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One-to-One
A motivational intervention for resistant pregnant smokers

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Abstract

The purpose of this prospective, randomized controlled study was to determine the efficacy of an intensified, late pregnancy, smoking cessation intervention for resistant pregnant smokers ($n = 269$). Participants received 3–5 min of counseling plus a self-help booklet at their first prenatal visit and seven booklets mailed weekly thereafter; at 28 weeks, all had been smoking in the past 28 days. The experimental group received a stage of change-based, personalized feedback letter and two telephone counseling calls using Motivational Interviewing (MI) strategies. The control group received care as usual. The 34th week cotinine data demonstrated no overall difference between groups. However, an implementation analysis suggested that 43% of women who received the full intervention (E2) were classified as not smoking compared to 34% of the control group. At 6 weeks postpartum, 27.1% of the E2 group reported being abstinent or light smokers vs. 14.6% of the controls. No differences were detected at 3 and 6 months postpartum. Results lend preliminary but very modest support for this intervention with resistant pregnant smokers. Improvements in the intervention and implementation issues are discussed.

Keywords: Pregnant smokers; Pregnancy smoking cessation; Stages of change; Motivational interviewing

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1. Introduction

Adverse effects of cigarette smoking on pregnancy outcomes are well documented (e.g., Floyd, Rimer, Giovino, Mullen, & Sullivan, 1993), yet 20–25% of women smoke throughout pregnancy (Ernster, 1993; United States Department of Health and Human Services, 1991). The benefits of smoking cessation at any point during pregnancy are substantial. Babies have been found to have higher birth weights even when women quit smoking in their third trimester (Hebel, Fox, & Sexton, 1988; Windsor, Boyd, & Orleans, 1993). Reductions in pregnancy smoking are also associated with increased birth weight (Li, Windsor, Perkins, Goldenberg, & Lowe, 1993), making this a secondary alternative to cessation.

Many smoking cessation interventions, typically self-help materials and brief counseling, have been developed and tested for pregnant women (e.g., Ershoff, Mullen, & Quinn, 1989; Gielen et al., 1997; Kendrick et al., 1995; Windsor et al., 1985). Overall, results across studies suggest increased smoking cessation rates and subsequent infant birthweight as a result of intervention (Dolan-Mullen, Ramirez, & Groff, 1994; Floyd et al., 1993). However, smoking quit rates are often modest and vary substantially by the population sampled. Successful interventions with resistant, late pregnancy smokers have yet to be developed (Mullen, 1999).

Recommendations for enhancing interventions for pregnant smokers have included tailoring materials and counseling to the specific needs of the target population, as treatment response has been found to vary among subgroups of pregnant smokers (Ershoff et al., 1989; Gielen et al., 1997; Windsor et al., 1993). O'Campo, Davis, and Gielen (1995) recommend, in particular, that clinicians assess a pregnant woman's degree of nicotine dependence and readiness to change and tailor smoking cessation interventions accordingly. The Transtheoretical Model's stages of change have been successfully used for tailoring smoking cessation interventions (e.g., Prochaska & DiClemente, 1992). Additionally, there is evidence to suggest that the provider of the intervention, particularly the counseling component, may be critical. Interventions using peer counselors have proven less effective than those using professional health educators (e.g., Gielen et al., 1997). Programs that have relied on existing staff to deliver the intervention have produced mixed results. Dolan-Mullen et al. (2000), Kendrick et al. (1995), and Velasquez et al. (2000) reported the implementation of pregnancy interventions within existing systems using clinic staff to be problematic and likely to affect studies negatively.

Personalized, process-oriented feedback is an important and effective intervention strategy that may be especially suited for pregnant smokers; at least one early study found that smoking cessation materials tailored to pregnancy are more effective than general guides or manuals for quitting smoking (Windsor et al., 1985). Feedback based on personal questionnaire responses and generated by expert systems has proven to be superior to self-help materials for smoking cessation in many studies (DiClemente & Prochaska, 1998; Strecher, 1999). In addition, Motivational Interviewing (MI; Miller & Rollnick, 1991) may be ideal for resistant pregnant smokers as it is designed to increase problem recognition and the need for change. MI is thought to be especially beneficial for the many who are ambivalent about changing, such as those in the earlier stages of

change (i.e., precontemplators and contemplators; DiClemente & Prochaska, 1998). Although implementation has been a problem in pregnancy smoking studies (Velasquez et al., 2000), brief MI interventions have demonstrated efficacy in other settings. Positive results have been found for the treatment of hospitalized adult smokers, outpatient and inpatient adolescent smokers, opiate users, and other individuals with addictive behaviors (Colby et al., 1998; Miller & Rollnick, 1991; Saunders, Wilkinson, & Philips, 1995). Personalized and objective feedback delivered in a supportive, nonconfrontational context using the MI style and strategies may be a powerful intervention through which clients can resolve ambivalence and move to a point of decision and commitment to change (Miller & Rollnick, 1991).

