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A Randomized Controlled Trial of Financial Incentives to Low Income Pregnant Women to Engage in Smoking Cessation Treatment: Effects on Post-Birth Abstinence

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Objective: Evaluate the effectiveness of monetary incentives for increasing engagement in smoking cessation treatment and improving 6-month abstinence in low-income pregnant smokers. ***Method:*** Two-group randomized clinical trial recruiting low-income (Medicaid-registered) pregnant smokers receiving assistance through a perinatal support program. Participants were randomized to either an incentive (n = 505) or control condition (n = 509). All participants were offered identical smoking cessation counseling at contacts. Incentive condition participants received incentives for attending pre- and postbirth treatment contacts: $25 for each of 6 prebirth provider visits, $25–40 for each of 4 postbirth home visits at Weeks 1, 2, 4, and 6 (total = $130), $20 for each of 5 postbirth counseling calls and $40 for biochemically verified abstinence at the Week 1 and 6-month visits. Control condition participants received only $40 for attendance at the Week 1 and 6-month postbirth visits ($40 each). ***Main outcomes:*** Primary outcome was biochemically confirmed 7-day point-prevalence abstinence at 6-month postbirth follow-up. Secondary outcomes included number of home visits and phone calls taken over the first 6 months postbirth; biochemically confirmed abstinence at postbirth Week 1 visit; and self-reported smoking status at 2- and 4-month visits. ***Results:*** Incentive condition participants had a higher biochemically confirmed abstinence rate at 6-month postbirth than controls (14.7% vs. 9.2%, respectively: $p < .01$). This effect was mediated by incentive condition participants' greater acceptance of postbirth home visits and counseling calls. ***Conclusions:*** Moderate incentive payments for smoking treatment engagement (a mean of ≈$214 paid) increased low-income pregnant smokers' engagement and success in smoking cessation treatment.

What is the public health significance of this article?
Smoking during and after pregnancy has serious health consequences for mothers and infants. Low-income women are especially likely to smoke during pregnancy or resume smoking after it, making it vital to develop an intervention that increases long-term postbirth abstinence and that is suitable for widespread use. This research shows that modest financial incentives for engagement in smoking cessation treatment increased new mothers' attendance at postbirth treatment contacts and increased their smoking abstinence at a 6-month postbirth visit.

Keywords: pregnancy, low-income smokers, Medicaid, smoking cessation, incentives

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Smoking during pregnancy exacts serious human and economic costs. For instance, it causes multiple negative health consequences to both the mother and infant, with some of the harms to the infant being lifelong (e.g., early death, birth defects such as cleft palate, asthma, learning deficits; Bakker & Jaddoe, 2011; Centers for Disease Control & Prevention, 2002; Cnattingius, 2004; Dietz et al., 2010; Goodwin et al., 2017; Holz et al., 2014). Postbirth smoking also exacts a great toll on both the mother's and child's health (Hofhuis, de Jongste, & Merkus, 2003). Thus, it is vital to identify intervention strategies that reduce smoking both during and after pregnancy.

Unfortunately, many of the smoking cessation interventions used with pregnant smokers have yielded modest or inconsistent effects (Chamberlain et al., 2013; Jones, Lewis, Parrott, Wormall, & Coleman, 2016; Likis et al., 2014). However, the use of incentives to reinforce smoking abstinence has produced relatively promising effects (Cahill, Hartmann-Boyce, & Perera, 2016; Chamberlain et al., 2013; Higgins & Solomon, 2016; Lumley et al., 2009). Importantly, incentive programs can increase abstinence among low-income pregnant women (Higgins et al., 2012), who have especially high smoking prevalence rates (i.e., about 22–38% vs. about 13% in pregnant women in general; Centers for Disease Control & Prevention, 2007; Curtin & Mathews, 2016; Graham, Hawkins, & Law, 2010; Kandel, Griesler, & Schaffran, 2009; Likis et al., 2014). However, vital questions exist concerning the use of incentive programs for perinatal smoking.

First, although there is considerable evidence that such programs increase abstinence rates during pregnancy (Higgins & Solomon, 2016), there is less evidence that they produce persistent postbirth abstinence (Su & Buttenheim, 2014; although see Tappin et al., 2015). A recent Cochrane meta-analysis (Cahill et al., 2015) examined the effects of incentives on postbirth abstinence. Although this analysis showed a significant beneficial effect on postbirth abstinence, only four trials assessed abstinence at 6-months postbirth. Three of these were relatively small trials, with sizable potential voucher pay-outs and highly intense and frequent monitoring of smoking. In essence, little is known about the persistence of postbirth abstinence among low-income women in response to an incentive program that is feasible for real world delivery. The reduction of postbirth relapse is vital since about half or more of women who quit smoking during pregnancy, with or without treatment, will relapse postbirth (≈50–80%; Jones et al., 2016; Lemola & Grob, 2008; Martin et al., 2008; Prady, Kiernan, Bloor, & Pickett, 2012; Tran, Reeder, Funke, & Richmond, 2013), and low-income women may be especially likely to relapse (Harmer & Memon, 2013).

