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Examining two different schedules of financial incentives for smoking cessation among pregnant women[☆]

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ABSTRACT

Objective. To examine whether an efficacious voucher-based incentives intervention for decreasing smoking during pregnancy and increasing fetal growth could be improved without increasing costs. The strategy was to redistribute the usual incentives so that higher values were available early in the quit attempt.

Method. 118 pregnant smokers in greater Burlington, Vermont (studied December, 2006–June, 2012) were randomly assigned to the revised contingent voucher (RCV) or usual contingent voucher (CV) schedule of abstinence-contingent vouchers, or to a non-contingent voucher (NCV) control condition wherein vouchers were provided independent of smoking status. Smoking status was biochemically verified; serial sonographic estimates of fetal growth were obtained at gestational weeks 30–34.

Results. RCV and CV conditions increased point-prevalence abstinence above NCV levels at early (RCV: 40%, CV: 46%, NCV: 13%, $p = .007$) and late-pregnancy (RCV: 45%; CV: 36%; NCV, 18%; $p = .04$) assessments, but abstinence levels did not differ between the RCV and CV conditions. The RCV intervention did not increase fetal growth above control levels while the CV condition did so ($p < .05$).

Conclusion. This trial further supports the efficacy of CV for increasing antepartum abstinence and fetal growth, but other strategies (e.g., increasing overall incentive values) will be necessary to improve outcomes further.

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Cigarette smoking is the leading preventable cause of poor pregnancy outcomes in the U.S. and other industrialized countries, increasing risk for catastrophic pregnancy complications as well as adverse effects that extend into childhood and beyond (Cnattingius, 2004; Cohen et al., 2010; Kandel et al., 2009; Rogers, 2008; Stene-Larsen et al., 2009). These adverse effects are medically serious and an economic drain on health care systems. For all of these reasons, more effective smoking-cessation interventions for pregnant women are sorely needed. Another reason why improvements are needed is that economically disadvantaged women have disproportionately high rates of smoking during pregnancy (Higgins et al., 2009; Kandel et al., 2009) and thus more effective cessation interventions can aid in efforts to decrease the unsettling

problem of health disparities (e.g., CDC, 2010; Higgins and Chilcoat, 2009).

Interventions that use financial incentives increase antepartum cessation rates several fold above control levels while also increasing fetal growth (Higgins et al., 2012; Lumley et al., 2009). While incentive-based interventions are promising, there is ample room for improvements. In prior trials, only about 35–40% of women treated with incentives achieved antepartum abstinence (Heil et al., 2008; Higgins et al., 2004a, 2010). The present trial was conducted with the goal of improving outcomes achieved with an efficacious voucher-based incentive intervention without increasing the overall costs of the incentives (~\$1180 maximal earnings). Instead, the schedule of incentives was revised to provide higher monetary value incentives early in the quit attempt as early success predicts late-pregnancy abstinence (Higgins et al., 2006). Thereafter, the value of incentives was reduced from the usual levels such that overall potential maximal earnings remained unchanged. Counseling intensity was also increased above levels in prior incentive trials with the rationale that it might improve

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general treatment responsiveness (Fiore et al., 2008; Windsor et al., 1985, 1993).

Method

Participants

Participants were recruited from obstetric practices and the Women, Infants, and Children (WIC) office in Burlington, VT. Study inclusion criteria were smoking in the past 7 days, gestational age ≤ 25 weeks, reside within the county in which clinic is located, plan to remain in the geographical area for ≥ 6 months following delivery, and English speaking. Exclusion criteria were incarceration, previous participation in a voucher-based incentive trial for smoking cessation, currently residing with a trial participant, and regular use of opioid, psychomotor stimulant, or antipsychotic medications.

All women receiving prenatal care at referring clinics completed a brief questionnaire on smoking status. A total of 297 women were deemed potentially eligible for the study and successfully contacted by study staff (Fig. 1). One hundred thirty (44%) were enrolled; 63 (21%) expressed interest, but failed to complete the enrollment process; 104 (35%) refused participation. Among women who agreed to participate, 44 were randomly assigned to the revised contingent voucher (RCV) condition, 44 to the usual contingent voucher (CV) condition, and 42 to the non-contingent voucher (NCV) control condition. The only criterion for withdrawing someone from the trial following treatment assignment was pregnancy termination/fetal demise; 12 women (4 RCV, 5 CV, and 3 NCV) were withdrawn based on that criterion, leaving 118 women whose results were used in the primary analysis on smoking status (Table 1). The University of Vermont Institutional Review Board approved this study and all participants provided written informed consent.

