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## Initial evaluation of a real-world Internet smoking cessation system

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### Abstract

To significantly reduce smoking prevalence, treatments must balance reach, efficacy, and cost. The Internet can reach millions of smokers cost-effectively. Many cessation Web sites exist, but few have been evaluated. As a result, the potential impact of the Internet on smoking prevalence remains unknown. The present study reports the results, challenges, and limitations of a preliminary, large-scale evaluation of a broadly disseminated smoking cessation Web site used worldwide (QuitNet). Consecutive registrants ( $N=1,501$ ) were surveyed 3 months after they registered on the Web site to assess 7-day point prevalence abstinence. Results must be interpreted cautiously because this is an uncontrolled study with a 25.6% response rate. Approximately 30% of those surveyed indicated they had already quit smoking at registration. Excluding these participants, an intention-to-treat analysis yielded 7% point prevalence abstinence (for the responders only, abstinence was 30%). A range of plausible cessation outcomes (9.8%–13.1%) among various subgroups is presented to illustrate the strengths and limitations of conducting Web-based evaluations, and the tensions between clinical and dissemination research methods. Process-to-outcome analyses indicated that sustained use of QuitNet, especially the use of social support, was associated with more than three times greater point prevalence abstinence and more than four times greater continuous abstinence. Despite its limitations, the present study provides useful information about the potential efficacy, challenging design and methodological issues, process-to-outcome mechanisms of action, and potential public health impact of Internet-based behavior change programs for smoking cessation.

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## Introduction

Some 5 million of the world's 1.25 billion smokers die annually (World Health Organization, 2002). Interventions are needed that are low cost, accessible, and sustainable and that reach large populations (Glasgow, Vogt, & Boles, 1999). Most cessation interventions reflect a tradeoff between low reach/high efficacy/high cost and high reach/low efficacy/low cost (U.S. Public Health Service [USPHS], 2000), ultimately affecting population impact (impact=reach  $\times$  efficacy; Abrams et al., 1996). Self-help materials can reach large numbers of smokers but have low (<4%) efficacy (Lancaster & Stead, 2002; Lichtenstein & Hollis, 1992; USPHS, 2000). In contrast, less than 7% of smokers use expensive clinic-based programs of high efficacy (>25%–35%; USPHS, 2000). The ultimate impact of cessation interventions on whole populations is unknown because most randomized clinical trials (e.g., USPHS, 2000) involve small samples of self-selected, motivated participants treated under ideal conditions (Abrams et al., 1996; Curry, Grothaus, McAfee, & Pabiniak, 1998). New interventions must bridge the tradeoffs between reach, efficacy, and cost to reduce population smoking prevalence and disease burden more efficiently (Niaura & Abrams, 2002).

The Internet has the potential to address reach, efficacy, and cost to optimize impact on smoking prevalence. Worldwide Internet use now exceeds 675 million (GlobalReach, 2003). About 60% of the U.S. population uses the Internet (Spooner, 2003), and almost 7 million Americans have searched for information on how to quit smoking (Fox & Fallows, 2003). The “digital divide” between individuals of low and high socioeconomic status has narrowed (Lenhart et al., 2003; Pastore, 2001) and should continue to do so as access increases among diverse populations. Expert systems can provide tailored treatment in real-time to individual needs on a populationwide basis (i.e., mass-customization; Rimer & Glassman, 1999; Skinner, Campbell, Rimer, Curry, & Prochaska, 1999; Velicer, Prochaska, Fava, Laforge, & Rossi, 1999). The availability of the Internet 24 hr a day, 7 days a week, 365 days a year (24/7/365) can prevent relapse through sustained and proactive support (Brandon, Herzog, & Webb, 2003; Brownell, Marlatt, Lichtenstein, & Wilson, 1986), and the anonymity of online interactions can facilitate social support (Kramish Campbell et al., 2001). Although initial development costs may be high, the costs of maintaining Internet programs are relatively fixed, resulting in greater efficiency as utilization increases.

