Efficacy of Telephone Counseling for Pregnant Smokers

A Randomized Controlled Trial

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OBJECTIVE: Reducing tobacco use in pregnancy is a public health priority. Brief smoking counseling during prenatal care is effective but generates modest cessation rates. Telephone counseling is an effective smoking cessation method that could offer pregnant women convenient access to more intensive smoking cessation counseling.

METHODS: The efficacy of proactive pregnancy-tailored telephone counseling for smoking cessation was compared with a "best-practice" brief-counseling control in a randomized controlled trial of 442 pregnant smokers referred by prenatal providers and a managed care plan. Trained counselors using cognitive-behavioral and motivational interviewing methods called intervention subjects throughout pregnancy and for 2 months postpartum (mean = 5 calls, mean total contact = 68 minutes). Controls received one 5-minute counseling call.

RESULTS: Cotinine-validated 7-day tobacco abstinence rates in intervention and control groups were 10.0% and 7.5% at end of pregnancy (odds ratio [OR] 1.37, 95% confidence interval [CI] 0.69–2.70; number needed to treat = 40) and 6.7% versus 7.1% at 3 months postpartum (OR 0.93, 95% CI 0.44–1.99). The intervention increased end-of-pregnancy cessation rates among 201 light smokers (< 10 cigarettes/day at study enrollment) (intervention 19.1% versus control 8.4%; OR 2.58, 95% CI 1.1–6.1; number needed to treat = 9.3) and among 193 smokers who attempted to quit in pregnancy before enrollment (intervention 18.1% versus control 6.8%; OR 3.02, CI 1.15–7.94; number needed to treat = 8.8); 63% of the sample (n = 267) was in one of these subgroups.

CONCLUSION: Proactive pregnancy-tailored telephone counseling did not outperform a brief "best practice" intervention among pregnant smokers. The intervention had efficacy in light smokers and in women who had attempted cessation earlier in pregnancy. Future studies should confirm whether telephone counseling benefits these groups of pregnant smokers.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, #NCT00181909.

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LEVEL OF EVIDENCE: I

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Reducing tobacco use during pregnancy is a U.S. public health goal for 2010 because cigarette smoking is the leading preventable cause of low birth weight and is associated with other adverse pregnancy outcomes, including long-term negative impacts on children.[1,2] Although 15–42% of smokers quit spontaneously after learning that they are pregnant, 11–22% of U.S. women smoke throughout pregnancy.[2,3–5] Effective interventions for pregnant smokers have been identified. Brief counseling of 3–5 minutes by a trained provider during prenatal care visits supplemented by written material increases smoking cessation rates by 30–70% and is recommended by national clinical practice guidelines, but the cessation rates generated by this intervention are modest.[6–9]

Efforts to increase the intensity of counseling support for pregnant smokers have generally not produced better success than the recommended brief intervention.[10–12] A meta-analysis of 48 intervention studies found that they produced a 6% reduction in the number of women who continued to smoke throughout pregnancy.[6] Better methods are clearly needed.

Counseling smokers by telephone is an effective smoking cessation strategy that might be useful for pregnant women. Telephone counseling is a cost-effective way to deliver a standardized, high-quality intervention to individuals who are geographically dispersed, and it could offer pregnant women a convenient, flexible, private way to receive repeated tailored counseling contacts.[13–15] Telephone counseling for smoking cessation is efficacious for the general population of smokers, and free telephone counseling services are widely available.[15–18] Telephone counseling programs for pregnant women have been developed, but their efficacy has not been demonstrated.[12,19,20] In 2 previous trials, telephone counseling for pregnant women did not outperform a "best practice" brief intervention provided at prenatal care visits, but limitations in study design and intervention quality were cited as potential explanations for the lack of effect.[12,20]

To address this gap, we conducted a randomized controlled trial that tested the efficacy of a proactive, pregnancy-tailored telephone counseling intervention for pregnant smokers who were recruited from prenatal care practices and a managed care organization. The intervention used motivational interviewing, a counseling style that aims to enhance an individual's readiness to change behavior.[21] We expected that it could help pregnant smokers, who feel strong social pressure to quit but often have ambivalence about taking action and face considerable barriers to success.[19] The study hypothesis was that telephone counseling would increase smoking cessation rates at the end of pregnancy and 3 months postpartum, compared with a "best-practice" brief-counseling control.

