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Characteristics of smokers reached and recruited to an Internet smoking cessation trial: A case of denominators

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Abstract

The Internet can deliver smoking cessation interventions to large numbers of smokers. Little is known about the feasibility, reach, or efficacy of Internet cessation interventions. Virtually no data exist on who enrolls in cessation programs or on differences between those who complete enrollment and those who do not. This paper reports recruitment and enrollment findings for the first 764 participants in an ongoing randomized controlled trial that tested the efficacy of a widely disseminated Internet smoking cessation service (www.QuitNet.com) alone and in conjunction with telephone counseling. Study participants were recruited through Internet search engines using an active user sampling protocol. During the first 16 weeks of the study, 28,297 individuals were invited. Of those, 11,147 accepted the invitation, 5,557 screened eligible, 3,614 were recruited, 1,489 provided online informed consent, and 764 were confirmed eligible and enrolled. Of those who were at least curious about a cessation trial ($n=11,147$), 6.9% enrolled. Of those who were eligible and recruited ($n=3,614$), 21.1% enrolled. Depending on the denominator selected, results suggest that 7% to 21% of smokers interested in cessation will enroll into a research trial. Internet recruitment provides unique challenges and opportunities for managing sample recruitment, analyzing subsamples to determine generalizability, and understanding the characteristics of individuals who participate in online research.

Background

The Internet holds great promise as a method to reach and treat smokers. The number of smokers seeking information online exceeds 8 million in the United States (Fox, 2005). There have been several studies of Internet-based smoking cessation treatment (Etter & Perneger, 2001; Feil, Noell, Lichtenstein, Boles, & McKay, 2003; Koo & Skinner, 2005; Stoddard et al.,

2005; Strecher, Shiffman, & West, 2005). In addition to establishing the effectiveness of online cessation treatments, researchers also need to document the feasibility of online recruitment, and determine whether participants reached, recruited, and enrolled in a study via the Internet differ from other participant groups.

Several methods for recruiting smokers into Internet trials have been described (Lenert & Skoczen, 2002; Cobb, Graham, Stoddard, & Rabiuss, 2005b), including direct email and posts to online newsgroups, chat rooms, or Web sites. These methods have yielded widely variable response rates depending on the population sampled, the recruitment methodology, and the denominators selected and reported (Feil et al., 2003; Koo & Skinner, 2005; Stoddard et al., 2005; Strecher et al., 2005). This variability highlights an important methodological consideration in conducting Internet research: To estimate the reach of a recruitment approach and the generalizability of results, it is important to document the target population, the number exposed to recruitment, the number who respond, the number eligible, and the number who actually participate (Abrams et al., 1996; Dzewaltowski, Glasgow, Klesges, Estabrooks, & Brock, 2004). In the majority of Internet studies cited above, these data are not reported or not clear. This information also is important if researchers are to understand the characteristics of smokers and the barriers they may encounter when responding to research opportunities on the Internet.

One mechanism for online recruitment, “active user interception sampling,” intercepts Internet users while they surf the Internet and replaces the expected page with a study invitation (Kaczmirek & Neubarth, 2005). In contrast to the methods reported in other Internet studies, this approach recruits Internet users in accordance with the links they select, and only invites individuals who navigate through the invitation page. This approach has two distinct advantages: (a) Internet users may be more likely to respond to the intercept page than to reactive recruitment methods; and (b) tracking mechanisms make it possible to determine the number of individuals exposed to the study invitation, allowing for accurate calculation of reach parameters at each step of the recruitment process. This method was employed in the present study.

The present study is part of an ongoing randomized controlled trial (RCT) that tests the efficacy of an Internet smoking cessation Web site (www.QuitNet.com) and proactive telephone counseling. Recruitment leverages QuitNet’s top-ranked position on major search engines to recruit Internet users seeking smoking cessation assistance. We describe the recruitment process of the first 764 participants in this study to demonstrate the feasibility of Internet recruitment and to highlight methodological issues.

Method

Recruitment

Internet users from the United States were recruited based on use of the terms *quit(ing) smoking* or *stop(ping) smoking* in a major search engine query (AOL, MSN, Yahoo, Google) and no known prior visit to QuitNet (no cookie detected). When a user clicked on a link to QuitNet in the results of a search engine query, an intercept page appeared inviting them to participate in a study to test how well Internet and telephone treatment helped people to quit. If they accepted, they were asked 10 questions (age, smoking rate, age of first puff, time to first cigarette after waking, number of quit attempts in past year, gender, race, education, zip code, and prior use of QuitNet). Three questions determined preliminary eligibility (aged ≥ 18 , ≥ 5 cigarettes/day, no prior QuitNet use); remaining questions were used to characterize the largest possible denominator of potential study participants.