This single-blind, prospective, randomized pilot study was conducted to evaluate the effectiveness of a brief telephone counseling intervention, "One-to-One," using stage-based personalized feedback and MI strategies to increase smoking cessation in a sample of late pregnancy smokers who failed to stop smoking with a minimal intervention program. It was hypothesized that posttreatment and postpartum smoking rates would be lower for women in the experimental group compared to those receiving only "usual care." In addition, as the intervention contained several components, secondary analyses were conducted to assess variability in implementation and corresponding intervention response.

2. Method

2.1. Measures

Data for the present study were collected at the first prenatal visit (intake), during the 28th and 34th weeks of pregnancy, and 6 weeks and 3 and 6 months postpartum. Fig. 1 depicts the sample's progression through measurement and intervention.

2.1.1. Intake screening form

This 18-item, self-administered "Prenatal Health Form" was used to screen women for prepregnancy and early pregnancy smoking at the first prenatal visit. This instrument provided the requisite demographic and smoking history information. Response formats for items such as educational level and number of cigarettes per day were categorical. Smoking status was determined using a multiple-choice screening question that included the response, "I smoke regularly, but I cut down for this pregnancy." This question has been tested with a similar population where it missed $\leq 14\%$ of the smokers but identified 40% more smokers than a dichotomous response question, "Do you smoke?" (Mullen, Carbonari, Tabak, & Glenday, 1991).

2.1.2. 28th week eligibility interview

All prepregnancy smokers were interviewed by telephone at approximately their 28th week of gestation. This instrument was designed to evaluate clinic health education services and to determine eligibility for one of two concurrent studies. Participants were assigned

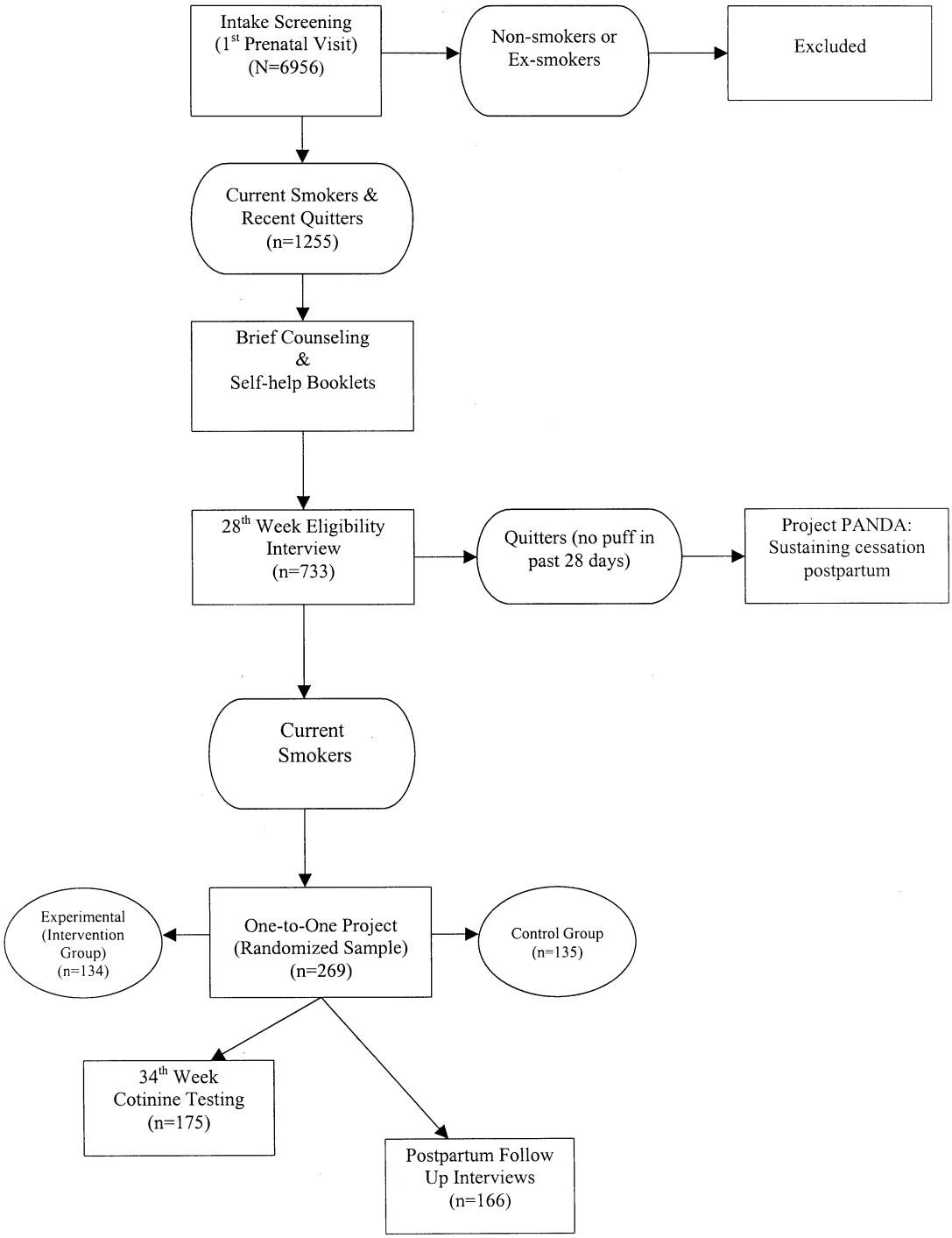

Fig. 1. Progression of the sample through measurement and intervention.

accordingly: (1) Those who had quit smoking (abstinent for 28 days at 28 weeks) were enrolled in Project PANDA (Mullen, DiClemente, & Bartholomew, 2001), a large intervention trial to prevent postpartum return to smoking; and (2) Those who continued to smoke were randomized to this One-to-One smoking cessation pilot study.

