Preventing Postpartum Smoking Relapse
A Randomized Clinical Trial

Michele D. Levine, PhD; Yu Cheng, PhD; Marsha D. Marcus, PhD; Melissa A. Kalarchian, PhD; Rebecca L. Emery, MS

**IMPORTANCE** Most women who quit smoking during pregnancy will relapse postpartum. Previous efforts to prevent postpartum relapse have been unsuccessful at increasing rates of sustained abstinence.

**OBJECTIVE** To evaluate the relative efficacy of 2 different approaches to prevent postpartum smoking relapse.

**DESIGN, SETTING, AND PARTICIPANTS** Pregnant women who recently had quit smoking were recruited before the end of pregnancy. Intervention sessions were conducted through a combination of telephone calls and in-person visits beginning at delivery and continuing through 24 weeks postpartum. Participants completed assessments at the prenatal baseline and at 12, 24, and 52 weeks postpartum. Participants were recruited between March 2008 and December 2012. The dates of the analysis were April 2014 to February 2015.

**INTERVENTIONS** Women received postpartum-adapted, behavioral smoking relapse prevention intervention and were randomly assigned to an enhanced cognitive behavioral intervention that included additional specialized strategies and content focused on women's postpartum concerns about mood, stress, and weight (Strategies to Avoid Returning to Smoking [STARTS]) or a supportive, time and attention–controlled comparison (SUPPORT). Intervention began before delivery and continued through 24 weeks postpartum.

**MAIN OUTCOMES AND MEASURES** The primary outcome was biochemically confirmed sustained tobacco abstinence at 52 weeks postpartum. Secondary outcomes were self-reported mood, levels of perceived stress, and degree of concern about smoking-related weight gain.

**RESULTS** The study cohort comprised 300 participants (150 randomly assigned to each group). Their mean (SD) age was 24.99 (5.65) years. Overall, 38.0% (114 of 300), 33.7% (101 of 300), and 24.0% (72 of 300) of the sample maintained abstinence at 12, 24, and 52 weeks' postpartum, respectively. There were no differences between the intervention groups in abstinence or time to relapse. Self-reported depressive symptoms and perceived stress significantly improved over time, and improvements were similar for both intervention groups. Women with more depressive symptoms and higher levels of perceived stress were more likely to relapse (hazard ratio, 1.02; 95% CI, 1.00-1.04; \( P = .04 \) for depressive symptoms and hazard ratio, 1.04; 95% CI, 1.01-1.07; \( P = .003 \) for stress).

**CONCLUSIONS AND RELEVANCE** An intervention designed to address women's concerns about mood, stress, and weight did not differentially improve rates of sustained tobacco abstinence postpartum compared with a time and attention–controlled comparison. Women in STARTS and SUPPORT reported postpartum improvements in mood and stress, and the experience of fewer depressive symptoms and less perceived stress was related to sustained abstinence. Given that most pregnant quitters will relapse within 1 year postpartum and that postpartum smoking has negative health consequences for women and children, effective interventions that target postpartum mood and stress are needed.

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any women quit smoking during pregnancy but most resume smoking within the first year postpartum. Postpartum smoking increases women’s health risks and exposes infants to tobacco smoke, which has been linked to sudden infant death syndrome, ear infections, respiratory tract illness, and asthma, as well as deficits in cognitive performance. Therefore, preventing postpartum smoking relapse would have beneficial health effects for women, infants, and children. Although some interventions designed to prevent postpartum relapse have increased the duration of postpartum smoking abstinence, the longer-term efficacy of postpartum relapse prevention programs has been equivocal. Rates of sustained smoking abstinence after intervention range from 1% to 72% depending on the length of follow-up, population studied, and the use of biochemical validation of abstinence. Most important, rates of postpartum abstinence have been particularly low (1%-9%) when smoking is validated using both expired-air carbon monoxide and salivary cotinine levels.

Adapting interventions to address factors related to postpartum relapse may improve the success of postpartum smoking relapse prevention interventions. Although nicotine dependence, minority group membership, younger age, and lower socioeconomic status have been related to increased risk of smoking relapse postpartum, few modifiable correlates of postpartum smoking have been identified. Our group’s work and that of others have documented that women, positive affect and fewer smoking-related weight gain concerns predict a slower return to smoking postpartum, while rapid relapse was associated with lower weight postpartum.