Assessments

Participants completed questionnaires examining sociodemographic, smoking, and psychiatric characteristics, and provided breath and urine specimens at a study-intake assessment. Modified versions of this battery were completed one month after the intake assessment (early-pregnancy assessment), at the end of pregnancy (≥ 28 weeks gestation; late-pregnancy assessment), and at 2-, 4-, 8-, 12-, and 24-weeks postpartum. At these

assessments and throughout the abstinence-monitoring period (see below), breath specimens were analyzed using carbon monoxide (CO) monitors and urine cotinine levels determined using onsite enzyme immunoassay testing. To be considered a non-smoker at these assessments, a woman had to report no smoking for the past seven days and meet the urine-cotinine abstinence criterion.

Treatment interventions

Abstinence-monitoring schedule

Upon study entry, women chose one of the next two Mondays as a quit date. All participants were requested to attend the clinic or be met by a staff member at an alternate site for the initial 5 days of the cessation effort; in week 2, monitoring decreased to 2 \times /weekly (Mondays & Thursdays) for next 7 weeks, then weekly (Wednesdays) for 4 weeks, and then once every other week (every other Wednesday) until delivery in the CV and NCV conditions, but in the RCV condition the schedule was every other week through week 12 and then every third week through delivery to equate potential earnings across the three conditions. Following delivery all three conditions were back on the a weekly monitoring schedule for 4 weeks, followed by every other week through 12-weeks postpartum when regular abstinence monitoring ended save for a 24-week follow-up assessment. Women who failed to achieve abstinence or relapsed could (a) continue trying to achieve abstinence as the frequency of monitoring was leaned or (b) recycle back through the entire progression. The latter recycling option was only available once per woman, and was used comparably in the RCV, CV, and NCV conditions (40%, 46%, and 41% of women, respectively).

Other services

Participants received usual care for smoking cessation provided through their obstetric clinics. Study staff provided additional cessation counseling to all participants during four visits within two weeks of study entry, at the final antepartum visit, and during three postpartum study visits. For women who quit during pregnancy, brief counseling also occurred during routine smoking-status monitoring visits whenever temptations to smoke were reported. As a counseling guide, we used a printed booklet tailored for pregnant smokers (ACOG, 2001). This additional cessation counseling was not included in our prior trials (Higgins et al., 2012).

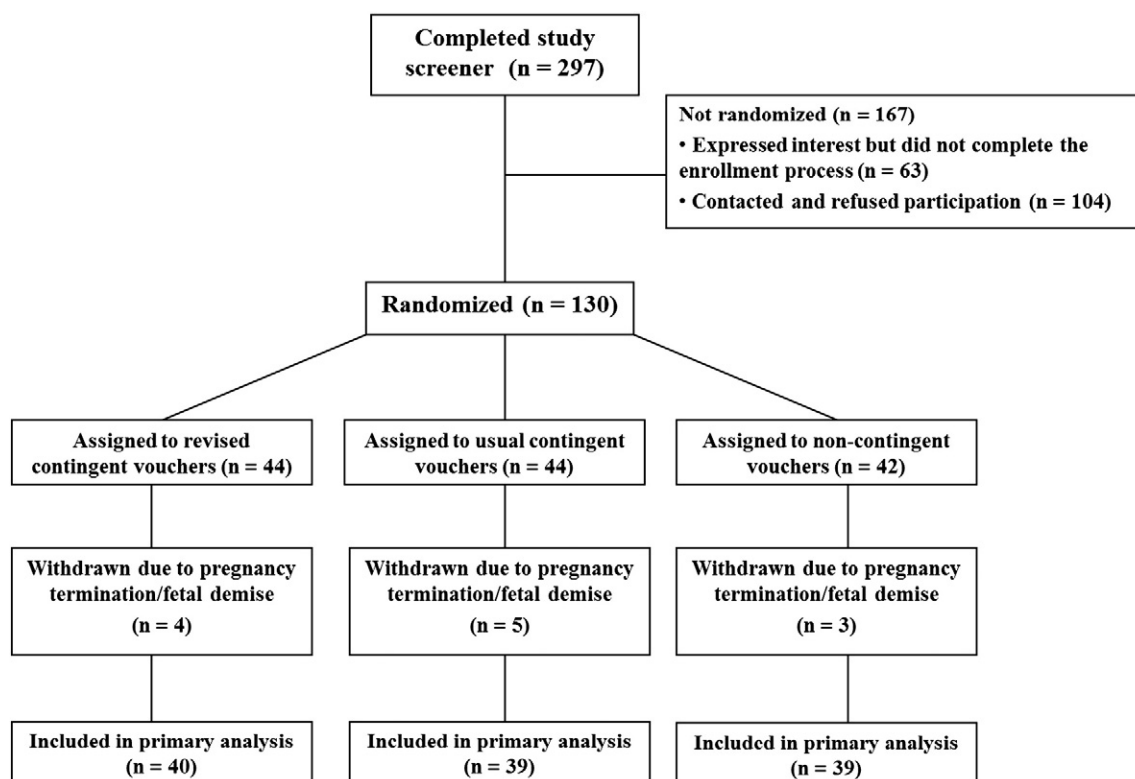


Fig. 1. The flow of participants through the study. Participants were pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

Table 1
Participant characteristics.