The recruitment software allowed investigators to control the rate of enrollment to manage research staff workload relative to fluctuations in recruitment volume and to ensure attainment of race and gender recruitment goals. When volume was high, a proportion (e.g., 1 of every 3) of eligible users was recruited. Those not recruited, as well as ineligible participants, were directed to the QuitNet home page.

If eligible, participants were asked to provide online informed consent, their name, and telephone number. Within 48 hr, a research assistant confirmed eligibility and consent, administered a baseline telephone assessment, and randomized the participant to study condition. All available recruitment process information was logged in real-time to a relational database (Microsoft SQL Server 2000; Microsoft 2000).

Results

Recruitment

Consistent with the CONSORT guidelines (Moher, Schulz, & Altman, 2001), Figure 1 shows the denominator at each step of recruitment. During the first 7 months of the study, 28,297 individuals were invited: 47.1% were referred from Google, 32.8% through Yahoo!, 17.6% through MSN (17.6%), and 2.6% through AOL. The most common search term was *quit smoking* (50.6%), followed by *stop smoking* (20.9%), and *quitting smoking* (16%). Adjusted for local time, the majority (60.3%) of individuals were recruited during work hours (9 A.M. to 5 P.M.).

Of the 28,297 invited to participate, 39.4% (11,147) accepted, 32.2% declined, and 28.4% abandoned (closed their browser). Of the 11,147 who accepted, 10,692 (96%) proceeded to the eligibility screening page and 455 (4%) abandoned. Of those who reached the eligibility screening page, 52.0% (5,557) were eligible, 4.2% (444) were ineligible, and 43.9% abandoned. Individuals were determined ineligible for one or more of the following reasons: Under age 18 (347); prior use of QuitNet (262); and smoking <5 cigarettes per day (252), with 20 of those already quit. Although 5,557 individuals were eligible, 1,943 were told the study was not currently recruiting and were redirected to QuitNet. Thus, 3,614 individuals were asked to provide online informed consent; 41.2% (1,489) consented and 58.8% (2,125) abandoned.

Of the 1,489 people who provided online consent, 51.3% (764) were confirmed eligible, completed the baseline assessment, and were randomized to treatment; 27.5% were unreachable; 4.5% were no longer interested in participating; 14.0% (208) were ineligible; and 2.8% were scheduled for the baseline phone assessment, although they were not yet enrolled at the time of this report. Of the 208 ineligible, 181 (87%) had already quit smoking.

Calculating reach estimates

Reach estimates vary depending on the denominator selected: 2.7% of all Internet users seeking cessation information (28,297); 6.9% of those who demonstrated preliminary interest in the study (11,147); 13.7% of those who were eligible to participate (5,557); 21.1% of those eligible and recruited (3,614); and 51.3% of those consented (1,489).

Randomized vs. others—Randomized participants were older, more likely to be female, and less likely to be White than those eligible and recruited (Table 1). Demographic differences were primarily related to investigator control of the recruitment process. Differences were also noted in smoking variables, such that the final sample smoked at a higher rate, was more likely to smoke within 30 min of waking, had made more quit attempts in the previous year, and began smoking at an earlier age (all *p* values <.01). There were no differences between subgroups on education or time of recruitment.

Randomized sample—The majority of study participants were female (60.5%), White (86.4%), and college educated (48.4%). The mean age was 35.6 years ($SD=10.25$). Most participants (88.2%) were planning to quit in the next 30 days (Preparation). On average, participants smoked 20.29 cigarettes per day ($SD=9.91$), had their first puff at age 14 ($SD=3.55$), and became daily smokers at age 17 ($SD=3.4$). Participants made an average of 2.86 quit attempts in the past year ($SD=4.83$) and reported higher levels of desire to quit ($M=9.02$, $SD=1.43$) than confidence ($M=6.16$, $SD=2.25$). Average score on the Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerström, 1991) was 5.04 ($SD=2.36$), with 44% of participants scoring 6 or above, indicating a high level of nicotine dependence (Fagerström, Kunze, Schoberberger, et al., 1996). Participants were generally Internet savvy, with 74.6% having used the Internet for at least 5 years, 74.3% using the Internet several times a day, and 83.2% with broadband (Table 2).

