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Clinical Trials and Tribulations: Lessons Learned from Recruiting Pregnant Ex-Smokers for Relapse Prevention

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Abstract

The development of smoking cessation and relapse-prevention interventions for pregnant and postpartum women is a public health priority. However, researchers have consistently reported substantial difficulty in accruing this population into clinical trials. The problem is particularly acute for relapse-prevention studies, which must recruit women who have already quit smoking because of their pregnancy. Although an important target for tobacco control efforts, these individuals represent an extremely small subgroup of the general population. This paper describes multiple recruitment strategies utilized for a clinical trial of a self-help relapse-prevention program for pregnant women. The effectiveness of the strategies and the direct expense per participant accrued are provided. A proactive recruitment strategy (telephoning women whose phone numbers were purchased from a marketing firm) was ultimately much more successful than a variety of reactive strategies (advertisement, press releases, direct mail, web placement, healthcare provider outreach). There were few differences between proactively and reactively recruited participants on baseline variables; the primary difference was that the former had smoked fewer cigarettes per day and reported lower nicotine dependence prior to quitting. Strengths and limitations of the recruitment strategies are discussed.

The risks associated with smoking during pregnancy are well established and highly publicized (Britton, 1998; CDC, 1995; United States Department of Health and Human Services [USDHHS], 1990, 2001). Consequently, an increasing proportion of women (estimates range from 15% to 60%) spontaneously quit smoking immediately prior to or during their pregnancy (Ershoff et al., 2000; Morasco et al., 2006). However, maintenance of tobacco abstinence among pregnant and postpartum women remains a challenge. Smoking relapse rates among pregnant and postpartum women range from 70–80%, with

approximately half of these women resuming smoking within the first twelve weeks post-delivery (Fingerhut et al., 1990; Ockene, 1993; Polanska et al., 2005; USDHHS, 2001). Postpartum smoking exposes the infant to environmental tobacco smoke, which is associated with a range of health problems in children including middle ear infection, asthma, sudden infant death syndrome, behavioral problems, and developmental delays (Charlton, 1994; USDHHS, 2006). Of course, by resuming smoking, the mother also re-exposes herself to the myriad health risks associated with tobacco use. Given the high rate of self-quit among pregnant smokers, as well as the success of interventions designed to motivate pregnant women to quit smoking (Melvin et al., 2000), pregnancy and the early postpartum period appear to offer unique opportunities to provide smoking relapse-prevention interventions, although such efforts have met with at best modest success to date (Mullen, 2004).

Recruiting participants for clinical trials can be challenging in general (e.g., Harris et al., 2003; Ross et al., 1999), and this has been particularly the case for smoking cessation trials of pregnant women, which often have difficulty meeting accrual goals (e.g., Cinciripini et al., 2000; Emmons et al., 2000; Goldenberg et al., 2000; Pollak et al., 2006; Ruggiero et al., 2003; Solomon et al., 2000; Strecher et al., 2000). Trials focusing on relapse prevention with this population have the additional challenge of recruiting from a yet smaller proportion of the population: pregnant women who smoked prior to their pregnancy but are currently abstaining from smoking. Moreover, we would expect that most women who are motivated to enroll in a relapse-prevention trial are from the subset who (a) desire to remain abstinent after they give birth, and (b) recognize that postpartum relapse is a risk, despite their success at maintaining abstinence during pregnancy.

We are currently accruing participants in a randomized controlled trial testing a relapse-prevention self-help intervention for pregnant and postpartum exsmokers. As with other studies involving this population, we initially experienced substantial difficulties with participant recruitment. We therefore experimented with several recruitment strategies prior to finding one that has been successful. In the interest of assisting future researchers in this area, the primary goal of this report is to describe the various recruitment strategies that we attempted, along with their rates of success and cost consequences. The numerous recruitment approaches employed in the current study can be classified into two main categories – reactive and proactive (e.g., Harris et al., 2003; Marcus et al., 2000). Reactive recruitment refers to an approach that involves informing the public about the availability of a research program and waiting for interested individuals to contact the program. Media advertisement is the classic example of a reactive strategy. With a proactive approach, the program reaches out to the specific population of interest and directly solicits participation in the research. Unsolicited telephone outreach is an example.