	Revised contingent vouchers (n = 40)	Contingent vouchers (n = 39)	Non-contingent vouchers (n = 39)	p-Value
Demographics				
Age (years)	24.1 ± 4.2	24.9 ± 5.1	24.7 ± 5.4	.75
% Caucasian	90	100	89	.11
Education				.63
% > 12 years of education	23	18	23	
% = 12 years of education	62	67	51	
% < 12 years of education	15	15	26	
Weeks pregnant at baseline	10.0 ± 4.2	10.1 ± 4.1	10.7 ± 4.5	.74
% primigravida	67	62	64	.89
% married	10	18	21	.41
% with private insurance	32	20	18	.27
% working for pay outside of home	70 ^a	38 ^b	56 ^{ab}	.02
Smoking characteristics				
Age first started smoking cigarettes	14.9 ± 3.4	16.3 ± 3.1	15.2 ± 2.1	.09
Cigarettes per day pre-pregnancy	17.7 ± 8.8	19.5 ± 7.7	17.8 ± 8.7	.55
Cigarettes per day at baseline	9.5 ± 5.8	8.7 ± 7.6	7.8 ± 5.3	.49
% living with another smoker	82	85	77	.66
% with no smoking allowed in home	55	67	61	.57
% with none or few friends/family who smoke	22	28	31	.70
% attempted to quit pre-pregnancy	80	77	62	.14
Number of quit attempts during pregnancy	0.8 ± 1.6	0.6 ± 1.3	0.5 ± 1.1	.54
Minnesota Nicotine Withdrawal Scale total score	1.6 ± 0.8	1.4 ± 0.7	1.5 ± 0.9	.58
Psychiatric symptoms				
Stress rating	6.3 ± 2.8 ^a	4.8 ± 2.5 ^b	5.8 ± 2.5 ^{ab}	.04
Beck Depression Inventory	11.1 ± 7.0	9.8 ± 7.4	10.8 ± 7.1	.38
% history of depressive symptoms	42	36	46	.65

Note: Values represent means ± SD unless otherwise indicated. Means/percentages with a common letter do not differ significantly at $\alpha \leq .05$ in pairwise comparisons. Participants were 118 pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

Usual contingent voucher (CV) condition

Vouchers redeemable for retail items were earned contingent on submitting breath CO specimens ≤ 6 ppm during the initial five days of the cessation effort. Beginning in Week 2, vouchers were delivered contingent on urine-cotinine levels ≤ 80 ng/ml, a criterion that required a longer duration of smoking abstinence than breath CO (Higgins et al., 2007a). Voucher delivery was independent of self-reported smoking status and based exclusively on meeting the biochemical-verification criterion. Unauthorized failure to complete a scheduled assessment was treated as a positive test result consistent with an intent-to-treat approach (Friedman et al., 1998). Vouchers began at \$6.25, and escalated by \$1.25 per consecutive negative specimen to a maximum of \$45.00, where they remained barring positive test results or missed abstinence monitoring visits. Positive test results or missed visits reset the voucher value back to the original low value, but two consecutive negative tests restored the value to the pre-reset level.

Revised contingent voucher (RCV) condition

The same voucher schedule as outlined above was followed in this RCV condition except that potential earnings were rescheduled, moving \$296.25 forward as bonuses available during Weeks 1–6 by meeting a ≤ 4 ppm breath CO criterion during Week 1, testing cotinine negative at the first urine test on the 2nd Monday of the quit attempt, and thereafter by submitting two cotinine-negative specimens per week through Week 6. More specifically, bonuses earned by reaching a cutoff of ≤ 4 ppm CO during Week 1 started at \$18.75 and increased by \$3.75 for each successive negative sample reaching a maximum potential bonus of \$33.75 for the 5th consecutive negative specimen meeting the ≤ 4 -ppm CO cutoff during Week 1. Women in this condition earned the same incentive as in the CV condition if they met the ≤ 6 ppm CO but not the ≤ 4 ppm cutoff in Week 1. The goal was to provide bonuses for those who could achieve this more stringent criterion and thus decrease the likelihood of low-level smoking that can undermine longer-term abstinence (Higgins et al., 2006), but assure that a woman still received an incentive if she met the slightly more liberal ≤ 6 ppm criterion effective in prior trials (Higgins et al., 2012). Testing cotinine-negative on the 2nd Monday resulted in an additional bonus of \$87.50 above usual CV incentive earnings on that date. Five more bonuses of \$15.50 each were available on Thursdays (2nd test day of each week) during Weeks 2–6 if a woman also had tested negative for smoking at the earlier test conducted that same week. This set of bonuses was designed to reinforce an initial period of continuous abstinence based upon results from our prior studies (Higgins et al., 2006, 2007a).