Some features of incentive-based interventions for smoking may discourage their widespread use. For instance, they tend to involve frequent treatment contact, use large incentive payments, and require frequent biochemical ascertainment of smoking status (e.g., Cahill et al., 2015; Donatelle et al., 2004; Hand, Heil, Sigmon, & Higgins, 2014; Higgins et al., 2010; Higgins et al., 2007; Higgins & Solomon, 2016; Higgins et al., 2012; Lussier, Heil, Mongeon, Badger, & Higgins, 2006; Silverman, Chutuape, Bigelow, & Stitzer, 1999). Only a few studies have used incentives for pregnant smokers in real world conditions (e.g., without frequent biochemical assessment). However, one lacked biochemical confirmation of effectiveness (Tappin et al., 2015) and another provided no intergroup comparisons of smoking outcomes (Ierfino et al., 2015). Thus, although incentive interventions have been used successfully in real world applications with nonpregnant smokers (Halpern et al., 2015; Volpp et al., 2009), there is little evidence that incentive interventions appropriate for real world use can enhance postbirth abstinence.

The current study evaluated an incentive-based intervention for pregnant smokers that primarily targeted postbirth abstinence and that was designed to reduce barriers to dissemination if found to be effective. Much of the treatment occurred postbirth and the primary outcome was biochemically confirmed abstinence at 26 weeks postbirth. Further, most of the incentive payments were contingent upon postbirth counseling engagement rather than on abstinence per se. This made contingent payment more practicable because participants could earn reinforcement without frequent biochemical ascertainment (e.g., participants could be mailed vouchers for participating in phone counseling). Third, the total amount of contingent payment was moderate in magnitude ($214 paid in this study vs. amounts often >$400 paid; Higgins et al., 2012). And, finally, the incentive intervention was made available as an adjuvant to an ongoing state-supported intervention program that is delivered to low-income pregnant women (the *First Breath* program). Thus, the incentive program was compatible with real world prebirth and postbirth care.

Method

Setting

This research was conducted by the University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) at the University of Wisconsin School of Medicine and Public Health, in collaboration with the State of Wisconsin Department of Health Services, and the Wisconsin Women's Health Foundation (WWHF). For over a decade, the WWHF has coordinated First Breath (FB), a perinatal smoking cessation program, that provides support services and smoking cessation counseling to women during and after pregnancy. This research project was funded by the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services as part of the Affordable Care Act's Medicaid Incentives for Prevention of Chronic Disease Demonstration Project. This study was approved by the University of Wisconsin Health Sciences Institutional Review Board.

Study Design and Randomization

Participants were randomized, prebirth, to either an incentive or control condition immediately following screening for participation and consent. Participants in the two conditions were offered the same smoking counseling, but Incentive participants were offered greater incentives for attending treatment visits and calls. FB staff used randomization tables prepared by the UW-CTRI to randomize women upon consent. Separate computer determined randomization tables were created based on race (White/non-White) and county with proportional randomization (1:1) into the incentive and control conditions.

Participant Recruitment

Potential participants were identified by FB providers at participating FB sites, which all serve pregnant women, and the provid-

ers encouraged participation in the study (see Figure 1 for the CONSORT diagram). Identification and enrollment of potential recruits by FB personnel occurred from September 2012 to April 2015 and was promoted by WWHF communications and outreach to FB sites. The WWHF offered these FB personnel training and technical assistance to facilitate their role in the recruitment. These FB sites (public health departments and private and community health clinics providing perinatal health care services across Wisconsin) are agencies affiliated with the WWHF. Originally designed to occur in FB agencies from only five target counties, recruitment was gradually expanded to 127 agencies in 35 counties in Wisconsin. Upon identification of a potential participant, FB providers provided contact information to WWHF staff who then screened and consented potential participants by phone during the prebirth period. The WWHF also directly recruited women into the research via direct community outreach (e.g., to community baby showers, health fairs), linking these women to a FB provider if they did not have one. Regardless of referral route, WWHF staff described the study to potentially eligible participants and screened all referrals for study eligibility by phone.

Inclusion criteria were female, pregnant, not involved in another stop smoking research study, and willingness to quit or cut down on smoking in the next 30 days (if not already quit) or, if already quit, desire to stay quit after the birth, daily smoker (at least one cigarette each day for at least one week) at some time point within the last 6 months, health insurance coverage by the Wisconsin Medicaid program, enrolled in a participating HMO, and willingness to engage in the study procedures. To be entered in Medicaid in Wisconsin an individual or family must be under federal poverty level guidelines: https://www.dhs.wisconsin.gov/medicaid/fpl.htm. Participants could enroll at any point during their pregnancy. Once FB staff obtained verbal consent, copies of the consent and other study information were mailed to each participant. Consent involved description of the minimum amount of payment that a participant would receive in her experimental condition. No comparison data on incentive compensation in the two conditions were provided.