Current stage of change for pregnancy smoking cessation was also assessed: *Precontemplation* (PC) was defined as not giving serious thought to quitting during the remaining months of pregnancy; *Contemplation* (C) included those who reported giving serious thought to quitting during the rest of pregnancy but had not made a quit attempt; *Preparation* (PA) was defined either as giving serious thought to quitting and having made a quit attempt during pregnancy or not currently smoking but for less than 2 days; *Action* (A) included those who currently quit for 2 or more days. This algorithm was adapted from the original Transtheoretical Model's staging algorithm for smoking (DiClemente et al., 1991).

2.1.3. 34th week cotinine testing

Anonymous urine samples were collected post-intervention during clinic visits and analyzed for cotinine, a metabolite of nicotine, to determine the effect of the intervention. These analyses used enzyme immunoassay (cutoff ≥ 80 ng/ml was used to indicate smoking; Jacob, Wilson, & Benowitz, 1981).

2.1.4. Postpartum interviews

Postpartum telephone interviews were conducted at 6 weeks and 3 and 6 months. These interviews consisted of approximately 80 questions about pregnancy, pregnancy outcomes, various health-related behaviors, and infant feeding and health. Smoking prevalence data were gathered at each time point using a multiple-choice question, indicating that women were "not smoking at all, not even a puff," "not smoking most of the time but had a few puffs every now and then," "not smoking most of the time but had some days when I smoked," "smoking more or less regularly," or "smoking most of the time but had some periods of not smoking."

2.2. Sample and procedure (see Fig. 1)

The sample was drawn from 21 satellite locations of three large multispecialty clinics in the Houston and Dallas metropolitan areas. Thus, all participants were members (or dependents of members) of group insurance plans. Women were screened for eligibility at their first prenatal visit. Preliminary eligibility was based on fluency in English, age (18 years or older), smoking frequency (≥ 5 cigarettes per week prior to pregnancy), and gestational age at first prenatal visit (≤ 20 weeks). Intake Screening Forms were completed by 99% of women ($n = 6956$) initiating prenatal care at the clinics over a 17-month recruitment period. Current smokers were identified and counseled for 3–5 min by a nurse or technician who also gave them the first of a series of eight self-help booklets, with the remaining seven booklets mailed weekly thereafter. Previously, this program was found to improve cessation rates (Ershoff et al., 1989). Prepregnancy smokers who quit recently and were at risk for relapse during pregnancy were also provided counseling and booklets.

At the 28th week of pregnancy, a brief telephone interview by a clinic representative was attempted with all women who met the preliminary eligibility criteria ($n = 1255$). Of these, 522 women were no longer in care at the clinic, had a fetal demise or abortion, had a new due date that indicated gestational age > 34 weeks, or could not be reached. Only 3% refused the interview. Of the 733 women interviewed, 269 who reported that they had smoked at least a puff during the previous 28 days and had telephone access were eligible for the One-to-One study reported in this manuscript and represent the full *Randomized Sample*. Random assignment to either the experimental or control group was determined from a computer-generated random number list. Experimental group members were informed that clinic personnel would be calling to discuss their smoking and that they would also receive a series of newsletters and a video, as would their partner. Five newsletters and one 15-min videotape, oriented generically to issues of late pregnancy and postpartum, including sleep deprivation, weight loss, and smoking, were mailed at 2-week intervals beginning in the 39–40th week of pregnancy. These materials were designed to enhance support for healthy behavior changes during pregnancy and postpartum and were described in more detail elsewhere (Mullen et al., 2001). Data collection and intervention implementation during pregnancy were adopted as routine clinic procedures and required no formal, written consent. Attempts were made to obtain post-intervention urine samples at approximately the 34th week of pregnancy from all women in the full Randomized Sample; however, missed appointments and clinic logistics rendered this impossible. Urine samples were collected anonymously on 175 of the 269 randomized women during clinic visits and analyzed for cotinine. The only markers attached to the cotinine samples were a coded ID number that indicated experimental group status and the amount of intervention received. These women (Intervention $n = 84$; Control $n = 82$) represent the *Anonymous Cotinine Subsample*.

In order to obtain important postpartum follow-up data, women in the randomized sample were recruited to participate in a university-based, postpartum "Mother and Infant Health Survey." The study purpose was described as gathering information and learning about the total pregnancy and motherhood experience via telephone interviews in the year after birth; smoking was one of the many topics discussed. A total of 166 of the 269 randomized women returned their consent forms for participation in the confidential postpartum follow-up survey; the overall response rate is 61%. Similar rates were found for both intervention and control conditions. Participants were mailed a small honorarium ranging from US$10 to US$35 for each postpartum interview completed. These women will be referred to as the *Postpartum Follow-up Subsample*.

