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# Telephone Intervention for Pregnant Smokers
## A Randomized Controlled Trial

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**Introduction:** Pregnant smokers are advised to quit; however, many struggle to do so. Behavioral counseling can increase quitting success, but the efficacy of telephone counseling for pregnant smokers has not been established. This study tests the efficacy of pregnancy-specific counseling, embedded in the ongoing operations of a state quitline.

**Design:** In this two-group RCT, participants were randomly assigned to the intervention (telephone counseling plus self-help materials, *n*=584) or the control group (self-help materials only, *n*=589).

**Setting/participants:** Participants were pregnant smokers (N=1,173) in the first 27 weeks of gestation who called a state quitline between September 2000 and May 2003 for help with quitting.

**Intervention:** The primary component of the intervention was telephone counseling using a semi-structured protocol developed specifically for pregnant smokers. It drew its basic structure and clinical content from a previously tested counseling protocol for adult quitline callers, while including pregnancy-specific content and additional counseling sessions (nine rather than the standard five).

**Main outcome measures:** Subjects were evaluated on prolonged abstinence at the third trimester (about 29 weeks gestation) and at 2 and 6 months postpartum. Data were analyzed in 2015.

**Results:** Abstinence was higher for the intervention than the control group at the end of pregnancy (30-day abstinence, 29.6% vs 20.1%; $p<0.001$), 2 months postpartum (90-day abstinence, 22.1% vs 14.8%; $p<0.001$), and 6 months postpartum (180-day abstinence, 14.4% vs 8.2%; $p<0.001$). Cotinine-corrected (≤13 ng/mL) 7-day abstinence rates at the end of pregnancy supported the intervention effect (35.8% vs 22.5%, $p<0.001$).

**Conclusions:** A pregnancy-specific counseling protocol, embedded in a state quitline, was effective in helping pregnant smokers quit and stay quit postpartum. Wide adoption of this

intervention could help reduce the rate of maternal smoking and prevent its devastating health consequences.

## Introduction

Pregnant women are advised to refrain from behaviors potentially harmful to their health or to the health of their baby, such as using alcohol, taking certain medications, and smoking.[1,2] The Surgeon General's report states that smoking during pregnancy increases the risk of pregnancy complications, premature delivery, low birth weight infants, stillbirth, and sudden infant death syndrome.[3] Many pregnant smokers heed the advice to quit and quit smoking as soon as they find out they are pregnant.[4] Yet, more than half of pregnant smokers (52.5%–56.1%) continue to smoke throughout pregnancy.[5] Many want to quit, but struggle to do so. Despite 20 years of research, ways to help pregnant smokers quit remain limited.[6,7] Nicotine-replacement therapy has been proposed as a possible approach[8–10] with some calling for higher dosing owing to faster nicotine metabolism during pregnancy.[11] However, pharmacotherapy is controversial because of its potential to harm the fetus[12–15] and lack of evidence of effectiveness for pregnant smokers.[13,16] Limitations on use of pharmacotherapy increase the importance of behavioral counseling for this population.

There have been many randomized trials of cessation interventions for pregnant women, most using behavioral counseling alone or in combination with incentives, support partners, videos, or hypnosis. Overall, participants who received interventions were more likely to be abstinent at the end of the pregnancy (risk ratio [RR]=1.44, 95% CI=1.19, 1.75) than those in the control groups.[6] They were also less likely to have a low birth weight child (RR=0.83, 95% CI=0.73, 0.95) or preterm birth (RR=0.86, 95% CI=0.74, 0.98) than those in the control groups.[7] The most effective behavioral intervention was offering financial incentives. Intensity and theoretic underpinnings of interventions did not lead to significant differences in efficacy. However, modality of behavioral intervention did play a role. In-person interventions, either one on one or group, were effective. Only two of 11 studies of telephone intervention resulted in significant

effects, one also offered financial incentives in the form of a lottery and the other was significant at the end of pregnancy, but not at 6 months postpartum.[17,18]