MATERIALS AND METHODS

This randomized controlled trial was approved by the Human Subjects Committee of Partners HealthCare System. Subjects were enrolled from September 2001 to July 2004.

Pregnant women identified as current cigarette smokers at a prenatal care visit were recruited if they had smoked at least 1 cigarette in the past 7 days, were 18 years of age or older, at 26 weeks or less of gestation, willing to consider altering their smoking during the pregnancy, reachable by telephone, English-speaking, and expected to live in New England for the next year. To encourage the participation of all eligible pregnant smokers, the study was described as an effort to help women make decisions about smoking during pregnancy; a commitment to reduce or quit smoking was not required.

Pregnant smokers were identified from 2 sources: 1) Tufts Health Plan, a nonprofit Massachusetts-based network-model managed care organization, and 2) a group of community-based prenatal care practices. At Tufts Health Plan, a pregnant woman's smoking status is recorded on an Obstetrical Risk Assessment Form completed by her prenatal provider and sent to the Plan to register her for obstetric services. Tufts Health Plan clinical services department personnel, trained by research staff, reviewed the forms to identify and recruit eligible smokers. Because this recruitment strategy did not yield a sufficient number of subjects, a second recruitment method was developed. Using a list of all Massachusetts obstetric care providers, we identified 140 obstetric or family practices that provided prenatal care and invited them to refer patients to the study. Sixty-five practices agreed to refer patients, and 35 sent in 1 or more referral forms. Smoking status on all recruitment forms was identified with a multiple-choice questionnaire that improves the accuracy of self-report of smoking in pregnancy.[22]

A pregnant smoker identified by either recruitment mechanism was sent a letter informing her about the study. A study counselor called to recruit her, obtain verbal informed consent, conduct a baseline assessment, assign her to a treatment condition, and initiate the appropriate intervention. Women were assigned to treatment conditions using a computer-generated randomization list arranged in balanced blocks of 4 and stratified by referral source (Tufts Health Plan versus community practice). The list was contained in the computer-assisted interviewing application used for the study and accessible only to the application's developer. Counselors could not view the list; the application revealed the next assignment only after the smoker had consented to participate in the study.

At enrollment, all subjects were mailed a validated pregnancy-tailored smoking cessation booklet[23]; their prenatal care providers were sent the American College of Obstetricians and Gynecologists (ACOG) smoking cessation practice guideline[9] and a reminder to address smoking at the subjects' visits. The study intervention was provided in addition to this usual care. To ensure that all control participants received a standardized intervention consistent with

the evidence-based "best practice" recommendation,[8,9] the enrollment call concluded with a trained counselor providing brief smoking counseling (≤ 5 minutes). Smokers who requested further assistance were referred to the Massachusetts telephone quitline.

Intervention subjects received a series of telephone calls accompanied by additional mailed written materials. Each subject had a dedicated counselor who offered up to 90 minutes of counseling during pregnancy and up to 15 minutes of counseling over 2 months postpartum. The counselor tailored the schedule of calls to the subject's needs. The intervention content was consistent with the 5-step smoking cessation counseling guideline[8] and drew on social learning theory, the transtheoretical model of change, the health belief model, and the principles of motivational interviewing.[21,24–26] Counseling targeted pregnancy-related issues and was individually tailored to each subject's readiness to quit and interest in other pregnancy- and health-related topics. Individual counseling modules developed for specific cessation, health, and pregnancy issues were used as appropriate. At the initial call, the counselor and the subject worked together to set goals and make a plan for smoking cessation or reduction. Counseling of smokers not ready to quit focused on cognitive strategies to increase readiness to change. Smokers who were ready to quit received an intervention focused on cognitive-behavioral cessation and relapse-prevention techniques. Enhancing self-efficacy and social support were incorporated for all participants. After the initial call, subjects were mailed a personalized worksheet. After each call, they received a summary letter and targeted written materials.

Counselors had a bachelor's or master's degree in social work, psychology, or public health. They received a week-long training program that taught motivational interviewing, cognitive-behavioral counseling, stage-based smoking cessation protocols, and information about smoking and pregnancy. Training methods included readings, didactic presentations, demonstrations, skills practice, and supervised counseling. Throughout the study, counselors met twice monthly with the counseling supervisor to review their cases. Each counselor taped one week's sessions per month and reviewed them with the supervisor to assess compliance with the counseling protocol and use of motivational strategies.