Interviewers were trained to follow a protocol. To help assure that information was collected according to the protocol, 7% of the interviews were evaluated (either live or on audiotape) for clarity, bias, and handling of difficult topics. These evaluations yielded satisfactory compliance with the interview protocols. In addition, postcards were mailed to 15% of the interviewees to verify that the interviews had been conducted, that interviewers had adhered to high standards of courtesy, and that interviewees had received their honoraria. With a 67% postcard return rate, all confirmed having been interviewed, and other responses were positive. All study and consent processes were approved by the human subjects protection committees at the participating universities and clinics.

2.3. Intervention

The One-to-One intervention consisted of three components: (1) one 20–30-min telephone counseling call using MI strategies and techniques conducted within the 2 weeks following the 28th week interview; (2) a personalized, stages of change-based feedback letter mailed within a week following the first counseling call; and (3) a final MI-based, telephone counseling call conducted 4–5 days after the feedback letter was sent.

The MI counseling calls were adapted from the Motivational Enhancement Therapy developed for Project MATCH (Miller, Zweben, DiClemente, & Rychtarik, 1992). Using a directive yet client-centered therapeutic style, MI is designed to produce rapid, internally motivated change by employing strategies that mobilize the client's own change resources. Strategies include providing the client with specific feedback on her own situation and condition, emphasizing personal responsibility for change, and offering a menu of specific cognitive and behavioral strategies for the client to utilize in changing the problem behavior (Miller & Rollnick, 1991). The MI counselor assists the client in resolving ambivalence by clarifying personal goals and values (e.g., personal health and infant health) and amplifying the discrepancy between these goals/values and current behavior (e.g., smoking). Emphasis in this study was placed on the baby's health and also on benefits to the woman.

Counselors were provided with client information sheets so that counseling sessions could be individualized according to stage of change, partner smoking status, exposure to others smoking, and current cognitive/behavioral coping strategies. The first MI call focused on building motivation for change by eliciting self-motivational statements, exploring ambivalence about change, obtaining a commitment to change, and making an individualized plan for smoking reduction or abstinence. Assessment data collected during this interview were used to develop a personalized feedback letter. The second MI counseling call included discussing the feedback letter, reassessing commitment to change, building motivation, and reevaluating the change plan.

Personalized feedback letters were computer-generated via an expert system and based on information obtained from women at the 28th week interview and the first MI counseling call. Letters were approximately two pages in length and printed on letterhead stationary from the woman's prenatal clinic. Each letter was tailored to stage of change and included individualized messages addressing parity, level of smoking and tobacco addiction, exposure to others smoking (especially partner), pros and cons of smoking, levels of temptation to smoke and confidence to abstain, and cognitive and behavioral coping strategies or processes of change. Feedback messages were stored in a database management program, and the combination of messages received by each woman was determined by her answers to specific assessment items. There were over 10,000 possible combinations of messages.

Master's level counselors and nurse health educators were trained and supervised regularly by the first and second authors. A detailed, author-constructed, therapy protocol was used to train counselors, guide treatment, and standardize implementation. MI training included

didactic meetings, reading assignments, role playing, and viewing videotapes of expert MI sessions. Sessions were audiotaped and discussed at weekly supervision meetings to monitor protocol adherence and to correct deviations.

2.4. Analysis

Reported analyses were conducted using SAS 6.12, a software statistics program (SAS Institute, 1991). The Randomized Sample ($n = 269$) experimental and control groups were compared on sociodemographic and smoking history variables using analysis of variance and χ^2 procedures. If significant baseline differences were detected (criterion $p < .05$), these variables, when possible, served as covariates in subsequent analyses.

Four primary analyses were conducted. First, initial efficacy of the intervention was evaluated by comparing the Randomized Sample experimental and control groups on post-treatment smoking abstinence assessed via urine cotinine at 34 weeks. Due to the categorical nature of the outcome variables, logistic regression procedures were employed. Second, logistic regression also was used to test the effectiveness of the intervention in the postpartum period by comparing the Postpartum Follow-up Subsample ($n = 166$) experimental and control groups on self-reported postpartum smoking. Few women reported total abstinence precluding a postpartum abstinence analysis ($n = 12$, 11, and 11 at 6 weeks and 3 and 6 months postpartum, respectively). Therefore, those who responded that they were "not smoking at all, not even a puff" or "not smoking most of the time but had a few puffs every now and then" were combined as nonsmokers or light smokers and compared to those who reported smoking more regularly. Third, intervention implementation efficacy was evaluated by comparing differences in both 34th week cotinine and self-reported postpartum smoking among three subgroups who received varied amounts of the intervention and with the control group (Table 1). These groups were created post hoc and resulted from participant self-selection due to availability and acceptance of the intervention components. Finally, the relationship between participants' initial stage of change for stopping smoking during pregnancy assessed at the 28th week and their postpartum smoking status was explored using logistic regression procedures.