Discussion

Preliminary results from this ongoing study demonstrate the feasibility of using an active user-intercept protocol to recruit smokers into a research trial. Linking a study recruitment protocol to highly utilized search engines through active user sampling results in very high initial reach (28,297) to a large sample of smokers looking for cessation assistance. There are significant portions of this initial pool of participants that drop out of the recruitment flow prior to enrollment. Using the broadest population denominator, preliminary results suggest that approximately 2.7% of Internet users looking for online cessation information will enroll in a research trial such as this one. However, this denominator may be overly conservative and not appropriate to estimate reach: It is analogous to counting all newspaper subscribers who read an advertisement for a cessation trial, many of whom will not even call the research center. Other potential denominators to estimate the reach of this recruitment approach to the population of interest are those who indicated some preliminary interest (11,147) and/or those who were eligible (5,557) and recruited (3,614). Reach estimates using these denominators were 6.9%, 13.7%, and 21.1%, respectively. Given that more than 8 million smokers use the Internet to find cessation information each year (Fox, 2005), active user sampling could potentially reach thousands of smokers with the opportunity to participate in a research trial.

The final sample differs from eligible participants on daily smoking rate, time to first cigarette, number of previous quit attempts, and age of first puff, suggesting a sample of heavier, more dependent smokers who may be more motivated to quit smoking. Education level did not appear to influence enrollment. Differences in race and gender were also observed, but may be attributed to investigator control of recruitment. Including a small number of additional questions in online eligibility screening allows for such comparisons and seems to be well accepted by participants. As in other studies of Internet cessation (Etter & Perneger, 2001; Feil et al., 2003; Koo & Skinner, 2005; Stoddard et al., 2005), the majority of our sample is comprised of younger, female, college-educated individuals with substantial Internet experience. The ability to adjust recruitment volume (oversampling or undersampling) based on race and gender has been critical to meeting goals for under-represented minority populations. To date, we have used this feature primarily to control enrollment of White females who comprised 62% of the participants enrolled in the first 3 months. Minority recruitment has proceeded more slowly, with Blacks enrolling at the highest rate among minority groups. Although online recruitment can be used to conduct preliminary eligibility screening and consent, eligibility and consent should be reconfirmed prior to randomization.

As reported in Cobb, Graham, Bock, Papandonatos, and Abrams (2005a), many individuals turn to the Internet for support within days of their quit. In the present study, individuals were excluded who had not smoked at all in the prior 24 hr. This stringent eligibility criterion was selected since this is one of the first large-scale randomized controlled trials of Internet smoking

cessation. As a result, approximately 24% (181 of 764) of potential participants were determined to be ineligible. Since the majority of quit attempts in the United States are unassisted (Center for Disease Control and Prevention, 2002), and since the Internet is a readily available resources for recent quitters, future studies should examine the efficacy of Internet-based cessation programs in preventing relapse.

The Internet raises unique reporting, methodological, and analysis issues. Traditional Web server log files may provide insufficient data to determine actual numbers of individuals reached. To understand barriers to studying enrollment encountered by smokers, and to determine the generalizability of the final sample, Internet smoking cessation trials should obtain and retain information about those not enrolled. This preliminary study must be interpreted cautiously and awaits independent replication. As with most other clinical trials, only a small portion of potential participants enrolled in this study. However, results suggest that Internet-based research using active user-intercept recruitment is feasible. Creative strategies can be used to sample participants, estimate a variety of parameters of reach (denominators), and measure aspects of potential selection bias that are implicit in all traditional clinical trials but often cannot readily be estimated (e.g., those who read a newspaper advertisement for a study but never respond).