Assessment was done by telephone interview at baseline, end of pregnancy (28 weeks to term), and 3 months postpartum. Follow-up assessments were conducted by a research assistant, not by study counselors. Participants who reported nonsmoking for the past 7 days at end-of-pregnancy or postpartum assessments were asked to mail in a saliva sample for biochemical verification and reimbursed $50 for each sample received. Saliva samples were tested for cotinine, a nicotine metabolite. At end of pregnancy, 47 (66%) of 71 requested samples were received, and nonsmoking was verified in 37 (79%) of returned samples. At 3 months postpartum, 37 (80%) of 46 subjects who reported abstinence provided a saliva sample, and abstinence was confirmed in 29 (78%) of returned samples. Intervention and control groups did not differ on return and confirmation rates.

The primary outcome measure was cotinine-verified 7-day point-prevalence nonsmoking at end of pregnancy. Subjects were counted as smokers if they were lost to follow-up, failed to provide a saliva sample, or had a saliva cotinine concentration greater than 20 ng/mL. Secondary outcomes were cotinine-verified 7-day nonsmoking at 3 months postpartum, sustained abstinence (cotinine-verified 7-day abstinence at both outcome points), significant reduction in smoking (≥ 50% decrease in cigarettes per day from baseline) assessed by self-report, and number of quit attempts (defined as ≥ 24 hours of self-reported abstinence) between enrollment and end of pregnancy.

Demographic factors were age, race/ethnicity, education, marital status, employment status, and health insurance. Pregnancy-related factors were parity and weeks of gestation at enrollment. Smoking-related measures were age of smoking initiation, daily smoking rate (current and before pregnancy), time between awakening and first cigarette (measure of nicotine dependence),[27] number of quit attempts since becoming pregnant, intention to quit during pregnancy,[28] pregnancy-related pros and cons of smoking,[29] perceived risks and benefits of smoking in pregnancy, smoking status of partner and household members, and household smoking policy.

Mediating factors (self-efficacy and social support for cessation) were assessed at baseline and follow-up. Separate questions assessed the level of social support for nonsmoking that a participant perceived from 1) her partner and 2) from family, friends, and coworkers. Overall social support was measured with 3 items that asked how often the following were available: "someone you can count on to listen to you when you need to talk," "someone to give you information to help you understand a situation," and "someone to turn to for advice about how to deal with a problem or make a difficult decision."[30] Self-efficacy was assessed with a global measure of confidence in the ability to quit and 2 measures of confidence in being able to avoid smoking when around other smokers and when "you are angry,

anxious, sad, or depressed." Past depressive symptoms were assessed with an item from the SF-36 scale.[31] Current depressive symptoms were assessed with an item from the Mental Health Index.[32] Stress was measured with the 4-item Perceived Stress Scale.[33] Data were collected at follow-up on a participant's use of other smoking cessation treatments and on the efforts made by her prenatal provider.

Primary efficacy analyses were done on an intention-to-treat basis, excluding from analysis subjects who miscarried (n = 11 in the intervention group and n = 10 in the control group). The χ^2 test was used to assess the significance of between-group differences. Logistic regression analysis was used to adjust for the potential confounding effect of baseline group differences ($P \leq .10$) on cessation outcomes. The stratification factor (recruitment source) was included as an independent variable in these analyses. Multiple logistic regression analysis was also done to identify factors that were independently associated with validated cessation at end-of-pregnancy.

We estimated a 15% end-of-pregnancy cessation rate for the "best practice" control condition, based on previous work in insured populations,[12,34] and a 25% end-of-pregnancy cessation rate for the intervention group. The sample size required to detect an effect size of 10% with 80% power, using a one-tailed significance level of .05, is 217 per group (434 total). Two-sided P values are reported in this paper; conclusions do not change with one-sided tests.

RESULTS

Between September 2001 and June 2004, 1,444 pregnant smokers were referred to the study–1,035 from Tufts Health Plan and 409 from 35 community practices. Of these, 1,322 (92%) were reached for screening, and 665 of them (50%) were eligible (Fig. 1). The major reasons for ineligibility were referral after 26 weeks of gestation, miscarriage, and patient denial of smoking in past week. Eligible and ineligible women did not differ in mean age (28.8 versus 28.4 years, $P = .15$), but eligible women were earlier in gestation (12.8 versus 16.1 weeks, $P < .001$).