Treatment and Assessment

Prebirth treatment contacts. Smoking cessation counseling began from the point of consent that occurred during pregnancy. A maximum of six prebirth visits were possible under the FB inter-

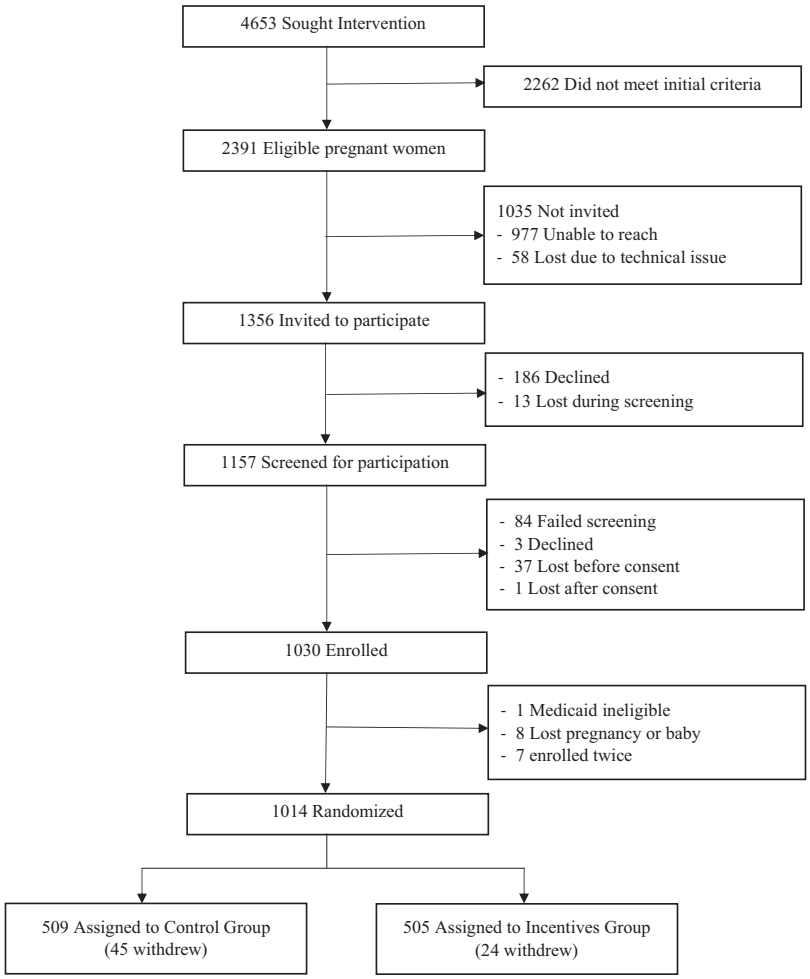

Figure 1. Consort diagram.

vention program (see Figure 2); these were scheduled on an ad hoc basis by each FB agency with a goal of conducting as many as practicable given the woman's point in gestation. Prebirth counseling treatment was based on the 2008 Public Health Service Clinical Practice Guideline (Fiore et al., 2008), was the same for the two experimental conditions, and was delivered at the participants' visits to FB agencies. In addition to smoking counseling, FB providers at prebirth visits also discussed women's social support, their stress level, and the importance of breastfeeding. Incentive condition participants received $25 for each prebirth counseling session (at the FB provider's agency/clinic) they participated in, while control condition participants received no incentives. FB providers delivered counseling at all prebirth visits were FB providers (nurses, medical assistants and health educators) who were employees of FB agencies and who had been trained by WWHF staff. These providers transmitted data to the WWHF on the dates of the tobacco cessation counseling sessions, and whether the sessions met length criteria for incentive delivery.

Postbirth treatment contacts. The smoking counseling and the schedule of contacts were the same for both the incentive and the control conditions. FB health educators who were employed by WWHF (vs. FB agencies), delivered all postbirth smoking counseling (see Figure 2) and reminded participants of incentive contingencies in each condition. The first postbirth home visit was scheduled to occur 1–3 weeks postbirth. The FB health educators-providers were at least bachelor's degree-level employees trained by WWHF in smoking cessation intervention and in the research protocol. Postbirth counseling was largely focused on smoking, and involved relatively little discussion of other topics such as breastfeeding. There were four home visits (30–60 min) and five calls (10–20 min) scheduled over the first 6-month postbirth (see Figure 1) with smoking counseling offered at all contacts. The calls were intended to be evenly spaced between visits, but scheduling was flexible in order to increase call completion. If possible, a participant had the same WWHF FB health educator for all visits and phone contacts. Although originally planned to last 12 months (11 contacts), the participation duration was reduced to 6 months to increase enrollment within the allotted funding period. The type and timing of FB contacts over the first 6-months postbirth were unaffected by the protocol change.