Non-contingent voucher (NCV) control condition

In this condition, vouchers were delivered independent of smoking status. Voucher values were \$15.00 per visit antepartum and \$20.00 per visit postpartum, values that resulted in payment amounts comparable to average earnings in the CV condition in prior trials (Heil et al., 2008). All else was the same as in the CV and RCV conditions.

Serial ultrasound examinations and birth outcomes

Two serial ultrasound examinations were performed at approximately 30 and 34 week gestation to estimate fetal growth. Serial ultrasound assessments generated individualized estimates of fetal growth in the mid third trimester that could be compared between treatment conditions. The analysis of repeated measures afforded by serial ultrasound provides greater statistical power than related measures collected at a single time point (e.g., birth weight), and is sensitive to incentive-based smoking cessation interventions (Heil et al., 2008). Seventy women completed both assessments (25 RCV, 25 CV, 20 NCV). Measures included estimates of biparietal diameter, head circumference, abdominal circumference, and femur length obtained by an obstetrician who was blind to participant treatment condition and smoking status using standardized techniques. Head circumference, abdominal circumference and femur length were combined according to the method of Hadlock et al. (1985) to calculate estimated fetal weight gain. Estimates were also made of lean body mass accretion in the fetal thigh employing previously reported techniques (Bernstein et al., 1997). All measurements were performed in triplicate and the mean value was assigned as the best estimate of the specific parameter.

Infant birth outcomes were obtained from the maternal medical record.

Statistical methods

The primary analysis of smoking status was based on all participants randomized with the exception of women withdrawn due to pregnancy termination/fetal demise ($n = 118$) (Friedman et al., 1998). Two women delivered twins and were omitted from analyses of birth outcomes. Fetal growth outcomes were based on 70 women who delivered singletons and completed both ultrasound assessments. Treatment conditions were compared on participant characteristics using chi-square tests for categorical measures and analysis of variance for continuous measures. For outcomes with a significant overall p-value, pairwise comparisons were examined using least significant difference (LSD) tests for continuous outcomes and pairwise chi-squares for

the categorical outcomes. Logistic regression was used to compare treatment conditions on point prevalence abstinence and dichotomous birth outcomes and analysis of variance was used to compare them on antepartum negative smoking-status tests and gestational age at delivery. Significant F-tests were followed with pairwise comparisons using *t*-test and effect sizes (Cohen's *d*, with 95% confidence limits). Analysis of covariance was used to compare treatment conditions on birth weight using pre-pregnancy BMI as a covariate and to compare treatment conditions on fetal growth, using fetal sex and gestational age at first ultrasound as covariates. Two baseline characteristics (age first started smoking cigarettes and ratings (0–10) of stress for past week) were also included as covariates in that analysis as they differed significantly between treatment conditions and were correlated with fetal growth outcomes. All analyses were performed using SAS Version 9 statistical software (SAS Institute, Cary NC). Statistical significance was determined based on $p \leq .05$.

Results

Participant characteristics

Only two characteristics differed significantly between treatment conditions: more of those assigned to the RCV condition worked outside the home compared to the CV but not the NCV conditions, and those assigned to the RCV condition reported higher mean ratings of stress across past week than those assigned to the CV but not the NCV conditions (Table 1). These two characteristics were not significantly correlated with smoking abstinence or birth outcomes. We also compared participant characteristics among women who completed both ultrasound assessments (Table 2). The difference in mean stress ratings noted in the overall sample remained significant in this subgroup and the age of smoking initiation differed as well.

Smoking abstinence

The RCV and CV incentive conditions increased antepartum 7-day point prevalence abstinence levels above those observed in the NCV control condition (Fig. 2). There were significant treatment effects at the early-pregnancy assessment (Wald $\chi^2 [2] = 9.8$, $p = .007$), with 40.0%, 46.1%, and 12.8% of women assigned to the RCV, CV, and NCV

conditions abstinent, respectively (Fig. 2, upper panel). In pairwise comparisons, women assigned to the RCV condition differed from those assigned to NCV condition ($p = .01$, OR = 4.5, 95% CI = 1.5–14.1), and the CV condition differed from NCV as well ($p < .01$, OR = 5.8, 95% CI = 1.9–18.0). Those assigned to the two incentive conditions did not differ from each other ($p = .58$, OR = 0.78, 95% CI = 0.3–1.9). Abstinence differences at the late-pregnancy assessment followed a similar pattern (Wald $\chi^2 [2] = 6.4$, $p = .04$), with 45.0%, 35.9%, and 18.0% of women assigned to the RCV, CV, and NCV conditions abstinent, respectively (Fig. 2, lower panel). In pairwise comparisons, the RCV condition differed significantly from the NCV condition ($p = .01$, OR = 3.7, 95% CI = 1.3–10.5) while the difference between CV and NCV trended in the same direction ($p = .08$, OR = 2.6, 95% CI = 0.9–7.3). Again, the two incentive conditions did not differ from each other ($p = .41$, OR = 1.5, 95% CI = 0.6–3.6).