Few evaluations of Web-based smoking cessation programs have been conducted. A pilot study ( $N=49$ ) by Lenert et al. (2003) reported a 1-month abstinence rate of 18% (7-day point prevalence abstinence). Another uncontrolled study (Stoddard et al., in press) evaluated the efficacy of individually tailored information and online quit smoking guides and reported a 1-month 7-day point prevalence abstinence rate of 3.5% using intention-to-treat (ITT) analysis. A second uncontrolled study by this group (Lenert, Muñoz, Perez, & Bansod, 2004) evaluated the efficacy of adding proactive, individually timed E-mail messages to this program. The 1-month 7-day point prevalence abstinence (using ITT analysis) was higher among subjects receiving E-mail messages than among those who used the control Web site (13.6% vs. 7.5%). Feil, Noell, Lichtenstein, Boles, and McKay (2003) examined the efficacy of online and traditional recruitment methods to a new Internet program and found that search engines and user groups yielded 54% and 19% of participants, respectively. An ITT analysis of the 370 program users who completed a 3-month follow-up yielded an 18% abstinence rate (7-day point prevalence abstinence). In a European study, 3,501 purchasers of a nicotine patch who proactively logged on to use a free Internet program and then consented to participate in a research study (76%) were randomly assigned to a tailored versus an untailored program (Strecher, Shiffman, & West, in press). To be eligible, the participant's target quit date had to be within 7 days of enrollment. At the 3-month follow-up, the tailored condition outperformed the untailored condition (22.8% vs. 18.1%, respectively), based on ITT analysis of continuous abstinence for 10 weeks. Collectively, these studies are a promising start in evaluating Web-

based smoking cessation programs. However, more studies are needed that use research methods that retain maximal external validity to determine the impact among all smokers looking for treatment on the Internet (Abrams et al., 1996).

A review of smoking cessation Web sites available in June 2002 (Bock et al., 2004) reported great variability in the quality and usability of sites on the Web: (a) Only 46 of 202 sites offered cessation treatment, (b) five provided extensive coverage of the USPHS guidelines (Abrams et al., 2003; USPHS, 2000), and (c) few sites used real-time interactivity to tailor treatment, omitting a key advantage of the Internet (Abrams, Mills, & Bulger, 1999). QuitNet was ranked among the five best Internet cessation programs (Bock et al., 2004). It is an established cessation Web site ([www.quitnet.com](http://www.quitnet.com)) that is highly utilized, with more than 335,000 registered users as of May 2004. Despite its adoption and endorsement by several state departments of health and its widespread international use, the efficacy of QuitNet has yet to be evaluated.

Several methodological challenges must be addressed in conducting research to evaluate the population impact of Internet cessation programs. Chief among these challenges is preserving internal validity while maximizing external validity (Eysenbach, 2002; Feil et al., 2003). For example, contamination in control groups may be difficult to prevent because of unrestricted access to the Internet. Key components of clinical trials (e.g., verification of eligibility, informed consent, treatment fidelity) may pose practical challenges to implementation via the Internet (Eysenbach, 2002) and may decrease participation (e.g., Stoddard et al., in press). Although considered the gold standard for evaluating intervention efficacy, randomized clinical trials may not yield the most relevant information for dissemination research and policy (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Tunis, Stryer, & Clancy, 2003) with regard to the overall public health impact of the Internet on smoking cessation (Abrams et al., 1996). Clinical trials of smoking interventions typically enroll only current smokers, often those who are motivated to quit smoking within a specified time period. Although this approach is ideal for determining the efficacy of an intervention with regard to cessation, it does not address the overall population impact of the intervention. The Internet may be effective in preventing relapse in recent quitters as well as promoting cessation in those intending to quit. Indeed, a recent study evaluated a relapse prevention intervention for recent quitters (Brandon et al., 2003). Thus a public health approach to evaluation might include all users of an Internet program, regardless of their smoking status when they began using the program. The present study is a large-scale, uncontrolled evaluation of QuitNet that raises several design and methodological considerations in evaluating Internet interventions.

## Method

### Subjects and enrollment

Participants were recruited from consecutive users who had registered with QuitNet during a 14-day window 90 days prior to the follow-up survey. QuitNet offers two versions of its system: a basic version available free of charge to anyone, and an enhanced version available through a prepaid subscription to sponsored members (e.g., corporate employees, state residents). The present study was limited to users of the free version. Users were sent an E-mail that explained the study and included a clickable link to the survey. To increase response rates, a reminder E-mail was sent to nonresponders 2 and 6 days after the initial E-mail offering US\$20 and US \$40 incentives, respectively. An encrypted identifier embedded in the clickable link tied the follow-up survey to the user's pre-existing QuitNet record.