Given links among postpartum smoking, stress, mood, and weight concerns, we reasoned that an intervention adapted to postpartum demands and designed to address stress, mood, and weight concerns would improve rates of sustained postpartum abstinence. Accordingly, we conducted a randomized clinical trial to evaluate the relative efficacy of a postpartum-specific smoking relapse prevention program called Strategies to Avoid Returning to Smoking (STARTS) and a supportive, time and attention-controlled comparison (SUPPORT). The SUPPORT intervention provided the same postpartum-specific relapse prevention information and controlled for the effects and amount of therapeutic time but did not address mood, stress, and weight concerns that were targets of the STARTS intervention. We hypothesized that (1) women in STARTS would have higher rates of smoking abstinence and a longer period of sustained abstinence than those in SUPPORT; that (2) sustained abstinence would be associated with improvements in mood, perceived stress, and smoking-related weight concerns; and that (3) women in STARTS would evidence greater changes in these variables than women in SUPPORT.

Methods

Study Design
The trial protocol was approved by the University of Pittsburgh Institutional Review Board, and participants provided written informed consent. As detailed previously, women who quit smoking in their current pregnancy were randomly assigned to STARTS or SUPPORT during the third trimester of pregnancy. Randomization schedules were generated by a statistician (Y.C.) at the start of the study, were stratified by self-reported race (black or white), and took place at the individual level. Women were informed of intervention assignment at the prenatal baseline. Intervention began immediately after delivery, when relapse risk is high, and continued through 24 weeks postpartum. Women completed assessments at the prenatal baseline and at 12, 24, and 52 weeks postpartum. Women were compensated on completion of each assessment, and the amount of compensation increased over time, for a total of no more than $170 for completing all assessments.

Intervention involved brief telephone and in-person sessions. As designed, interventionist contact time was higher (P < .001) for in-person sessions (mean [SD], 26 [12] minutes; range, 5-90 minutes), which were conducted at the participants’ homes, community centers, and other locations selected by postpartum women for convenience, than for telephone sessions (mean [SD], 14 [7] minutes; range, 3-90 minutes). To incentivize meeting in person, women were given gift certificates ($20) to stores that sold infant goods.

Participants
Participants were recruited between March 2008 and December 2012 (Figure 1). The dates of the analysis were April 2014 to February 2015. Pregnant women who self-reported smoking daily for at least 1 month during the 3 months before becoming pregnant, smoked at least 5 cigarettes per day before quitting, had not smoked during the past 2 weeks, and were motivated to stay quit were recruited from prenatal smoking cessation programs, obstetric and pediatric offices, and women's health clinics. At enrollment, smoking cessation was documented using the timeline follow-back methodology and an expired-air carbon monoxide level of 8 ppm or less. Motivation to stay quit was assessed on a 4-point scale ranging from 0 (not at all motivated) to 3 (extremely motivated). Women with a score of at least 2 were considered motivated to stay quit. Four women reporting acute substance use problems or psychiatric symptoms that
warranted immediate treatment on structured clinical inter-
vw (Primary Care Evaluation of Mental Disorders, Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Axis I Disorders) were excluded. Baseline characteristics of women in STARTS and SUPPORT were similar, except that those randomized to STARTS had higher baseline weight self-efficacy than women randomized to SUPPORT (Table 1).

Interventions
As detailed elsewhere, interventions were adapted to meet the needs of postpartum women based on previous work. All women received individualized, evidence-based smoking relapse prevention information and were randomly assigned to either a postpartum-specific relapse prevention intervention (SUPPORT) or an enhanced cognitive behavioral intervention (STARTS). A manual was used to guide both in-
tervention conditions, and intervention topics and skills were presented in a standardized fashion. Women also received written information at each session.