It is somewhat surprising that telephone counseling was not more successful given that smoking-cessation "quitlines" have become a staple of tobacco control.[19,20] Quitlines are easy to access, have broad appeal, and a strong research basis.[19,20] The convenience of telephone-based counseling has long been a key factor in attracting smokers who seek behavioral treatment.[19] Quitlines would seem to be an ideal way to reach pregnant smokers.[21–23] More than 90% of U.S. quitlines reported that they provide specialized materials for pregnant smokers and additional training for counselors on how to help them quit.[24] However, no study has yet documented an empirically validated pregnancy-specific telephone counseling protocol, effective into postpartum.

This paper presents findings from an RCT testing the efficacy of a pregnancy-specific counseling protocol, embedded in the ongoing operations of a state quitline. The study tested two hypotheses: (1) that telephone counseling would increase the cessation rate during pregnancy; and (2) that the difference between the intervention and control groups would be maintained postpartum.

## Methods

### Design and Allocation Strategy

The trial used a two-group design. Subjects were stratified by whether they were current smokers (97.4%) or recent quitters (2.6%) and randomly assigned (1:1) to the intervention (*n*=584) or control condition (*n*=589). A power calculation indicated that 602 subjects per group would provide power of 0.80 with an α-level of 0.05 to detect an increase in the continuous abstinence rate from 8% to 16% counting subjects not reached for evaluation as smokers. Random

allocation to condition was done by computer using blocks of 20; staff were blind to group assignment until the end of the intake, when the appropriate script was presented. The conditions were equivalent in the proportion of women who were already quit at the time of intake (2.9% for the intervention and 2.4% for the control condition, $p$=0.57). One subject in the control group subsequently asked to be removed from the study and was not evaluated. All other subjects were scheduled for evaluation in the third trimester (about 29 weeks gestation), and 2 months and 6 months postpartum based on the due date provided at intake.

**Participants**

Participants were recruited between September 2000 and May 2003 from among callers to a state quitline. During the intake process, women aged 18–45 years were asked if they were pregnant, assessed for eligibility, and invited to participate if they met study criteria. Women were able to participate regardless of whether they were in prenatal care and the intervention was provided without relationship to healthcare providers.

To be eligible, participants had to be first-time quitline callers, current smokers who were willing to quit within 1 month or recent quitters (i.e., quit within 2 weeks), pregnant <27 weeks, and speak English or Spanish. Active psychiatric disorders, current substance or alcohol abuse, and being in recovery for <6 months were exclusion criteria. Callers were also excluded if they specifically requested counseling (precluding randomization), planned to use pharmacotherapy, or provided insufficient contact information.

This study recruited 1,173 pregnant smokers. During the recruitment period, 3,121 pregnant smokers called the quitline and were assessed for study eligibility; 1,269 were eligible (40.6%) (Figure 1). The greatest sources of ineligibility were gestation >26 weeks (44.8%, $n$=829) and insufficient contact information such as no name, address, or telephone number (38.4%, $n$=711). Of the 1,269 eligible clients, 1,173 agreed to participate (92.4%); 58% were white, 21% black,

13% Hispanic, 2.5% Asian, 3.6% American Indian, and the remaining 2% were other. The mean age of the subjects was 26.3 (SD=6.1) years and 66% had a high school education or less.

**Study Procedures**

Potential participants were told about the study and the process for randomization into condition. They were also told that at they would be asked to provide a saliva sample at evaluation to test for exposure to nicotine, a procedure that allowed for biochemical validation of their self-reported smoking status and acted as a "bogus pipeline" to increase the accuracy of report.[25] Subjects in both the intervention and control conditions, regardless of smoking status, were asked at the third trimester evaluation to provide a saliva sample by mail. The salivary collection kit included an explanation of the test and confidentiality assurance, an instruction sheet, a small plastic vial, gum to generate saliva, and a padded, stamped return envelope. Subjects received a $5 check for returning the sample. After receipt (median transit time, 5 days), samples were stored in a freezer at 0º Fahrenheit and sent to an external laboratory (Department of Anesthesiology Assay Laboratory at the University of Calfiornia, San Diego) for analysis of cotinine using a monoclonal enzyme-linked immunosorbent assay procedure sensitive to 0.1 ng/mL. A cut off of 13 ng/mL was used to verify smoking status.[26]