We also compared treatment conditions on the mean percentage of all antepartum toxicology tests negative for smoking and the largest number of consecutive negative tests (Fig. 3, upper and lower panels, respectively). Negative toxicology tests included CO-negative specimens ($CO \leq 6$) during the initial week of treatment and cotinine-negative specimens (≤ 80 ng/ml) during all subsequent antepartum abstinence monitoring visits. Regarding mean percentage of negative tests, women assigned to the RCV, CV, and NCV conditions averaged 56.0%, 55.4%, and 31.0% negative tests, respectively ($F [2,115] = 6.2$, $p = .003$). In pairwise comparisons, those assigned to the RCV condition differed from those in the NCV condition ($p < .01$, Cohen's $d = 0.70$, 95% CI = 0.24–1.15) and those assigned to the CV condition also differed from those assigned to the NCV condition ($p < .01$, Cohen's $d = 0.68$, 95% CI = 0.22–1.13). The two incentive conditions did not differ from each other ($p = .91$, Cohen's $d = 0.01$, 95% CI = -0.43 – 0.45). Regarding mean (+SEM) consecutive negative tests, those assigned to the RCV, CV, and NCV conditions averaged 10.9 ± 1.3 , 14.8 ± 2.0 , and 5.8 ± 1.1 consecutive negative toxicology tests ($F [2,115] = 8.5$, $p < .001$), respectively. In pairwise comparisons, those assigned to RCV differed from those assigned to the NCV conditions ($t [1,115] = 2.4$, $p = .02$; Cohen's $d = 0.53$, 95% CI = 0.08–0.98) and those assigned to the CV condition differed from

Table 2
Participant characteristics among those who completed ultrasound assessments.

	Revised contingent vouchers (n = 25)	Contingent vouchers (n = 25)	Non-contingent vouchers (n = 20)	<i>p</i> -Value
Demographics				
Age (years)	24.5 \pm 4.7	24.7 \pm 4.1	24.1 \pm 4.0	.89
% Caucasian	96	100	85	.09
Education				.69
% > 12 years of education	29	20	25	
% = 12 years of education	54	68	50	
% < 12 years of education	17	12	25	
Weeks pregnant at baseline	11.0 \pm 4.7	9.9 \pm 4.3	10.8 \pm 4.9	.69
% Primigravida	60	64	60	.95
% married	16	24	15	.68
% with private insurance	32	28	20	.66
% working for pay outside of home	64	48	50	.47
Smoking characteristics				
Age first started smoking cigarettes	14.6 \pm 2.6 ^b	16.7 \pm 3.3 ^a	14.7 \pm 2.2 ^b	.02
Cigarettes per day pre-pregnancy	17.2 \pm 8.0	19.9 \pm 8.8	16.9 \pm 6.6	.37
Cigarettes per day at baseline	9.8 \pm 5.7	7.0 \pm 5.8	7.2 \pm 5.0	.17
% living with another smoker	84	80	70	.51
% with no smoking allowed in home	44	60	65	.32
% with none or few friends/family who smoke	20	24	30	.74
% attempted to quit pre-pregnancy	84	84	65	.22
Number of quit attempts during pregnancy	0.7 \pm 1.2	0.8 \pm 1.5	0.6 \pm 1.1	.82
Minnesota Nicotine Withdrawal Scale total score	1.9 \pm 0.8	1.5 \pm 0.8	1.7 \pm 0.8	.35
Psychiatric symptoms				
Stress rating	6.9 \pm 2.4 ^a	5.2 \pm 2.6 ^b	5.6 \pm 2.4 ^{ab}	.05
Beck Depression Inventory	13.1 \pm 7.5	10.9 \pm 8.5	12.0 \pm 7.1	.62
% history of depressive symptoms	52	52	40	.66

Note: Values represent mean \pm SD unless otherwise indicated. Means/percentages with a common letter do not differ significantly at $\alpha \leq .05$ in pairwise comparisons. Participants were 70 pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

