Original investigation

Efficacy of a Nurse-Delivered Intervention to Prevent and Delay Postpartum Return to Smoking: The Quit for Two Trial

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Abstract

Introduction: Most pregnant women who quit smoking return to smoking postpartum. Trials to prevent this return have been unsuccessful. We tested the efficacy of a nurse-delivered intervention in maintaining smoking abstinence after delivery among pregnant women who quit smoking that was tailored on their high risk of relapse (eg, had strong intentions to return).

Methods: We recruited 382 English-speaking spontaneous pregnant quitters from 14 prenatal clinics and randomized them to receive either a smoking abstinence booklet plus newsletters about parenting and stress (control) or a nurse-delivered smoking abstinence intervention that differed in intensity for the high and low risk groups. Our primary outcome was smoking abstinence at 12 months postpartum.

Results: Using intent-to-treat analyses, there was a high rate of biochemically validated smoking abstinence at 12 months postpartum but no arm differences (Control: 36% [95% confidence interval [CI]: 29–43] vs. Intervention: 35% [95% CI: 28–43], $P = .81$). Among women at low risk of returning to smoking, the crude abstinence rate was significantly higher in the control arm (46%) than in the intervention arm (33%); among women at high risk of returning to smoking, the crude abstinence rate was slightly lower but not different in the control arm (31%) than in the intervention arm (37%).

Conclusions: Low-risk women fared better with a minimal intervention that focused on parenting skills and stress than when they received an intensive smoking abstinence intervention. The opposite was true for women who were at high risk of returning to smoking. Clinicians might need to tailor their approach based on whether women are at high or low risk of returning to smoking.

Implications: Results suggest that high-risk and low-risk women might benefit from different types of smoking relapse interventions. Those who are lower risk of returning to smoking might benefit from stress reduction that is devoid of smoking content, whereas those who are higher risk might benefit from smoking relapse prevention.

Introduction

Even though many women stop smoking while pregnant, up to 90% resume smoking by their child's first birthday.¹⁻³ Women who return to smoking after delivery increase their own long-term risk of smoking-related complications and put their infants at risk as well. Infants in smoking households suffer disproportionately from sudden infant death syndrome and a variety of respiratory problems, including asthma and ear infections.⁴ Given the health benefits of sustained smoking abstinence after delivery for both mothers and babies, effective strategies for preventing resumption of smoking are needed.

Several interventions designed to prevent smoking resumption have been tested in large scale randomized controlled trials. Although some have prevented return to smoking short-term, none has resulted in successful biochemically-validated abstinence by 1 year postpartum.⁵⁻¹⁰ Many of these interventions included face-to-face counseling that attempted to help women build skills to resist returning to smoking. Some included mailed newsletters. Despite theoretically-based interventions, relapse rates are still high with no apparent arm differences favoring the intervention. Some of the lack of long-term success of these interventions may be related to short duration of interventions that spanned only 3 months postpartum. Thus, the intervention did not provide support in real time as women face common triggers to returning to smoking, such as returning to work (typically at 3 months) and stopping breastfeeding (typically at 6 months). Also past interventions did not differ in their intensity based on women's risk of returning to smoking so those women who did not intend to return to smoking received the same intensity of intervention as those who knew they would struggle.

In response to the need to conceptualize different ways to help pregnant quitters, Pletsch¹¹ proposed a model for tailoring a smoking resumption prevention intervention to contextual factors experienced by pregnant and postpartum women. Based on motivational theory, the model outlines risk profiles and proposes to match women to different levels of intervention intensity based on those risk profiles. The model describes three categories of risk factors: bio-behavioral (ie, confidence in staying abstinent, nicotine dependence, and intention to stay abstinent postpartum), pregnancy-specific (ie, sensory changes in taste or smell of cigarettes, pressure from friends and family), and co-conditions (ie, partner smoking and depression). Thus, an intervention that is tailored in intensity to provide more support to women who are more likely to return to smoking and less to those who are lower risk might fare better than a "one size fits all" intervention and outperform a control condition. The aim of this randomized controlled trial was to assess the efficacy of a 9-month, nurse-delivered tailored intervention (Quit for Two) in preventing postpartum smoking resumption among women who quit smoking during pregnancy.