Prior smoking cessation research has found differences between participants recruited via proactive versus reactive strategies. Reactively recruited participants (e.g., those responding to newspaper advertisements) were more likely to be female and in the contemplation stage of the transtheoretical model (Prochaska & DiClemente, 1983) compared to proactively recruited participants, who were more highly educated, reported greater income, and had better health and lower depression (Harris et al., 2003; Prochaska et al., 2001; Velicer et al.,

1995). Reactively recruited participants have also been found to be more likely to be eligible for a given study and to enroll in the study when eligible (Harris et al., 2003).

The secondary goal of this report is to compare participants accrued via proactive and reactive recruitment strategies to examine whether differences found in previous smoking cessation studies, or any other differences, would appear among participants of a relapse-prevention study for pregnant exsmokers. Information about differential participant characteristics would help guide future researchers in their recruitment planning.

Methods

Overview of Clinical Trial

We had previously developed a series of eight self-help booklets designed to prevent relapse to smoking among individuals who had recently quit smoking. These *Forever Free*TM booklets have been found to be efficacious in two clinical trials (Brandon et al., 2000, 2004). In the second trial, rates of smoking at 2-year follow-up (7-day point-prevalence) were 21.1% for individuals who received the eight booklets, compared to 36.6% for the comparison group that only received the first booklet, a relative reduction of 35%. Moreover, the intervention had a substantially more favorable cost-effectiveness ratio (cost per quality-adjusted life year saved) (Brandon et al., 2004; Chirikos et al., 2004) than comparable ratios for conventional smoking cessation interventions (Cromwell et al., 1997; Curry et al., 1998).

The efficacy and ease of administration of the *Forever Free* self-help intervention led to the development of a parallel intervention for pregnant and postpartum women. Although pregnant ex-smokers face many of the same risk factors that predict relapse in the general population (e.g., depression, weight concerns, low social support), these factors may be particularly potent among pregnant and postpartum women (Quinn et al., 2006). Importantly, the motivation to remain abstinent differs among general population quitters and pregnant ex-smokers (Stotts et al., 1996, 2000). Clinical experience indicates that smokers in general tend to quit with the goal of continued abstinence, yet many pregnant women who quit smoking are motivated primarily by concerns about the health of the fetus, and therefore plan to abstain only during their pregnancy (Curry et al., 2001; Roske et al., 2006). Women also face unique stressors after they give birth, such as: identity confusion during the transition between pregnancy and postpartum, the reintroduction of smoking cues (e.g., spousal smoking) that were avoided during pregnancy, and the increased stress of caring for a new baby (Quinn et al., 2006). These topics and others were incorporated into a new set of 10 *Forever Free for Baby and Me*TM booklets. For more information on the development and content of these booklets, see Quinn et al. (2006).

In the ongoing clinical trial we are comparing the efficacy of the *Forever Free for Baby and Me* booklets to usual care, comprising existing materials available from the National Cancer Institute and the American Cancer Society. We are attempting to recruit 714 pregnant women who have already quit smoking because of their pregnancy. The women are randomly assigned to the two conditions and followed up through 12 months postpartum. Because the interventions are delivered by mail, there are no geographic limitations on the

sample. Participants receive accelerating compensation of \$20 – \$35 for completing each of four assessment packets, totaling \$110 for full participation.

Measures

Telephone Screening—Research staff administered a telephone screening questionnaire to women who we reached through either reactive or proactive strategies. The following inclusion criteria were assessed: 18 years of age or older, able to read and speak English, currently in their 4th to 8th month of pregnancy, smoked at least 10 cigarettes per day for at least one year prior to their pregnancy, quit smoking because of their pregnancy, and reported no tobacco use in the previous 7 days.

Baseline Assessment—Women who met eligibility criteria were mailed a baseline questionnaire assessing demographics, smoking history (including a retrospective measure of the Fagerström Test for Nicotine Dependence; Heatherton et al, 1991), vulnerability to depression (item from the Depression Proneness Inventory; Alloy et al., 1990), and current level of depression (Center for Epidemiological Studies Depression Scale [CES-D]; Radloff, 1977). In addition, several pregnancy-related variables were measured (e.g. nausea, plans for breastfeeding).

Recruitment Strategies and Costs

Accrual is ongoing, but this report is limited to recruitment that occurred between 05/01/04 and 06/05/06. Following is a description of the different recruitment strategies employed in this study, together with estimates of the direct cost to the trial of implementing each strategy, the number of participants whose recruitment can be attributed to each strategy, and the corresponding direct cost-per-participant (CPP); see Table 1. We note here that the cost estimates take the relatively narrow perspective of our clinical trial, not a broader social perspective that would mandate tallying all costs, irrespective of who incurs them.