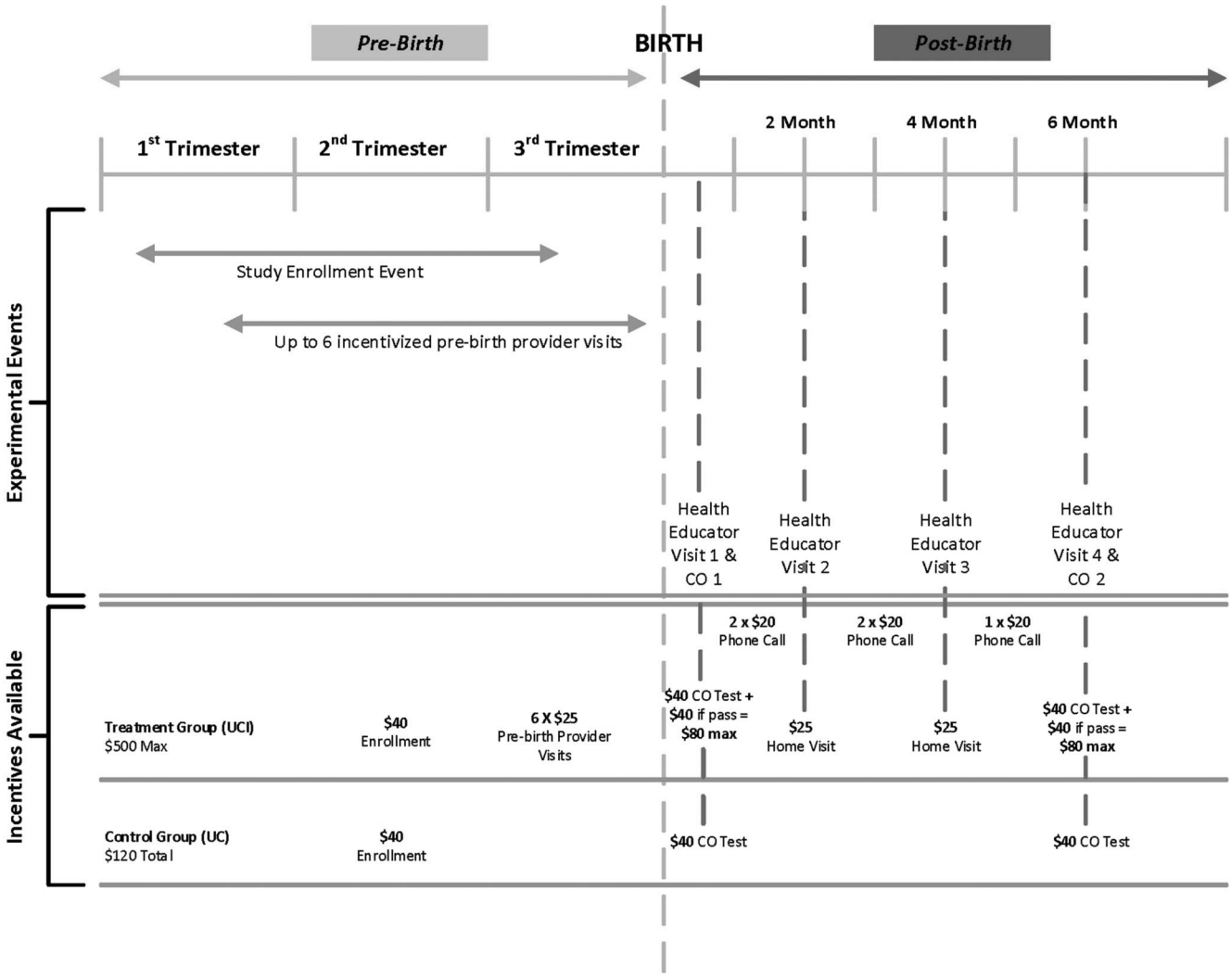

Figure 2. Treatment contacts and payments.

For both prebirth and postbirth counseling for both conditions, FB provider-counselors ("providers") used a manual based on the USPHS Guideline (e.g., including discussion of intrinsic motives to quit, recognition of smoking triggers, coping encouragement and planning, review of previous successes and challenges). Counseling rigor was supported by initial training, quarterly file reviews, and supervised home visits done by WWHF supervisors. WWHF providers received ongoing training involving monthly group refresher meetings (2 hours/month), quarterly supervised visit and file review (4 hours/quarter), annual in-service training (8 hours/year), and ad hoc one-on-one and group training as needed. For FB-only providers, required training included 2 hours of initial training and 1 hour of refresher training annually, while recommended training included one full-day training session annually, one half-day of supervised intervention practice annually, and 1 hour of continuing education webinars quarterly.

Incentive treatment. Figure 2 shows the schedule of incentive payments. The study compensated all participants $40 for study registration/enrollment and $40/visit for attendance at Postbirth Visit 1 (1–3 weeks postbirth) and Postbirth Visit 4 (at Month 6). Participants attending Visits 1 and 4 completed exhaled breath carbon monoxide (CO) testing to biochemically verify self-reports of abstinence from smoking; participants with CO test values of <7 ppm (ppm) were considered to be abstinent. Thus, control condition participants could receive up to $120. Incentive condition participants received a further $25/visit for any of the six prebirth visits they completed, $25/visit for attendance at Postbirth Visits 2 and 3, $20/call for completion of five postbirth calls, and $40/visit for biochemically confirmed abstinence at Postbirth Visits 1 and 4. Thus, incentive condition participants could receive up to a total of $500 for meeting all payment criteria. To receive the incentives for the treatment contacts, a minimum duration of 10 min for calls and 20 min for visits was used. Multiple attempts were made to schedule all calls and visits, with the same protocol being used in both treatment conditions. Incentive payments were triggered by WWHF tracking of visit and call completion and distributed by WWHF staff via mail (for prebirth visits and postbirth calls) or in-person (for postbirth visits). In each condition, the participants were regularly reminded during their clinical contacts of the payments that they would receive appropriate to their experimental condition.

Assessments. Assessments were administered at baseline (enrollment) and at all FB contacts (both phone and in person). At baseline, responses to the following were gathered: sociodemographic variables, smoking history, Medicaid ID# (required for mandated federal reporting), motivation and confidence to quit/reduce smoking, barriers to cessation, past quit attempts, general health information, and goals. A UW-CTRI baseline assessment also captured initial levels of relevant constructs: current depressive symptoms (Andresen, Malmgren, Carter, & Patrick, 1994; Vilagut, Forero, Barbaglia, & Alonso, 2016), the intent of the women to breastfeed (on a 1–10 confidence scale), and perceived social support (via the Wisconsin Social Support Scale; Gustafson et al., 2001). These assessments were tracked across the postbirth visits. A breath CO test was administered at the first postbirth contact and the 6-month visit. Self-reported smoking status was assessed at all FB program contacts. Postbirth assessments included the Wisconsin Smoking Withdrawal Scale (Welsch et al., 1999), smoking variables (e.g., maximum cigarettes per day [cpd] in the past week), motivation to quit, confidence in their ability to quit, extratreatment and intratreatment support for quitting, and mood and anxiety items. All assessment data gathered by FB staff were uploaded electronically to UW-CTRI researchers through secure Web based data collection and transmission (Qualtrics, Provo, UT).