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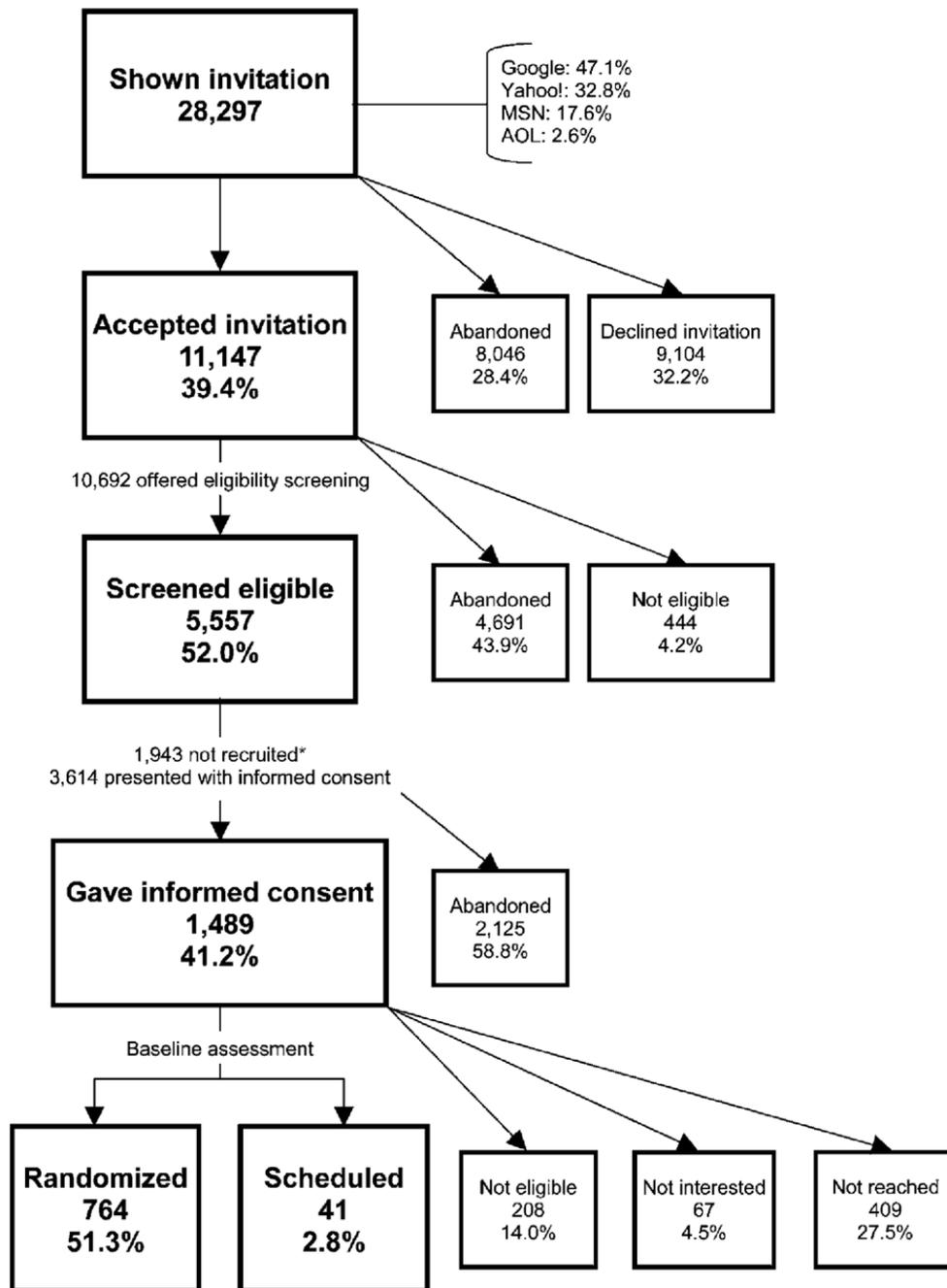


Figure 1. Preliminary recruitment data (March 8, 2005 to October 24, 2005).

Table 1

Comparison of randomized sample to denominators of interest on preliminary screening data.

Variable	Randomized (n=764)		All others consented (n=725)		All others recruited (n=2,850)		All others eligible (n=4,793)	
	Mean/percent	SD	Mean/percent	SD	Mean/percent	SD	Mean/percent	SD
Age	35.12	10.31	32.59***	10.18	33.59***	10.53	33.98**	10.54
Gender (% female)	60.5		57.9		50.0***		57.7	
Education (highest grade completed)								
Grade 1–8	0.3		0.2		0.4		0.5	
Grade 9–11	2.4		3.6		3.4		3.3	
Grade 12 or GED	19.8		19.6		21.6		21.4	
College 1–3 years	48.4		46.1		44.1		44.7	
College 4 years or more	29.2		30.5		30.5		30.1	
Race								
White	86.4		85.5		85.2**		91.0***	
Black	7.5		6.6		5.6		3.4	
Asian	3.7		4.7		6.0		3.7	
Native Hawaiian/Other Pacific Islander	0.5		1.8		1.6		1.0	
American Indian/Alaska Native	2.0		1.4		1.6		0.9	
Time of recruitment								
Early morning (6 A.M.–9 a.m.)	11.4%		9.0%		9.5%		9.5%	
Work hours (9 a.m.–5 p.m.)	60.2%		58.9%		59.6%		58.9%	
Early evening (5 p.m.–9 p.m.)	16.4%		17.9%		18.8%		18.8%	
Overnight (9 p.m.–6 a.m.)	12.0%		14.2%		12.0%		12.8%	
Daily smoking rate	21.10	10.09	20.30	9.86	19.76***	9.56	20.00**	9.48
Time to first cigarette								
Within 5 min	38.1		37.5		35.1***		35.3**	
6–30 min	39.8		36.0		36.8		36.8	
31–60 min	14.8		15.6		15.9		16.5	
After 60 min	7.3		10.9		12.1		11.4	
No. quit attempts past year	2.88	5.94	2.16**	4.69	2.42	6.18	2.39*	5.97