Furthermore, with one exception, we include only the direct expenses of materials and services by independent providers in our cost calculations. We assume that the value of senior research staff time spent in initiating recruitment strategies is generally small and roughly equal across the set of strategies included in this study. The exceptional case is the substantial staff time needed to conduct the telephone outreach strategy. Although some of this work was conducted by volunteer undergraduate research assistants, we felt that their time inputs needed to be quantified and valued by relevant market wage rates. As in our previous work (Brandon et al., 2004; Chirikos et al., 2004), we tallied the amount of staff time spent on telephone outreach and then valued it at a rate of \$13.66 per hour (the median 2005 hourly wage for correspondence clerks in the United States). In view of these limitations, we treat the computed CPP ratios in Table 1 only as a rough index of the economic efficiency of each recruitment strategy, not as fully refined indicators of their cost-effectiveness.

Childbirth educators—In proposing this research, our original intention was to recruit pregnant women via childbirth education classes throughout the state of Florida. We had a relationship with a statewide childbirth educator certification program that would allow us access to 423 childbirth educators within the state. We planned to offer them incentives for

distributing information about our study to their students and former students. By the start of the accrual phase of the research, however, two unanticipated barriers emerged. First, the statewide certification contract was awarded to a new organization with which we did not have a relationship. Nevertheless, we attempted to contact childbirth educators through other means. The more problematic barrier was that the activation date of the privacy rule of Health Insurance Portability and Accountability Act (HIPAA) had recently passed. We found that the initial reaction of hospital administrators to HIPAA was to deny permission for the childbirth educators working in their hospitals to cooperate with outside researchers, despite the fact that our program was HIPAA compliant and approved by the university's IRB. (Our very recent experience suggests that as administrators became more familiar and comfortable with HIPAA, they have become somewhat more accommodating once again.) Because of these barriers, we abandoned our original recruitment strategy and attempted the others described below.

National magazine advertisement—In an attempt to reach a large number of potential participants, we placed a single, 1/3 page, black-and-white display advertisement in *American Baby*, a national baby magazine that is distributed at no-cost to pregnant women and is displayed in most OB-GYN offices. The magazine reports a circulation of approximately 2 million, half of whom are pregnant women. This advertisement (as with the other recruitment materials mentioned below) conveyed information about the prevalence of postpartum smoking relapse and the health benefits of continued tobacco abstinence, and it announced the availability of a study that would provide self-help materials at no cost to participants. A toll-free telephone number was provided for further information. The advertising agency, which designed and placed the ad, charged us \$3,800 and the direct expense of the magazine space itself was \$13,100. The total direct cost to our trial of this strategy was \$16,900, and resulted in the recruitment of 15 women. (CPP = \$1,127)

Other media advertisements—We hired the North American Precis Syndicate (NAPS) to prepare and distribute nationally a written press release and a 30-second video feature story, costing \$8,060. NAPS distributed our editorial copy to 10,000 newspapers and sent the video news release to 1,000 television stations throughout the U.S. The information is provided free of charge to these news organizations. Recent coverage reports from NAPS indicate that the newspaper press release generated 340 newspaper articles in 23 different states (total circulation of 20,383,536), and the video press release was broadcast 168 times in 40 different states (estimated viewership of 101,129,806). We also placed several similar display ads in local newspapers, costing \$4,000. In addition, local television and radio networks conducted interviews with our staff about our project. Lastly, a press release was also distributed by a national fax broadcast to 6,220 newspapers costing \$584. Together the direct expense for the above strategies was \$12,644 and 2 participants were recruited. (CPP = \$6,322)

Healthcare provider outreach—Posters and business cards were created publicizing the availability of materials to help pregnant women stay smoke free, and providing a toll-free phone number for more information. A mailing list of 1,714 Florida-based obstetricians and gynecologists was purchased from the American College of Obstetricians and Gynecologists