## Description of the intervention

QuitNet incorporates the USPHS guidelines for best practice (USPHS, 2000) and includes the following features: (a) diagnostic tools and tailored information, (b) social support available 24/7/365 from peers and experts, and (c) recommendations and support for U.S. Food and Drug Administration (USFDA)-approved pharmacotherapy (USPHS, 2000).

**Diagnostic tools and tailored cessation information**—Diagnostic tools include the Fagerström Tolerance Questionnaire (Fagerström & Schneider, 1989) for nicotine dependence, a “Why Do You Smoke” questionnaire (adapted from National Cancer Institute materials), and the stages of change (Prochaska & DiClemente, 1983). An interactive tool assists smokers in setting a quit date. Reminders and encouragement to set a quit date occur throughout the system, which provides targeted and tailored information to each user based on this quit date and other available information (e.g., gender, quitting history, medication status). A quitting guide provides users with evidence-based information about smoking cessation, with some of the content organized around the stages of change (Prochaska & DiClemente, 1983). A customized quitting calendar, tailored by the user’s quit date, provides cognitive-behavioral coping strategies related to preparing to quit, coping with withdrawal, and relapse prevention. The calendar is integrated with a personalized journal so that users can self-monitor progress and increase self-efficacy. An interactive feature (Q-Gadget) calculates the amount of money a user has saved since quitting (or will save once quit), an estimate of “life saved” (Shaw, Mitchell, & Dorling, 2000), and how long the user has been smoke-free. This feature also provides real-time notification of new messages from other QuitNet members and indicates whether a user has identified any quitting buddies. A list of local smoking cessation resources throughout the United States is available, searchable by zip code. Tailored proactive support and follow-up also are provided (e.g., E-mail messages that take into account a user’s quit date, medication plan, and the like). Based on quit date, medication usage, age, gender, and prior usage patterns within the site, a dynamically generated list of suggested next steps (analogous to an individualized treatment plan) is presented to each user after he or she logs in.

**Social support**—Social support is provided 24/7/365 through a large community of members. Threaded forums (asynchronous messaging), an internal E-mail system, and chat rooms (synchronous, real-time messaging) allow subscribers to send and receive messages. About 2,000 messages per day are posted in public forums, and thousands more are exchanged privately.

**Expert counseling**—Individual counseling is provided by online expert counselors who are certified through the Massachusetts Tobacco Treatment Specialist Training Program (Pbert, Ockene, Ewy, Leicher, & Warner, 2000). Users can send the counselors private messages or post questions in a public forum. Counselors manage the “Ask the Expert” forum and reply to incoming requests primarily during business hours 7 days a week.

**Medication support**—A pharmaceutical guide provides comprehensive information and instructions for use of USFDA-approved medication and other products. A summary chart reviews various features of medications (e.g., prescription vs. over the counter, potential side effects, dosing requirements) so that users can compare different options. Frequently asked questions (FAQs) about medication are displayed to users based on their stated medication preferences. Expert counselors also provide support related to medication use and adherence.

## Web site accessibility and volume of users

QuitNet performs no active recruitment. It is available to smokers through two main channels: free public Internet access and paid contracts. The publicly available version was evaluated in the present study. A subscription fee is required to unlock some advanced features not discussed

in detail here, notably direct access to counseling staff, use of several additional tailored expert systems, and unlimited use of the social support system. Customized and rebranded versions of QuitNet are provided to contracting state health departments and corporations (full access is provided because the contractor pays for every registered user). All versions (public access and paid contracts) operate in the same environment and have a single support community; therefore, regardless of the means by which users access QuitNet, they all participate in the same online community. In queries using the terms *stop smoking* or *quit smoking*, QuitNet has been in the top three results of the largest search engine ([www.google.com](http://www.google.com)) since 1998. As of May 2004, Google referred an average of 650 visitors to the site each day (over 237,000 referred each year).

Smokers can interact with the free QuitNet system as anonymous or registered users. Anonymous users are able to browse noninteractive, nontailored materials only. About 2,400 unique anonymous users browse QuitNet daily (over 870,000 per year). In 2003, an average of 8,350 new users registered with QuitNet each month (over 100,000 per year). Registration with the system is encouraged and includes questions on demographics and smoking history (e.g., smoking rate, stage of change, number of 24-hr quits in the past year, medications used to quit, and nicotine dependence). The number of questions is deliberately kept low to decrease barriers to enrollment; further information is acquired on a need-to-know basis. An E-mail address is required, but no other personally identifying information is collected. All participants in the present study were registered users.

