action of arm and condition were also included as predictors in multivariate analyses. Unstandardized regression coefficients (B), standard error estimates (SE), P values, odds ratios (OR), and the 95% confidence intervals for the odds ratios (95% CI) generated in multivariate logistic regression analyses are reported below. Interactions among independent variables were tested but were not reported if nonsignificant. All data analyses were conducted by the authors using SPSS software.

Sample size

We enrolled 1,869 participants, yielding over 250 participants in the three randomly assigned conditions who provided written consent and initiated treatment (by picking up patches). Cell sizes were sufficient to detect a 10% difference between the abstinence rates for the three conditions, assuming 12% abstinence in the Patch Only condition, at $\alpha = 0.05$ with power = 0.80 in the random-assignment arm.

Results

The demographic characteristics of patients who enrolled in the study are summarized in Table 1. Participants were recruited from 12 primary care clinics that returned more than 50 smoker interest forms to research staff. Five clinics were removed from recruitment analyses because the data suggested that clinic personnel did not reliably report smokers who were *uninterested* in treatment. Inspection of the data from these clinics revealed a record-keeping problem; over 50 invitation acceptances but zero to seven refusals were returned. Inclusion of data from such clinics would have spuriously inflated estimates of smoker interest. These excluded clinics did not appear to have sufficient buy-in to the research agenda, but did use the research study as a service for their patients, as indicated by their asymmetrical adherence to the study protocol. Excluded clinics tended to

Table 1
Characteristics of study enrollees[a] ($N = 1,869$)

Variable	Percentage (%)	n
Gender		
Female	58.4	1091
Male	41.1	769
Race/ethnicity		
White	65.6	1226
African-American	27.0	504
Other Minority	5.9	111

Variable	Mean	(SD)
Age (years)	39.6	(12.1)
Highest grade completed	12.7	(2.3)
Cigarettes smoked per day	21.7	(9.1)

[a] Note that n's do not always sum to N and percentages do not always sum to 100 due to missing data.

have high patient to clinician ratios, suggesting that clinician burden interfered with protocol adherence. Three of the excluded clinics were federally funded community health centers, one was a city-owned community health center, and one was part of a nonprofit provider network.

Due to efforts to estimate acceptance rates conservatively, only seven clinics were retained for recruitment analyses. Of the 4,174 invitations to participate in the study made at these seven clinics, 2,835 (67.9%) were accepted. This estimate of treatment interest may be conservative since unidentified smokers may have been recorded as refusing at more than one office visit (due to confidentiality concerns, patients refusing to participate were not identified to research personnel). Acceptance rates by gender and race/ethnicity are displayed in Table 2.

Hierarchical logistic regression models predicting interest at the clinic were fit to the data. Because the age logit was nonlinear, age was dichotomized (ages 18–47 were coded as 0; ages 48 and above were coded as 1). Dummy coding was used for racial/ethnic group contrasts, with White patients as the reference group. Effects coding was used for contrasts by clinic. After controlling for clinic, age, and race/ethnicity, women were 1.18 times more likely than men to accept the clinic invitation ($B = 0.17$, SE = 0.08, $P < 0.03$, OR = 1.18, 95% CI = 1.02–1.37). The contrast between African-American and White patients was significant when entered in the first step in the model ($B = 0.35$, SE = 0.09, $P < 0.001$, OR = 1.42, 95% CI = 1.21–1.68), but not after clinic, age, and gender were also entered ($B = 0.15$, SE = 0.12, $P < 0.22$, OR = 1.16, 95% CI = 0.92–1.48).

We attempted to contact each of the 2,835 patients who expressed interest at the recruitment clinics and an additional 762 patients recruited from five clinics that were excluded from recruitment analyses. We succeeded in contacting 3,032 (84.3%) of these 3,597 patients by telephone. The phone screen resulted in 1,869 participants being enrolled in the study. This represents 61.6% of the 3,032 people we were able to reach by telephone and 77.8% of the 2,401 screened patients who met eligibility criteria for the study. Twenty-four (1.3%) of the 1,869 participants who enrolled later withdrew from the study.

Of the 1,869 smokers who enrolled in the study, 908 (48.6%) were randomly assigned to select their own treatment intensity. Of these participants, 228 (25.1%) selected

Patch Only, 297 (32.7%) selected *Patch + CQ*, and 383 (42.2%) selected *Patch + CQ + Counseling*. A goodness-of-fit chi square test revealed that these percentages differed significantly from the equal distribution across cells expected by chance [$\chi^2(2, N = 908) = 39.85, P < 0.001$].

