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A pilot study on voucher-based incentives to promote abstinence from cigarette smoking during pregnancy and postpartum

Stephen T. Higgins, Sarah H. Heil, Laura J. Solomon, Ira M. Bernstein, Jennifer Plebani Lussier, Rebecca L. Abel, Mary Ellen Lynch, Gary J. Badger

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We report results from a pilot study examining the use of vouchers redeemable for retail items as incentives for smoking cessation during pregnancy and postpartum. Of 100 study-eligible women who were still smoking upon entering prenatal care, 58 were recruited from university-based and community obstetric practices to participate in a smoking cessation study. Participants were assigned to either contingent or noncontingent voucher conditions. Vouchers were available during pregnancy and for 12 weeks postpartum. In the contingent condition, vouchers were earned for biochemically verified smoking abstinence. In the noncontingent condition, vouchers were earned independent of smoking status. Abstinence monitoring and associated voucher delivery was conducted daily during the initial 5 days of the cessation effort, gradually decreased to every other week antepartum, increased to once weekly during the initial 4 weeks postpartum, and then decreased again to every other week for the remaining 8 weeks of the postpartum intervention period. Contingent vouchers increased 7-day point-prevalence abstinence at the end-of-pregnancy (37% vs. 9%) and 12-week postpartum (33% vs. 0%) assessments. That effect was sustained through the 24-week postpartum assessment (27% vs. 0%), which was 12 weeks after discontinuation of the voucher program. Total mean voucher earnings across antepartum and postpartum were US$397 (*SD* = US$414) and US$313 (*SD* = $142) in the contingent and noncontingent conditions, respectively. The magnitude of these treatment effects exceed levels typically observed with pregnant and recently postpartum smokers, and the maintenance of effects through 24 weeks postpartum extends the duration beyond those reported previously.

Introduction

Maternal smoking is a leading preventable cause of poor pregnancy outcomes and infant morbidity and mortality (Floyd, Rimer, Giovino, Mullen, & Sullivan, 1993; U.S. Department of Health and Human Services, 2001). Effective interventions exist for promoting smoking cessation during pregnancy, but cessation rates are often low (<20%), especially among women who are less educated and heavier smokers (Dolan-Mullen, Ramirez, & Groff, 1994; Solomon, Secker-Walker, Skelly, & Flynn, 1996). Additionally, the majority of women who successfully quit smoking during pregnancy relapse within 3–6 months following delivery (Fingerhut, Kleinman & Kendrick, 1990; McBride, Pirie, & Curry, 1992).

A recent report on the use of voucher-based incentives with pregnant smokers noted a substantial increase above the usual cessation rates observed in this population (Donatelle, Prows, Champeau, & Hudson, 2000). In that trial, 220 pregnant smokers were randomly assigned to receive a smoking-cessation self-help kit only or the kit plus vouchers contingent on biochemically verified smoking abstinence. Those in the voucher condition also designated

Stephen T. Higgins, Ph.D., Departments of Psychiatry and Psychology; Sarah H. Heil, Ph.D., Rebecca L. Abel, B.S., Mary Ellen Lynch, R.N., Department of Psychiatry; Jennifer Plebani Lussier, M.A., Department of Psychology; Laura J. Solomon, Ph.D., Departments of Psychology and Family Practice; Ira M. Bernstein, M.D., Department of Obstetrics and Gynecology; Gary J. Badger, M.S., Department of Medical Biostatistics, University of Vermont, Burlington, VT.

Correspondence: Stephen T. Higgins, Ph.D., Department of Psychiatry, University of Vermont, 38 Fletcher Place, Burlington, VT 05401, USA. Tel.: +1 (802)-656-9615; Fax: +1 (802)-656-9628; E-mail: stephen.higgins@uvm.edu

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a significant other to participate in the trial with them. The pregnant women and significant others received vouchers contingent on the former's smoking status during the pregnancy and for 2 months postpartum. Smoking status was assessed monthly, and vouchers were worth US$50 at each assessment for the pregnant smokers and US$50 for the first test and US$25 for each subsequent test for the significant others. Costs of the vouchers were covered through donations from local health care organizations, businesses, and foundations. Biochemically confirmed smoking cessation rates at the end of pregnancy were 32% versus 9% in the voucher and control conditions, respectively, and 21% versus 6% at the 2-month postpartum assessment. Abstinence levels after the voucher program was discontinued at 2 months postpartum were not reported. The magnitude of these treatment effects exceeded those observed among pregnant smokers in several decades of research on this topic and thus warrants further investigation.