Subjects provided oral consent for participation, which was documented in the database, and were sent a consent document that described the study and their participation in detail. The study was conducted in compliance with the appropriate Human Research Protection Program (#990252) and registered May 2014 in Clinicaltrials.gov (NCT02144883).

**Interventions**

All subjects received a self-help packet that included the American Cancer Society's *Make Yours a Fresh Start Family*, fact sheets on secondhand smoke, and additional tips for quitting while pregnant. The self-help materials served as the comparison condition to the intervention.

Intervention subjects received five additional mailings designed to remind them of their commitment to quitting and of the availability of quitline counseling support. Mailings included a pamphlet on pregnancy facts and a refrigerator magnet with the quitline number sent at 4.5 and 6 months gestation, respectively. At 7.5 months gestation, participants were mailed a social support planning worksheet developed in-house. A congratulatory card was sent after the birth and a brochure on parenting newborns was mailed 1 month postpartum.

The primary component of the intervention was telephone counseling using a semi-structured protocol developed specifically for pregnant smokers. It drew its basic structure from a previously tested counseling protocol for adult quitline callers, while including pregnancy-specific content and additional counseling sessions.[27–30]

The treatment approach and the pregnancy-specific clinical topics are detailed elsewhere.[27] Briefly, counseling addressed an array of pregnancy-specific topics such as misunderstanding of health risks, perceived loss of control over timing of quitting, emerging self-image as a non-smoking parent, management of mood, and remaining smoke-free following the birth.

Counseling consisted of nine sessions: one comprehensive pre-quit call lasting about 45 minutes, five shorter follow-up calls (1, 3, 7, 14, and 30 days after the quit date), one 30-minute pre-birth call scheduled about 32 weeks gestation, and two follow-up sessions 2 weeks and 4 weeks after the birth. Smokers and recent quitters received the same counseling except for the discussion of setting a quit date with smokers. Counselors initiated all calls. This proactive approach fostered a positive counseling relationship, provided accountability, created opportunities to address wavering motivation, reduced attrition, and minimized relapse.[28]

Twenty-one veteran staff members provided the counseling. Prior to working with clients, they received instruction on fetal development and the physical and mental changes experienced by

women during pregnancy and training on the pregnancy-specific protocol. Counseling utilized a semi-structured protocol that provided the minimal acceptable content for each call. Counselors met for weekly group supervision facilitated by onsite clinical psychologists to discuss the counseling protocol and individual cases.[27]

**Measures**

At baseline, in addition to being asked demographic characteristics, subjects were asked whether they had health insurance (classified as private insurance, government insurance such as Medicaid, or no insurance), whether this was their first child, who they lived with, and whether that person(s) smoked. Subjects were classified as having a spouse or significant other or not and as living with another smoker or not. Subjects were asked about restrictions on smoking in the household with options of no restrictions, some indoor restrictions, and complete ban on smoking indoors. Subjects provided information about their smoking including whether they were a daily smoker or not, the number of cigarettes they smoked each day, the number of cigarettes they smoked each day 6 months earlier (prior to the pregnancy), and how soon after they wake up they typically smoke their first cigarette (classified as within 30 minutes or after 30 minutes). Other measures included readiness to quit (classified as within 1 week or after 1 week) and length of their last quit (classified as <14 days or ≥14 days). Subjects were asked to determine, on a scale of 0–10 with 0 being not at all confident and 10 being very confident, how confident they were that they could go without smoking for 1 week.