Of 665 eligible women, 442 (66%) enrolled in the study (254 from Tufts Health Plan and 188 from community practices). Women were randomly as-

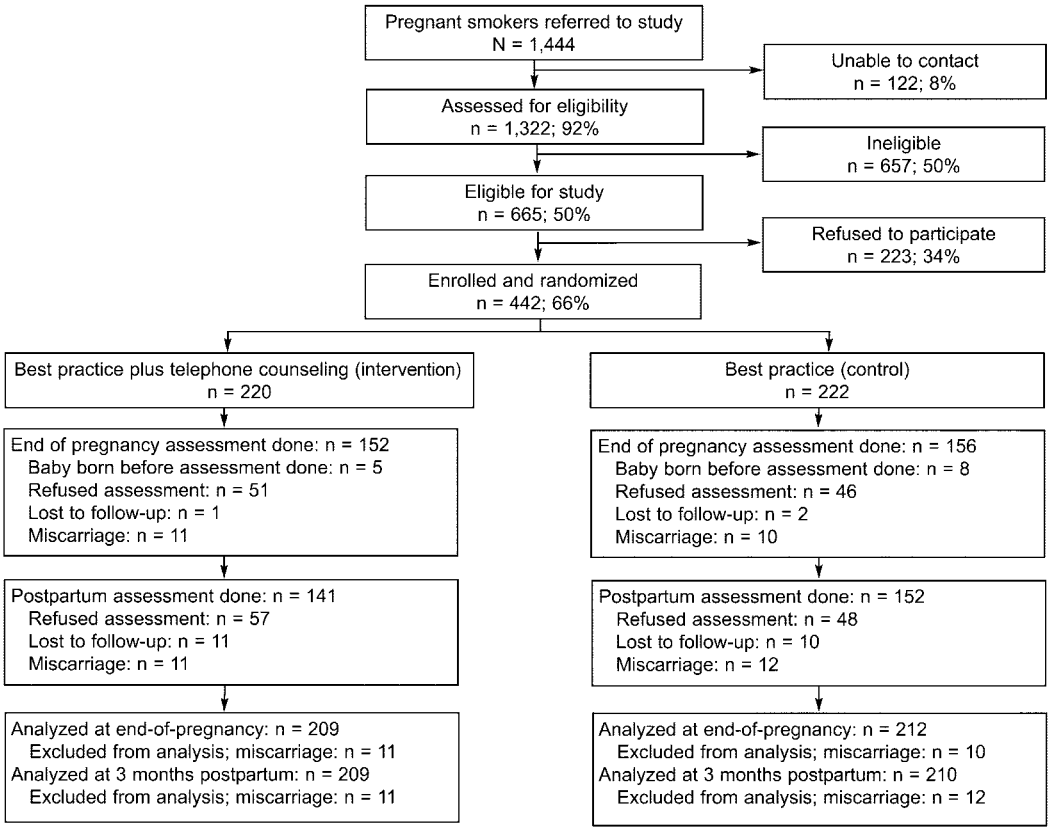

Fig. 1. Study flow diagram.

Rigotti. Telephone Counseling for Pregnant Smokers. Obstet Gynecol 2006.

signed to intervention (n = 220) or best-practice control (n = 222) groups. Women who enrolled, compared with those who declined to participate, were younger (28.5 versus 29.5 years, $P = .04$) and less likely to live with a partner (73.5% versus 86.2%, $P = .01$). They did not differ in race (87.5% versus 93.2% white, $P = .12$), education (13.0 versus 14.4 years, $P = .24$) or weeks of gestation (12.6 versus 13.3 weeks, $P = .14$).

Table 1 displays the characteristics of the study sample at baseline. Control and intervention groups were well balanced. Nearly all subjects (n = 428, 97%) were daily smokers. On average, subjects in both groups had cut their daily cigarette use in half after learning of their pregnancy but before study enrollment. Almost all subjects intended to quit in the next month. They reported having strong social support for quitting but not strong confidence in their ability to succeed.