The present pilot study was conducted to further assess the efficacy of vouchers for promoting abstinence in pregnant smokers and to extend assessments to the period after vouchers were discontinued. The use of vouchers exchangeable for retail items as incentives for abstaining from substance abuse was begun as a novel intervention for outpatient treatment of cocaine dependence (Higgins et al., 1991; for review, see Higgins, Alessi, & Dantona, 2002; Higgins, Heil, & Lussier, 2004). Research in that area indicates that an initial period of sustained abstinence is important to sustaining abstinence after the vouchers are discontinued (Higgins, Badger, & Budney, 2000; Higgins, Wong, Badger, Ogden, & Dantona, 2000). Extending that notion to the treatment of pregnant smokers is complicated by the increase in relapse risk postpartum. To establish initial abstinence antepartum and then protect against relapse risk postpartum, the voucher-based intervention used in the present study began at a relatively high intensity that gradually tapered downward during the antepartum period, followed by an increase in intensity again during the initial postpartum weeks and a second tapering downward across 12 weeks of postpartum treatment. Assessments were conducted out to 24 weeks postpartum, which was 12 weeks after discontinuation of the voucher-based intervention.

Method

Subjects

Participants were recruited from one of three large group obstetric practices or one single-practitioner obstetric practice in the greater Burlington, Vermont, area. Study inclusion criteria were self-report of being a current smoker (even a puff in past 7 days) at a prenatal visit, residing within the city limits of the study clinic, planning to remain in the geographical area for 6 months following delivery, and being English speaking. Exclusion criteria were incarceration, having previously participated in the study, or currently residing with someone who participated in the study. Because this was a pilot study, we did not use gestational age as an inclusion–exclusion criterion. All women receiving prenatal care at these clinics completed a brief questionnaire regarding basic sociodemographic information and smoking status. Those who endorsed smoking in the past 7 days were contacted subsequently by study staff in person or by phone regarding study participation. A total of 100 women were deemed study eligible; 58 agreed to participate, and 42 declined. Of the 58 who agreed to participate, 31 were assigned to the contingent voucher condition and 27 to the noncontingent condition (voucher conditions are described below). The only criterion for withdrawing someone from the trial following treatment assignment was pregnancy termination or fetal demise. Five women were withdrawn from the study based on that criterion (one in the contingent condition and four in the noncontingent condition), leaving 53 women whose results were used in analyses of study outcome.

Among the 53 participants who contributed to the analyses, 37 were assigned to one of the two treatment conditions as consecutive study admissions; the other 16 participants were randomized to the two conditions. Assigning participants as consecutive admissions continued until study staff became experienced and comfortable with the study protocol, at which time random assignment to the two experimental conditions was initiated in preparation for a fully randomized trial scheduled to follow this study. All participants provided written informed consent, and the study was approved by the University of Vermont Institutional Review Board.

Assessments

Participants completed questionnaires examining sociodemographics; current smoking status and history; smoking environment; and motivation, confidence, and intentions to quit smoking. They also provided breath carbon monoxide (CO) and urine specimens for cotinine analysis at the study intake assessment; second prenatal visit (for those who entered the study before that visit); end of pregnancy ($\geq$32 weeks gestation); and 2, 4, 8, 12, and 24 weeks postpartum. We used an onsite enzyme immunoassay test to determine cotinine levels for purposes of implementing the voucher program, with a cutpoint of 80 ng/ml. For study outcome purposes, urine specimens collected at the end of pregnancy and at the 12-week (end of incentive program) and 24-week (end of study) postpartum assessments were analyzed by an outside laboratory using gas chromatography/mass

spectrometry and the same 80-ng/ml cutpoint. Smoking abstinence in all outcome results reported here is defined as a self-report of no smoking, not even a puff, in the past 7 days confirmed by a urinary cotinine level of 80 ng/ml or less. All point-prevalence abstinence rates reported here are based on all women assigned to the two conditions minus the five withdrawn because of pregnancy termination or fetal demise ($n = 53$).