Independent evaluators (not counselors) conducted follow-up telephone interviews to assess smoking status and quitting near the end of the pregnancy (about 29 weeks gestation), at 2 months postpartum, and at 6 months postpartum based on the due date. Evaluators made up to 30 attempts to reach a subject over different times of the day and days of the week before classifying them as a no contact. Subjects received a $5 check for each completed evaluation.

To reduce demand characteristics and increase accuracy of self-reported smoking, evaluated subjects were asked: *Which category best describes you? "I smoke," "I smoke, but I cut down," or "I don't smoke,"* rather than the more common *Do you smoke?*[31] Subjects were then asked about any quit attempts made, the length of the first and last attempt since the last evaluation, slips or relapses if any, and use of quitting aids. Anchoring quit attempts to actual dates is consistent with other studies,[29,30] and allows for the analysis of several outcomes. The primary outcome measure was prolonged abstinence at the time of the evaluation, defined as self-reported 30-day abstinence in the third trimester (about 29 weeks gestation), 90-day abstinence at 2 months postpartum, and 180-day abstinence at 6 months postpartum. A secondary outcome measure was the quit attempt rate, which was defined as the proportion of subjects who made a quit attempt that lasted ≥24 hours within 90 days of enrollment. The use of multiple measures and reliance on self-report for studies in which subjects are not seen face to face are consistent with previous recommendations.[32] However, one caveat is that pregnant smokers may be subject to greater levels of bias in their report than other groups. Use of a saliva sample procedure was designed to increase the accuracy of reporting.[25]

**Statistical Analysis**

Initial analysis included a check of baseline characteristics between the randomized conditions. Pearson chi-square was used to test for equality and 95% CIs were calculated for the percentages.[33]

The chi-square test for proportions was used to compare the intervention group to the self-help group.[33] To determine prolonged abstinence, relapse was defined as smoking on 2 consecutive days. Abstinence rates were analyzed using both intention to treat in which all subjects lost to follow-up were coded as smokers and complete case analysis based only on subjects with evaluation data.[34] Finally, an additional analysis of 7-day abstinence at the third trimester

evaluation was conducted to biochemically confirm the intervention effect. For this analysis, subjects' cotinine-verified smoking status replaced self-report where possible. All analysis was performed with SAS, version 9.4.

## Results

Table 1 shows the equivalence of randomized conditions on individual characteristics at baseline. About 47% were aged 18–24 years and nearly two thirds had a high school education or less. There was considerable ethnic diversity: More than 40% were ethnic minorities with high representation of African Americans (21%) and Hispanic/Latinos (13%). Only 31% of women had private health insurance, another 53% had insurance through Medicaid, and 15% had no health insurance. Less than 50% of these pregnant women had a spouse or significant other. Fifty-five percent were in their first 13 weeks of pregnancy (range, 1–27 weeks; mean, 13.1 [SD=6.3] weeks). About 40% of the subjects stated that this pregnancy was their first.

Table 2 compares the groups on smoking characteristics. There were no significant differences between the conditions, but many subjects were exposed to environmental cues to smoke; 56.7% lived with other smokers and only 48.8% had a complete household ban on smoking. At the time of enrollment, subjects had already decreased their smoking, from an average of 19.6 (SD=10.8) cigarettes/day 6 months prior to calling the quitline, to 11.2 (SD=8.1) cigarettes/day at enrollment ($p<0.001$).

During the study, 64 women in the counseling group and 51 women in the self-help group reported miscarriage or termination of the pregnancy, with no difference noted between conditions ($p=0.19$).

Of the 584 subjects randomly assigned to counseling, 71.2% received at least one counseling session with a mean of 4.0 follow-up sessions. Only 20.7% of subjects received counseling postpartum; the average number of postpartum calls for those who received them was 1.5.

Thirteen subjects in the self-help group (2.2%) called the quitline after randomization and requested further help with quitting. These subjects were provided with the pregnancy-specific counseling and received an average of 3.9 sessions. They were included in the analysis as part of the control group.