Methods

Participants

We recruited pregnant women from 14 prenatal clinics in a Southeastern state, including an academically-affiliated clinic, various urban and rural county health departments, private clinics, and clinics affiliated with an Army medical center. Eligibility criteria included: 18 years of age or older, spoke English, were registered for prenatal care, and had a history of smoking, defined as having smoked at least 100 cigarettes in their lifetimes and at least 5 cigarettes a day immediately prior to learning of the pregnancy.¹² To participate, women were required to have been continuously abstinent

from tobacco for at least 1 month prior to their baseline survey; we biochemically-validated this self-reported abstinence via breath samples to assess carbon monoxide and saliva to test for nicotine.

At two of the clinics, staff reviewed all new obstetric patient charts weekly and mailed women with a history of tobacco a letter from their providers. The letter informed them of the study and provided a toll-free number if they preferred not to be contacted about study participation. Study staff contacted women who did not call the 800-number. At all other clinics, nurses introduced the study during their initial OB intake process. Nurses asked women to sign a form agreeing to be contacted by our research staff about the study. Staff contacted these women early in their pregnancies and then again starting at 28 weeks (range 28-32 weeks) gestation to reassess eligibility and conduct the baseline survey for women who were eligible and willing to participate. Because there could have been a time lag of several weeks between the screening and baseline data collection, we maintained contact with women by sending them a card or small baby-related item once a month. Participants were compensated for completing each survey. The Institutional Review Boards at the two sites at which we conducted the research approved this protocol.

Measures

Risk Factors for Resumption

We initially categorized women based on the three categories of risk: bio-behavioral, pregnancy-specific, and co-condition; however, there was little variance in pregnancy-specific or co-condition factors (eg, 95% of women said they quit for their baby; few had high depression scores based on Edinburgh Postnatal Depression Scale¹³). Therefore, only the bio-behavioral risk factors were used for determining higher and lower risk for returning to smoking. The bio-behavioral risk factors included nicotine dependence, intention to return to smoking, and confidence to remain quit (ie, self-efficacy). We assessed nicotine dependence with the two-item Heatherton Smoking Index¹⁴ (ie, number of cigarettes smoked per day and minutes to first cigarette); a cutoff of 5 or greater was deemed high risk. We assessed intention to return to smoking postpartum with Stotts and colleagues³ likelihood of resumption question. A likelihood of resuming score of 4 or more was deemed high risk. We assessed confidence to quit with a one-item measure; a score of 5 or less was considered high risk. Women were considered high risk for smoking resumption if any one of these bio-behavioral risk factors was scored "high risk." Those deemed low risk had none of the risk factors. Risk assessment occurred before randomization; randomization was stratified on risk group.

Outcomes

We assessed 7-day point prevalence abstinence (primary outcome) and continuous abstinence (secondary outcome) at 6 weeks, 6 months, and 12 months after delivery. At each follow-up time-point, we also assessed Time Line Follow-back recall¹⁵ in which women report their smoking daily using a calendar. We used time line follow back calendar to calculate time to resumption, which was defined as the number of days from the baby's birth until the resumption of smoking. Resumption was defined as at least one cigarette 3 days in a row or intermittent smoking that continued for the rest of follow-up.

After women reported being abstinent from smoking at the 6-weeks, 6-months, and 12-months postpartum assessment, staff asked them provide a 1mL saliva sample at each encounter to test

for cotinine, a by-product of nicotine. Saliva samples were analyzed for the presence of cotinine using radio-immunoassay (RIA). The presence of cotinine was tested based on an antiserum produced by injecting *trans*-4-carbozycotinine bound to albumin. Both the inter- and intra-assay variations are lower than 6%, and results are comparable to those produced by gas-liquid chromatography. The sensitivity of this procedure is 0.5mg/dL. Cotinine is a highly sensitive measure for identifying smokers. All women reporting smoking abstinence were also asked to provide a breath sample; a carbon monoxide reading of less than 10 ppm was considered consistent with smoking abstinence. We report all of the measures we assessed in the study.