Treatment interventions

Abstinence-monitoring schedule. On entering the study, participants chose one of the two subsequent Mondays as their quit date. Beginning on the quit date, participants reported to the study clinic or were met by clinic staff at a site convenient for them for abstinence monitoring. The monitoring schedule for voucher delivery was the same for participants in the contingent and noncontingent vouchers conditions. In both conditions, voucher delivery was daily for the initial 5 days of the cessation effort (Monday through Friday). Beginning in the second week, monitoring decreased to twice weekly (Mondays and Thursdays) for the next 7 weeks, then once weekly for 4 weeks (Wednesdays), and then every other Wednesday until delivery. During the postpartum period, monitoring was increased to once weekly for the initial 4 weeks (Wednesdays) and then was every other Wednesday for the next 8 weeks, with abstinence monitoring ending at the end of week 12. No monitoring occurred between the end of postpartum intervention at week 12 and the final 24-week postpartum assessment.

Contingent voucher condition. Vouchers redeemable for retail items were earned by submitting breath specimens that had CO levels of 6 ppm or less during the initial 5 days of the cessation effort in order to detect and reinforce initial cessation efforts. Beginning in week 2 of abstinence monitoring, vouchers were delivered contingent on urinary cotinine levels of 80 ng/ml or less, a criterion that required a longer duration of smoking abstinence, compared with breath CO. Voucher delivery was independent of self-reported smoking status and based exclusively on meeting the biochemical-verification criterion. Vouchers began at US$6.25 and escalated by US$1.25 per consecutive negative specimen to a maximum of US$45.00. 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. No cash was ever given to participants, and all voucher purchases were made by clinic staff. Overall, women assigned to this condition attended 63.7% (531/833) of the scheduled antepartum and postpartum abstinence monitoring sessions, with total mean voucher earnings of US$397 ($SD$ = US$414, range = US$0–US$1,135).

Noncontingent voucher condition. In this condition, vouchers were delivered independent of smoking status. Voucher values were US$11.50 per visit antepartum and US$20.00 per visit postpartum, which were estimated to be sufficient to sustain participation in abstinence monitoring and to result in payment amounts that were comparable to the average earnings in the contingent condition. All else was the same as in the contingent voucher condition. Overall, women assigned to this condition attended 63.3% (426/673) of the scheduled antepartum and postpartum abstinence monitoring sessions, with total mean voucher earnings of US$313 ($SD$ = US$142, range = US$35–US$517).

Other services. In addition to the monitoring and voucher-based incentives mentioned above, participants received whatever was usual care for smoking cessation provided through their obstetric clinics, which typically involved provider inquiry regarding smoking status and a discussion of the advantages of quitting during pregnancy. Study staff did not attempt to influence those clinic practices. As part of the study intervention, all participants received a pamphlet from study staff at the initial intake assessment that was designed for pregnant women and outlined reasons for quitting smoking and strategies on how to quit (Secker-Walker, Solomon, Flynn, Skelly, & Mead, 1998a). Those who were abstinent at the end-of-pregnancy assessment received a pamphlet highlighting reasons to remain abstinent postpartum (Secker-Walker, Solomon, Flynn, Skelly, & Mead, 1998b).

Statistical analysis

Contingent and noncontingent treatment conditions were compared on subject characteristics using chi-square tests and t tests. Fisher's exact test was used to test for differences between treatment conditions in the proportion of subjects meeting the biochemically confirmed abstinence criterion at the end of pregnancy and at 12 and 24 weeks postpartum. The Breslow–Day chi-square test of homogeneity was used to determine whether treatment differences in abstinence rates were homogeneous across the two methods of assignment (i.e., subjects consecutively assigned vs. randomized). For tests of homogeneity involving cell frequencies of zero, 0.5 was added to each cell in order to have defined odds ratios prior to computing the Breslow–Day statistic. Analyses were performed using SAS statistical software. Statistical significance was determined based on an alpha level of .05.

Results

No significant differences in sociodemographics or smoking characteristics and attitudes were noted between women in the contingent and noncontingent voucher conditions at the study intake assessment (Table 1).

We had a more limited amount of information available on characteristics of the 42 women who declined the study. Based on the information available, we detected no significant differences between study participants and those who declined. Comparing study participants to decliners, respectively, we found the following characteristics: Race was 94% versus 95% White, $\chi^2(1) = .04$, $p = .85$; mean years of education was 11.6 ($SD = 2.0$) versus 11.2 ($SD = 2.3$), $t(93) = -.90$, $p = .37$; mean age was 22.7 years ($SD = 4.9$) versus 24.6 years ($SD = 4.7$), $t(93) = 1.92$, $p = .06$; gestational age was 14.0 weeks ($SD = 7.4$) versus 11.8 weeks ($SD = 6.2$), $t(93) = -1.48$, $p = .14$; and mean number of cigarettes smoked per day in the week prior to the prenatal care visit was 10.3 ($SD = 8.6$) versus 12.4 (SD = 9.6), $t(93) = 1.12$, $p = .27$.