(\$330), and other mailing lists were compiled for midwives, obstetric nurses, childbirth educators, and other perinatal healthcare providers in the state of Florida. Each provider was mailed a packet containing 2 posters for their offices and 10 cards to be distributed to patients, with an invitation to request additional materials. Additionally, materials were sent to local and state government programs, such as the health departments, Women, Infants, and Children (WIC) programs, and Healthy Start programs. Flyers and business cards were distributed at conferences for health care professionals, a conference for Lamaze International (\$200), and health fairs for pregnant women through the community. The direct expense to the trial of this strategy was \$7,200 and has led to the accrual of 17 women. (CPP = \$424)

Direct mail—We purchased mailing addresses of 22,000 pregnant women in Florida from a marketing research company, List Service Direct, that sells mailing lists for specific demographic groups, including pregnant women. We mailed these women oversized postcards designed by an advertising agency. The cards summarized the health risks associated with postpartum smoking and the difficulties that many new mothers face in maintaining tobacco abstinence. The cards introduced the study and provided our toll-free phone number. The direct expense of this strategy was \$10,200 and it led to 10 women recruited into the study. (CPP = \$1,020)

Websites—Links to our flyer were placed on pregnancy-related websites, such as the March of Dimes, iVillage, and BabyZone. Because our study provided a service to all participants, the websites did not charge us. We thus treat the direct costs of this intervention as zero, though we note again that this does not mean the intervention was costless from a social perspective. Four women were recruited by this strategy.

Health insurance partnership—We established a relationship with the United HealthCare insurance network. They sent a letter promoting our study to 3,000 women enrolled in their Healthy Pregnancy Program. We were not charged for this service, so the cost to the trial is treated as zero. Two women were recruited.

American Legacy Foundation—The American Legacy Foundation's "Great Start" program provides free telephone-based counseling services for pregnant women interested in quitting smoking. We entered into an agreement with the Foundation in which they would refer to our project any pregnant women callers who had quit smoking, and we would refer to them women who did not meet our inclusion criteria. According to the statistics provided by the Great Start program, they receive approximately 25–30 calls per month from pregnant women. There was no direct expense to the trial of this strategy; however, no women were recruited via this method.

Obstetric screeners—We developed a single-page screening form to distribute to patients at OB-GYN offices and local health departments. Although all obstetric offices in the area local to the research site were contacted and most of the health departments in Florida were approached, only 27 sites consented to using our screening form. The form assesses basic eligibility requirements and allows the patient to consent to be contacted by our research staff. To reduce the stigma associated with responding to questions about

smoking during pregnancy, and to encourage completion of the surveys, they also assessed additional pregnancy-related health behaviors, such as nutrition. The medical offices and health department agreed to distribute the forms to all their pregnant patients, and to mail us the completed forms. We then telephoned the eligible women. The direct expense of printing and distributing the screening form was \$500, from which 24 women were recruited. (CPP = \$19)

Telephone outreach—We purchased, from Dataman Group and List Service Direct (two direct marketing companies), telephone numbers of women reportedly in their 3rd to 5th month of pregnancy. Purchase of such demographically defined mailing or telephone lists has become a more frequent strategy for recruiting participants across a wide range of research domains, including infant development (Kraebel & Gerhardstein 2006), alcoholism (Seaton et al., 2004), adolescent gambling (Winters et al., 1993), cancer prevention (Bowen et al., 2004), and health promotion (Hays et al., 2003). Information provided by the company indicated that the phone numbers were compiled from the following sources: Lamaze classes, baby registries, mail order purchases, magazine subscriptions, and questionnaire data. Each month we purchase 3,000 nationwide telephone numbers at a cost of 20 cents per number (monthly cost = \$600). Our telephone outreach staff calls these numbers and requests to speak with the pregnant woman in the household. If a pregnant woman is reached, she is screened, and if eligible she is invited to participate in the study. Although each phone call is brief, when a potentially eligible participant is reached, the call usually lasts approximately 3–5 minutes to complete the screening questions, describe the study, and obtain verbal HIPAA authorization.

We attempt to call each telephone number up to three times until we actually speak to someone. We are successful in recruiting one participant for approximately every 70 numbers called, which requires an estimated 120 separate calling attempts. Approximately 96% of eligible women agree to participate after the study has been described to them. On average we now recruit 35–50 women each month through this method. To accrue the participants described in this report, we had been recruiting for 16 months, using 5–6 females operators who place phone calls for 200–250 hours per month (cost = \$3075/month). The cost of the lists plus staff time to make the calls is estimated at \$58,800. This has been our most successful and consistent recruitment strategy, yielding 338 participants. (CPP = \$174)

Categorizing Recruitment Approaches

Telephone outreach was the lone proactive recruitment strategy. All other strategies were considered reactive because individuals must have chosen to initiate contact with our research program in response to recruitment materials.