Once registered, users are referred to the “My Quit” page, the starting point for all interactions. A list of recommended next steps is presented based on an algorithm using the stages of change, previous site utilization, and other data (e.g., medication plan, gender). Although the system provides a series of suggested steps, users are free to use components of the site in any order. User interaction with the system is logged to a relational database that tracks usage data such as time, date, and duration of logins; content used; and use of social support components.

## Measures

The follow-up survey conducted 90 days after registration was, of necessity, brief and consisted of 11 items that assessed the following outcomes (available on request from corresponding author): 7-day point prevalence abstinence; actual quit date; number of 24-hr quit attempts during the past 3 months; longest duration of continuous abstinence in the past 3 months; use of treatment resources during the past 3 months, including pharmacotherapy; and smoking rate, stage of change, desire and confidence to quit, and time to first cigarette after waking for those still smoking (Fagerström & Schneider, 1989). All other data on those surveyed were extracted from the QuitNet database, including demographics (age, gender, race, education level); smoking history; baseline stage of change; and Web site usage patterns (e.g., number of logins, minutes per login, interactions with other users and counselors). Site usage is tracked by the system through short-term (length of session) and long-term (persistent between sessions) cookies, allowing for identification of users throughout their life cycle whether logged in or not.

## Statistical analysis

The primary outcome measure was self-reported 7-day point prevalence abstinence at 3 months postregistration. Approximately 30% of those surveyed indicated at registration that they had already quit smoking. Primary outcome analyses excluded these subjects and examined abstinence using both a strict ITT analysis, which counts all nonresponders as smokers, and an adherence sample analysis of responders only. To examine the potential public health impact of QuitNet, we also examined quit rates with recent quitters included in the denominator. Finally, we analyzed cessation outcomes among several subgroups of those surveyed: (a)

participants who were quit at registration, to determine the percentage that maintained abstinence, (b) the entire sample excluding participants with bounced E-mail addresses, and (c) the entire sample excluding participants who visited the Web site only once or twice. Frequency tables were used to summarize the categorical data, and nonparametric tests were used to determine the statistical significance level. We used *t* tests for normally distributed continuous and ordinal variables and logistic regression to identify predictors of abstinence. All analyses were performed using the SPSS v. 11.

## Results

### Recruitment outcomes

A total of 1,501 registered users of the free QuitNet service were surveyed during the 14-day window. Some 185 surveys (12.3%) were returned because of invalid E-mail addresses (bounced). An incentive was offered to nonresponders 2 days (US\$20) and 6 days (US\$40) after the initial E-mail. Of 1,316 surveys delivered successfully, 385 (29.3%) were completed. Of all 385 responders, 181 (47.0%) responded without an incentive, 128 (33.2%) responded to the US\$20 incentive, and 76 (19.7%) responded to the US\$40 incentive.

### Bounced versus nonresponders versus responders

As shown in Table 1, no differences were found in baseline smoking rates between bounced, nonresponder, and responder groups (smoking rate=21.3±9.6 cigarettes per day). Subjects with bounced E-mails were younger than responders and were less likely to be female, to be White, to have attended at least some college, to visit the site more than once, and to be in the action stage of change. Compared with survey responders, nonresponders were younger and were less likely to be female, to be White, to visit the site more than once, and to be in the action stage of change. Subjects with bounced E-mails and non-responders spent fewer minutes on QuitNet than responders and had logged in to use the site less recently than responders. Nonresponders did not differ from responders in level of education.

Among the 385 survey responders, 70.9% were female, 91.4% were non-Hispanic White, and 47.5% had a college degree or higher. Responders were on average 38 years of age (*SD*=11.2; range=16–81). Responders resided in over 20 countries, with the largest representation from the United States (81.3%), Canada (7.8%), and Great Britain (3.9%).