All study participants had the opportunity to pick up free nicotine patches from their pharmacy. Of the 1,869 smokers who enrolled, pharmacies reported that 1,586 (84.9%) collected patches (see Table 2 for pick-up rates by gender and race/ethnicity). A multivariate logistic regression that included age, treatment condition, assignment arm, and cigarettes per day as control variables suggested that, relative to White participants, both African-American ($B = -0.91$, SE = 0.15, $P < 0.001$, OR = 0.40, 95% CI = 0.30–0.58) and other minority participants ($B = -0.54$, SE = 0.26, $P < 0.05$, OR = 0.58, 95% CI = 0.35–0.98) were significantly less likely to pick up their patches. Patch pick-up did not differ as a function of control variables.

Of the 1,250 (80% of treatment initiators) participants reporting patch use at the 1-year follow-up, 1,186 (94.9%) reported using at least some of their patches. In addition, 944 (75.5%) reported using patches for at least 4 weeks and 628 (50.2%) reported that they had used patches for the full 8 weeks. On average, participants reported using patches for 5.74 weeks (SD = 2.74). Side effects were cited as reasons for discontinuation of patch use by 162 of 1,274 (12.7%) respondents. The most frequently reported adverse events associated with patch use included skin irritation, itchiness, and unusual dreams.

In addition to receiving free patches, 1,311 participants had the opportunity to enroll in the CQ program. CQ staffers successfully enrolled 902 (68.8%) eligible participants. Two additional participants enrolled but later withdrew. Only 111 (8.5%) said they were not interested in enrolling. CQ was unable to contact 244 (18.6%) of eligible participants. Enrollment information was missing for 52 (4.0%) of CQ-eligible participants.

Of the 701 participants eligible to attend counseling sessions, 471 (67.2%) attended at least one session and 285 (40.7%) attended all four available sessions. Participants attended two sessions on average (mean = 2.1, SD = 1.8).

Point-prevalence and continuous abstinence rates at each follow-up point by treatment condition are shown

Table 2
Number (and proportion) of men, women, and participants of different races/ethnicities accepting the study invitation, picking up patches, and achieving point-prevalence abstinence at 1-year follow-up

	Male	Female	White	African-American	Other minority
Accepted clinic invitation	1102 (65.7%)	1720 (70.8%)	1969 (67.0%)	708 (73.8%)	83 (64.7%)
Picked up patches	669 (87.0%)	912 (83.6%)	1101 (89.8%)	373 (74.0%)	89 (80.2%)
Point-prevalence abstinence[a]	92 (13.8%)	111 (12.2%)	159 (14.4%)	32 (8.6%)	8 (9.0%)

[a] Seven-day point prevalence CO-confirmed abstinence among participants who picked up their patches.

in Table 3. Abstinence was determined by self-report and CO confirmation (at 6 and 12 months). Follow-up phone rates did not differ by condition at any time point (86.5% were reached at 2 weeks, 83.1% at 12 weeks, 85.1% at 6 months, and 80.9% at 1 year). Rates of CO confirmation of abstinence rates were higher in the *Patch + CQ + Counseling* (74.6%) condition than the *Patch Only* (61.8%) or *Patch + CQ* (58.5%) conditions at 6 months but did not differ by condition at 1 year post-quit (75.2% overall). Only 2 (0.7%) of the 270 people who reported abstinence at the 1-year follow-up had discordant CO readings, but 65 people (24.1%) did not complete CO testing and were treated as smoking.

A multivariate logistic regression predicting point-prevalence abstinence at 1-year post-cessation was conducted. Assignment arm and condition were entered in one step, followed by gender, race/ethnicity, age, years of education, and cigarettes smoked per day. Results showed that treatment condition and study arm were not predictive of point-prevalence abstinence [step $\chi^2(2, N = 1,549) = 2.65, P < 0.45$]. The finding of no effect due to treatment condition or study arm was confirmed by a logistic regression analysis of continuous abstinence (see Table 3). Similarly, no treatment effects were obtained with a survival analysis ($P > 0.10$).

Additional analyses using the same control variables as above were conducted to determine whether utilization of available treatment components predicted abstinence. Use of patches for at least 4 weeks as reported at the 1-year follow-up significantly predicted abstinence ($B = 0.46$, SE = 0.21, $P < 0.03$, OR = 1.58, 95% CI = 1.04–2.39). In another model using the same control variables, enrollment in CQ was not predictive of abstinence ($B = -0.23$, SE = 0.29, $P < 0.43$, OR = 0.80, 95% CI = 0.46–1.39). In contrast, there appeared to be a dose response relationship between counseling and abstinence. Among those in the counseling condition, 9.0% of those who attended zero sessions, 4.8% who attended one session, 7.1% who attended two sessions, 14.3% who attended three sessions, and 21.1% who attended four sessions were abstinent at 1 year [$\chi^2(1, N = 612) = 22.66, P < 0.001$]. In a logistic regression, the number of counseling sessions attended predicted abstinence ($B = 0.40$, SE = 0.09, $P < 0.001$, OR = 1.50, 95% CI = 1.25–1.79).