Cognitive behavioral strategies, including preparation for high-risk periods, management of slips, and creation of a relapse plan, successfully have decreased smoking relapse risk in general\textsuperscript{41-43} and during the postpartum period.\textsuperscript{17,20} Therefore, in both interventions women were asked to monitor urges to smoke and discussed strategies to address cravings and high-risk situations. However, SUPPORT focused only on behavioral urges to smoke, whereas STARTS also incorporated cognitive behavioral techniques to challenge thoughts and beliefs related to smoking urges. Increasing social contacts, balancing needs with those of their infant, addressing smoking-specific weight concerns, promoting healthy weight loss after pregnancy, and using physical activity as an alternative to smoking also were targeted in STARTS.\textsuperscript{32,44}

### Treatment Fidelity

Interventions were delivered by female, master’s-level clinicians trained to criteria on both approaches. To evaluate interventionist fidelity, ensure distinction between STARTS and SUPPORT, and prevent therapist drift, sessions were audio recorded, and clinicians received weekly group supervision. Trained independent raters (M.D.L. and R.L.E.) listened to audio recordings of a random 10% of sessions to assess the degree to which interventionists adhered to the protocol. Intervention fidelity was defined as the percentage of sessions globally rated as compliant to each protocol out of the total number of sessions rated.

### Primary Outcomes

The primary outcome was biochemically confirmed sustained tobacco abstinence at 52 weeks postpartum. At each assessment, women were interviewed about any smoking since their last assessment using a timeline follow-back format,\textsuperscript{34} and expired-air carbon monoxide and a salivary cotinine sample were collected. Relapse was defined as the self-report of 7 consecutive days of smoking, a carbon monoxide level exceeding 8 ppm, or a cotinine level exceeding 15 μg/L (to convert cotinine level to nanomoles per liter, multiply by 5.675).\textsuperscript{45,46} In all cases where carbon monoxide level or cotinine level indicated smoking, women were coded as relapsed. Women who dropped out of treatment were considered to have relapsed as of the day after the last visit on which abstinence was verified. Time to relapse postpartum was determined by counting the number of days between delivery and the first day of 7 consecutive days of smoking.

### Table 1. Participant Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (N = 300)</th>
<th>STARTS (n = 150)</th>
<th>SUPPORT (n = 150)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>24.99 (5.65)</td>
<td>24.97 (5.74)</td>
<td>25.01 (5.57)</td>
<td>.96</td>
</tr>
<tr>
<td>No. of cigarettes smoked daily, mean (SD)</td>
<td>11 (9)</td>
<td>10 (7)</td>
<td>12 (11)</td>
<td>.27</td>
</tr>
<tr>
<td>No. of years of smoking, mean (SD)</td>
<td>8.49 (5.65)</td>
<td>8.49 (5.75)</td>
<td>8.49 (5.56)</td>
<td>.99</td>
</tr>
<tr>
<td>No. of previous quit attempts, mean (SD)</td>
<td>4 (4)</td>
<td>4 (4)</td>
<td>3 (3)</td>
<td>.84</td>
</tr>
<tr>
<td>Fagerstrom Test for Nicotine Dependence, mean (SD)</td>
<td>3.20 (2.04)</td>
<td>3.22 (2.01)</td>
<td>3.19 (2.07)</td>
<td>.89</td>
</tr>
<tr>
<td>Motivation to stay quit, mean (SD)</td>
<td>2.72 (0.57)</td>
<td>2.68 (0.58)</td>
<td>2.77 (0.55)</td>
<td>.19</td>
</tr>
<tr>
<td>No. of weeks quit at baseline, mean (SD)</td>
<td>17.33 (11.73)</td>
<td>16.42 (11.76)</td>
<td>18.21 (11.69)</td>
<td>.22</td>
</tr>
<tr>
<td>Prepregnancy body mass index,\textsuperscript{a} mean (SD)</td>
<td>27.28 (7.51)</td>
<td>26.79 (7.15)</td>
<td>27.78 (7.85)</td>
<td>.26</td>
</tr>
<tr>
<td>CES-D score, mean (SD)</td>
<td>15.46 (9.88)</td>
<td>15.37 (9.87)</td>
<td>15.54 (9.89)</td>
<td>.88</td>
</tr>
<tr>
<td>PSS score, mean (SD)</td>
<td>22.50 (8.27)</td>
<td>22.25 (8.63)</td>
<td>22.75 (7.91)</td>
<td>.61</td>
</tr>
<tr>
<td>Weight concerns score, mean (SD)</td>
<td>3.96 (2.21)</td>
<td>3.79 (2.20)</td>
<td>4.12 (2.21)</td>
<td>.20</td>
</tr>
<tr>
<td>Weight self-efficacy score, mean (SD)</td>
<td>6.30 (2.26)</td>
<td>6.63 (2.05)</td>
<td>5.96 (2.46)</td>
<td>.01</td>
</tr>
<tr>
<td>Black race, No. (%)</td>
<td>163 (54.3)</td>
<td>82 (54.7)</td>
<td>81 (54.0)</td>
<td>.91</td>
</tr>
<tr>
<td>Education level of high school or less, No. (%)</td>
<td>137 (45.7)</td>
<td>69 (46.0)</td>
<td>68 (45.3)</td>
<td>.21</td>
</tr>
<tr>
<td>Household annual income &lt;$30 000, No. (%)</td>
<td>234 (78.0)</td>
<td>119 (79.3)</td>
<td>115 (76.7)</td>
<td>.96</td>
</tr>
<tr>
<td>Nulliparous, No. (%)</td>
<td>156 (52.0)</td>
<td>84 (56.0)</td>
<td>72 (48.0)</td>
<td>.64</td>
</tr>
<tr>
<td>Lifetime psychiatric disorder history, No./Total No. (%)</td>
<td>83/276 (30.1)</td>
<td>41/136 (30.2)</td>
<td>42/140 (30.0)</td>
<td>.98</td>
</tr>
<tr>
<td>Substance use disorder</td>
<td>91/276 (33.0)</td>
<td>43/136 (31.6)</td>
<td>48/140 (34.3)</td>
<td>.64</td>
</tr>
<tr>
<td>Anxiety disorder</td>
<td>163 (54.3)</td>
<td>82 (54.7)</td>
<td>81 (54.0)</td>
<td>.91</td>
</tr>
<tr>
<td>Eating disorder</td>
<td>25/276 (9.1)</td>
<td>2/136 (1.4)</td>
<td>3/140 (2.1)</td>
<td>.68</td>
</tr>
</tbody>
</table>