3. Results

Initial comparisons of demographic variables revealed no differences between the experimental and control groups ($n = 269$). Overall, at intake, this sample of pregnant smokers had a mean age of 28 years; the majority were White (78.8%), married (68.4%),

Table 1
Intervention implementation groups

Group	*n*	Intervention
C	135	None provided (control group)
E0	43	None received (experimental group)
E1	17	One counseling call and feedback letter received (experimental group)
E2	74	Both counseling calls and feedback letter received (experimental group)

living with their husband or partner (84.8%), employed at least part-time (78%), and had a high school or higher education level (90%). About 41% were pregnant with their first baby, and 35% were having their second.

Table 2
Characteristics of experimental and control groups at first prenatal visit and 28th week of pregnancy

	Experimental ($n = 134$)	Control ($n = 135$)
Sociodemographics		
Age [*M* (S.D.)]	28.6 (5.1)	28.1 (5.7)
Married (%)	65.7	71.1
Living with partner/husband (%)	85.5	84.1
Race		
White (%)	81.3	76.3
African American (%)	12.7	12.6
Hispanic (%)	3.7	8.2
Other (%)	2.2	3.0
Education		
< High school graduate (%)	9.0	11.1
High school graduate (%)	33.6	39.3
Some college (%)	47.8	40.7
≥ College graduate (%)	9.7	9.0
Employed outside home (%)	81.7	74.6
Parity (prior live births)		
0 (%)	37.8	44.8
1 (%)	35.6	34.3
2 (%)	17.0	14.9
3 or more (%)	9.6	6.0
Smoking before pregnancy		
No. of cigarettes per week *		
5–60 (%)	42.1	57.0
>61 (%)	57.9	43.0
Minutes to first cigarette		
<20 (%)	37.6	35.1
20–59 (%)	37.6	40.3
>60 (%)	24.8	24.6
No. of years smoked		
<5 (%)	18.7	20.2
6–10 (%)	26.9	29.1
11–15 (%)	41.0	37.3
>16 (%)	13.4	13.4
Partner smokes (%)	69.6	62.5
Stage of change at 28th week		
Precontemplation (%)	14.8	18.8
Contemplation (%)	23.0	18.8
Preparation (%)	57.8	60.2
Action (%)	4.4	2.3

* $p < .01$.

Group differences were found on number of cigarettes smoked per week at baseline (Table 2). For level of smoking comparisons, categorical responses (due to scannable response format) for number of cigarettes smoked per week at intake were divided into low (5–60 per week) and high (>61 per week). More experimental group women were found to be in the high cigarette group [$\chi^2(1, n=269)=5.98, p \leq .02$]. The control group consisted of 57% of women in the low and 43% in the high cigarette groups. The distribution in the experimental group was exactly opposite, 42% in the low and 58% in the high cigarette groups. There were no differences, however, on number of minutes to the first morning cigarette nor on number of years smoked at intake. Thus, although appropriate randomization procedures were employed, experimental group women were heavier smokers.

3.1. Intervention effects

3.1.1. Randomized sample

As stated previously, as a result of logistical difficulties at the clinics, urine samples were collected on a subset ($n=175$) of the full Randomized Sample. Initial analyses performed to assess for differential group cotinine collection found no differences in retention between the experimental and control groups. Overall, urine data were collected from 41% and 39% of the experimental and control groups, respectively. Comparisons on demographic and smoking history variables between women who provided urine samples and the full sample also revealed no differences. Thus, the urine samples appeared not to have been collected in any systematically biased manner, and these 175 women seemed representative of the full sample.

Contrary to our primary hypothesis, no differences were found between experimental and control group women on post-treatment, 34th week smoking status measured via urine cotinine [$\chi^2(1, n=175)=0.230, p \leq .64$]. Thirty-four percent of women in the control group were classified as abstinent compared to 32% in the experimental group. Although there were significant baseline differences between the two groups on number of cigarettes smoked, anonymous collection of the urine samples precluded statistically controlling for this variable in analyses.

3.1.2. Postpartum follow-up subsample

These analyses were performed on those who consented to the postpartum follow-up study ($n=166$) and not the total randomized sample. Initial comparisons evaluated whether

Table 3
Percent of self-reported nonsmokers or light smokers at 6 weeks and 3 and 6 months postpartum by experimental group controlling for baseline level of smoking

	Control ($n=82$; %)	Experimental ($n=84$; %)
6 weeks *	14.6	24.1
3 months	17.1	16.9
6 months	17.1	12.2

Sample sizes for the experimental group at 3 and 6 months were 83 and 82, respectively. Control group sample sizes remained the same.

* $p<.01$.

consenters to participate in the postpartum study differed from nonconsenters on demographic and smoking history variables measured at the 28th week of pregnancy. No differences were found. In addition, no treatment group by consent status differences were found, indicating that women who consented to the postpartum interviews were evenly distributed between the experimental (66% consenters) and control (62% consenters) conditions. These 166 women appeared to be representative of the full sample and seemed not to have been distributed across groups in a systematically biased fashion.