Point-prevalence abstinence rates by gender and race/ethnicity appear in Table 2. Gender was not predictive of abstinence ($B = -0.12$, SE = 0.16, $P < 0.46$, OR = 0.89, 95% CI = 0.65–1.21). African-American participants were significantly less likely than White participants to be abstinent at 1 year post-quit ($B = -0.60$, SE = 0.22, $P < 0.01$, OR = 0.55, 95% CI = 0.36–0.84), whereas other minority participants were not ($B = -0.48$, SE = 0.39, $P < 0.22$, OR = 0.62, 95% CI = 0.29–1.32). Smoking heaviness, a proxy for nicotine dependence level, significantly and negatively predicted abstinence (cigarettes per day; $B = -0.02$, SE = 0.01, $P < 0.02$, OR = 0.98, 95% CI = 0.96–1.00).

Discussion

The results of this study suggest that the majority of primary care patients who smoke are willing to enter smoking cessation programs offered through their clinics, prefer more intensive treatment when given a choice, and will initiate a treatment regimen (e.g., pick up free NRT). At the 1-year follow-up, nearly 13% of treatment initiators achieved biochemically confirmed abstinence, with no apparent effect of the psychosocial treatments offered.

1. Are primary care patients who smoke willing to enter a free smoking cessation treatment program involving nicotine patches and possible counseling?

Over two-thirds of the patients identified as smokers in participating primary care clinics were willing to receive information regarding treatment. More than three-quarters of the eligible patients screened by telephone and over one-half of the patients identified as smokers at the clinic were enrolled in the study. These response rates stand in stark contrast to past research on referral programs in primary care [9,10]. Our results provide support for the argument that many primary care patients will accept treatment if it is free, appropriately incorporated into the health care delivery system so as to ensure convenience, and encouraged through proactive recruitment.

Our strategy of integrating treatment referral in clinic flow during vital sign assessment was designed to: (1) shift the responsibility for referral from over-burdened primary care clinicians [18] to medical assistants, (2) capitalize on the "teachable moment" created by the salience of health concerns in the clinical milieu[10,19], and (3) minimize the demands of treatment on smokers (i.e., they only had to express interest to be enrolled, patches were available from

Table 3
Intent-to-treat CO-confirmed point-prevalence (and continuous) abstinence rates at 6 month and 1 year follow-ups by treatment condition among smokers who picked up their patches

		Time since cessation	
		Six months (%)	One year (%)
Random assignment	Patch Only (n = 273)	12.1 (11.0)	11.7 (9.2)
	Patch + CQ (n = 263)	13.7 (12.5)	15.2 (8.0)
	Patch + CQ + Counseling (n = 274)	16.1 (14.6)	13.5 (10.6)
Self-selected assignment	Patch Only (n = 181)	12.2 (11.6)	10.5 (6.6)
	Patch + CQ (n = 258)	12.8 (10.5)	9.7 (6.2)
	Patch + CQ + Counseling (n = 337)	15.7 (13.9)	14.8 (10.4)
Overall	(N = 1586)	13.9 (12.5)	12.8 (8.7)

local pharmacies, CQ called patients at home, and counseling sessions were held at patients' regular clinics at no cost to patients). Our efforts to remove as many financial and logistical barriers to treatment utilization as possible may have contributed to our elevated utilization rates.

2. What is the preferred intensity of psychosocial treatment among interested primary care patients?

Nearly three-quarters of participants elected to receive some form of psychosocial intervention in addition to the nicotine patch, and over 40% elected face-to-face counseling sessions in addition to phone consultation and supportive mailings, suggesting that psychosocial treatment components are attractive to many smokers interested in quitting.

3. Do smokers adhere to the treatment regimen once enrolled?

Most participants took advantage of some of the resources available to them. The vast majority of enrollees initiated treatment by picking up patches. Nearly all respondents who picked up patches reported using at least some patches, with over 75% reporting patch use for at least 4 weeks and nearly 50% reporting use for 8 weeks as prescribed. Similarly, over two-thirds of those participants eligible for the phone and mailing support program (CQ) enrolled. Participation in the in-person counseling sessions was somewhat lower, with participants attending only one-half of the sessions on average.

4. How effective are the combined pharmacological and psychological tobacco dependence treatments offered in this study, and does their effectiveness differ as a function of random assignment vs. self-selection of treatment?