Abbreviations: CES-D, Center for Epidemiologic Studies Depression; PSS, Perceived Stress Scale; STARTS, Strategies to Avoid Returning to Smoking; SUPPORT, a supportive, time and attention–controlled comparison.

* STARTS vs SUPPORT.

\textsuperscript{a} Calculated as weight in kilograms divided by height in meters squared.
Secondary Outcomes

Self-efficacy for weight management after quitting smoking and smoking cessation-specific weight concerns were assessed at baseline and 12, 24, and 52 weeks postpartum. Current depressive symptoms were assessed using the Center for Epidemiologic Studies Depression Scale, which is less sensitive than other depression scales to somatic symptoms that may be common during the postpartum period. Women completed the Perceived Stress Scale to assess the degree to which they appraise situations as stressful.

Statistical Analysis

Sample size was estimated based on the power to detect differences in the proportion of women relapsing to smoking in STARTS and SUPPORT at 24 and 52 weeks postpartum. Relapse rates from previous postpartum smoking relapse prevention trials have demonstrated absolute improvements of 11% to 27% in abstinence rates at 24 weeks postpartum. Given that STARTS would be more intense than interventions used in previous studies, we estimated an 18% increase in abstinence rates relative to usual care at 24 weeks postpartum. We also estimated that abstinence rates in SUPPORT would be somewhat higher than those observed in nontreatment control groups. Therefore, we projected abstinence rates at 24 weeks postpartum of 53% and 37% for the STARTS and SUPPORT interventions, respectively. Using an α level of .05 and a 2-tailed test for differences in proportions, 150 women per intervention group yielded 80% power to detect a 16% difference (53% vs 37%) in the proportion abstinent at 24 and 52 weeks postpartum.