Smokers in the counseling group were not significantly more likely to make a quit attempt than those in the control group. Among those evaluated at the third trimester, 56.1% in the intervention group and 52.6% in the control group had made a quit attempt that lasted at least 24 hours ($p$=0.24).

Table 3 shows the primary outcomes, self-reported prolonged smoking abstinence. In the third trimester (about 29 weeks), complete case analysis indicated that 34.8% of the counseling group and 22.3% of the materials group had been abstinent for ≥30 days ($p$<0.001). At 2 months postpartum, the 90-day abstinence rates were 29.7% for counseling subjects and 18.5% for materials subjects ($p$<0.001). By 6 months postpartum, 23.7% of counseling and 11.7% of self-help subjects had been abstinent for ≥180 days ($p$<0.001).

Using intention-to-treat analysis, the abstinence rates were lower, but the patterns were the same. At the end of the pregnancy, 29.6% of the counseling group and 20.1% of the self-help group were abstinent for at least 30 days (RR=1.5, 95% CI=1.2, 1.8, $p$<0.001). The intervention effect was still evident at 2 and 6 months postpartum. At 2 months postpartum, 22.1% of the counseling group and 14.5% of the self-help group were abstinent for ≥90 days (RR=1.5, 95% CI=1.2, 2.1, $p$<0.001). By 6 months postpartum, 14.2% of the counseling group and 8.2% of the self-help group were abstinent for ≥180 days (RR=1.7, 95% CI=1.2, 2.4, $p$<0.001).

Saliva samples were requested from all subjects at the third trimester evaluation. Return rates for saliva samples were 24.1% with no differences between the self-help and counseling groups

($p$=0.73). The coding cut off for smokers was 13 ng/mL of cotinine. Analysis of the cotinine-corrected 7-day abstinence rates at the end of pregnancy confirmed the intervention effect. The self-reported 7-day abstinence rate was 44.9% and 34.6% for the counseling and self-help groups, respectively ($p$<0.001). The cotinine-corrected 7-day abstinence rate was 35.8% for counseling condition and 22.5% for the self-help condition ($p$<0.001).

## Discussion

This is the first RCT to demonstrate that a telephone-based, pregnancy-specific protocol without financial incentives can increase smoking cessation during pregnancy, with a sustained effect in the postpartum period. The protocol was designed to promote quit attempts and prevent relapse. The study indicated that the primary impact of the intervention was to prevent relapse. The effect was maintained up to 6 months postpartum.

At the end of pregnancy, women in the intervention condition were 1.5 times more likely to be abstinent than those in the control condition. This effect size compares favorably to the RR of 1.4 described in the 2013 Cochrane Review of interventions for pregnant smokers.[6] In that review, the intervention effect was due to the success of group and clinic programs and financial incentives; none of the telephone-based programs were successful (unless they also included financial incentives).

The counseling protocol used in this study differed from usual quitline counseling in content, structure, and intensity. It included pregnancy-specific content and offered more counseling sessions as well: nine sessions rather than the standard five-call protocol.[27]

Success of this study may be due in part to an emphasis on fidelity in delivery of the intervention. A clinically rich protocol can fail if it is not delivered as intended. To ensure a high-quality intervention, counselors used a semi-structured protocol, which allowed for consistent

delivery of the pregnancy-specific counseling. Fidelity was facilitated through ongoing monitoring of the procedural aspects of the project including whether appropriate attempts were made to reach clients in a timely way. In addition, counselors received weekly supervision that focused on adherence to the protocol both procedurally and with regard to content.

This study had several strengths. The first was the RCT design, which included a large sample size (N=1,173), biochemical validation of smoking status, and follow-up to 6 months postpartum by independent evaluation staff. This design permits a more definitive conclusion of efficacy. In addition, the research was conducted in the context of a widely accessible, publicly funded program. Embedding the testing of the intervention in a real-world quitline setting contributes to the generalizability of the findings.