Intervention

Women were randomized in a 1:1 ratio to the intervention arm or the control arm using a database programmed into laptop computers. During the last trimester of pregnancy, women in both arms received one relapse prevention booklet from the series, *Forever Free for Baby and Me: A Guide to Remaining Smoke Free*. Women in the control arm were mailed a total of 11 monthly newsletters with general health messages for pregnant and postpartum women. The newsletters contained no information about smoking but focused more on parenting skills and stress management. Each newsletter included a recipe, information on developmental milestones for infants, and a puzzle or other word game. Monthly topics are shown in Table 1.

Women randomized to the intervention arm did not receive newsletters. They were assigned to one of two levels of stepped-care based on their bio-behavioral risk profile. Those designated as lower risk were offered one in-person session and one phone call during the third trimester of pregnancy, as well as seven calls postpartum that spanned until 9 months postpartum (calls were spaced more tightly in early postpartum and further apart later in postpartum). Those designated as higher risk were offered one in-person session and two calls during the third trimester of pregnancy as well as 11

calls postpartum again until 9 months postpartum. During the first in-person session, all women received a tailored feedback summary summarizing their risk factors for resumption. The nurse counselor reviewed the feedback summary and helped women identify one or two issues as most important to address to remain smoke free. During each subsequent session, the nurse counselor reviewed goals set during the previous session and helped women identify one or two significant barriers to staying smoke free. Nurse counselors asked women to set a new goal at the end of each session. In addition, at each session, nurse counselors referred women to appropriate community resources to help with specific stressors mentioned by the woman such as health care, child care, recreation, housing, clothing, psychological counseling, food, transportation, and substance abuse services. The counseling protocol was based on Social Cognitive Theory¹⁶ and was informed by Motivational Interviewing¹⁷ and relapse-prevention principles (eg, envisioning tempting situations and responses to them, reminding self of motivators for staying smoke free, building confidence by realizing skills used to stay smoke free during pregnancy, etc.).

Nurse counselors attended a 32-hour training to learn the protocol and Motivational Interviewing. Prior to conducting counseling sessions with participants, the nurse counselors conducted mock counseling sessions with each other and with the supervisor. The supervisor and nurses counselors provided feedback to each other on the mock counseling sessions. Each nurse counselor had to complete a "certification" counseling session with the supervisor before speaking with participants. Counselors audio recorded all of their sessions. The clinical supervisor listened all sessions completed for the first three cases for each nurse. After the first three cases, the supervisor randomly selected and listened to one session per month for each nurse counselor. This was approximately 10% of the cases completed by each nurse counselor. The supervisor used the Motivational Interviewing Treatment Integrity Scale,¹⁸ a brief system for coding Motivational Interviewing intervention fidelity, when providing feedback. In addition, the nurse counselors met with the supervisor on a bi-weekly basis to discuss specific cases and practice, as recommended.¹⁹ The supervisor was also available for consultation between scheduled appointments. In addition, nurse counselors rated participant engagement (1 = not engaged to 7 = completely engaged) and perceived difficulty of the session (1 = Not at all difficult to 7 = Very difficult). The mean engagement score was 6.3 (*SD* = 0.4), and the mean level of perceived difficulty of the session was 1.7 (*SD* = 0.3).

Statistical Methods

The primary objective of this trial was to test whether the abstinence rate at 12 months postpartum was higher in the intervention arm than in the control arm; this effect was tested with a one-sided alpha of 0.025. We based power calculations for this outcome on the assumptions of a total accrual of 400 women, an 18% lost-to-follow-up rate, and an intention to treat analysis assuming that women lost to follow-up had resumed smoking. Under these assumptions, the chi-square test has 81% power to detect an arm difference in abstinence rates of 0.25 versus 0.37; this calculation assumes abstinence rates of 0.30 and 0.45. Secondary objectives were to estimate the arm effect on abstinence at 6 weeks and 6 months, on continuous point prevalent abstinence at 12 months, and on time-to-resumption. Time to resumption was defined as the time from the baby's birth until the resumption of smoking, where women who remained quit throughout the time were censored at the date last