The 13% point-prevalence abstinence rate observed in this study is consistent with the 14% abstinence rate in transdermal nicotine patch studies (based on a mixture of point-prevalence and continuous abstinence rates) reported in the most recent Cochrane systematic review [20], but slightly lower than the 18% estimated abstinence rate reported in the 2000 Clinical Practice Guideline [6]. Our observed 1-year abstinence rate is higher than the 10% rate for placebo conditions estimated in meta-analyses [6,20].

We did not find evidence that psychosocial treatment intensity was significantly predictive of point-prevalence or continuous abstinence. Our sample was sufficiently large to detect 10% increments in abstinence rates, but not smaller effects. Those who received CQ materials plus the patch were 1.11 times more likely to be abstinent than those who received only patches. Those receiving counseling were 1.28 times more likely to be abstinent at 1 year post-quit than those receiving only patches. These modest effects are surprising since considerable data suggest that face-to-face counseling and CQ can be efficacious [6,21,22], although some researchers have failed to find an additive effect for counseling or CQ when paired with pharmacotherapy [23–27]. Based on a Cochrane systematic review of 14 studies, Lancaster and Stead [28] computed an estimated odds ratio of 1.62 for individual behavioral counseling relative to no

counseling condition. Similarly, the 2000 Clinical Practice Guideline estimated smokers receiving counseling were 1.7 times as likely to be abstinent as those not receiving counseling [6]. These effect sizes calculated based on meta-analyses are considerably larger than the effect of our highest intensity treatment.

Our psychosocial treatments may not have been effective because, in contrast to the typical randomized controlled trial in which the majority of participants fully adhere to treatment [29–31], a modest portion of our participants were exposed to full-strength treatments. The dose response relationship between counseling session attendance and abstinence rates suggests that if more participants had taken full advantage of available psychosocial treatments, significant treatment effects might have emerged. Therefore, a better test of psychosocial treatments among "treatment acceptors" would involve more accessible treatments, such as proactive quitlines [11,32,33].

5. Do smokers of different genders and races/ethnicities respond differently to the treatments offered in this study in terms of acceptability, utilization, and benefit?

We found one significant gender effect. Women were more likely to accept the initial study invitation than were men. This finding is consistent with past research suggesting that women who smoke are more willing to enter formal treatment programs than are men [5,7,12,13].

We found significant racial/ethnic differences in willingness to enter treatment, utilization of treatment, and response to treatment. African-American patients, who differed from White patients in terms of age, smoking heaviness, and education level, were more likely to accept the study invitation than were White patients (when clinic, a variable confounded with race/ethnicity, was not included). Thus, we, like Ahluwalia et al. [34] have found encouraging evidence that African-American smokers are receptive to formal cessation programs offered proactively in medical settings. African-American and other minority participants were less likely to pick up their patches than were White participants, and abstinence rates were significantly lower among African-American than among White participants. These findings suggest that lack of interest is not the crucial barrier keeping minority patients, particularly African-American patients, from entering formal smoking cessation treatment. Instead, barriers seem to keep African-American smokers from *utilizing*, and *benefiting from*, available treatments.

Although this study provided evidence that primary care patients are willing to enter and adhere to treatments made available through their local clinic, the results are qualified by some important limitations. First, the provision of free patches and repeated contacts with all participants in this study may reduce the generalizability of these findings to real-world settings. Potential quitters often must pay at least an insurance co-payment for NRT. However, as more health care organizations agree to sponsor free cessation pharmacotherapy, this limitation becomes less problematic. Indeed, the

results of this study could be used to argue that free treatment be made more widely available. Second, the feasibility of exporting a treatment package such as this one must be examined. Although every clinic contacted agreed to participate, not every clinic's staff was willing or able to screen patients for smoking status and forward relevant information to the research staff. Thus, some significant portion of primary care clinics may not be willing or able to carry out the minimal requirements of the recruitment procedures. Third, difficulty in securing full adherence to the study protocol by clinic staffers may have affected the integrity of our data. To guard against this, we excluded recruitment data from clinics that obviously did not adhere to our protocol, but subtle biases may have nevertheless been present in remaining clinics. Unobtrusive compliance checks in clinics might have revealed such biases.

This community-based study suggested that a large majority of smokers identified in primary care settings are receptive to messages regarding smoking cessation assistance. Even more encouraging, the majority of people who enrolled in the study used some of the cessation tools made available to them. The specific psychosocial treatment components offered in this study did not significantly influence abstinence rates. It is possible, however, that alternative treatments or alternative treatment delivery strategies yielding higher utilization rates could help the majority of smokers in primary care settings who express interest in quitting smoking.

Acknowledgments

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