An additional strength of the study is that the protocol was shown to be effective with participants from diverse ethnic backgrounds. Moreover, many of these women were economically disadvantaged and lacked the social support that can facilitate behavior change. More than half lived with another smoker, a known predictor of relapse.[35] Less than half had the support of a spouse or significant other. Proactive counseling may have provided needed support during the difficult process of quitting smoking.

**Limitations**

At the same time, the study had some limitations. First, the study does not support a determination of which aspects of the intervention were effective, as it was not designed to test individual components nor did it test standard cessation counseling against pregnancy-specific counseling. Rather, it was designed to test the pregnancy-specific counseling by comparing against a materials-only condition. The significant effect might have been due to counseling content, the timing or number of sessions, materials sent, or some combination. Second, the

return rate for biochemical validation of self-report was low (24.1%). Although there was no difference in the return rates between conditions, low rates limit conclusions about misreporting rates and increase the reliance on the bogus pipeline aspect of the procedure to ensure reliable self-report.[25] Third, testing the intervention protocol with pregnant smokers who called for help with quitting limits the generalizability of the results beyond this population. Interventions with smokers who do not call for service but are directly referred by healthcare providers or others have been less effective than interventions with smokers who call for help themselves.[20] Although callers, even those who heard about the program through their healthcare provider, may be ambivalent about quitting (most smokers are), calling indicates a degree of motivation. Proactive recruitment pulls from a broader sample of smokers and would include those who are less motivated to quit. This may explain why interventions with proactively recruited pregnant smokers have found no difference in outcome by condition.[36]

## Conclusions

This study is the first to establish that telephone counseling without the use of financial incentives can be effective in helping pregnant smokers quit and stay quit postpartum. These results should spur more studies to replicate and, perhaps extend, research in this area. In previous studies of telephone counseling, counseling impacted cessation through two mechanisms.[29,30] First, it increased the proportion of smokers who made a quit attempt. Second, it increased the proportion of smokers who were able to stay abstinent after they made a quit attempt. However, in the current trial, there was no difference in the quit attempt rate between the intervention and control groups. The effect of counseling appeared mainly in preventing relapse. Given that only about 50% of the women made a quit attempt, there is room for enhancing the intervention effect by including an element in the protocol to increase the quit

attempt rate. One promising method is to use financial incentives to increase quit attempts during pregnancy.[6,7]

In the meantime, state quitlines might consider adopting this pregnancy-specific protocol.[27] Considering the devastating health consequences of smoking during pregnancy, the availability of an evidence-based pregnancy-specific program holds promise to positively impact this major public health problem.

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Shu-Hong Zhu served as Principal Investigator and designed the study; Sharon Cummins helped with design, supervised implementation, and wrote the first draft. All authors developed and refined the counseling and contributed to the final draft. The trial was registered in Clinicaltrials.gov (NCT02144883).