Table 1. Monthly Topics for Control Group Newsletters

Month	Topics
1	Postpartum mind and body
	Caring for new born
2	Sleeping for mother and baby
	Infant feeding
3	Returning to work and daycare
	Couple time and intimate relations
4	Self-care for moms
	Understanding your babies cries
5	Establishing routines
	Connecting with other mothers
6	Time management for busy moms
	Healthy diet and exercise for busy moms
7	Dealing with baby colds
	Asking friends and family for help
8	Coping with separation anxiety
	Child safety
9	Traveling with baby
	Parenting styles
10	Dealing with family stress
	Making memories/family traditions
11	Health and safety on a budget
	Encouraging reading

seen. A planned exploratory objective was to estimate the interaction of arm with bio-behavioral risk profile in the prediction of abstinence at 12 months. The arm effects for the dichotomous outcomes were assessed with the logistic regression model controlling for a priori covariates: site, education (high school or less vs. post high school) and nicotine dependence (0 = not at all dependent to 6 = very dependent). The proportional hazards model was used to estimate the association of arm with time to resumption, using the same set of covariates. Within the intervention arm, we used covariate-adjusted logistic regression to estimate the association of abstinence at 12-months with the proportion of sessions completed, defined as the number of sessions completed divided by the number of sessions assigned (dichotomized at 50%). The logistic regression model was used to estimate the association of proportion of sessions completed (dichotomized at 50%) with various participant baseline characteristics. *P*-values for the secondary and exploratory objectives are presented as descriptive statistics only; that is, they are not judged for significance but are presented solely to show the strength of evidence against the null hypothesis.

Results

We recruited 382 women: 41% were African American, 49% had more than a high school education, 50% were married or living with

a partner, 38% were recruited from the military base, 62% were not employed for pay, 33% were nulliparous, 59% had a partner who smoked (some partners did not live with them; Table 2). Forty-three percent ($N = 165$) of the women had a low risk profile meaning they scored low on all three of the bio-behavioral factors. Among the 217 women with a high bio-behavioral risk profile, 77% reported low confidence to stay abstinent. The median proportion of sessions completed by the low and high-risk women was comparable (mean = 4.3 vs. 6.2) despite the difference in sessions offered (9 vs. 14).

Primary Analyses

Abstinence rates were high, although the difference between arms on 12-month postpartum abstinence was not statistically significant (Control: 0.35 vs. Intervention: 0.36, $P = .81$). As shown in Table 3, arm differences on abstinence at 6-week postpartum, 6-month postpartum and continuous abstinence were not clinically meaningful. As a sensitivity analysis, we compared the intent-to-treat method with multiple imputation and found comparable results. Arm differences for 6-months postpartum abstinence for intent-to-treat and imputation methods were not significant (odds ratio [OR]: 1.22, 95% confidence interval [CI]: 0.68–1.53, $P = .35$) and (OR: 1.17, 95% CI: 0.78–1.76, $P = .43$), respectively. Median time to resumption for the Control and Intervention arms was 153 days (95% CI: 96–210) and 145 days (95% CI: 98–192), respectively.

Table 2. Participant Characteristics

Characteristics	Total ($N = 382$)	Control ($N = 194$)	Stepped-care ($N = 188$)
	%	%	%
Age (M, SD)	25 (5)	25 (5)	25 (5)
History of smoking index (HSI) (M, SD)	2 (2)	2 (2)	2 (1)
Partnered (%)	50	52	47
Education (%)			
Less than high school	18	16	21
High school/ General Educational Development (GED)	33	30	36
Vocational school	7	7	7
Some college	33	39	28
College graduate or higher	9	9	9
Race (%)			
White	48	53	44
Black	41	39	43
Other	11	8	13
Employment (%)			
Full-time	24	23	25
Part-time	14	15	14
Not employed	62	62	61
Site (%)			
Academic and health department	62	60	64
Military-affiliated	38	40	36
First pregnancy (%)	33	32	34
Wantedness of this pregnancy			
Pregnant sooner	15	13	16
Pregnant later	44	45	44
Pregnant at this time	23	25	20
Did not want to be pregnant now or later	18	17	20
Partner smokes (%)	59	60	58
Likelihood to resume smoking after birth of baby (somewhat to extremely likely) (%)	42	43	42
Confidence to remain off cigarettes after birth of baby (≤ 5 where 1 = not at all and 7 = extremely) (%)	54	60	48
Bio-behavior risk factors (%)			
Low risk	43	38	48
High risk	57	62	52