### Smoking cessation outcomes

The 27 users who indicated they were “never smokers” at registration (six respondents, 17 non-respondents, and four bounced E-mails) were excluded from all analyses. We also excluded from primary outcome analyses the 450 subjects (30%) who indicated at registration that they had already quit smoking. Using a strict ITT analysis counting all nonresponders (including bounced E-mails) as current smokers (*n*=1,024), we found a 7-day point prevalence abstinence rate of 7% at the 3-month follow-up. Among those quit, 90% were continuously quit for 30 days or longer, yielding a 30-day point prevalence abstinence rate of 5.9%. Self-reported 7-day point prevalence abstinence among the sample of responders only (*n*=223) was 30%. No differences were found in baseline smoking rate or baseline motivational stage between quitters and smokers. Consistent with the public health approach described earlier, we conducted another ITT analysis that included in the denominator all nonresponders as well as those who were quit at baseline (*n*=1,474). This analysis yielded a point prevalence abstinence rate of 11.5%. Among responders only (*n*=379), the point prevalence abstinence rate was 44.6%.

### Cessation analyses of subgroups

Among participants who were already quit at registration, almost half (47%;  $n=211$ ) indicated they had quit 1 week or less before registration. Using ITT analysis ( $n=450$ ), we found the 7-day point prevalence abstinence rate to be 22.7%; among those quit, 99% (101/102) were continuously quit for 30 days or longer. The 7-day point prevalence abstinence rate among responders only ( $n=156$ ) was 65.4%.

To minimize the high rate of dropout often seen in Internet studies, it has been suggested that a run-in period be utilized (Eysenbach, 2002). Preceding the start of a clinical trial, users would be required to return to the Web site several times prior to enrollment and randomization, and only returning users would be enrolled and randomized. From a population impact perspective, this requirement reduces generalizability and may overestimate impact. However, given that some of the participants we surveyed ( $n=523$ ) visited QuitNet only once, we were interested in evaluating what the quit rate (action/maintenance excluded) might look like had we used this run-in technique while still using a strict ITT analysis with the appropriate denominator. Among those who used the Web site more than once ( $n=488$ ), 7-day point prevalence abstinence was 9.8%, and among those who used the Web site on more than two occasions ( $n=336$ ), the quit rate was 13.1%.

Related to this issue is the number of participants who were lost to follow-up because of bounced E-mail addresses. A second technique to minimize dropout would be to validate E-mail addresses at study enrollment. To estimate what the quit rate would be had we validated E-mail addresses, we excluded participants with bounced E-mail addresses from the denominator and found that 7-day point prevalence abstinence (ITT;  $n=892$ ) increased from 7% to 8%.

### Program and process-to-outcome relationships

Subjects who were still smoking at follow-up had significantly reduced their daily cigarette consumption from baseline ( $20.7\pm 10.5$  to  $13.9\pm 9.5$ ,  $t=10.42$ ,  $p<.001$ ). Among those still smoking, 58.4% indicated smoking within 30 min of waking. At follow-up, current smokers were asked to rate their desire to quit smoking and their confidence in their ability to quit on a 10-point scale (1=not at all confident, 10=very confident). Respondents reported high levels of desire ( $M=8.7$ ,  $SD=1.6$ ) to quit smoking but somewhat lower levels of confidence ( $M=6.2$ ,  $SD=2.5$ ).

Quitters differed from smokers on Web site utilization as shown in Table 2. These analyses included only those participants who were current smokers at baseline. As has been noted in other studies (e.g., Feil et al., 2003), patterns of Web site utilization vary widely. Given the skewness of Web site utilization variables, we report the median and interquartile range, which are more informative than means and standard deviations. Compared with smokers, quitters logged in more frequently, spent more total time online, and viewed more pages. Quitters also participated more extensively than smokers in the various opportunities for social support.

A composite measure of Web site utilization intensity (number of logins  $\times$  duration in minutes per login) was very highly correlated with use of support resources (number of E-mails sent, number of E-mails received, number of E-mail senders, number of E-mail recipients; all Pearson  $r>.65$ ; all  $p$ -values  $<.01$ ), suggesting that greater Web site use was largely a function of involvement in the support community. It is possible that motivation accounts for the relationship between Web site use (intensity, use of social support) and smoking outcome. However, baseline motivation was not significantly correlated with Web site use (intensity, use of social support) or with smoking outcomes (all Pearson  $r<.02$ ,  $p>.60$ ).