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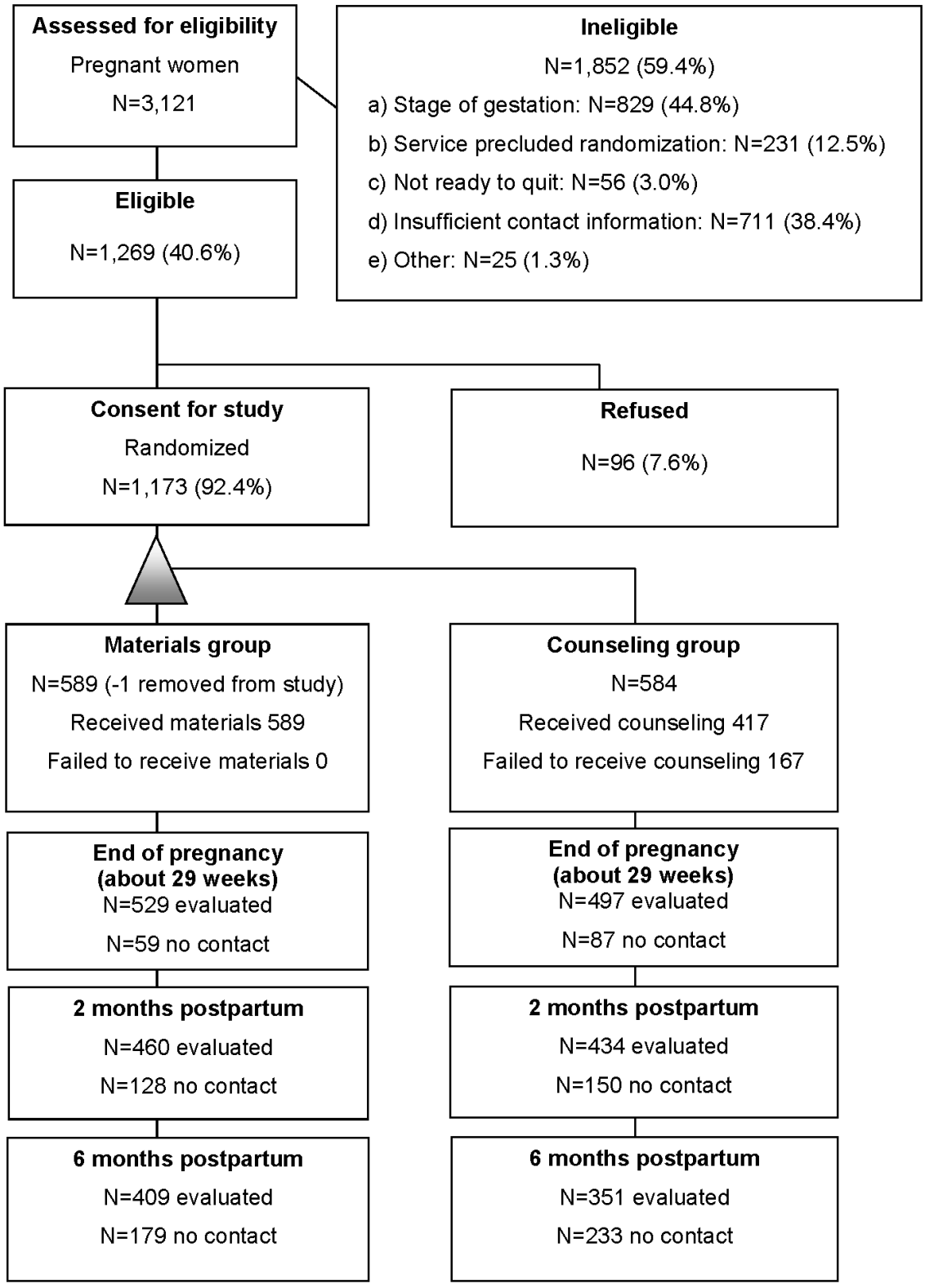


**Figure 1.** Flow of participants in the RCT.

**Table 1.** Individual Characteristics by Randomly Assigned Condition

| | **Total** **%** | **Intervention (n=584) % (95% CI)** | **Materials only (n=588)[a] % (95% CI)** |
|---|---|---|---|
| Age | | | |
| 18-24 | 46.8 | 47.4 (43.4-51.5) | 46.2 (42.1-50.2) |
| 25+ | 53.2 | 52.6 (48.5-56.6) | 53.8 (49.8-57.9) |
| Education | | | |
| High school or less | 65.9 | 66.7 (62.9-70.6) | 65.0 (61.1-68.9) |
| Ethnicity | | | |
| White | 58.1 | 55.9 (51.8-59.9) | 60.2 (56.3-64.2) |
| Black | 20.9 | 23.0 (19.6-26.4) | 18.8 (15.6-21.9) |
| Hispanic | 12.9 | 13.5 (10.7-16.3) | 12.3 (9.6-15.0) |
| Asian | 2.5 | 2.4 (1.2-3.7) | 2.6 (1.3-3.8) |
| American Indian | 3.6 | 3.1 (1.7-4.5) | 4.1 (2.5-5.7) |
| Other | 2.1 | 2.1 (0.9-3.2) | 2.1 (0.9-3.2) |
| Insurance | | | |
| Private | 31.2 | 29.1 (25.4-32.9) | 33.2 (29.4-37.1) |
| Medicaid | 53.4 | 56.7 (52.6-60.7) | 50.2 (46.1-54.3) |
| None | 15.4 | 14.2 (11.3-17.1) | 16.6 (13.6-19.7) |
| Spouse/significant other | | | |
| Yes | 48.9 | 46.2 (42.2-50.3) | 51.5 (47.5-55.6) |
| Gestational age | | | |
| 13 weeks or less | 55.3 | 55.5 (51.4-59.5) | 55.1 (51.1-59.1) |
| 14 weeks or more | 44.7 | 44.5 (40.4-48.6) | 44.9 (40.9-48.9) |
| First baby | | | |
| Yes | 39.6 | 40.5 (35.7-45.2) | 38.7 (34.1-43.3) |