Table 3. Covariate-Adjusted Rates of Women's Self-Report of 7-Day Point Prevalent Abstinence

	Control arm ^a (N = 194)		Stepped care arm ^b (N = 188)	
	Rate (95% CI)	% (n) LTF ^b	Rate (95% CI)	% (n) LTF
6-weeks postpartum	0.53 (0.46–0.60)	0.14 (26)	0.52 (0.45–0.59)	0.13 (25)
6-months postpartum	0.35 (0.28–0.42)	0.17 (32)	0.39 (0.32–0.46)	0.17 (32)
12-month postpartum	0.36 (0.29–0.43)	0.17 (32)	0.35 (0.28–0.42)	0.12 (24)
Continuous abstinence	0.21 (0.15–0.27)	0.25 (49)	0.20 (0.13–0.25)	0.27 (50)

CI = confidence interval. Covariates included were site, education and nicotine dependence.

^aControl = Standard care plus booklet, *Forever Free for Baby and Me: A Guide to Remaining Smoke Free* plus monthly parenting/stress newsletters.

^bLTF (Lost-To-Follow-up).

Descriptive statistics indicated a possible interaction between arm and bio-behavioral risk profile; the test of this interaction had a *P*-value of .04. Among the 165 low-risk women, the 12-month crude abstinence rates for the Intervention and Control arms were 0.33 and 0.46, respectively, giving a rate difference of -0.13 (95% CI: +0.02 to -0.28). Thus, women who were low risk did worse in the intervention arm. In the 217 high-risk women, the crude rates were 0.37 and 0.31, respectively, giving a rate difference of 0.06 (95% CI -0.06 to +0.19).

Association of Abstinence With Proportion of Sessions Completed

We estimated the association of abstinence with the proportion of sessions completed (dichotomized as <50% vs. ≥50%) in the 188 women in the intervention arm (calculated differently for the low- and high-risk women). The odds of remaining abstinent among women who received 50% or more of the assigned sessions was 1.84 times higher (95% CI: 0.99–3.40) than the odds of remaining abstinent among women who received less than 50% of the sessions. Only a high depression score of 12 or greater was significantly associated with receiving at least 50% of the assigned sessions (OR 2.5, 95% CI 1.17–5.41) compared to depression score less than 12; education, race, partnership status, site, age, addiction score, likelihood of smoking resumption, and partner smoking status were not associated with receiving at least half of the intervention sessions.

Predictors of Abstinence

Women were more likely to remain abstinent at 12 months if they were recruited from the Army medical center (OR 1.73, 95% CI: 1.08–2.80) and if they reported during pregnancy that they did not intend to return to smoking (OR 2.74, 95% CI: 1.70–4.45). Among women who stated that they were somewhat, very, or extremely likely to go back to smoking, 76% returned to smoking. Of those who said they were not at all or not very likely to resume smoking, only 54% returned to smoking. No other factors (eg, education, partner smoking, etc.) were related to abstinence.

Discussion

We are among the many investigators who have found similar abstinence rates in our intervention and control arms. Even though we provided more intervention sessions to women who theoretically were at higher risk of relapse based on their bio-behavioral profile, provided our intervention through 9 months postpartum, and had nurses link women to community services, we found equal abstinence rates in both arms. We did find an interesting result, however, that differs from others who did not stratify on risk of relapse. We

found that women who were at lower risk of returning to smoking had high abstinence rates, compared to those found in other bio-chemically-validated relapse prevention trials, when they received an intervention with almost no smoking content but instead with a strong focus on parenting and stress. Women who were low risk were more likely to return to smoking when they received the intensive smoking relapse prevention counseling. Women at higher risk had slightly higher, but not statistically significant, improved abstinence with intensive smoking relapse prevention counseling.