Using logistic regression, we examined whether use of social support and intensity of Web site use predicted two measures of abstinence at follow-up: 7-day point prevalence abstinence and continuous abstinence. For each outcome, we first fit social support and intensity of Web site use separately and examined whether they interacted with baseline stage of motivational readiness. No significant stage main effects or interactions were detected, and that variable was dropped from all subsequent models. Participants who participated in any aspect of the support community were more than three times as likely to be quit ( $OR=3.24$ , 95%  $CI=1.76-5.93$ ,  $p<.0001$ ) and four times as likely to be continuously abstinent for 2 months or longer ( $OR=4.03$ , 95%  $CI=2.10-7.72$ ,  $p<.0001$ ). We also examined whether greater duration and frequency of treatment (i.e., intensity) was associated with better cessation outcomes as reported in the USPHS (2000) guideline. Using univariate logistic regression with a post-hoc median split of high versus low intensity Web site use as the predictor, we found that high Web site users were more than twice as likely to be quit ( $OR=2.34$ , 95%  $CI=1.23-2.46$ ,  $p<.01$ ) and to be continuously abstinent for 2 months or longer ( $OR=6.07$ , 95%  $CI=2.46-14.96$ ,  $p<.0001$ ), compared with low Web site users.

Because intensity and social support predicted cessation outcomes, and because social support increases with intensity ( $\chi^2=205.7$ ,  $p<.001$ ), we examined whether degree of social support mediated the effect of intensity on cessation (Baron & Kenny, 1986). Confirming the mediation hypothesis requires that, in a bivariate logistic regression, the effect of intensity is attenuated after adjusting for the effect of social support. Mediation was found with 7-day point prevalence abstinence as the outcome: The odds ratio for the effect of intensity declined from 2.34 to 1.52 (95%  $CI=0.74-3.12$ ,  $p>.05$ ) after adding social support to the model. By contrast, high social support continued to almost triple the odds of quitting ( $OR=2.71$ , 95%  $CI=1.39-5.31$ ,  $p<.01$ ) relative to low social support even after adjusting for intensity. With continuous abstinence as the outcome, we found no evidence of mediation, that is, adjusting for social support did not attenuate the effect of intensity, with the adjusted odds ratio remaining essentially unchanged at 4.08 (95%  $CI=1.56-10.66$ ,  $p<.01$ ).

Finally, we examined use of other treatment resources (in addition to QuitNet) during the study period. Approximately 57% of respondents used some form of medication, and 28.4% of respondents used some form of therapy (e.g., individual counseling, acupuncture). Quitters were not more likely to use behavioral or pharmacological treatment compared with smokers, and use of other treatment resources was not predictive of smoking status.

## Discussion

To our knowledge, this is the first study of a widely disseminated, high-volume Internet smoking cessation program with a sample of typical Internet users. It is a real-world evaluation that maximizes external validity by sampling all users of an Internet program, including recent quitters, who registered sequentially during a 2-week period. At the 3-month follow-up, a strict ITT analysis of those who were smoking at baseline yielded a 7-day point prevalence abstinence rate of 7%; among responders only, the point prevalence abstinence rate was 30%. However, several limitations with regard to internal validity (e.g., no control group, lack of randomization) should be considered when interpreting results. Given these limitations, we present a range of efficacy estimates and potential population impact rather than one single cessation coefficient.

Almost 30% of participants registered with QuitNet after they had quit. Including in the denominator those who were already quit at baseline, we found via ITT analysis a point prevalence abstinence rate of 11.5%; among responders only the rate was 44.6%. Recent research has begun to address the feasibility of preventing relapse in smokers who have already quit on their own (Brandon et al., 2003). Over 16 million Americans try to quit on their own

each year, but less than 5% maintain abstinence for 3 months (Centers for Disease Control and Prevention, 2002). Thus more than 15 million smokers relapse. A widely accessible and effective relapse prevention service could produce a significant impact on smoking prevalence and could be used in conjunction with any other cessation treatment. In the present study, 22.7%–65.4% of those who were quit at baseline maintained their quit status at 3 months. There is great, untapped potential to affect smoking prevalence by preventing relapse or at least attenuating the steep relapse curve seen in self-quitters and minimal interventions (Hughes, Keely, & Naud, 2004). Further research using a randomized design and comparison group is needed to determine the degree to which QuitNet services were responsible for preventing relapse among those already quit at baseline.