Outcomes. The primary outcome was biochemically confirmed 7-day point-prevalence abstinence at the 6-month follow-up visit. For the primary outcome, a total of 316 of 509 (37.9%) control condition participants had missing data; a total of 145 of 505 (28.7%) incentive condition participants had missing data. Participants with missing data for the primary outcome were counted as smoking. Secondary outcomes included number of postbirth home visits and phone calls taken; biochemically confirmed abstinence at the Postbirth Week 1 visit; and self-reported smoking status at the 2- and 4-month visits.

Analytic methods. Treatment condition differences in binary abstinence outcomes were tested via logistic regression models and via risk differences (RDs; i.e., the difference between the Control and Incentive abstinence rates). CIs (95%) for RDs were calculated using Proc Freq (SAS Institute Inc) via the RISKDIFF option. ORs were computed so that incentive condition related increases in abstinence relative to the control condition were bounded positively from 1. Condition differences in treatment engagement (e.g., number of postbirth home visits and counseling calls) were tested using Proc GLM (SAS Institute, 2004). Mediation analyses were computed via the SAS PROCESS macro (Hayes, 2013). The a priori Type I error rate was set at .05.

The original grant proposal estimated power based on a total sample size of 3,100 participants but recruitment was slower than anticipated and the ultimate sample size was $N = 1{,}014$. Recalculation of power based on $N = 1{,}014$ for a potential effect size of 15% versus 25% yielded power >.95.

Results

Baseline Sample Characteristics

Table 1 shows that at baseline, the sample, on average, entered the study at the 14th week of gestation (median = Week 15), was young (mid-20's), about 50% racial minority, and the majority had at least a high school education. Nearly 60% smoked >10 cpd, more than half smoked within 30 min of waking, and about 50% lived with a smoker. The average score on the CES-D-10 was just over 10, slightly above the 8–10 score range for subclinical depression symptoms (Andresen et al., 1994).

Smoking Outcomes

Table 2 presents key smoking outcomes for the two groups.

Postbirth Visit 4 at 6 months. The incentive condition achieved modestly higher point prevalence abstinence at this follow-up time point than did the control group: 14.7% versus 9.2%, respectively (RD = −5.42, confidence interval [CI]: −9.40 to −1.44, $p < .01$). The self-reported abstinence rates (not biochemically confirmed) for the incentive and control conditions were 16.0% and 10.6%, respectively, RD = −5.3, CI: −9.60 to −1.26, $p < .02$.

Table 1
Baseline Sociodemographic and Smoking-Related Variables by Treatment Group

Variable	Treatment group	
	Control (n = 509)	Incentive (n = 505)
Week of gestation at entry into the study, *M* (*SD*)	14.7 (8.3)	14.7 (8.2)
Age, *M* (*SD*)	26.1 (5.1)	26.7 (5.4)
Race, %		
White	47.2%	45.4%
% Black or African American	36.9%	39.8%
% Asian	.8%	.2%
% American Indian/Alaska Native	2.0%	1.0%
% Other	2.8%	1.0%
% Refused/do not know/missing	7.5%	8.5%
Ethnicity		
% Hispanic	5.3%	4.8%
% Non-Hispanic	81.7%	81.8%
% Refused to answer/missing	13.0%	13.5%
Education		
% Less than high school	3.7%	4.2%
% Some high school	20.6%	20.6%
% High school or GED	34.2%	34.3%
% Some college or 2-year degree	25.55	22.0%
% College degree	3.0%	5.4%
% Refused to answer/missing	13.0%	13.7%
Marital status		
% Single	31.8%	32.3%
% In a relationship	27.9%	26.7%
% Living with a partner	16.1%	14.7%
% Married	7.9%	8.5%
% Widowed/divorced/other	1.8%	3.4%
% Refused to answer/missing	14.5%	14.55
Baseline heaviest cigarettes per day		
% 1–10 cigarettes	39.3%	38.4%
% 11–20 cigarettes	39.1%	39.4%
% >20 cigarettes	17.5%	19.4%
% Refused to answer/missing	4.1%	2.8%
Age first started smoking daily, *M* (*SD*)	16.4 (3.3)	16.3 (3.4)
FTCD Item 1		
% smoking within 30 Min	58.4%	54.7%
% Smoking after 30 min	24.8%	30.1%
% Refused to answer/missing	16.9%	15.3%
Living with a smoker, % yes	52.1%	50.1%
Prior use of nicotine replacement therapy, % yes	13.6%	12.1%
Prior use of varenicline, % yes	2.6%	2.6%
Prior use of bupropion, % yes	1.2%	1.4%
Tried to quit on own, % yes	15.9%	12.3%
Tried reduction in smoking, % yes	23.2%	26.1%
Confidence in quitting,[a] *M* (*SD*)	4.0 (1.1)	4.1 (1.1)
Motivation to quit,[b] *M* (*SD*)	4.3 (1.0)	4.3 (1.1)
CES-D-10,[c] *M* (*SD*)	10.6 (6.5)	10.8 (6.7)

Note. FTCD = Fagerstrom Test of Cigarette Dependence (Fagerstrom, 2012; Heatherton et al, 1991).
[a] Confidence in Quitting was rated on a 1 to 5 scale (1 = not at all; 5 = extremely confident about quitting). [b] I am Motivated to be Tobacco Free was rated on a 1 to 5 scale (1 = not at all; 5 = extremely motivated). [c] Center for the Epidemiological Studies of Depression Short Form (CES-D-10; Bjorgvinsson, et al., 2013).