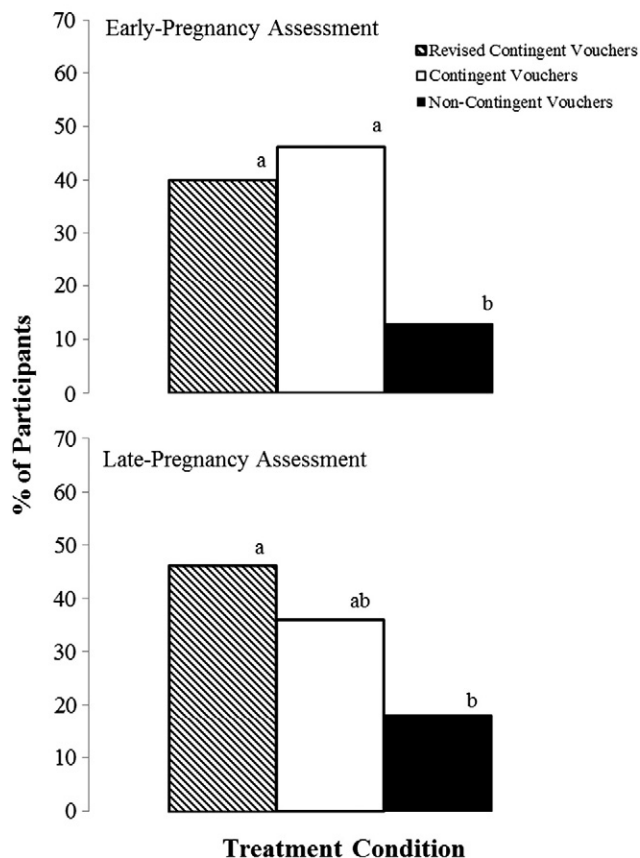
Antepartum Abstinence: 7-Day Point-Prevalence

Fig. 2. Upper panel: 7-day point-prevalence abstinence rates for each treatment condition from an antepartum assessment conducted at approximately one month after the start of the intervention (early-pregnancy assessment). Lower panel: 7-day point-prevalence abstinence rates for each treatment condition from an antepartum assessment conducted at approximately 28-week gestation (late-pregnancy assessment). Conditions that do not share a common letter differ at $\alpha < .05$. Participants were 118 pregnant smokers in greater Burlington, VT, studied 2006–2011.

NCV ($t [1,115] = 4.1, p < .001$; Cohen's $d = 0.93$, 95% CI = 0.46–1.4). There was not a significant difference between the RCV and CV conditions although a trend favoring the CV condition was noted ($t [1,115] = 1.8, p = .08$; Cohen's $d = 0.40$, 95% CI = –0.05–0.84).

When we repeated these comparisons in the subgroup of women who completed both ultrasound assessments, the patterns largely remained the same with one notable exception in the measure of consecutive negative toxicology tests. There was a significant treatment effect ($F [2,66] = 6.4, p = .003$) with averages (\pm SEM) of 11.2 ± 1.9 , 17.5 ± 2.0 , and 7.2 ± 2.2 consecutive negative tests in the RCV, CV, and NCV conditions, respectively. In pairwise comparisons the difference between the RCV and NCV conditions was no longer significant ($p = .17$) and the trend towards a difference between RCV and CV in the larger data set achieved significance ($p = .03$).

No significant treatment effects were noted in postpartum abstinence levels in the overall sample (Table 3). At the 24-week assessment, abstinence levels in the RCV and CV conditions (17.9% and 15.4%, respectively) were two-fold greater than levels in the NCV condition (7.7%) although those differences were not statistically significant (RCV vs. NCV: OR = 2.6, 95% CI = 0.6–11.0; CV vs. NCV: OR = 2.2, 95% CI = 0.5–9.4).

Mean total voucher earnings did not differ significantly across the three treatment conditions ($\$557.08 \pm 64.54$, $\$443.65 \pm 73.69$,

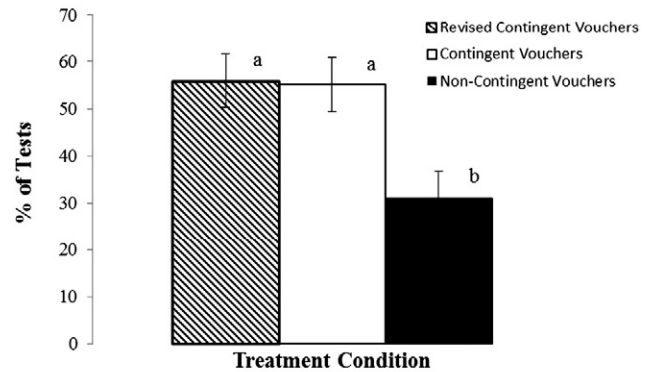
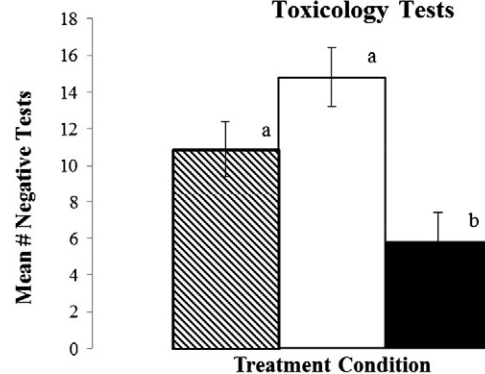
Mean % Negative Toxicology Tests**Mean Consecutive Number of Negative Toxicology Tests**