Given the broad reach and 24/7/365 accessibility of Web-based interventions, the population impact of even the most modest of the cessation rates reported here is substantial. The high volume of traffic to the Web site alone (>100,000 users per year) could result in 7,000 new quitters per year and 22,700 potential prevented relapses per year (using the most stringent 7% and 22.7% ITT rates, respectively). The number of smokers who have ever searched for cessation information on the Internet (about 6 million in recent years; Fox & Fallows, 2003) underscores the public's desire for smoking cessation interventions. The potential public health impact of Internet programs is astounding if one assumes worldwide accessibility (over 675 million users, 25% smokers=169 million smokers). Moreover, the added costs associated with millions more Internet users are low (once relatively fixed development costs are absorbed); in contrast, telephone- and clinic-based programs must add staff, meeting space, and other expenses as utilization increases.

Process-to-outcome analyses were consistent with the USPHS guideline in that frequency and duration (intensity) of treatment and use of social support were predictive of quitting (Fiore et al., 1996; USPHS, 2000). Just as greater intensity of face-to-face treatment produces better outcomes, more intensive and sustained use of QuitNet was associated with better cessation outcomes. Use of Internet social support was associated with more than three times greater cessation and with more than four times greater likelihood of continuous abstinence for more than 2 months. Social support mediated the relationship between intensity of use and 7-day point prevalence abstinence, suggesting that active involvement in a support community is a key ingredient to quitting.

The present study also documents the importance of a functional community to provide 24/7/365 social support. Although it is well recognized that social support is related to successful cessation outcomes, it has been difficult to create and sustain such support in traditional face-to-face clinical or telephone interventions, especially after the treatment terminates (Lichtenstein, Glasgow, & Abrams, 1986). Prior studies of other online interventions (Markus, 1987; McKay, King, Eakin, Seeley, & Glasgow, 2001; Preece, 2000) do not have the level of social support options seen on QuitNet. The Internet provides a promising new channel to sustain social support for as long as the user wants it.

The process-to-outcome results linking intensity of QuitNet use and social support with positive cessation outcomes warrant further study. Process-to-outcome analyses can (a) address the cost-effectiveness or efficiency of specific intervention components, (b) determine the active components in a treatment program, (c) identify the minimum intervention-necessary criteria to produce efficient outcomes, and (d) determine how much tailoring is sufficient to produce an optimal effect (Abrams et al., 1999). Qualitative research should be conducted to examine the diverse types of social support networks that have emerged spontaneously among QuitNet users, some of which have been sustained since its inception in 1995. The present study demonstrates the potential of the Internet to gather detailed process-to-outcome data regarding Web site utilization that provide a clear picture of treatment utilization (i.e.,

frequency, duration, and general usage patterns) and that permit examination of mechanisms of action and mediators.

Conducting research via the Internet provides opportunities to ask new questions and employ very large sample sizes for subgroup analyses. However, Internet research is also methodologically challenging (Feil et al., 2003). Conducting research via the Internet forces explicit analysis of some of the threats to internal and external validity that are often not raised in conventional clinical trials. One set of threats to internal validity involves selection bias or differential dropout bias. If a control group involves another treatment modality (e.g., telephone) and participants are expecting or prefer a Web-based treatment, differential dropout may occur. Likewise, a Web-based control group that is not credible also can result in differential dropout or contamination because users differentially seek other treatments. These challenges are not unique to Internet research; indeed, participants in all clinical trials can avail themselves of other interventions or drop out of treatment at any time. In an era of increasingly stringent human subjects protections, conducting research via the Internet poses particular challenges to obtaining informed consent (Eysenbach, 2002). Several researchers have successfully used online recruitment, enrollment, and informed consent procedures (including electronic signatures, e.g., Lenert et al., 2004; Stoddard et al., in press), which should serve as benchmarks for future trials using real-world designs. Other methodological issues are discussed elsewhere (e.g., Eysenbach, 2002; Feil et al., 2003; Strecher et al., in press).

The data-gathering capabilities of the Internet afford a unique opportunity to examine in detail the effects of different analytical approaches but also raise numerous unresolved questions. Should individuals with bounced E-mail addresses be included in outcome analyses? Should one-time Web site visitors be considered users of an intervention condition? Should individuals who are recently quit at baseline be included in some outcome analyses? Determining the true population cessation rate is important when estimating societal impact of cessation treatments in general, not just for Internet programs (Abrams et al., 1996; Shiffman, Mason, & Henningfield, 1998). To do so requires a balance between external validity and internal validity, and real-world approaches that utilize key components of practical clinical trials (Tunis et al., 2003). To create a new public health model for the 21st century, such approaches include recruiting a diverse population of participants (including recent quitters) and collecting data on a broad range of outcome indices.