Results

Response Rates

Once a participant is screened over the phone and consents to participate in the study, she has been considered “recruited.” We recruited 421 women, 83 through reactive strategies,

and 338 using the proactively strategy. Women who subsequently return the baseline questionnaire are considered “enrolled.” We enrolled 384 participants, 72 reactively-recruited, 312 proactively-recruited, for nearly-equivalent response rates of 87% and 92% respectively, Yates $\chi^2 = 1.92$, $p = 0.17$.

Subsequent analyses use data from the baseline questionnaires of the 384 enrolled participants. Because the goal of these analyses was not hypothesis testing, but rather identifying any potential group differences that may influence future decisions about recruitment strategy, we used an alpha of .05 without correction for study-wise error. Two-tailed t-tests were conducted for continuous variables and chi-square tests were used for categorical variables. All variables examined are displayed in Table 2.

Demographic variables—Of the range of demographic variables examined, only employment status differed significantly between groups, with fewer proactively-recruited women being currently employed (37% vs. 57%), $\chi^2 = 10.74$, $p < .05$.

Pregnancy-related variables—The only significant difference appeared on self-reported health status, which was measured on a 1–5 scale ranging from “poor” to “excellent.” Although both groups rated their health high, proactively recruited women reported slightly better health (4.33) than reactively recruited women (4.10), $t(379) = 2.08$, $p = .04$.

Depression variables—Participants completed the CES-D, which assesses symptoms of depression. The scores range from 0 to 60, with higher numbers indicating greater depression symptomatology. In addition to the CES-D, participants completed a single depression proneness item. This single item assesses whether she is the type of person who easily becomes very depressed, sad, blue, or down in the dumps using a 7-point Likert scale ranging from 1, *I never become depressed*, to 7, *I become depressed very easily*. Both groups reported low levels of depression symptomatology with equivalent CES-D scores. However, reactively recruited participants reported higher depression proneness (3.92 vs. 3.40), $t(379) = 2.18$, $p = .03$.

Smoking variables—Reactively recruited participants reported smoking a greater number of cigarettes per day prior to quitting (17.51 vs. 14.33), $t(379) = 3.46$, $p = .001$. Similarly, reactively-recruited women reported higher total scores on the Fagerström Test of Nicotine Dependence (4.40 vs. 3.57), $t(381) = 2.85$, $p = .005$. Although all women reported abstaining from tobacco during the telephone screening, some reported on their returned baseline questionnaire that they had smoked during the 7 days prior to completing that questionnaire. Although more proactively-recruited women reporting smoking in the past week compared to the reactively-recruited women (13.5% vs. 5.6%), the difference did not quite reach statistical significance, $\chi^2 = 3.47$, $p = .06$.

Discussion

In an effort to accrue pregnant women for a smoking relapse-prevention intervention, we attempted a range of recruitments strategies. Table 3 summarizes the advantages and disadvantages of each strategy. The majority of these strategies were variations of traditional

reactive strategies. That is, they involved publicizing the availability of an intervention and counting on interested individuals to contact the research program for more information and to enroll. Among the reactive strategies were expensive advertisements in local and national media, a direct mail marketing campaign, and free publicity via websites and a major health insurance company. They all failed, yielding very few participants at a high cost per participant. In contrast, the sole proactive recruitment strategy, telephoning pregnant women whose names we purchased from a marketing firm, has yielded a steady rate of accrued participants, at the moderate estimated cost of \$174 per participant. It is interesting that the recruitment approach that has yielded the second most participants was screening patients in local obstetric offices. Although we classified this as a reactive strategy, in fact it could be considered as a reactive-proactive hybrid. Women voluntarily contacted us by completing the screener, but they did not know at that time that our study involved an intervention for tobacco use. Thus, they were not self-selecting for tobacco-related assistance per se. This strategy had a comparatively low CPP of roughly \$19, but there were a limited number of local clinics that were willing to distribute our screening forms, and it was difficult to maintain their participation over time.