There are several possible explanations for this finding. One is that our approach to assigning bio-behavioral risk of smoking resumption was not valid or precise enough in this clinical setting. However, others have found that these bio-behavioral variables predict sustained abstinence.²⁰ Another is that the two interventions differentially affected the natural trajectories of high- and low-risk women as they transition from pregnancy to postpartum. It can be hypothesized but has not been empirically tested that the natural trajectory among high-risk women after they deliver and receive no help to maintain their smoking abstinence likely involves many changes: (1) her motivation to stay quit which was high during pregnancy decreases postpartum as much of the motivation was externally driven by the pregnancy, (2) her confidence to stay abstinent from cigarettes decreases as her ability to resist smoking wanes and others do not support her staying abstinent now that she is no longer pregnant, (3) her urges to smoke increase as she likely returns to situations where others are smoking and again she does not get special treatment as a pregnant quitter, (4) her stress increases with the needs of a newborn, and (5) her coping decreases being sleep-deprived with many demands on her time.²¹

In contrast, women who are at low risk of relapse might not experience the drop in motivation and confidence or the spike in urges to smoke as they have decided during pregnancy not to return to smoking. They have made an internal decision to not smoke and become a permanent quitter, not a temporary quitter. They will still have increases in stress and decreases in coping after the baby is born as most new mothers do.

Thus, an intervention that provides tips to prevent return to smoking could help combat the natural trajectory for high-risk women by: (1) preventing the drop in motivation with frequent reminders of reasons to remain smoke free, (2) preventing the drop in confidence by pointing out ways she has been successful, and (3) preventing the increase in urges by teaching her ways to deal with her urges. This type of intervention might be effective because it is based in part on Self-Regulation Theory,²² which posits that for people to change, they first need to control their impulses and understand their triggers. Given most postpartum women do not “plan” to return to smoking,²⁰ resisting spontaneous urges or triggers in their

environment is critical. Having daily reminders of why they want to stay smoke-free can keep them on target likely better than a monthly phone call or home visit. The intervention that focuses on smoking relapse also builds on psychosocial factors from Social Cognitive Theory¹⁶ by bolstering self-efficacy (confidence they can remain smoke free) and increasing motivation. Alternatively, an intervention that only provides tips on parenting for high-risk women would only prevent some of the increase in stress and also increase coping; however, this intervention might be insufficient to prevent many from returning to smoking as it does not address the critical issues of motivation, confidence, or urges.

For low-risk women, this parenting intervention might work well as it addresses women's added stress and lower ability to cope, which could be enough as they might not have the steep decreases in confidence and motivation and increases in urges that high-risk women do. In contrast, when low-risk women receive the smoking relapse intervention that targets motivation, confidence, and urges, unintended negative consequences might occur. The constant reminders about why they should not return to smoking actually could increase their urges, lower their confidence, and lower their motivation. Intention implementation theory posits that once a person has enacted her plan according to her intentions, when she is asked to reflect on her motivation for making the choice, her motivation and confidence can actually be undermined.²³ Thus, a parenting intervention might work best for low-risk women who do not need help with their smoking. On the other hand, a smoking relapse intervention might help high-risk women whereas a parenting intervention would not offer enough help with their smoking-related needs. Thus, women who were confident at the outset that they would not return and who did not intend to return to smoking might have had their confidence shaken by having a counselor continue to ask them about their plans and set goals to prevent relapse. These results suggest that for women who are unlikely to return to smoking, one way to help them is to support them in their parenting efforts. We have no direct test of how many women would have maintained their abstinence in the absence of any intervention, but compared to the literature on the rate of smoking resumption, it seems the newsletters had an effect above usual care.

Women from the Army medical center were more likely to be abstinent than those recruited from county health departments. Although we do not know whether women used medications to help them stay abstinent, we do know that women from the Army medical center had more favorable social determinants of health (eg, were more likely to be partnered, have stable housing, and have a higher education) than women from the county health departments. These social determinants might have been related to women being more able to refrain from returning to smoking.