Loss to follow-up was relatively low and not significantly different in the two treatment conditions. End-of-pregnancy, 12-week postpartum, and 24-week postpartum assessments were completed with, respectively, 90% (27/30), 87% (26/30), and 87% (26/30) of participants in the contingent voucher condition versus 100% (23/23), 91% (21/23), and 87% (20/23) of those in the noncontingent voucher condition.

Biochemically confirmed 7-day point-prevalence abstinence levels were significantly greater in the contingent than the noncontingent conditions at the end-of-pregnancy ($p = .025$), 12-week postpartum ($p = .003$), and 24-week ($p = .007$) postpartum assessments (Table 2). No evidence indicated that these treatment differences in abstinence depended on whether subjects were assigned randomly or as consecutive admissions ($p > .30$ for all three assessment times). Among subjects assigned randomly, abstinence levels in the contingent versus noncontingent conditions were 25% (2/8) versus 0% (0/8), 25% (2/8) versus 0% (0/8), and 25% (2/8) versus 0% (0/8) at the end-of-pregnancy, 12-week postpartum, and 24-week postpartum assessments. Among those assigned as consecutive admissions, abstinence levels in the contingent versus noncontingent conditions were 41% (9/22) versus 13% (2/15), 27% (6/22) versus 0% (0/15), and 27% (6/22) versus 0% (0/15) across the same assessments.

Table 2. Biochemically confirmed 7-day point-prevalence abstinence

All participants	Contingent	Noncontingent
End of pregnancy	37% (11/30)	9% (2/23)*
12 weeks postpartum	33% (10/30)	0% (0/23)*
24 weeks postpartum	27% (8/30)	0% (0/23)*

*$p < .05$.

Discussion

The treatment effects observed while the voucher program was in place in the present study replicate those reported previously by Donatelle et al. (2000) using a voucher-based incentive program. The Donatelle et al. study involved monthly monitoring

Table 1. Subject characteristics

Characteristic	Contingent[a] ($n = 30$)	Noncontingent[a] ($n = 23$)	p value
Demographics			
Age (years)	22.8 ± 4.9	22.5 ± 4.9	.83
Education (years)	11.7 ± 2.1	11.6 ± 1.9	.92
% White	93	96	.72
% Married	30	13	.14
% Private insurance	10	13	.73
% First pregnancy	57	48	.52
Weeks pregnant at intake	15.6 ± 7.5	11.8 ± 6.8	.06
Smoking characteristic			
Cigarettes/day prepregnancy	23.3 ± 11.9	22.7 ± 10.4	.83
Cigarettes/day in past 7 days	9.9 ± 8.8	10.8 ± 8.5	.70
Age started smoking (years)	14.1 ± 2.6	13.7 ± 1.7	.47
Intake carbon monoxide (ppm)	12.5 ± 9.5	10.3 ± 5.4	.30
Intake urinary cotinine (ng/ml)	1070 ± 712	1229 ± 606	.40
Living with other smoker(s) (%)	83	65	.13
Smoking attitudes			
Amount want to quit[b]	3.9 ± 0.3	3.9 ± 0.4	.96
Confidence to quit[b]	3.1 ± 0.8	2.9 ± 0.7	.40
Intend to quit while pregnant[c]	4.5 ± 0.8	4.6 ± 0.6	.47

Note. Values represent mean ± *SD*, unless otherwise specified.
[a]Treatment groups are described in the text.
[b]Assessed by a four-point scale: 1 = none, 4 = a lot.
[c]Assessed by a five-point scale: 1 = definitely not, 5 = definitely.