Limitations of the present study include a low response rate, short follow-up period, and lack of randomization to a comparison condition. These limitations are threats to both internal and external validity. The low response rate introduces selection bias and limits generalizability and is most likely related to the observational nature of this study (i.e., we had not requested participation in a follow-up survey at registration). It has been suggested that the relative ease of recruiting subjects via the Internet is offset by relatively high dropout rates (Eysenbach, 2002). Indeed, other studies of Internet cessation interventions have reported short-term (1 to 3-month follow-up) response rates of 26%–56% (Feil et al., 2003; Lenert et al., 2004; Stoddard et al., in press; Strecher et al., in press). Although the bounced and nonresponder groups were considered current smokers in the ITT analyses, some of these individuals may have quit (or maintained their quit) having received the information and support they needed from QuitNet. If true, then the ITT analyses may be unduly conservative (Hall et al., 2001).

Given that Web-based smoking cessation interventions are in a relatively nascent stage of development, we opted to focus on short-term (3-month) outcomes in this preliminary investigation. Once stronger evidence of short-term efficacy is available, future studies will need to determine if the effects of the intervention are maintained over time. A shorter follow-up period was selected to maximize response rates because validity of E-mail addresses (as measured by bounce rates) tends to deteriorate over time and because E-mail was our only

method of follow-up contact with participants given that we did not validate E-mail addresses at registration. To address the limitations of the present study, future efforts will need to use a carefully selected control group in a randomized design with informed consent, longer follow-up periods, adequate response rates, and little differential dropout.

In summary, results of this evaluation of an existing and widely utilized Internet smoking cessation intervention are promising. Despite the limitations of the present study, useful information is provided about the feasibility, potential efficacy, process-to-outcome mechanisms of action, and potential public health impact that can be achieved through Internet-based behavior change programs for smoking cessation. The present study highlights the challenges of balancing internal and external validity that are at the heart of all types of translational clinical and dissemination research. The present study raises many design and methodological issues and helps to point the way toward more rigorous evaluation. Evaluation of all the popular smoking cessation Web sites is recommended because consumers and health care policy makers have a right to know whether programs they encounter on the Internet meet minimal evidence-based guidelines (Bock et al., 2004) and whether they are effective when used as intended (USPHS, 2000).

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**Table 1**

Demographic, smoking history, and Web site utilization characteristics of study sample

	Responders (n=385)	Nonresponders (n=931)	Bounced (n=185)
Age (years)	37.3±11.2	34.3±10.6***	35.2±10.9*
Gender (female)	70.9%	63.2%**	61.6%*
Ethnicity (White)	91.4%	82.9%**	83.5%**
Education (some college or more)	85.2%	79.5%	74.6%**
Stage of change (action)	39.2%	24.6%***	23.2%***
Cigarettes per day	21.24±9.6	20.08±11.4	21.57±12.8
Total time online (min)	540.55±1883.4	157.81±805.01***	94.2±254.77***
Web site use (1×only)	30.7%	52.0%***	57.5%***
Last login (number of days)	45.9±42.4	76.6±36.1***	76.6±33.5***

Note. Between-group differences were analyzed using *t* test (means) and chi-square (proportions). Nonresponders and bounced were each compared to responders.

\*  
*p*<.05;

\*\*  
*p*<.01;

\*\*\*  
*p*<.001.

**Table 2**

Median (interquartile range) of QuitNet utilization among quitters and smokers

	Quitters (n=67)	Smokers (n=156)
Number of logins	9 (1–42)	2 (1–5)***
Average session length in minutes	12 (7–20)	14.5 (8–23)
Total number of minutes online	103 (33–339)	33 (17–82.5)***
Total number of pages viewed	128 (31–366)	34 (17–87)***
Percentage posting at least one time in public forums	19.4	4.5***
Percentage with at least one buddy	19.4	9.6*
Percentage who sent Qmail to at least one person	25.4	9.0**
Percentage who received Qmail from at least one person	41.8	20.5***

*Note.* Between-group differences were analyzed using Wilcoxon *W* test for continuous data (median) and chi-square (proportions).

\*  $p < .05$ ;

\*\*  $p < .01$ ;

\*\*\*  $p < .001$ .