Intervention group participants received a mean

Table 1. Baseline Characteristics of the Study Sample

Characteristic	Intervention Group (n = 220)	Control Group (n = 222)
Demographic factors		
Age (y)	28.9 ± 6.7	28.1 ± 5.8
Years of education	13.1 ± 2.2	13.0 ± 1.9
Race (non-Hispanic white)	194 (88)	192 (87)
Married or living with partner	167 (76)	158 (71)
Employed in past year	192 (87)	201 (91)
Health insurance		
Private	166 (75)	156 (70)
Public	44 (20)	52 (23)
Other	10 (5)	14 (6)
Pregnancy		
Nulliparous*	112 (51)	94 (42)
Weeks of gestation*	13.1 ± 4.8	12.2 ± 4.4
Smoking behavior		
Age started smoking regularly	15.3 ± 3.0	15.2 ± 2.9
Cigarettes per day		
Current	10.4 ± 7.4	10.0 ± 7.1
Before this pregnancy	20.9 ± 9.1	20.8 ± 8.3
First morning cigarette within 30 min†	100 (45)	89 (40)
Made quit attempt in this pregnancy‡	113 (51)	91 (41)
Plan to quit smoking in next 30 d	188 (86)	181 (82)
Confidence in ability to quit		
A lot	27 (12)	28 (13)
Some	137 (62)	141 (64)
None or not much	56 (26)	53 (24)
Social support for quitting (a lot)		
From family, friends, and coworkers	175 (80)	173 (78)
From partner‡	180 (85)§	162 (77)§
Smoking in environment		
Partner smokes*	149 (71)§	130 (62)§
Any household member smokes	144 (65)§	131 (59)
No smoking permitted inside home	96 (44)	86 (39)
Perceived harm of smoking (a lot)		
To self	204 (93)	197 (89)
To baby	170 (77)	163 (73)
Psychosocial factors		
Depressive symptoms in past month¶	4.4 (1.3)	4.4 (1.3)
History of depression	89 (40)	85 (38)
Perceived stress scale#	10.5 ± 3.5	10.4 ± 3.4

Data are expressed as n (%) or mean ± standard deviation.
* $.05 \leq P < .10$.
† Measure of nicotine dependence.[34]
‡ $P < .05$.
§ Percentages were calculated excluding missing data.
¶ Scale: 1–6, where 1 = all of the time, 6 = none of the time.
# Range: 0–16; higher number indicates greater perceived stress.

of 5 calls (range 0–20), of which a mean of 4 calls occurred during pregnancy and one call occurred postpartum. Ninety-six percent (n = 212) of the intervention group participants received at least one counseling call: 11% (n = 24) had 1 call, 56% (n = 124) had 2–5 calls, and 29% (n = 64) had more than 5 calls. In total, subjects received an average of 68 minutes of counseling, of which a mean of 63 minutes occurred during pregnancy. In contrast, 91% (n = 203) of control group subjects received the one counseling call; its mean duration was 5 minutes, consistent with brief intervention.

We excluded from analysis 21 women who had a miscarriage before the end-of-pregnancy assessment (Fig. 1). End-of-pregnancy assessments were completed in 308 (73%) of 421 eligible women (73% of intervention subjects, 74% of control subjects). Postpartum assessments were completed in 293 (70%) of 419 eligible women (67% of intervention subjects, 72% of controls). Neither follow-up rate differed between study arms. At end of pregnancy, subjects lost to follow-up did not differ from those who were followed in age, race, education, marital status, cigarettes per day, or gestational age at enrollment. Follow-up rates did vary by health insurance type (82% public versus 70% private insurance, $P = .04$) and referral source (78% for community practices versus 70% for Tufts Health Plan, $P = .05$).