Whereas we had little difficulty using traditional reactive strategies (advertising and press releases) to recruit individuals who recently quit smoking for our previous relapse-prevention studies (Brandon et al., 2000, 2004), the failure of the reactive recruitment strategies in the current study can be attributed to several causes. The most straightforward explanation is that the population of interest—women in month 4–8 of their pregnancy, who had quit smoking due to the pregnancy—constitutes a much narrower sub-group of the general population. Based on census and epidemiological data on birth rates, smoking prevalence, and pregnancy-related cessation, we estimate that approximately 0.06% of the U.S. population was eligible for our study at any given point in time. However, this explanation is not sufficient, in that a direct mail campaign to 22,000 pregnant women produced only 10 responses from the approximately 2,000 recipients who should have been eligible for the study.

Pregnant exsmokers may be particularly resistant to reactive recruitment strategies for several reasons. First, compared to others who quit smoking, pregnant women are more likely to be motivated by extrinsic factors (e.g., health of fetus, social pressure, nausea) to suspend their smoking during their pregnancy, rather than attempting to quit permanently (Curry et al., 2001, Roske et al., 2006; Stotts et al., 2000). Women who intend to resume smoking after giving birth presumably are less likely to seek help for maintaining their tobacco abstinence (although one-third of our reactive sample reported that they did not plan to “quit for good”). Second, those women who do indeed intend to maintain their abstinence after delivery may not feel that they need further assistance after successfully abstaining during several months of pregnancy. They may not anticipate or appreciate the confluence of factors that drive relapse after delivery (e.g., stress and negative mood, reduced social support, weight concerns). Thus, from the already limited number of pregnant exsmokers, a relapse-prevention intervention is likely to attract primarily those few who both plan to maintain tobacco abstinence after delivery and anticipate that they may need assistance to do so. While recognizing the difficulty of altering these motivational factors via brief messages, we nevertheless attempted to do so in our recruitment materials by emphasizing the health

benefits (to the mother and her children) of maintaining tobacco abstinence, while also conveying the prevalence of postpartum relapse. We were apparently unsuccessful in these efforts.

Reactive recruitment strategies, which required pregnant women to initiate telephone contact with us, may have also been a mismatch for the typical demographic characteristics of pregnant women who had been smokers—younger, less educated, with lower socioeconomic status than the general population. They may have been unlikely to have seen the newspaper and magazine advertisements and press reports, and felt too uncomfortable or busy to place a telephone call to our program. Thus, those pregnant women who arguably are most vulnerable to relapse and most in need of services may have been the least likely to see or respond to our reactive recruitment efforts. Moreover, because of the stigma associated with smoking in general, and smoking during pregnancy in particular, women may have been hesitant to self-refer to our program—despite the fact that they had ceased smoking for their pregnancy.

A final barrier that we repeatedly encountered—with both pregnant women and health care professionals—derived from the novelty of our intervention. Whereas the public health message to quit smoking during pregnancy has been widely disseminated, there has been relatively little promotion regarding the prevention of postpartum relapse. Consequently, we often encountered confusion about the purpose of our intervention and the population of interest. Despite our best attempts to describe our program in our recruitment materials and in verbal communications, it was difficult to dissuade individuals of their belief that we were seeking pregnant smokers for a smoking-cessation program, as opposed to pregnant exsmokers for a relapse-prevention program. It is likely that potential participants who glanced superficially at our advertisements, focusing on the keywords “smoking” and “pregnancy,” may have assumed that it was promoting smoking cessation and dismissed it as irrelevant because they had already quit smoking. Until there is a wider public health campaign to promote postpartum abstinence, this barrier will be difficult to overcome.

In contrast to the poor response rate to our reactive recruitment strategies, nearly all eligible women whom we reached via proactive telephone calls agreed to enroll in the study, and 92% of these did indeed enroll by returning the completed baseline questionnaires. Once we reached an eligible woman, she had little reason not to enroll. She would receive potentially helpful materials at no cost, and she would be paid for completing questionnaires. Indeed, the same social stigma that may have inhibited some women from contacting us may have also inhibited women from declining our offer once we reached them, despite our efforts to avoid any degree of social coercion. If this were the case, we would expect that proactively recruited women would be less motivated to remain abstinent than reactively recruited women. This difference has been found in smoking cessation studies comparing the two general strategies, with reactively recruited participants having a greater readiness and motivation to quit (Prochaska et al., 2001), as well as being more likely to be eligible for the study and to enroll in the study when eligible (Harris et al., 2003). Our own evidence is mixed on this point. Whereas the two groups did not differ in their enrollment rates (i.e., returning the baseline questionnaire) or in their plans to maintain postpartum abstinence, there was a trend ($p = .06$) for proactively recruited women to be more likely to have

smoked during the week before completing the baseline questionnaire (14% vs. 6%, respectively). We must await the results of the clinical trial to learn whether proactively recruited women were more likely to relapse. Similarly, the full results will indicate whether the groups differ in attrition rates over the course of the study.