We compared the proportions of women who maintained abstinence at 12, 24, and 52 weeks postpartum using χ² tests based on intent to treat. We then fit a generalized mixed-effects model with the logit link function to compare abstinence rates across each assessment. Models included terms for intervention group, time (12, 24, and 52 weeks), their interaction, and the stratification factor of race. We evaluated all of the demographic variables listed in Table 1 to determine their contribution to abstinence and retained the baseline covariates associated with abstinence rates over time in multivariable analyses. The interactions of significant predictors and randomization group also were included to determine if the intervention effect was moderated by covariates. For time to relapse, Kaplan-Meier curves were constructed to compare differences in the number of days women remained abstinent from smoking between intervention groups. Cox proportional hazards models were run to control for race and to evaluate the effects of intervention group and demographic variables on relapse time. The final model included intervention group, race, and the 3 significant demographic covariates (age, number of cigarettes smoked per day, and weeks of cessation during pregnancy). Cox proportional hazards models also were used to evaluate the interactive effects between these 3 demographic variables and intervention group.

We examined the effect of intervention group over time on hypothesized secondary outcomes using linear mixed-effects models. Models included fixed terms for intervention group, time, race, and the group by time interaction. Participation was included as a random term to account for dependence among repeated measures from the same individual.

To examine the relationship between mood, stress, and weight concerns over time to relapse, we used repeated assessments of these variables to predict relapse during the subsequent assessment interval. Cox proportional hazards models (controlling for race) and the baseline covariates that were significantly related to relapse time (age, number of cigarettes smoked per day, and weeks of cessation during pregnancy) were fit using time-dependent covariates of mood, stress, and weight concerns, which make use of the variables most proximal to the relapse event to model relapse rate in the next interval.

Results

Fidelity, Session Completion, and Study Retention

Across conditions, 91.2% (155 of 170) of sessions were rated as compliant to the intervention. There were no differences (P = .08) in fidelity ratings between sessions conducted in person (95.1% [78 of 82]) or over the telephone (87.5% [77 of 88]). However, a significantly greater proportion (P = .003) of sessions in the SUPPORT condition (96.7% [89 of 92]) were rated as being compliant to the intervention than sessions in the STARTS condition (83.3% [65 of 78]). Women completed a mean (SD) of 10.93 (3.77) of the 13 sessions, and 85.7% (257 of 300) of women completed all 13 intervention sessions. Session completion rates did not vary as a function of intervention for telephone sessions (mean [SD], 4.37 [2.38] sessions for STARTS and 4.66 [2.54] sessions for SUPPORT; P = .29) or in-person sessions (mean [SD], 5.31 [2.15] sessions for STARTS and 5.53 [1.82] sessions for SUPPORT; P = .36). However, across interventions women completed more in-person sessions (54.6% [1626 of 2980]) than telephone sessions (45.4% [1354 of 2980]) (P < .001).

Retention rates throughout the study period were high (Figure 1). Although a significantly greater proportion (P = .03) of women in STARTS (15.3% [23 of 150]) than in SUPPORT (7.3% [11 of 150]) were lost to follow-up at 52 weeks, attrition rates at the end of the intervention were similar (P = .18) between STARTS (9.3% [14 of 150]) and SUPPORT (5.3% [8 of 150]).

Sustained Abstinence Postpartum

In the total sample, 38.0% (114 of 300), 33.7% (101 of 300), and 24.0% (72 of 300) of women maintained biochemically confirmed smoking abstinence at 12, 24, and 52 weeks postpartum, respectively. Rates of sustained abstinence did not differ as a function of intervention group (P > .10 for all) (Table 2).

Four baseline covariates were significantly associated with abstinence over time and were included in the model. Black women and women with a high school education or less were more likely to relapse than white women and those with higher education (odds ratio [OR], 2.10; 95% CI, 1.27-3.52; P = .004 for race and OR, 1.90; 95% CI, 1.12-3.22; P = .02 for education). Conversely, age and weeks quit at baseline were negatively associated with relapse rates (OR, 0.93; 95% CI, 0.89-0.97; P < .001 for every year increase in age and OR, 0.93; 95%
CI, 0.91-0.95; P < .001 for every extra week quit at baseline). No interactions between intervention group and demographic predictors were significant (P > .20 for all). Moreover, controlling for baseline variables, neither group nor the group by time interaction was significantly related to postpartum abstinence (Table 3).