Table 2 displays smoking cessation outcomes. Cotinine-validated 7-day point-prevalence abstinence rates in the intervention and best-practice control groups were 10.0% versus 7.5% (odds ratio [OR] 1.37, 95% confidence interval [CI] 0.69–2.70, $P = .39$; number needed to treat = 40) at end of pregnancy (primary endpoint) and 6.7% versus 7.1% (OR 0.93, 95% CI 0.44–1.99, $P = 1.00$) at 3 months postpartum. Because of the small number of women with validated cessation at end of pregnancy (n = 37) or 3 months postpartum (n = 19), these outcome data could not support a meaningful multiple logistic regression analysis to adjust for potential confounders. However, in an exploratory analysis, the odds ratios did not change appreciably after adjusting for baseline group differences of $P < .10$ (parity, weeks gestation at enrollment, prior quit attempt in this pregnancy, and partner social support), referral source, age, and cigarettes/day. Within the intervention group, women who received 5 or more counseling calls had higher end-of-pregnancy validated cessation rates than women who received fewer calls (10/52 = 19% versus 11/157 = 7%, $P = .01$). Intervention and control groups did not differ significantly in cotinine-validated sustained abstinence (abstinence at both end of pregnancy and postpartum assessments), in any self-reported smoking cessation measure, or in the proportion of smokers who made a quit attempt during pregnancy or reported a significant reduction in daily cigarette use at end of pregnancy. (Table 2)

Next, we examined the efficacy of the intervention in subgroups defined by baseline factors. As

Table 2. Smoking Cessation Outcomes by Study Arm

Outcome Measure	Intervention (n = 209)	Control (n = 212)*	Odds Ratio (95% CI)	*P*
Tobacco abstinence (7-day)				
Cotinine-validated				
End of pregnancy†	21 (10.0)	16 (7.5)	1.37 (0.69–2.70)	.39
Three months postpartum	14 (6.7)	15 (7.1)	0.93 (0.44–1.99)	1.00
Sustained abstinence‡	10 (4.8)	7 (3.3)	1.46 (0.54–3.90)	.47
Self-report				
End of pregnancy	41 (19.6)	30 (14.2)	1.48 (0.88–2.48)	.15
Three months postpartum	24 (11.5)	22 (10.5)	1.11 (0.60–2.05)	.75
Sustained abstinence‡	18 (8.6)	11 (5.2)	1.70 (0.78–3.70)	.18
Significant reduction§				
End of pregnancy	61 (29.2)	46 (21.7)	1.49 (0.96–2.31)	.09
Three months postpartum	37 (17.7)	34 (16.2)	1.11 (0.67–1.86)	.69
Quit attempt¶				
End of pregnancy	93 (44.5)	101 (47.6)	0.88 (0.60–1.29)	.55

CI, confidence interval.
* N = 210 for all 3-month postpartum outcomes (excludes 2 subjects with fetal loss after end of pregnancy assessment).
† Prespecified primary outcome measure.
‡ Sustained abstinence = cotinine-validated 7-day point-prevalence abstinence at end-of-pregnancy and 3 months postpartum.
§ Fifty percent or greater reduction in self-reported number of cigarettes/day between enrollment and outcome point. Individuals with missing data are assumed to have made no change.
¶ Intentional tobacco abstinence lasting > 24 hours between study enrollment and end-of-pregnancy assessment. Individuals with missing data are assumed to have made no change.

Table 3 shows, the intervention increased cotinine-verified abstinence at end of pregnancy among the 201 women who were light smokers (< 10 cigarettes/day at study enrollment) (intervention, 19.1% versus control, 8.4%, OR 2.58, 95% CI 1.10–6.06, $P = .036$, number needed to treat = 9.3) but not among the 220 heavier smokers. The intervention also increased end-of-pregnancy cessation rates among the 193 smokers who had made a quit attempt earlier in pregnancy before study enrollment (intervention, 18.1% versus control, 6.8%, OR 3.02, CI 1.15–7.94, $P = .029$, number needed to treat = 8.8). A total of 267 subjects (63.4% of the sample) was included in one or both of the subgroups in which the intervention was efficacious. Nonsignificant differences consistent with intervention efficacy were seen among subjects with nonsmoking partners and those who were confident of their ability to quit (Table 3). The intervention was not effective in subgroups defined by parity, intention to quit in 30 days, social support, current or past depression symptoms, health insurance, or recruitment source (data not shown). The intervention did not significantly increase cessation rates at 3-month postpartum in any subgroup.

Using multiple logistic regression, we did an exploratory analysis to identify factors that were independently associated with validated nonsmoking at end of pregnancy. Four factors were strong predictors of quitting: fewer cigarettes per day (< 10 versus ≥ 10), younger age (< 25 versus ≥ 25 years), strong confidence in the ability to quit, and having a no-smoking policy in the home. Limited by the small number of women with validated end-of-pregnancy cessation (n = 37), the 2 strongest independent predictors of cessation selected from the multiple logistic regression model were fewer than 10 cigarettes per day at enrollment (OR 2.94, 95% CI 1.37–6.29) and age less than 25 years (OR 2.41, 95% CI 1.20–4.82).