Variable	Randomized (n=764)		All others consented (n=725)		All others recruited (n=2,850)		All others eligible (n=4,793)	
	Mean/percent	SD	Mean/percent	SD	Mean/percent	SD	Mean/percent	SD
Age at first puff	14.48	3.51	14.80	3.57	14.96***	3.71	14.87**	3.69

Note. Comparison group for all t-test and chi-squared analyses is randomized (n=764). All others consented=1,489 minus 764=725. All others recruited=3,614 minus 764=2,850. All others eligible=5,557 minus 764=4,793.

* p<.05;

** p<.01;

*** p<.001.

Table 2

Baseline characteristics of participants randomized to treatment.

Variable	Randomized (N=764)	
	Mean/percent	SD
Demographic variables		
Age (mean)	35.6	10.25
18–29	33.1	
30–49	55.9	
50–64	10.6	
65 and older	0.4	
Gender (percent female)	60.5	
Education (highest grade completed)		
Grade 1–8	0.3	
Grade 9–11	2.4	
Grade 12 or GED	19.8	
College 1–3 years	48.4	
College 4 years or more	29.2	
Race		
White	86.4	
Black	7.5	
Asian	3.7	
Native Hawaiian or Other Pacific Islander	0.5	
American Indian or Alaska Native	2.0	
Income		
<US\$10,000	3.4	
US\$10,000–US\$20,000	8.7	
US\$20,000–\$30,000	16.4	
US\$30,000–\$40,000	17.5	
US\$40,000–\$50,000	13.9	
US\$50,000–US\$75,000	19.4	
US\$75,000–\$100,000	10.3	
>US\$100,000	10.4	
Marital status		
Married	41.5	
Cohabiting	16.0	
Single	19.0	
Separated	3.5	
Divorced	18.7	
Widowed	1.3	
Employment status		
Full-time	71.3	
Part-time	9.8	
Unemployed	4.6	

Variable	Randomized (N=764)	
	Mean/percent	SD
Homemaker	5.9	
Retired	2.1	
Student	6.3	
Smoking variables		
Age at first puff	14.08	3.55
Age onset of daily smoking	16.95	3.44
Daily smoking rate	20.29	9.91
No. quit attempts past year	2.86	4.83
Baseline stage of change		
Precontemplation	0.1	
Contemplation	11.6	
Preparation	88.2	
Fagerström Test for Nicotine Dependence	5.04	2.36
Desire to quit	9.02	1.43
Confidence in quitting	6.16	2.25
Internet use variables		
Duration of Internet use		
Less than 1 year	2.5	
1–2 years	2.1	
2–5 years	20.8	
More than 5 years	74.6	
Frequency of Internet use		
Several times a day	74.3	
About once a day	17.0	
3–5 days per week	5.9	
1–2 days per week	2.1	
Every few weeks or less often	0.7	
Type of Internet connection		
Dial-up connection	16.8	
Broadband connection	83.2	
Health status variables		
Perceived health status		
Excellent	8.1	
Very good	37.5	
Good	36.2	
Fair	14.4	
Poor	3.8	
Ever had smoking related illness (percent yes)	59.1	
Body mass index		
Underweight	2.0	
Normal weight	39.3	

Variable	Randomized (N=764)	
	Mean/percent	SD
Overweight	32.0	
Obese	26.7	
Psychosocial variables		
Any alcohol use (percent yes)	70.4	
Used more than meant to past year (percent yes)	61.8	
Wanted or needed to cut down (percent yes)	27.2	
Perceived Stress Scale	6.25	3.25
Center for Epidemiological Studies—Depression Scale	9.38	5.79