Some participants were not currently smoking at baseline enrollment during their pregnancy. Among those *abstinent* at baseline (n = 199: 100 of 505 of incentive participants and 99 of 509 of control participants), biochemically confirmed 7-day point-prevalence abstinence rates at 6-months were 32% and 24.2% for the incentive and control conditions, respectively; RD = −7.76, CI: −20.20 to 4.70, p = .2237. Among those smoking at baseline (n = 815), the 7-day biochemically confirmed abstinence rates at 6-months for the incentive and control conditions were 10.4% and 5.6%, respectively; RD = −4.76, CI: −8.47 to −1.05, p < .02.

Visit 4 was scheduled to occur at about 180 days postbirth. The incentive and control participants attended this visit a mean of 204 (*SD* = 23.8) and 205 (*SD* = 26.3) days postbirth, respectively (F = 0.27, df = 1,674, p > .05).

Postbirth Visits 1–3 at Week 1and Months 2 and 3. The 7-day biochemically confirmed abstinence rates at Visit 1 were 17.0% versus 13.4%, for the Incentive and Control conditions respectively, RD = −3.67, CI = −8.08 to 0.74, p = .1035. Data for postbirth Visits 2 and 3 are presented in Table 2.

Other Visit-Based Outcomes

Incentive participants reported a lower maximum cpd across all four time points than did the controls: for Visits 1–4, means for the two conditions were, respectively, Visit 1 = 5.29 versus 6.00 (n = 739); Visit 2 = 4.97 versus 6.04 (n = 641); Visit 3 = 5.00 versus 6.00 (n = 585); and Visit 4 = 4.83 versus 6.32 (n = 673); differences were significant across Visits 2–3 (Fs = 3.96–20.8, ps = .047-.0001). Results also showed that even among individuals not claiming abstinence at 6-months follow-up, Incentive participants reported smoking fewer cigarettes (the maximum cpd) than did controls *M*s = 6.08 (*SD* = 5.1) versus 8.01 (*SD* = 6.11), respectively; F = 16.31 (1, 552), p < .0001.

The incentive participants reported significantly higher motivation to quit smoking and greater confidence in ability to quit than did control participants at Visit 4. For motivation to quit smoking the ratings for the incentive and control conditions = 4.41 versus 4.20 (n = 674), F = 7.82, p = .005. For confidence in ability to quit, the Visit 4 ratings for the two conditions, respectively, were = 4.18 versus 3.97 (n = 670), F = 20.16, p < .01. The two conditions did not differ significantly on other measures gathered at visits, including measures of withdrawal, support, and depression.

Treatment Engagement

Prebirth treatment engagement. Incentive group participants completed a mean of 1.2 (*SD* = 1.4, n = 509) prebirth visits, whereas the control condition completed a mean of 0.9 visits (*SD* = 1.6, n = 505); medians for the two conditions were 1 and 0, respectively, a difference that was significant with the Kruskal-Wallis test (χ^2 = 5.6, p = .018).

Postbirth treatment contacts. Attendance rates for each of the four postbirth home visits for the incentive and control conditions are shown in Table 3. Incentive participants completed a greater mean number of postbirth home visits than did controls (2.96 [*SD* = 1.4] vs. 2.27 [*SD* = 1.5], respectively), F = 57.1, df = 1,1012, p = .0001.

Table 3 also shows the attendance rates for each of the 5 counseling calls. The mean numbers of calls taken by members of the two conditions were 3.5 (*SD* = 1.8, n = 505) for the incentive condition and 2.4 (*SD* = 1.7, n = 509) for the control condition (F = 102.2, df = 1,1012, p < .0001).

Table 2
Postbirth 7-Day Point-Prevalence Abstinence Outcomes by Treatment Group

Postbirth endpoint	Abstinence rates, *n* abstinent/total (%)		Abstinence risk difference (95% CI), *p* value[b]	Unadjusted odds ratio (95% CI)[c]
	Control	Incentive	Control vs. incentive	Control vs. incentive
Home Visit 1—1 Week Postbirth CO-confirmed[a]				
7-day point-prevalence abstinence rates	68/509 (13.36%)	86/505 (17.03%)	−3.67 [−8.08, .74], $p = .1035$	1.33 [.94, 1.88]
Home Visit 2—2 months postbirth self-reported				
7-day point-prevalence abstinence rates	44/509 (8.64%)	87/505 (17.23%)	−8.58 [−12.68, −4.48], $p < .0001$	2.20 [1.50, 3.24]
Home Visit 3—4 months postbirth self-reported				
7-day point-prevalence abstinence rates	40/509 (7.86%)	85/505 (16.83%)	−8.97 [−12.99, −4.96], $p < .0001$	2.37 [1.59, 3.53]
Home Visit 4—6 months postbirth CO-confirmed[a]				
7-day point-prevalence abstinence rates	47/509 (9.23%)	74/505 (14.65%)	−5.42 [−9.40, −1.44], $p < .01$	1.69 [1.14, 2.49]

Note. CI = confidence interval.
[a] Biochemical test of abstinence based on breath carbon monoxide (CO) test (passing based on CO value less than 7 parts per million). [b] Pairwise comparisons of Abstinence Risk Differences were tested via Proc Freq (SAS Institute) by specifying the RISKDIFF option which provides standard Wald asymptotic confidence limits for the risks. [c] Unadjusted odds ratios based on logistic regression analysis.