The unadjusted experimental–control group comparison on self-reported smoking status at 6 weeks postpartum failed to reach statistical significance [$\chi^2(1, n=165)=2.83, p \leq .09$]. Given the baseline differences on number of cigarettes smoked, however, a subsequent logistic regression analysis was performed using this variable as a covariate. Significant differences resulted between the experimental and control groups on self-reported postpartum smoking status [$\chi^2(2, n=165)=8.95, p \leq .01$]. Differences were in the expected direction; more of the experimental group (24.1%) reported no or light smoking compared to the control condition (14.6%; Table 3). No differences in smoking status were found at 3 and 6 months postpartum with neither adjusted nor unadjusted analyses.

3.1.3. Intervention implementation analyses

Since intervention women differed in the amount of the One-to-One intervention they received, we divided them into three subgroups based on level of implementation of the intervention (Table 1). Initial comparisons of baseline demographic and smoking history variables revealed differences among the three implementation subgroups and the control group on number of cigarettes smoked and partner smoking variables at the initial pregnancy assessment, both of which have been shown to influence smoking outcomes. Specifically, more of the women who received part or all of the intervention (E1 and E2; 65%) smoked >61 cigarettes per day at baseline compared to the control group (C; 43%) and women who were never reached by telephone thus receiving none of the intervention [E0; 43%; $\chi^2(1, n=269)=11.53, p \leq .009$]. In addition, 80% of women who received the full intervention (E2) had smoking partners, while only 63% of the C group reported the same [$\chi^2(1, n=269)=8.46, p \leq .037$]. Percentages of E0 and E1 groups who had smoking partners were

Table 4
Percent abstinence at 34 weeks indicated by cotinine analyses for the intervention implementation groups

	Control	Experimental			
	C ($n=86$; %)	E0 ($n=27$; %)	E1 ($n=15$; %)	E2 ($n=47$; %)	Individual comparisons
Not smoking * (<80 ng/ml)	33.7	18.5	13.3	42.6	E0,E1 < C,E2

Significant pairwise comparisons are designated by a less-than (<) symbol. If differences are not significant, a comma is used. C = control group; E0 = no intervention received; E1 = one counseling call and feedback letter received; E2 = full intervention.

* $p < .05$.

59% and 50%, respectively. Interestingly, women from the E1 or E2 group were heavier smokers and were more likely to have a partner who smoked.

First, intervention implementation effects were evaluated using post-treatment cotinine data from the Randomized Sample. Differences in urine cotinine values were detected among the four groups [$\chi^2(3, n = 175) = 7.70, p \leq .05$]. Women from the E2 group were more likely to be classified as not smoking compared to either E0 or E1 group. The C vs. E2 group comparison did not reach statistical significance; however, the experimental group consisted of nearly 10% more nonsmoking women (Table 4). These results are perhaps more striking in light of the experimental group's heavier smoking status at baseline and greater proportion of smoking partners. Again, urine samples were collected anonymously, precluding analyses in which these two baseline variables could be statistically controlled. The fact that urine samples were collected on only a subsample of subjects also decreased statistical power to detect differences.

Intervention implementation effects were then evaluated using the Postpartum Follow-up Subsample. Since we had the ability to track women in this subsample, we used baseline number of cigarettes smoked as a covariate in these analyses. Differences on self-reported postpartum smoking status were found among the four groups [$\chi^2(4, n = 165) = 13.27$, $p \leq .01$; Table 5). Specific group comparisons revealed that a greater proportion of women from the E2 group were classified as nonsmokers or light smokers (27.1%) compared to women in the C group (14.6%). Caution must be used when interpreting the above results, however, as subgroups were rather small and self-selected. At 3 and 6 months postpartum, no differences among the groups were found. Statistically controlling for partner smoking at baseline had no effect on the results.

3.2. Stages of change

An additional analysis evaluated the relationship between 28th week stage of change for stopping smoking during pregnancy and smoking status in the postpartum period using the Postpartum Follow-up Subsample ($n = 166$). Women who reported smoking at least a puff in the past 28 days were classified into one of four stages based on staging algorithm data collected during the 28th week interview: PC ($n = 30$); C ($n = 24$); PA ($n = 105$); A ($n = 7$). Results revealed

Table 5
Percent of self-reported nonsmokers or light smokers at 6 weeks and 3 and 6 months postpartum by intervention implementation groups controlling for baseline level of smoking

	Control	Experimental			
	C ($n = 82$; %)	E0 ($n = 28$; %)	E1 ($n = 8$; %)	E2 ($n = 48$; %)	Individual comparisons
6 weeks *	14.6	28.5	0	27.1	E1 < C < E0,E2
3 months	17.1	17.9	0	20.8	C,E0,E1,E2
6 months	17.1	14.8	0	14.6	C,E0,E1,E2

Significant pairwise comparisons are designated by a less-than (<) symbol. If differences were not significant, a comma is used. Sample sizes for E0 at 3 and 6 months are 27 and 26, respectively. All other sample sizes remained the same across time.

* $p < .05$.