Few subjects used other formal smoking treatment during pregnancy, and intervention and control groups did not differ in the use of other treatments. Fewer than 5% used any other counseling program, and 10% used nicotine replacement or bupropion. Use of these methods was not associated with more cessation. Groups did not differ in the proportion of subjects who received cessation assistance from their prenatal provider (data not shown). Intervention and control groups did not differ in their change in mediating factors (self-confidence in the ability to quit and social support for quitting smoking) between enrollment and end of pregnancy (data not shown). Depression symptoms differed little between baseline and end of pregnancy, and intervention and control groups did not differ at end of pregnancy in depression symptoms (data not shown).

Intervention group participants rated the telephone counseling program highly. Of 152 subjects who completed the end-of-pregnancy assessment, 115 (76%) were very satisfied with the program, 137 (90%)

Table 3. Smoking Cessation Outcomes at End of Pregnancy: Subgroup Analysis by Baseline Characteristics

		End-of-Pregnancy Cotinine-Validated 7-Day Tobacco Abstinence		
Baseline Characteristic	n	Intervention (n = 209) [n (%)]	Control (n = 212) [n (%)]	Odds Ratio (95% CI)
All subjects	421	21 (10.0)	16 (7.5)	1.37 (0.69–2.70)
Cigarettes/day at study entry				
Less than 10	201	18 (19.1)	9 (8.4)	2.58 (1.10–6.06)*
10 or more	220	3 (2.6)	7 (6.7)	0.38 (0.09–1.49)
Made quit attempt since start of pregnancy†				
Yes	193	19 (18.1)	6 (6.8)	3.02 (1.15–7.94)‡
No	228	2 (1.9)	10 (8.1)	0.22 (0.05–1.04)
Confidence in ability to quit				
Very confident	47	7 (30.4)	2 (8.3)	4.81 (0.88–26.30)§
Somewhat confident	270	13 (9.8)	9 (6.6)	1.54 (0.64–3.74)
Not at all confident	104	1 (1.9)	5 (9.8)	0.18 (0.02–1.57)
Nonsmoking spouse	136	9 (15.5)	5 (6.4)	2.68 (0.85–8.48)‖
Smoking spouse	268	11 (7.7)	11 (8.7)	0.88 (0.37–2.10)

CI, confidence interval.
* $P = .036$.
† Before study enrollment.
‡ $P = .029$.
§ $P = .072$.
‖ $P = .095$.

rated the calls as useful, 119 (78%) felt that the telephone counselor gave them a lot of support, 137 (90%) said that the calls helped them to think about their smoking behavior, and 122 (80%) said that the calls helped them to set health goals and make behavior changes.

DISCUSSION

This randomized controlled trial demonstrated the feasibility and acceptability, but not the efficacy, of a proactive telephone-delivered smoking cessation counseling program for pregnant women who were identified as smokers by their prenatal care providers. Participants rated the program highly, but it did not produce more smoking cessation at the end of pregnancy than a "best practice" control condition consisting of one 5-minute telephone call and a mailed booklet. The intervention was efficacious, however, in 2 large subgroups of pregnant smokers, light smokers and those who had tried to quit on their own earlier in pregnancy. Nearly two thirds of the study sample fell into one of these subgroups, suggesting that the intervention may have benefit for a substantial proportion of the pregnant smokers who do not quit before entering prenatal care. This hypothesis needs to be tested in a future trial.

Our results are consistent with the findings of 2 previous trials that tested telephone counseling against a brief clinical intervention in pregnant women.[12,20] Conclusions of the earlier studies were limited by methodological concerns or differences in study design. In one study, there was uncertainty about the quality of the telephone counseling because it was provided by nurses with no previous training in motivational interviewing or smoking cessation counseling, competing clinical responsibilities, and no monitoring of their performance.[12] In the other study, telephone counseling was provided by trained ex-smokers, not by counselors, and only 53% of women in the intervention condition received the prescribed telephone support calls because the study was designed as an effectiveness trial. Our study addressed these limitations and provides a strong test of the efficacy of multisession telephone counseling for pregnant smokers. The intervention was standardized and delivered by experienced counselors who were trained intensively, had close monitoring of their performance, and had adequate time dedicated to provide the intervention. Process measures indicated that the intervention group received a substantially larger dose of counseling than the control group. Randomization produced 2 groups that were comparable at baseline and had similar study completion rates. The small amount of smoking cessation assistance received outside the trial did not differ by study arm. Cessation outcomes were biochemically validated, and the sample size had adequate statistical power to test the hypothesis. Therefore, the intervention's lack of efficacy does not appear to be attributable to flaws in study design or conduct.