Although our nurse-delivered intervention did not differentially prevent women from returning to smoking postpartum, we did find an association between receiving more sessions and a greater likelihood of 12-month smoking abstinence. Completing sessions might be a proxy for motivation in that women who were more motivated to stay abstinent were more likely to take calls from the nurse and also more likely to stay abstinent. One big challenge was ensuring that women received the assigned number of interventions: high-risk women, assigned 14 sessions, completed a median of only 6, with one of these occurring prior to delivery. One unanticipated barrier to receiving the telephone-based intervention was cost constraints on the part of participants. Many participants used a cell phone as their primary, or only, phone, and, during the time of the study, many had limited minute plans. We missed many intervention sessions

as women told us that they deemed our intervention not "minute worthy" and would not "spend" their minutes talking to our nurse counselors. It also is possible that our intervention went too far out into postpartum. We hypothesized that women would appreciate a longer intervention; the data do not support this.

Our biochemically-validated cessation rates were relatively high compared to previously reported studies, particularly for low-risk women who received the newsletters. This high rate could be partly due to our assessing carbon monoxide and cotinine at each assessment, which can motivate women in both arms to quit smoking. With more than a third of the women reporting abstinence at 12 months postpartum, both the control and intervention arm rates were substantially higher than reported in other trials (approximately 15%–20% at 12-months postpartum).⁵ This abstinence rate was particularly surprising given our recruitment strategy, which did not rely on women volunteering to participate as these women tend to be most motivated to stay quit. One possible explanation is that our assessments of smoking status occurred during face-to-face interviews, which might have created an added layer of accountability for participants compared to a telephone interview.

This study has some limitations. First, we identified women early in pregnancy, and thus, lost some from that initial contact to when we could enroll them at 28 weeks gestation. The interaction between arm and risk group was small and should be replicated. Also, although we hoped to create an intervention that was disseminable by having nurses deliver the counseling, we do not have a test in real-world obstetric clinics to determine if nurses could provide this intervention (to those women who are at high risk of relapse). We also are unable to test for the effect of co-interventions (eg, bupropion). Finally, this study would have been stronger by including an arm that received no intervention. This study also has multiple strengths. Our sample was population-based in that we proactively recruited women rather than relied on women volunteering. Thus, our results are generalizable to many women who quit spontaneously for their pregnancy. Also, our sample was racially and socioeconomically diverse.

Our study is similar to others in that our smoking abstinence intervention did not outperform a minimal intervention in preventing postpartum return to smoking. Our abstinence rate was high, however, showing some promise for the intervention. For women who were low risk, providing parenting and stress management newsletters might be the most effective strategy. For women who are high risk, other approaches might be needed to engage and encourage participation. Future studies need to examine more closely how to help women who are at highest risk, that is, women who stop smoking but do not truly quit smoking.

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Declaration of Interests

None declared.

References

1. Colman GJ, Joyce T. Trends in smoking before, during, and after pregnancy in ten states. *Am J Prev Med.* 2003;24(1):29–35. doi:10.1016/S0749-3797(02)00574-3.