Table 6
Percent of self-reported nonsmokers or light smokers at 6 weeks and 3 and 6 months postpartum by staged groups

	PC ($n=30$; %)	C ($n=24$; %)	PA ($n=105$; %)	A ($n=7$; %)	Individual comparisons
6 weeks **	6.7	12.5	21.9	71.4	PC,C < PA < A
3 months *	6.7	8.3	21.2	42.9	PC,C < PA < A
6 months **	10.0	8.3	15.4	57.1	PC,C,PA < A

Significant pairwise comparisons are designated by a less-than (<) symbol. If differences were not significant, a comma is used. Sample sizes for the PA group are 104 and 103 at 3 and 6 months, respectively. All other sample sizes remained the same across time. PC = precontemplation; C = contemplation; PA = preparation; A = action stage of change.

* $p < .05$

** $p < .005$

significant stage differences related to postpartum smoking status [$\chi^2(3, n=166) = 14.02$, $p \leq .003$]. As would be predicted, more PC women reported smoking at 6 weeks postpartum than C women, proportionally more C women were smoking than PA women, and finally, more PA women were smoking than women in the A stage of change for stopping smoking during this pregnancy. The PC vs. C contrast, however, failed to reach statistical significance. Similarly, significant stage differences were found at 3 and 6 months postpartum [$\chi^2(3, n=165) = 8.23$, $p \leq .05$ and $\chi^2(3, n=165) = 14.08$, $p \leq .003$, respectively; Table 6). In light of the strong association between stage of change for pregnancy smoking and postpartum smoking, analyses were conducted to determine whether the experimental, control, or implementation groups differed with regard to stage. No differences by stage were found. Due to small numbers of subjects, it was not possible to examine the interaction of stage status with intervention efficacy.

4. Discussion

This randomized, small-scale pilot study investigated an intensified, late pregnancy smoking cessation intervention for women who had not stopped smoking spontaneously nor responded to a minimal intervention delivered early in pregnancy. The intervention based on personalized feedback, MI strategies, and the stage-of-change perspective was compared to "usual care" in the prenatal clinics. Cotinine-validated, end-of-pregnancy smoking was comparable between the Randomized Sample experimental and control groups. However, there are indications from both the 34th week cotinine and early postpartum self-report data that the One-to-One intervention, when delivered in its entirety, had a positive, albeit modest, effect on smoking outcomes. Women who received all pieces of the intervention were more likely to quit or reduce smoking in their last trimester and the early postpartum period at higher rates than their control counterparts.

Two factors should be considered when evaluating these results. First, although randomly assigned, experimental women were heavier smokers and had a higher proportion of smoking partners, both of which have been associated with poor smoking cessation outcomes (Fingerhut, Kleinman, & Kendrick, 1990; McBride & Pirie, 1990; McBride, Pirie, & Curry, 1992; Mullen, Richardson, Quinn, & Ershoff, 1997). As noted, the variance

attributable to these factors could not be statistically controlled in most analyses due to anonymous urine collection.

Second and perhaps more importantly, a large minority of the experimental group did not receive full exposure to the intervention. Only 55% of the experimental group received the full intervention; 13% received approximately half; and 32% were never able to be reached and received none of the intervention. Although confounded by self-selection, results of a post hoc implementation analysis indicated that a greater number of pregnant smokers who received the full intervention (i.e., two MI counseling calls and feedback letter) were abstinent at 34 weeks compared to those who received a lesser dose and nearly 10% of the fully exposed experimental group were abstinent compared to the control group.

Encouraging yet mixed results were also found early in the postpartum period with self-reported smoking rates. At 6 weeks postpartum, after accounting for baseline differences, fewer smokers were found among experimental women relative to those in the C group and women from the E2 group reported more abstinence or light smoking than those in the C group. However, it is unclear and anomalous why the E0 subgroup reported abstinence (or light smoking) rates comparable to the E2 group. These results differ dramatically from cotinine data collected anonymously at the 34th week, suggesting perhaps that this subgroup of women who were unavailable to the counselors delivering the intervention may be failing to accurately disclose postpartum smoking. Alternatively, this self-selected subgroup may not have needed any assistance in quitting and may have stopped smoking on their own between the 34th week of pregnancy and 6 weeks postpartum. Regardless of intervention implementation, however, intervention effects were not sustained later in the postpartum period.

Finally, with regard to stages of change, it is interesting that staging women for cessation during pregnancy even in the latter part of the prenatal period proved useful. In a prior study, we were able to stage *postpartum* cessation (Stotts, DiClemente, Carbonari, & Dolan-Mullen, 2000). Now, it seems that stages of change for *pregnancy* cessation also successfully predict smoking status in the postpartum period. Intervention development and evaluation using these identified stages is needed.

Although the results do not support an overall superiority of this intervention, there is some evidence to suggest modest efficacy of a stages of change and MI-based intervention for smoking cessation in resistant pregnant smokers. Difficulties of implementation and other barriers, such as partner smoking, in addition to the late pregnancy status of the women in this study created challenges that may have moderated effectiveness and which need to be addressed in future research.