Incentive Payments

All participants received an initial $40 payment for enrollment, which is not included in the following analyses. Incentive participants received an average of $29.16 for attendance at prebirth visits, $69.45 for postbirth calls, $88.99 for attendance at postbirth visits, and $26.21 for meeting CO abstinence criteria at Visits 1 and/or 4. Control participants received a mean of $53.05 for attendance at Postbirth Visits 1 and 4. Total mean payments made to participants in the two conditions across both prebirth and postbirth periods (excluding the initial $40 registration payment) were $213.83 for the incentive condition and $53.05 for the control condition.

Mediation

Mediation analyses used biochemically determined abstinence at 6 months ($N = 1{,}014$) as the outcome and the total number of postbirth home visits and counseling calls as the mediator. Analyses focused on whether the increase in visits and calls taken by incentive versus control participants could account statistically for the former condition's higher abstinence rate (14.65 vs. 9.23%, respectively). A simple logistic regression (nonmediational) model revealed that treatment condition affected 6-month abstinence, $c = -0.52$, $p < .01$. When number of visits was entered in the full mediational model (see Figure 3), the path (unstandardized regression coefficient) from treatment condition to number of visits (a) was significant ($a = 1.80$, $p < .0001$), as was the path from the number of visits to 6-month abstinence ($b = -0.32$, $p < .0001$). However, the direct path from treatment condition to outcome (c') was no longer significant in the full model ($c' = -0.02$, $p = .9070$). The indirect, mediated effect of number of calls (the product of paths a and b) was significant ($ab = -0.57$, $p < .0001$).

Discussion

This research evaluated the effects of an incentive program that was used as an adjuvant to an ongoing, real-world smoking intervention program for low-income (Medicaid registered) pregnant smokers (FB). The bulk of the incentives was contingent upon treatment engagement, not abstinence. The FB and incentive program were intended to promote and maintain cigarette abstinence during the postbirth period when relapse back to smoking is common (Harmer & Memon, 2013; Jones et al., 2016; Tran et al., 2013). The incentive program was designed so that it would possess external validity and dissemination potential. Therefore, it

Table 3
Number and Percentage of Participants Attending Each Postbirth Visit and Counseling Call in the Incentive and Control Conditions

Postbirth visit or call[a]	Attendance at postbirth visits, *n* (%)		Attendance at postbirth counseling calls, *n* (%)	
	Control ($n = 509$)	Incentive ($n = 505$)	Control ($n = 509$)	Incentive ($n = 505$)
1	359 (70.5%)	386 (76.4%)*	253 (49.7%)	343 (67.9%)***
2	261 (51.3%)	382 (75.6%)***	268 (52.7%)	348 (68.9%)***
3	221 (43.4%)	366 (72.5%)***	224 (44.0%)	362 (71.7%)***
4	316 (62.1%)	360 (71.3%)**	230 (45.2%)	346 (68.5%)***
5	—	—	228 (44.8%)	355 (70.3%)***

[a] There were a maximum of four post-birth visits and a maximum of five counseling calls.
* $p < .05$. ** $p < .01$. *** $p < .001$.

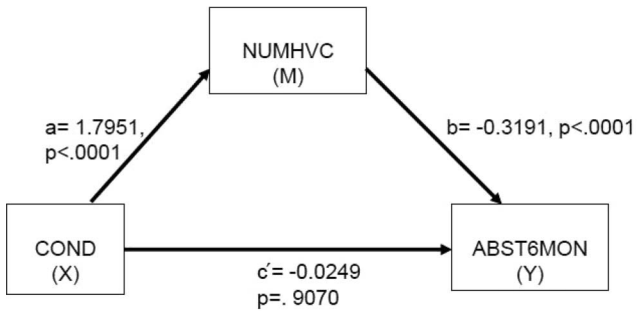

Figure 3. Mediation analysis. a, b, and c' = unstandardized regression coefficients. The path c' = direct effect of X on Y; c' estimates the difference between group means holding M constant (adjusted mean difference in analysis of covariance terms). M = total number of postbirth visits and calls completed.

did not require frequent meetings to secure biochemical evidence of abstinence, it used incentives of relatively modest magnitude (i.e., a total possible payment of $500, including a possible $460 after study enrollment, and an average delivered payment of $213.83/participant), and it was delivered by nonresearch clinical staff (of FB), which should enhance scalability (Glasgow, Vogt, & Boles, 1999; Riley, Glasgow, Etheredge, & Abernethy, 2013).