2. Kahn RS, Certain L, Whitaker RC. A reexamination of smoking before, during, and after pregnancy. *Am J Public Health*. 2002;92(11):1801–1808. doi:10.2105/AJPH.92.11.1801.
3. Stotts AL, DiClemente CC, Carbonari JP, Mullen PD. Postpartum return to smoking: staging a “suspended” behavior. *Health Psychol*. 2000;19(4):324–332. <http://dx.doi.org/10.1037/0278-6133.19.4.324>. Accessed December 28, 2015.
4. Mitchell EA, Milerad J. Smoking and the sudden infant death syndrome. *Rev Environ Health*. 2006;21(2):81–103. doi:10.1515/REVEH.2006.21.2.81.
5. Su A, Buitenheim AM. Maintenance of smoking cessation in the postpartum period: which interventions work best in the long-term? *Matern Child Health J*. 2014;18(3):714–728. doi:10.1007/s10995-013-1298-6.
6. Brandon TH, Simmons VN, Meade CD, et al. Self-help booklets for preventing postpartum smoking relapse: a randomized trial. *Am J Public Health*. 2012;102(11):2109–2115. doi:10.2105/ajph.2012.300653.
7. McBride CM, Baucom DH, Peterson BL, et al. Prenatal and postpartum smoking abstinence a partner-assisted approach. *Am J Prev Med*. 2004;27(3):232–238. doi:10.1016/j.amepre.2004.06.005.
8. Morasco BJ, Dornelas EA, Fischer EH, Oncken C, Lando HA. Spontaneous smoking cessation during pregnancy among ethnic minority women: a preliminary investigation. *Addict Behav*. 2006;31(2):203–210. doi:10.1016/j.addbeh.2005.04.022.
9. Reitzel LR, Vidrine JI, Businelle MS, et al. Preventing postpartum smoking relapse among diverse low-income women: a randomized clinical trial. *Nicotine Tob Res*. 2010;12(4):326–335. doi:10.1093/ntr/ntq001.
10. Secker-Walker RH, Solomon LJ, Flynn BS, et al. Individualized smoking cessation counseling during prenatal and early postnatal care. *Am J Obstet Gynecol*. 1994;171(5):1347–1355. doi:10.1016/0002-9378(94)90159-7.
11. Pletsch PK. A model for postpartum smoking resumption prevention for women who stop smoking while pregnant. *J Obstet Gynecol Neonatal Nurs*. 2006;35(2):215–222. doi:10.1111/j.1552-6909.2006.00036.x.
12. Ebrahim SH, Floyd RL, Merritt RK II, Decoufle P, Holtzman D. Trends in pregnancy-related smoking rates in the United States, 1987–1996. *JAMA*. 2000;283(3):361–366.
13. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987;150(150):782–786.
14. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict*. 1991;86(9):1119–1127. doi:10.1111/j.1360-0443.1991.tb01879.x.
15. Lewis-Esquerre JM, Colby SM, Tevyaw TO, Eaton CA, Kahler CW, Monti PM. Validation of the timeline follow-back in the assessment of adolescent smoking. *Drug Alcohol Depend*. 2005;79(1):33–43. doi:10.1016/j.drugalcdep.2004.12.007.
16. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice-Hall, Inc; 1986: 617.
17. Miller JH, Moyers T. Motivational interviewing in substance abuse: applications for occupational medicine. *Occup Med*. 2002;17(1):51–65, iv. www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=11726336. Accessed December 28, 2015.
18. Moyers TB, Martin T, Manuel JK, Hendrickson SM, Miller WR. Assessing competence in the use of motivational interviewing. *J Subst Abuse Treat*. 2005;28(1):19–26. doi:10.1016/j.jsat.2004.11.001.
19. Velasquez MM, Hecht J, Quinn VP, Emmons KM, DiClemente CC, Dolan-Mullen P. Application of motivational interviewing to prenatal smoking cessation: training and implementation issues. *Tob Control*. 2000;9(suppl 3):iii36–40.
20. Simmons VN, Sutton SK, Quinn GP, Meade CD, Brandon TH. Prepartum and postpartum predictors of smoking. *Nicotine Tob Res*. 2014;16(4):461–468. doi:10.1093/ntr/ntt177.
21. Mullen PD. How can more smoking suspension during pregnancy become lifelong abstinence? Lessons learned about predictors, interventions, and gaps in our accumulated knowledge. *Nicotine Tob Res*. 2004;6(suppl 2):S217–238. doi:10.1080/14622200410001669150.
22. Kanfer FH. Self-regulation: research, issues, and speculations. In: Neuringer C, Michael JL, eds. *Behavior Modification in Clinical Psychology*. New York, NY: Appleton-Century-Croft; 1970:178–220.
23. Gollwitzer PM. Mindset theory of action phrases. In: Van Lange A, Kruglanski AW, Higgins ET, eds. *Handbook of Theories of Social Psychology*. London, United Kingdom: Sage Publications; 2012:526–545.