[a] One subject requested to be removed from the study

*Note*: Boldface indicates statistical significance ($p<0.05$).

**Table 2.** Smoking Characteristics by Randomly Assigned Condition

| | **Total** | **Intervention (n=584)** | **Materials only (n=588)[a]** |
|---|---|---|---|
| | **%** | **% (95% CI)** | **% (95% CI)** |
| Daily smoker | | | |
| Yes | 97.8 | 97.8 (96.4-99.1) | 97.7 (96.4-99.1) |
| Cigarettes per day | | | |
| 1-14 | 68.9 | 66.8 (63.0-70.6) | 71.1 (67.4-74.8) |
| 15-24 | 26.0 | 27.6 (24.0-31.2) | 24.5 (21.0-28.0) |
| 25+ | 5.0 | 5.7 (3.8-7.5) | 4.4 (2.8-6.1) |
| First cigarette | | | |
| <=30 minutes | 65.3 | 65.0 (61.1-68.9) | 65.6 (61.7-69.4) |
| Ready to quit | | | |
| <=1 week | 91.5 | 91.2 (88.9-93.5) | 91.8 (89.6-94.1) |
| Confidence (0-10) | | | |
| <5 | 49.6 | 47.6 (43.4-51.7) | 51.7 (47.6-55.8) |
| Length of last quit | | | |
| <14 days | 48.1 | 51.2 (45.5-55.9) | 45.3 (39.8-50.8) |
| Complete home ban | | | |
| Yes | 48.8 | 47.2 (43.1-51.4) | 50.3 (46.1-54.5) |
| Other smoker in the home | | | |
| Yes | 56.7 | 54.6 (50.6-58.7) | 58.8 (54.9-62.8) |

[a] One subject requested to be removed from the study

*Note*: Boldface indicates statistical significance ($p<0.05$).

**Table 3**. Prolonged Abstinence Counseling and Control Group at Third Trimester and 2-months, and 6-months Postpartum

| | **Third trimester 30-day abstinence** | | | **2 months postpartum 90-day abstinence** | | | **6 months postpartum 180-day abstinence** | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Counseling % (N)** | **Materials % (N)** | **Risk ratio RR (95% CI)** | **Counseling % (N)** | **Materials % (N)** | **Risk ratio RR (95% CI)** | **Counseling % (N)** | **Materials % (N)** | **Risk ratio RR (95% CI)** |
| Complete Case | 34.8 (497) | 22.3 (529) | **1.6 (1.3-1.9)** | 29.7 (434) | 18.5 (460) | **1.6 (1.3-2.0)** | 23.7 (351) | 11.7 (409) | **2.0 (1.5-2.8)** |
| Intention-to-treat | 29.6 (584) | 20.1 (588) | **1.5 (1.2-1.8)** | 22.1 (584) | 14.5 (588) | **1.5 (1.2-2.0)** | 14.2 (584) | 8.2 (588) | **1.7 (1.2-2.4)** |

*Note*: Boldface indicates statistical significance ($p<0.05$).