There were no differences between intervention groups in time to relapse (log rank = 0.34, P = .56). Results of Cox proportional hazards models demonstrated no relationship between intervention group and relapse time, although 3 baseline variables were predictive of abstinence. Older women and those who quit earlier in pregnancy were less likely to relapse than younger women and those who quit later (hazard ratio [HR], 0.97; 95% CI, 0.93-1.00; P = .04 for age and HR, 0.97; 95% CI, 0.96-0.99; P = .001 for weeks quit), and women who smoked more heavily before quitting were more likely to relapse than women who smoked less heavily (HR, 1.02; 95% CI, 1.00-1.03; P = .02 for each increase in the number of cigarettes smoked). Demographic variables did not modify the relation of time to relapse (P > .30 for all).

**Changes in Depressive Symptoms, Stress, and Smoking-Specific Weight Concerns Over Time**

Depressive symptoms (P < .001) and perceived stress (P = .001) improved over time, and improvements were similar for both intervention groups (Figure 2). Although there was a slight decrease in smoking-related weight concerns over time in both groups (P = .02), the groups endorsed different levels of weight concerns across time (P = .05). Planned contrasts indicated that at 24 weeks postpartum women in STARTS reported significantly lower concerns about weight than women in SUPPORT (least squares mean, 3.27 vs 3.95; P = .009). The groups did not differ in weight concerns at any other assessment point.

After controlling for baseline differences, women with more depressive symptoms and higher levels of perceived stress were more likely to relapse (HR, 1.02; 95% CI, 1.00-1.04; P = .04 for the Center for Epidemiologic Studies Depression Scale and HR, 1.04; 95% CI, 1.01-1.07; P = .003 for the Perceived Stress Scale). Smoking-related weight concerns and weight self-efficacy were not associated with time to relapse (P > .10 for both).

**Discussion**

Contrary to the hypothesis, an intervention specifically designed to address women’s postpartum concerns about mood, stress, and smoking-related weight gain did not increase rates of sustained postpartum abstinence above those produced by a time and attention-controlled comparison condition that provided the same individualized, postpartum-specific relapse prevention intervention. Although these 2 interventions did not differ in efficacy, both interventions designed to address the unique needs of postpartum women were associated with rates of carefully documented cigarette abstinence throughout the postpartum year that are higher than those reported in other similar trials. Rates of biochemically confirmed abstinence among women in both interventions were excellent at 6 months (33.7% [101 of 300]), and one-quarter (24.0% [72 of 300]) of the women sustained abstinence throughout the 1-year period of postpartum follow-up. The observed abstinence rates were particularly impressive given that the study participants were young women with few educational or financial resources and that these rates reflect the use of a stringent biochemical validation standard.

Few interventions have addressed the issue of postpartum smoking relapse. Moreover, rates of longer-term postpartum abstinence after intervention in previous studies have been less than 25%, and interventions generally have been unsuccessful at helping women sustain abstinence postpartum. For example, Brandon et al20 found that self-help booklets marginally increased rates of point prevalent abstinence relative to usual care, but differences between groups did not persist after intervention ended. In addition, in that trial abstinence was not biochemically validated in all participants, and the sample consisted largely of white women who lived with a partner and had more than a high school education. Therefore, the high rates of 6-month and 12-month sustained tobacco abstinence observed in the present study suggest that interventions can improve postpartum abstinence among young, urban women from diverse backgrounds who may have limited educational or economic advantages.

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**Table 2. Biochemically Verified Relapse and Continuous Abstinence Rates for the STARTS and SUPPORT Interventions at Each Assessment**