The repeated telephone counseling contact provided by the intervention was expected to improve 2 factors that mediate smoking cessation success: social support for quitting and self-confidence in the ability to succeed.[8] The fact that our intervention did not alter either factor provides a potential explanation for the intervention's lack of effect on cessation. A more intensive telephone counseling intervention might alter these mediators and outperform brief counseling, but it is not clear that a more intensive program is feasible. Participants in our trial were offered more telephone counseling support during pregnancy than they actually used.

The proactive telephone counseling intervention did improve smoking cessation rates in 2 groups of pregnant smokers: those who were light smokers at study entry and those who had tried to quit earlier in pregnancy. This finding is consistent with evidence that pregnant and nonpregnant smokers who smoke fewer cigarettes per day are more likely to quit, either on their own or with an intervention.[2,4,5,8] Among pregnant women, an intervention that is effective in light smokers has substantial generalizability because so many pregnant smokers spontaneously reduce their smoking to low levels early in pregnancy. In this study, almost half of the subjects met the light smoking criterion of fewer than 10 cigarettes/day, even though their average prepregnancy smoking rate was 20 cigarettes/day. Telephone counseling was also effective in the subgroup of smokers who had tried to quit earlier in pregnancy. These appear to be women with a serious commitment to quitting who can use the skills and support offered by telephone counseling. In contrast, our intervention did not help smokers who had not already tried to quit during pregnancy, even though the large majority of them enrolled in the study with the stated intention of quitting smoking in the next 30 days.

It is important to note the difference between the telephone counseling in this trial and that provided by telephone quitlines.[15–17] In both cases, repeated proactive telephone counseling calls are offered. However, telephone quitlines serve smokers who make an initial call seeking help, whereas our study actively

recruited smokers who had not requested assistance but who had been identified and referred by prenatal care providers. The efficacy of a telephone quitline for pregnant smokers who are actively trying to quit is suggested by our subgroup analysis and deserves testing.

The low rates of smoking cessation observed in this study have 2 potential explanations. First, our study excluded women who quit spontaneously early in pregnancy before entering prenatal care. Therefore, our subjects were a more challenging group of smokers in whom cessation was less likely. Second, to broaden generalizability, we did not require pregnant women to commit to reducing or quitting smoking to enroll. The study protocol used a motivational interviewing strategy to attempt to help these smokers to commit to quitting. This approach has a strong theoretical rationale for smoking intervention, but evidence for its efficacy is mixed[35,36] and we did not find it to be effective. Negative results were also reported in a trial of motivational interviewing provided by trained midwives to pregnant smokers at home visits.[10]

Our findings should be interpreted in light of the study limitations. First, this trial tested the marginal effect of telephone counseling over a "best practice" brief intervention that likely exceeds usual clinical care. Our study design cannot determine whether telephone counseling is superior to usual care. Second, results of our subgroup analysis must be interpreted with caution and need to be confirmed in future studies. Third, because 34% of eligible smokers declined to participate, our findings cannot be generalized to all pregnant smokers. Fourth, the study did not measure outcomes such as birth weight to determine the clinical significance of the behavior changes achieved.

In conclusion, this randomized trial found that proactive pregnancy-tailored telephone counseling did not improve smoking cessation rates over a brief "best practice" intervention among all pregnant smokers who were referred for help by prenatal care providers. However, telephone counseling was effective for nearly two thirds of the sample who were light smokers at the start of prenatal care or who had tried to quit on their own during pregnancy. If future trials confirm these results, telephone counseling may be an effective method for these groups of pregnant smokers. Other strategies, including pharmacotherapy, are needed for pregnant smokers who do not try to quit before enrolling in prenatal care and who continue to smoke more than 10 cigarettes per day.

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