Fig. 3. Mean percent of all negative antepartum smoking-status tests conducted in each of the treatment conditions. Error bars represent ± 1 SEMs. Conditions that do not share a common letter differ at $\alpha < .05$. Participants were 118 pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

and $\$383.59 \pm 32.46$ in the RCV, CV, and NCV conditions, respectively, $F [2,115] = 2.19, p = .12$).

Fetal growth

There were significant treatment effects on estimated fetal weight ($F [2,60] = 5.5, p = .006$), abdominal circumference ($F [2,61] = 4.2, p = .02$), and femur length ($F [2,61] = 3.3, p = .04$) (Table 4). In pairwise comparisons, fetuses of mothers treated in the CV condition had greater increases in weight gain than fetuses of mothers treated in the NCV ($p < 0.05$, Cohen's $d = 0.84$, 95% CI = 0.22–1.45) and RCV conditions ($p < 0.05$, Cohen's $d = 0.20$, 95% CI = –0.36–0.76). Fetuses of mothers in the CV condition also had greater increases in abdominal circumference than NCV ($p < 0.05$, Cohen's $d = 0.74$, 95% CI = 0.13–1.34) and RCV ($p < 0.05$, Cohen's $d = 0.83$, 95% CI = 0.25–1.4). Lastly, fetuses of mothers in the CV condition showed greater increases in femur length than in the RCV condition ($p < 0.05$, Cohen's $d = 6.60$, 95% CI = 5.2–8.0), although not the NCV condition. There were no significant treatment effects on fetal head circumference, biparietal diameter, or lean thigh area.

Birth outcomes

There were no significant treatment effects on birth outcomes (Table 5), although across the five outcomes average outcomes were slightly better among infants born to mothers assigned to the CV compared to the NCV and RCV conditions.

Table 3
Biochemically-verified 7-day smoking abstinence postpartum.

Assessment	Revised contingent vouchers (n = 40)	Contingent vouchers (n = 39)	Non-contingent vouchers (n = 39)	p-Value
12 weeks (%)	18	23	18	.77
24 weeks (%)	18	15	8	.41

Participants were 118 pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

Discussion

These results provide further support for the efficacy of financial incentives as a smoking-cessation intervention for pregnant women (Higgins et al., 2012). To our knowledge, this is the sixth controlled trial with incentives demonstrating increases above control levels in smoking-cessation rates (Higgins et al., 2012) and the second trial to demonstrate increases in fetal growth (Heil et al., 2008). Most important to the purpose of the present study, we saw no evidence that revising the intervention to include larger-value incentives for early abstinence improved smoking abstinence levels in the RCV condition compared to our usual CV schedule, and there was evidence suggesting that the revised schedule was less effective at protecting fetal growth. A similar effort to improve upon outcomes of a voucher-based intervention for cocaine dependence by modifying the usual schedule to provide larger magnitude incentives in the form of bonuses for abstinence early in treatment also failed to improve outcomes above the usual arrangement (Silverman et al., 1998). Regarding the goal of devising strategies to increase the proportion of women who respond favorably to this incentive-based intervention, other strategies will be necessary. There are several strategies that merit consideration. Primary among them is offering greater incentive values for abstinence throughout the intervention, especially to heavier smokers (Higgins et al., 2009) an approach that has been demonstrated to improve outcomes with incentive-based interventions for illicit drug abuse (Higgins et al., 2007b; Lussier et al., 2006; Silverman et al., 1999). Other strategies such as combining the incentives with a smoking-cessation pharmacotherapy represent viable options to explore as well (Oncken and Kranzler, 2009).