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%)</th>
<th>SUPPORT (n = 150)</th>
<th>STARTS (n = 150)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 wk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsed</td>
<td>88 (58.7)</td>
<td>98 (65.3)</td>
<td></td>
<td>.23</td>
</tr>
<tr>
<td>Abstinent</td>
<td>62 (41.3)</td>
<td>52 (34.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 wk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsed</td>
<td>93 (62.0)</td>
<td>106 (70.7)</td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>Abstinent</td>
<td>57 (38.0)</td>
<td>44 (29.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>52 wk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsed</td>
<td>110 (73.3)</td>
<td>118 (78.7)</td>
<td></td>
<td>.28</td>
</tr>
<tr>
<td>Abstinent</td>
<td>40 (26.7)</td>
<td>32 (21.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Although rates of sustained tobacco abstinence postpartum were high overall, the hypothesis that a postpartum intervention designed to address women’s concerns about weight and changes in mood would increase rates of sustained abstinence was not supported. The comparison condition controlled for the effects of therapeutic time and attention, and both interventions evaluated were adapted to meet the needs of postpartum women, although STARTS (based on a model of relapse) involved cognitive behavioral techniques to address mood, stress, and weight concerns. Therefore, both interventions provided support to sustain nonsmoking, and the benefits of such nonspecific intervention support in psychosocial treatment have been well documented. Substantial research comparing interventions for disordered eating, alcohol use, and mood disorders has found no difference in outcomes between interventions when equivalent time and attention were provided. Similarly, the support and attention provided by a trained professional may have had an impact on the psychosocial outcomes in this study. Indeed, although the difference in abstinence rates was not statistically significant, the present findings indicate that the provision of interventionist support in both groups was associated with a higher rate of abstinence, as well as changes in stress, mood, and weight concerns that increase vulnerability to smoking. Given that pregnancy is the most common time for a woman to quit smoking but that rates of postpartum relapse to smoking are high,1-5 the present results suggest that providing support tailored to the needs of women after childbirth can sustain smoking abstinence, thereby improving the health of mothers and young children.11-15

### Table 3. Baseline Predictors of Abstinence, Controlling for Treatment Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>β Coefficient</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>−0.09</td>
<td>.02</td>
</tr>
<tr>
<td>No. of cigarettes smoked daily</td>
<td>0.04</td>
<td>.06</td>
</tr>
<tr>
<td>No. of years of smoking</td>
<td>0.01</td>
<td>.86</td>
</tr>
<tr>
<td>No. of previous quit attempts</td>
<td>0.01</td>
<td>.81</td>
</tr>
<tr>
<td>Fagerstrom Test for Nicotine Dependence score</td>
<td>−0.07</td>
<td>.38</td>
</tr>
<tr>
<td>Motivation to stay quit</td>
<td>−0.17</td>
<td>.52</td>
</tr>
<tr>
<td>No. of weeks quit at baseline</td>
<td>−0.07</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Prepregnancy body mass index</td>
<td>0.00</td>
<td>.84</td>
</tr>
<tr>
<td>Black race</td>
<td>0.75</td>
<td>.01</td>
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<td>High school education or less</td>
<td>0.74</td>
<td>.01</td>
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<tr>
<td>Household annual income &lt;$30 000</td>
<td>0.39</td>
<td>.26</td>
</tr>
<tr>
<td>Parity</td>
<td>−0.19</td>
<td>.49</td>
</tr>
<tr>
<td>≥1 Psychiatric disorders</td>
<td>0.23</td>
<td>.42</td>
</tr>
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</table>

Figure 2. Changes in Depressive Symptoms, Stress, and Weight Concerns Over Time for the STARTS and SUPPORT Interventions

The CES-D Scale ranges from 0 to 60, the PSS ranges from 0 to 56, and Weight Concerns and Weight Self-efficacy range from 1 to 10. Women in STARTS reported significantly decreased weight concerns than women in SUPPORT at the 24-week assessment. The 2 intervention groups did not differ in weight concerns at any other assessment point. CES-D indicates Center for Epidemiologic Studies Depression; PSS, Perceived Stress Scale; STARTS, Strategies to Avoid Returning to Smoking; and SUPPORT, a supportive, time and attention-controlled comparison.
Across conditions, women completed more visits in person than by telephone. However, women were incentivized to complete visits in person, which occurred in convenient locations, confounding the high rate of in-person visit completion. Although it is impossible to determine the relative efficacy of in-person and telephone contacts given that both delivery modalities improved mood and decreased stress, postpartum contact with health care professionals, as used in the management of postpartum mood,60 may positively affect rates of sustained tobacco abstinence.