Minimal intervention represents an appropriate and efficient first step toward increasing pregnancy smoking cessation, but for the unresponsive, a second step is needed (DiClemente, Dolan-Mullen, & Windsor, 2000). This intensified, individualized One-to-One intervention represented a next logical step in assisting pregnant smokers who fail to respond to state-of-the-art minimal smoking cessation interventions. The One-to-One intervention is intensified yet convenient, without extensive time requirements, and its components offer several advantages. First, it is conducted by telephone and mail at the convenience of the pregnant woman. Second, a professional counselor or health educator provides the intervention, eliminating the use of clinic staff who often has little time to spend on special projects.

Using clinic staff to provide smoking cessation interventions has been problematic in previous studies (Kendrick et al., 1995; Velasquez et al., 2000). Finally, One-to-One is based on intervention strategies and techniques found to be effective with other populations, i.e., personalized, stage-based feedback and MI strategies (e.g., Prochaska & DiClemente, 1992; Saunders et al., 1995). The provision of process-oriented feedback using MI strategies is an efficient method for conveying important, individualized information in a manner consistent with a woman's place and progress in the process of change. However, this type of intervention must also prove to be effective for pregnant women who are experiencing considerable difficulty in quitting smoking.

Brief motivational interventions are recommended for targeting people in earlier stages of change, and, therefore, seem particularly suited for resistant pregnant smokers. Clearly, however, the intervention and/or its implementation must be improved upon. There are two primary issues: Intensification and Implementation. With regard to intensification, more intervention points may be necessary as two telephone contacts and one feedback letter may not be sufficient for this resistant group. More counseling contacts including at least one that is "face-to-face," and an additional feedback letter highlighting progress (or lack thereof) may increase motivation for change and enhance effectiveness. Also, the intervention may be more successful when implemented earlier in pregnancy in order to capitalize on initial increases in motivation for change (Solomon, Secker-Walker, Skelly, & Flynn, 1996). Expanding the total time over which the intervention is conducted seems important as a 2–3-week intervention period is fairly short and clearly not sufficient, particularly late in pregnancy. Multiple and multicomponent interventions that begin early and are implemented throughout pregnancy may be necessary (DiClemente et al., 2000).

Intervention implementation is perhaps a more difficult issue but certainly needs to be improved upon in future research. Intervention via the telephone and mail, while low-cost, may not be a feasible method of delivery. In this study, approximately 30% of the experimental group did not receive even the first telephone call despite numerous contact attempts and messages left. These women comprise the most challenging group of pregnant smokers as they were clearly ambivalent about or not interested in participating in a smoking cessation program. Others have reported difficulty with similar telephone intervention methods (e.g., Ershoff et al., 1999). As Secker-Walker, Solomon, Flynn, Skelly, and Mead (1998) concluded, however, counselor–client contact at only once-a-month prenatal visits is also insufficient. A combination of face-to-face counseling sessions during prenatal visits and between appointment telephone contacts may be ideal.

The stages-of-change model provides a useful conceptualization of intentional behavior change and lends itself to intervention development. Stages of change for pregnancy smoking cessation assessed at the 28th week were highly related to postpartum smoking status and in the expected direction. Women in earlier stages of change were more likely to be smoking postpartum than those in the later stages. Unfortunately, it was not possible to assess the relationship between stages and immediate posttreatment smoking, but we presume that a similar relationship would have been found. As suggested in past research, the stages of change construct appears to be useful in understanding pregnancy smoking cessation (Stotts, DiClemente, Carbonari, & Dolan-Mullen, 1996; Stotts et al., 2000), and as

also suggested by others (e.g., O'Campo et al., 1995), interventions tailored to stage may prove to be more efficacious. These data suggest that most women were in the PA stage of change indicating that they were seriously considering stopping smoking during their pregnancies and had made at least one quit attempt, and many reported cutting down considerably from prepregnancy smoking levels. The final step into the A stage or abstinence, however, appears to be a large one. The challenge for researchers and clinicians alike is to develop strategies for pregnant smokers that will increase motivation and facilitate their movement through the process of change.

Limitations to this study should be noted. Study power may have been insufficient to detect differences when testing intervention implementation effects, i.e., comparing the E2 to the C group, as only about half of the experimental group received all components. Fluctuating samples sizes due to logistical constraints and modest consent rates may be considered a study weakness; however, significant attempts were made to ensure that subsamples were representative of the full Randomized Sample. Lack of biochemical validation of self-reported smoking in the postpartum period is also problematic. In attempt to minimize false reports, a multiple-choice format that has been shown to significantly improve disclosure of smoking was used to elicit smoking status (Mullen et al., 1991). Also, the nondisclosure rate may be somewhat lower in the postpartum period as social pressure for abstinence is somewhat diminished.

Women who continue to smoke throughout pregnancy are an interesting and difficult subgroup of smokers. Many researchers have attempted to intervene with these women but with limited success. It is clear that novel intervention strategies and techniques as well as improved methods of implementation must be developed and tested. Pharmacological adjuncts to behavioral treatments have improved smoking cessation rates in the general smoking population. Perhaps, the time has come to combine our most promising psychosocial interventions with pharmacological treatments to further decrease smoking rates among resistant pregnant smokers.

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