Incentive participants achieved higher rates of biochemically confirmed, 7-day point prevalence abstinence at 6-months postbirth than did controls. Incentive participants were also more likely to self-report 7-day point-prevalence abstinence at Postbirth Months 2 and 4 than were controls. Data suggested that the incentive condition significantly increased quitting among those who were smoking prebirth, and there was suggestive evidence that it successfully maintained abstinence among those who had quit in the prebirth period (not significant: the *N* was small for this comparison). Incentive condition participants also reported smoking fewer cigarettes/day even among those who were continuing to smoke. In all, the results suggest that the incentive intervention both helps abstinent smokers maintain their abstinence postbirth, helps smokers become abstinent postdelivery, and helps reduce smoking heaviness among those continuing to smoke.

The incentives were intended to increase treatment engagement. Indeed, incentive condition participants attended more prebirth treatment visits, more postbirth treatment visits, and took more postbirth phone calls than did the control participants. They also withdrew from the experiment at a lower rate than did control participants (see Figure 1). A mediational model showed significant mediational paths from treatment condition to number of postbirth home visits and calls, and from postbirth home visits and calls to 6-month abstinence. This analysis, therefore, supports the hypothesis that the incentives enhanced smoking cessation success by increasing treatment engagement.

Although the incentive treatment significantly increased 6-month abstinence rates, the effects were fairly modest. The biochemically confirmed 7-day point-prevalence abstinence rates at 6-months postbirth were 14.7% versus 9.2% for the incentive and control conditions, respectively. Such a 5% increase in abstinence rates could benefit public health, however. Smokers in this population are fairly young (26 on average), have infants and children in their homes, and face numerous other risk factors for smoking-related disease and disability. Their continued smoking could cause persistent harms to their offspring (Goodwin et al., 2017). Thus, the great human, health, and economic consequences of smoking in this population may make even modest effects highly important (Bakker & Jaddoe, 2011; Centers for Disease Control & Prevention, 2002; Cnattingius, 2004; Dietz et al., 2010; Holz et al., 2014). However, the FB smoking intervention program is fairly intense and expensive, involving up to four postbirth visits and five postbirth phone calls. And, although the incentive payments were relatively modest, their cost-effectiveness in this population relative to mass media campaigns is unknown.

The modest levels of abstinence observed in this study no doubt reflect the great difficulty in boosting abstinence in this population due to the numerous challenges they face: for example, high levels of stress due to poverty, coping with the challenges of a newborn, high levels of smoking in their social networks (see Table 1), their relative youth (see Diclemente, 2016), and dysfunctional beliefs about smoking (B. Christiansen, Reeder, Fiore, & Baker, 2014; B. A. Christiansen, Reeder, TerBeek, Fiore, & Baker, 2015). Such challenges no doubt account for the fact that smoking rates have not decreased in the Medicaid population over the past 20 years, despite large decreases in smoking prevalence among smokers in general (Zhu, Anderson, Zhuang, Gamst, & Kohatsu, 2017). In sum, the strategy of incentivizing treatment use may overcome some of the barriers to population based use of incentive therapy, especially as they occur for low-income smokers (Hand et al., 2014), and thereby aid a population faced with especially high rates of smoking and smoking related harms (Goodwin et al., 2017). If the benefits of incentivizing intervention contacts are replicated, it would be important to conduct future research that examines a range of incentive values for this approach and that compares it with other intervention strategies, including clinical and population based interventions, on the bases of cost-effectiveness and cost-benefit. It is important to note that the control participants received meaningful incentives for attendance at visits where treatment was delivered ($40/visit for attending Postbirth Visits 1 and 4 where biochemical ascertainment of smoking status occurred). It is possible that the effect sizes obtained would have been larger if the control participants had not also received some incentives for visit attendance. That is, there is no true nonincentive control condition.

This research has several limitations. It is possible that some participants quit or reduced their smoking just prior to the 6-month visit. Breath CO, which was used in this trial, has a relatively brief half-life; serum cotinine might have been more sensitive to detecting temporally remote smoking (Benowitz, Hukkanen, & Jacob, 2009; Benowitz, Jacob, Fong, & Gupta, 1994; Benowitz et al., 2002). Women had limited exposure to prebirth intervention despite their entry into the study at an average of 14 weeks of gestation. This limited exposure might have reduced the effects of the incentive intervention on abstinence. The low rate of attendance at the prebirth versus the postbirth contacts appears to be due to the fact that only the former required travel to the participating agencies. According to agency feedback, this population has a high no-show rate for prebirth clinic visits. There is also the possibility that FB staff were less likely to report patient contacts than were the WWHF staff who conducted postbirth contacts. Also, this was a pragmatic trial and thus there was no ongoing objective assessment (e.g., via analyses of recordings) of the counseling content. Finally, the mediational analysis did not control for smoking during the period of postbirth visit attendance. Therefore, failure in quitting might have caused disengagement from treatment rather than vice versa. In essence, the outcomes of the mediational analysis do not permit strong inference regarding causality.

This research shows that incentives for treatment engagement and abstinence significantly, but modestly, increased biochemically confirmed abstinence among low-income (Medicaid-registered) women six months after they had given birth. The incentives also increased treatment engagement and this effect appeared to account statistically for the effects of incentives on long-term abstinence. Finally, the incentive program was designed to permit ready dissemination; the potential incentive payments were relatively modest, the program did not require frequent monitoring of smoking status, and it was used as an adjunct to a real world, ongoing health program for low-income women and infants.

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