Earlier studies have also found reactively recruited smokers to be more highly educated, to have a greater income, to enjoy better health and lower depression, and to be predominantly female (Harris et al., 2003; Prochaska et al., 2001; Velicer et al., 1995). In the current study, though, we found few differences between the groups. Reactively recruited women were more likely to be employed (our proactive calls tended to reach women who were home rather than at work during the day and early evening), to report slightly poorer health, slightly greater proneness to depression, and to smoke more cigarettes per day, with greater nicotine dependence. These differences tended to be small, and had we controlled for multiple comparisons, only the two smoking-related variables (cigarettes per day and FTND score) would have retained statistical significance, consistent with previous research demonstrating that individuals seeking assistance for smoking cessation (including nicotine replacement) tend to be heavier, more dependent smokers (Shiffman et al., 2005).

We would not expect participants recruited via our proactive telephone calls to be as representative of the broader population as smokers who are reached via random-digit dialing (e.g., Prochaska et al., 2001). Random-digit dialing is a reasonable approach to recruiting for smoking cessation, given the relatively high prevalence of smoking (20–25%), but it would be a cost-inefficient means of reaching our much more narrowly defined target group (~0.06%). Thus, we relied upon telephone lists purchased from marketing research firms. Given the manner that they derive these lists and that their goal is to identify women with maximum purchase power, our sample is likely less diverse on socio-economic and ethnic/racial variables. In response to the latter concern, the marketing firms have agreed to over-sample racial minorities in the future telephone lists that they provide to us. Telephone lists, however, do not include individuals who lack a home phone number, which may include the economically disadvantaged as well as the growing number of households relying solely on mobile phones.

Pregnant women represent but one sub-group of smokers who have proven to be difficult to recruit for clinical trials. Other examples include low literacy populations, racial/ethnic minorities, low-income groups, adolescents, and cancer patients. Each recruitment strategy has advantages and disadvantages, and these may differ depending on the population of interest and the nature of the intervention. For example, although we found advertisements in the print media to be ineffective in recruiting pregnant women, such approaches might produce greater success in reaching older, more educated smokers. Conversely, broadcast media (radio, television) might be more effective in targeting specific market segments such as young, female, or minority smokers. Additionally, Internet-based marketing via banner ads and web panels might also yield responses from populations that are less narrowly-defined than recent exsmokers in months 4–8 of pregnancy. Ultimately, such conjectures must be put to the empirical test for recruiting specific populations to clinical trials. Thus, the sharing of novel recruitment techniques, their success rates, and their cost consequences should enhance the efficiency of subsequent clinical trials.

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Table 1

Comparison of All Recruitment Strategies Employed on Direct Recruitment Costs, Number of Participants Recruited, and Cost-Per-Participant (CPP)

Recruitment Strategy ¹	Direct Cost	Number Recruited	CPP
FL state childbirth education program	N/A	N/A	N/A
National magazine advertisement	\$16,900	15	\$1,127
Other media advertisements	\$12,644	2	\$6,322 ²
Healthcare provider outreach	\$7,200	17	\$424
Direct mail	\$10,200	10	\$1,020
Websites	\$0	4	\$0 ²
Health insurance partnership	\$0	2	\$0 ²
American Legacy Foundation	\$0	0	N/A
Obstetric screener	\$500	27	\$19
Telephone outreach	\$58,800	338	\$174

Notes:

¹ Six participants recruited through reactive strategies were unable to report how they had heard about the study, so they are not included in any of the CPP analyses.

² Caution is advised when interpreting CPP for strategies yielding very low numbers of participants and/or with zero costs.