Also deserving comment is the strategy of intensifying the frequency of backdrop counseling in the present study in an effort to increase general treatment responsiveness. We saw no evidence that this strategy increased abstinence rates above levels achieved with the usual CV condition in prior trials, which averaged 36%, 18%, and 18% at late-pregnancy, 12-week postpartum, and 24-week postpartum assessments, respectively, in the present trial compared to 34%, 24%, and 14% at those same assessments in our prior trial (Higgins et al., 2012). Where changes in abstinence rates were seen in the present relative to prior trials was in the NCV control condition. In prior trials, point-prevalence abstinence rates in that condition were 7%, 3%, and 1% at the late-pregnancy, 12-week, and 24-week postpartum assessments, respectively, whereas in the present trial they were 18%, 18%, and 8%. Whether these increases in cessation rates in the NCV control condition are

indeed attributable to the increased intensity of counseling cannot be known due to the absence of a low counseling intensity NCV control condition, although we know of no other potential explanation. In our prior trials we offered very minimal counseling above what was offered by providers as part of routine obstetrical care (Higgins et al., 2012). The results observed with the NCV condition suggest that at least some of the earlier differences observed between the CV and NCV conditions could be eliminated by providing more intensive counseling to the latter group during the early weeks of the intervention. That said, there are potential practical drawbacks to this strategy that should not be overlooked, including whether women would attend additional counseling sessions in the absence of the non-contingent vouchers that were provided to women in the NCV conditions in the present study. Of course, if such incentives have to be included to support attendance, then it would make the most sense to provide them contingent on both attendance and recent abstinence rather than just the former thereby getting the superior outcomes observed in the CV compared to the NCV conditions in the present study.

Birth outcomes in the CV condition in the present trial match closely outcomes observed previously in this condition underscoring the reliability of treatment outcomes in this condition. For example, mean birth weights (g) were 3344.8 ± 101.9 in the present trial compared to 3295.6 ± 63.8 in our prior trials (Higgins et al., 2010). The reason that differences between the CV and NCV conditions on these measures are reduced in the present compared to prior trials is attributable to increased abstinence rates in the NCV condition. Mean birth weight in the NCV condition in the present trial was 3188.6 ± 105.0 compared to 3093.6 ± 67.0 in the prior trial. Other birth outcomes in the CV condition in the present trial also match closely those observed in our prior trials, with % low birth weight deliveries in the present and prior trials being 7.9% and 5.9%, mean gestational age being 39.3 and 39.1 weeks, % preterm deliveries being 5.3% and 5.9%, and NICU admissions being 2.6% and 4.7%, respectively (Higgins et al., 2010).

This trial has the limitation of being conducted with a relatively small sample of largely rural, Caucasian young women in one U.S. state. How well this approach and associated treatment effects generalize to more diverse samples is largely an unanswered question although controlled trials conducted in at least one other U.S. state (Oregon) were positive (Donatelle et al., 2004). Considering the broad generality that has been observed with the use of financial incentives to decrease use of other substances and because these incentives interventions are based on the scientific principle of reinforcement (Higgins et al., 2004b; Lussier et al., 2006), we are optimistic that this strategy for

Table 4
Estimated fetal growth.

Measure	Revised contingent vouchers (n = 25)	Contingent vouchers (n = 25)	Non-contingent vouchers (n = 20)	p-Values
Fetal weight gain (g/week)	191.0 ± 9.5^b	228.5 ± 8.7^a	196.5 ± 7.1^b	.006
Abdominal circumference (cm/week)	1.03 ± 0.04^b	1.21 ± 0.05^a	1.05 ± 0.05^b	.02
Femur length (cm/week)	0.16 ± 0.01^b	0.20 ± 0.01^a	0.19 ± 0.01^{ab}	.04
Head circumference (cm/week)	0.68 ± 0.05	0.62 ± 0.04	0.63 ± 0.04	.63
Biparietal diameter (cm/week)	0.21 ± 0.01	0.21 ± 0.01	0.19 ± 0.02	.67
Lean thigh area (cm ² /week)	0.82 ± 0.08	0.88 ± 0.05	0.91 ± 0.05	.55

Note: Means (\pm SEM) with a common letter did not differ significantly at $p \leq .05$ in pairwise comparisons. Participants were 70 pregnant smokers in greater Burlington, VT, studied December, 2006–June, 2012.

Table 5
Infant outcomes at delivery.

Measure	Revised contingent vouchers (n = 37)	Contingent vouchers (n = 38)	Non-contingent vouchers (n = 36)	p-Value
Birth weight (g)	3284.9 ± 105.8	3344.8 ± 101.9	3188.6 ± 105.0	.56
% low birth weight	11	7	11	.87
Gestational age (weeks)	39.0 ± 0.3	39.3 ± 0.3	38.9 ± 0.3	.51
% preterm births	8	5	11	.66
% NICU admissions	8	2	11	.41

Note: Values represent mean (+ SEM) unless indicated. Note that there were fewer women in each treatment condition due to the availability of birth outcome data. NICU: Neonatal Intensive Care Unit. Participants were 111 infants in greater Burlington, VT, studied December, 2006–June, 2012.

reducing smoking during pregnancy will have efficacy in diverse samples and settings. Two important future challenges in this research effort are getting a larger proportion of women to respond and demonstrating the cost effectiveness of the approach.

Conflict of interest statement

None to declare.

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