of smoking status and a maximum of US$800 in incentives divided between the target smoker and a social support person. By contrast, the present study was more intensive, with greater than twice-monthly monitoring and a maximum incentive value of approximately US$1,200 targeted exclusively at the smoker. The magnitude of the abstinence effects observed in the two studies were comparable when the voucher programs were in place: 7-day point-prevalence abstinence at the end of pregnancy was 32% versus 9% in the incentive and control conditions in Donatelle et al. and 37% versus 9% in the present study. At the end of the incentive periods, which was 8 weeks postpartum in Donatelle et al. and 12 weeks postpartum in the present study, 7-day point-prevalence abstinence was 21% versus 6% and 33% versus 0%, respectively. Donatelle et al. did not report on abstinence after discontinuation of the voucher program, but in the present study 7-day point-prevalence abstinence was 27% versus 0% at the 6-month postpartum assessment (12 weeks after vouchers were discontinued). The abstinence rates at the end of pregnancy and the initial couple of months postpartum in both studies approximately double the 15%–18% abstinence rates often reported when using efficacious interventions with lower-income pregnant smokers (Dolan-Mullen et al., 1994). The sustained treatment effect observed at the 6-month postpartum assessment in the present study, to our knowledge, has not been observed previously with any intervention among low-income women.

The effects reported by Donatelle et al. (2000) and in the present report need to be replicated. Also, whether the relatively lower intensity of abstinence monitoring and incentive values used by Donatelle et al. are adequate or a more intensive intervention like the one used in the present study is needed to reliably produce the relatively high abstinence rates observed in these initial studies will have to be determined through parametric studies in which the voucher value and frequency of abstinence monitoring are varied systematically. Incentive studies involving illicit drug abusers and nonpregnant smokers indicate that such parametric factors influence outcome (Higgins et al., 2004). Those complexities notwithstanding, though, the results from these two studies suggest that voucher-based incentives may offer an effective strategy for increasing smoking-cessation rates in low-income pregnant and recently postpartum women.

Cost is an obvious practical issue with regard to voucher- and other incentive-based interventions. We have not yet specifically identified the total cost per patient of the present intervention beyond the voucher costs, nor have we dissociated clinical costs from those associated with researching the intervention. However, considering the substantial excess health care costs associated with maternal smoking, such interventions may very well prove to be cost-effective (Adams & Melvin, 1998; Centers for Disease Control and Prevention, 1997). For example, Miller, Villa, Hogue, and Sivapathasundaram (2001) estimated that maternal smoking results in additional medical costs during the year after birth of US$1,142–US$1,358 per smoking pregnant woman.

The results observed in the noncontingent voucher condition merit comment. The 9% abstinence rate observed antepartum is consistent with the 7%–9% abstinence rates observed with usual care in prior smoking cessation studies conducted in some of the same clinics that participated in the present study (Secker-Walker et al., 1994, 1998a). Similarly, the 0% abstinence rate observed postpartum in the present study is only slightly lower than the 3%–5% postpartum abstinence rates observed in those same prior studies (Secker-Walker et al., 1994, 1998a) and is consistent with the 0% postpartum abstinence rates reported with usual care in studies conducted elsewhere (e.g., Gebaurer, Kwo, Haynes, & Wewers, 1998; Lowe, Balanda, & Clare, 1998). This information suggests that the noncontingent vouchers had little or no effect on abstinence rates, which is consistent with results from other studies on cigarette smoking and other types of substance abuse in which noncontingent vouchers have been used (Higgins et al., 2004). For vouchers or other incentives to improve abstinence from substance abuse, a contingent relationship between their availability and abstinence is essential. Certainly, the strikingly low rates of abstinence observed antepartum and postpartum in the noncontingent condition in the present study provide further evidence of the recalcitrant nature of smoking in this population.

Although the results obtained in the contingent voucher condition in the present study are encouraging, the small number of women studied and the fact that the majority were assigned as consecutive admissions rather than being randomized to their respective treatment conditions underscores the need for caution and replication. The small sample size could adversely affect the precision of the estimate of the magnitude of treatment effects, although the comparability of abstinence rates observed during the voucher period in the present study and the Donatelle et al. (2000) study suggest that may not have been a substantive problem in the present study. Assignment of participants to treatment conditions as consecutive admissions increases the possibility that subject characteristics or external influences that changed over time, rather than the different treatment interventions, might have contributed to the differential treatment effects observed. The absence of significant differences in subject characteristics between the treatment conditions in the present study and the consistency of results across subjects randomized to treatment and those assigned as consecutive

admissions argues against the likelihood of the present results being an artifact of the research design, but only a replication using a fully randomized design can adequately address that possibility.

These limitations notwithstanding, we consider the present results and those of Donatelle et al. (2000) encouraging regarding the potential utility of voucher-based incentives for increasing smoking abstinence during pregnancy and postpartum in low-income smokers.

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