Table 2

Comparison of Two Recruitment Strategies on Demographic, Pregnancy, Depression, and Smoking Variables

			Recruitment Strategy	
			Reactive	Proactive
N			83	338
Demographic				
Race	(% minority)		12.5	11.9
Ethnicity	(% of Hispanic origin)		5.9	6.2
Education	(% 12 th grade)		88.9	88.4
Marital status	(% married/living together)		61.1	69.0
Employment	(% employed)		56.9	36.7 *
Income	<i>Median</i>		20–30K	30–40K
Age	<i>M</i> (S.D.)		26.54 (6.40)	25.98 (5.66)
# of people in home	<i>M</i> (S.D.)		2.92 (1.31)	3.21 (1.65)
# of children in home	<i>M</i> (S.D.)		0.75 (1.00)	0.95 (1.08)
Pregnancy				
# of pregnancies	<i>M</i> (S.D.)		1.89 (1.17)	2.16 (1.50)
# of miscarriages	<i>M</i> (S.D.)		1.70 (0.46)	1.70 (0.46)
Maternity leave planned (Wks)	<i>M</i> (S.D.)		10.94 (8.43)	11.58 (10.77)
Breastfeeding planned	(% planning)		76.4	74.6
Pregnancy health status ^I	<i>M</i> (S.D.)		4.10 (0.94)	4.33 (0.80) *
Pregnancy nausea ^I	<i>M</i> (S.D.)		2.57 (1.56)	2.79 (1.47)
Importance of postpartum weight loss ^I	<i>M</i> (S.D.)		4.26 (1.19)	4.30 (1.06)
Depression				
CES-D score ²	<i>M</i> (S.D.)		19.11 (10.21)	16.61 (10.78)
Depression proneness	<i>M</i> (S.D.)		3.92 (1.76)	3.40 (1.80) *
Smoking				
# smokers in home	<i>M</i> (S.D.)		0.79 (0.66)	0.69 (0.72)
Partner smoking status	(% smoking same amt.)			
Years smoked	<i>M</i> (S.D.)		9.57 (4.70)	8.80 (4.92)
# cigarettes smoked daily	<i>M</i> (S.D.)		17.51 (7.66)	14.33 (6.82) *
Greatest # cigarettes smoked	<i>M</i> (S.D.)		22.73 (8.82)	21.34 (9.24)
# prior quit attempts	<i>M</i> (S.D.)		2.84 (3.18)	4.62 (9.28)
FTND (pre-quit)	<i>M</i> (S.D.)		4.40 (2.22)	3.57 (2.25) *
Confidence in not smoking 6 mo. Postpartum ^I	<i>M</i> (S.D.)		3.46 (1.30)	3.61 (1.15)
Smoking status due to pregnancy	(% stopped completely)		93.0	86.8
Smoking in past 7 days	(%)		5.6	13.5
Current smoking status	(% <i>not</i> a smoker)		95.8	87.9
Original plan to quit for good	(%)		58.3	66.7
Current plan to quit for good	(%)		66.2	72.6

Notes:

*
 $p < .05$;

¹ Scale of 1 to 5: for health status, 5 is excellent; for nausea 5 is severe nausea; for importance of weight loss, 5 is extremely important; for confidence in not smoking, 5 is extremely confident.

² CES-D score ranges from 0 to 60, with higher numbers indicating greater depression symptoms.

Table 3

Advantages and Disadvantages of the Recruitment Strategies

Recruitment Strategy	Advantages	Disadvantages
Media advertisements	Broad reach; ability to target demographic segments; potentially cost-efficient	Extremely low yield; highly cost-inefficient; greater market segmentation may be needed
Healthcare provider outreach	Potentially highly representative sample; national scope possible; increases awareness of intervention among secondary audience of healthcare providers	Relatively low yield; provider compliance unknown; requires additional marketing and education to healthcare providers
Direct mail	National scope possible; little labor; broad reach	Low yield; non-representative pool; specific methods of acquiring names are proprietary and unknown; may produce privacy concerns among recipients
Websites	No cost to trial. Appeals to younger audiences	Low yield; likely non-representative sample
Referral partnerships (e.g., insurance companies; tobacco control foundations)	Low or no cost to trial.	Low yield; challenges in developing and maintaining partnerships.
Obstetric screener	Potentially highly representative sample; very cost-efficient	Limited yield; somewhat labor intensive; requires building and maintaining relationships with providers; limited to local areas; providers may resist due to HIPAA/patient privacy concerns.
Telephone outreach	Relatively cost-efficient; national scope possible	Highly labor intensive; non-representative pool; specific methods of acquiring names are proprietary and unknown; privacy concerns; misidentification as telemarketers; limited to land lines, whereas the population of interest increasingly uses cellular phones.