Consistent with previous work,3,24 younger women who were less educated and quit smoking later in pregnancy were at greatest risk for relapse and for doing so quickly. Although age and education level are not modifiable, strategies to promote smoking cessation before or early during pregnancy are needed. However, efforts to address prenatal cessation usually are not initiated until pregnancy has been confirmed, and most women quit spontaneously without intervention.61,62 Regardless of the route to prenatal smoking cessation, identifying mediators of postpartum relapse that are amenable to intervention, specific to the postpartum period, and easy to assess is important to efforts to increase sustained postpartum abstinence. We also addressed variables associated with smoking relapse that are commonly experienced postpartum and amenable to intervention. Depressive symptoms and perceived stress improved over time in both intervention groups. Although the decreases in depressive symptoms and stress may not have been the result of the interventions, as in previous work,21,30 we documented that improvements in mood and stress were associated with staying quit. However, weight gain concerns, which have been linked to smoking relapse generally48,63 and in the postpartum period specifically,27,28 were not associated with relapse in this trial. Weight gain concerns remained stable throughout the postpartum period, and it is possible that the lack of association between smoking-related weight gain and relapse reflects the particular salience of mood and stress to success at maintaining postpartum abstinence.

There are important limitations to this study. First, we examined potential mediators of relapse based on prior research, but additional predictors of postpartum smoking not addressed by either intervention also may be amenable to intervention. Second, it is also possible that, despite biochemically verified abstinence at the end of pregnancy, women relapsed before delivery. Although prenatal relapse would be expected equally across interventions, relapse before the beginning of the postpartum period might have diluted the efficacy of intervention. Third, the excellent treatment retention observed in this trial may not be replicated without the provision of incentives for receipt of in-person visits. Fourth, the interventions tested provided similar postpartum support, and the lack of a nonintervention control group prevents direct comparison with outcomes of women who do not receive treatment.

Conclusions

In summary, this randomized clinical trial evaluated the relative efficacy of 2 active interventions, both of which had been adapted to address the unique challenges of postpartum smoking relapse prevention. One intervention (based on a conceptual model of smoking relapse postpartum56) used cognitive behavioral strategies to address women’s concerns about mood, stress, and weight gain and deliver cognitive behavioral relapse prevention for postpartum women, while the other intervention provided the same relapse prevention content but did not address these areas, offering additional social support to serve as a time and attention–controlled comparison condition. These interventions did not differ in rates of sustained abstinence through 1 year postpartum. However, both interventions resulted in rates of sustained, biochemically confirmed abstinence through 1 year postpartum that are higher than has been reported in other trials with postpartum women. Although the lack of a nontreatment control group precludes direct conclusions about the efficacy of either the STARTS or SUPPORT intervention relative to no treatment, there are ample data documenting that more than 65%3–5,16 and as many as 90%64 of women will resume smoking postpartum without intervention. Therefore, research designed to address the ways in which treatments adapted to the needs of postpartum women can be disseminated is critical. For example, because the fidelity rating for interventionists was higher in the SUPPORT condition than in the STARTS condition, the potential ease of disseminating the SUPPORT intervention through community settings may be greater than that of the STARTS intervention. Indeed, given the health consequences of postpartum smoking for women and children, postpartum-specific intervention that prevents smoking relapse can improve maternal and child health.
Preventing Postpartum Smoking Relapse

Original Investigation Research

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Editor’s Note

Preventing Smoking Relapse After Delivery—Maintaining a Pregnant Pause

Mitchell H. Katz, MD

It is a public health success that 55% of women smokers quit during pregnancy.1 Women understand that smoking can harm their developing fetus, including premature birth, birth defects, and stillbirth, and this provides the necessary motivation for overcoming the tobacco addiction. Sadaly, 40% of women who quit smoking relapse within 6 months of delivery.1 This is not surprising. Anyone who has cared for a newborn understands the multiple stresses of this period, exacerbated by loss of sleep. Postpartum depression is common, and the desire to lose weight after pregnancy may also drive women back to smoking. Also, women may be more aware of the harms of smoking to their developing fetus than to themselves or to their growing child.

To decrease relapse to smoking, Levine and colleagues2 developed an innovative intervention based on cognitive behavioral techniques to challenge thoughts and beliefs relating to mood, stress, and weight gain. Women who had stopped smoking during pregnancy were randomized to this intervention vs a control group that received support in maintaining smoking cessation. At 52 weeks postpartum, there was no difference between the 2 groups.

Overall, 228 of 300 women (76.0%) were back to smoking at 52 weeks, after being able to stop smoking during pregnancy. Now, the challenge for interventionists is to build on that initial success.

Conflict of Interest Disclosures: None reported.