Financial incentives for smoking cessation in pregnancy. A randomised, controlled, multicentre clinical trial (the FISCP trial).

Supplementary material

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Introduction

The global prevalence of smoking during pregnancy is estimated to be 1.7% (95% CI: 0.0 to 4.5%); it varies by country and geographical regions. France with 19.7% of pregnant smokers (IC 95% 15.6 to 24.0) is the 13th highest prevalence among the 174 countries assessed.[1] There were 832 799 and 783 640 live births in France in 2010 and 2016, respectively[2] and the both perinatal surveys in these years showed that 17.0% and 16.2% of pregnant women smoked during the 3rd trimester. This corresponds to the exposure of 141 376 and 126 950 newborns. Among these women 12.2% and 12.3% smoked 1 to 9 cigarettes/day and 4.8% and 4.3% smoked 10 cigarettes or more/day.[3]

Methods

Recruitment

The maternity wards were contacted by word of mouth and all investigators signed a commitment to run the trial. All maternity wards were public hospital based and were involved routinely in antenatal care. Participating maternity wards were located in 13 French regions reflecting various contextual factors.

Participants

Participants were recruited by word-of-mouth, flyers, and advertisements in pharmacies, general practitioner offices and in the participating maternity wards. Assistance Publique-Hôpitaux de Paris, the sponsor, who was responsible for the good conduct and logistics, launched a national information campaign about the trial. After a phone interview for eligibility, pregnant smokers were invited to attend the closest maternity ward for a screening visit. Participation was also proposed during routine pregnancy visits. Investigators were midwives or physicians trained as smoking cessation specialists, were familiar with smoking cessation treatments and counseling and routinely treated pregnant smokers.

The research protocol was approved by the ethics committee (Comité de Protection des Personnes) Ile de France VI on April 17, 2015.

Interventions and payoffs structure

Financial incentives group

The payoffs were based on two principles: the reward for abstinence today and the reward for continuous (past) abstinences. Hence, the payoff increased with the number of times a participant had been abstinent but also with the number of successive abstinences.

If the participant was not abstinent ($\bar{A}$), she received a 20€ voucher as a show-up fee. If she was abstinent (A), she earned the show-up fee and an additional amount to reward her abstinence. If she was abstinent at the first post quit day visit, she was rewarded by an additional 40€ voucher. This amount then increased by 20€ progressively if she remained abstinent for the next visits (60, 80, 100, and 120€). If a participant was abstinent and then non-abstinent, the next time she was abstinent, the last abstinent payment recurred to reward her abstinence and avoid a penalty for the previous non-abstinence. **Supplementary Table 1** refers to four different scenarios of financial incentives (in euros) according to the abstinence of the participant over 6 visits.

If a participant did not show up for a visit but showed up for the next visit, the no-show-up visit was considered a non-abstinence visit; therefore, when she showed up at the next visit, the financial incentive was that of the last show-up visit.

A general expression allows us to determine the total payoffs after the total number of visits T according to each situation. Let Y_T^{IG} be the total payoff after T visits in the intervention group (IG):

$$Y_T^{IG} = 20 + [40.N_2^A.I_2^A + 20] + \sum_{t=3}^{T}(20.I_t^A.(N_t^A + 1) + 20) \ for\ t = \{3, \dots, T\}$$

The first visit is the inclusion and randomisation visit in both groups, and everyone gets 20 €.

N_t^A is the number of successive times a pregnant woman has been abstinent, measured at visit *t*. I_t^A is a dummy variable that is equal to 1 if the pregnant woman is abstinent at visit *t* and 0 otherwise.

Control group

Participants randomized to the control group received a €20 voucher at the end of each visit as a show-up fee, but as opposed to the intervention group, abstinence was not rewarded. The total payoff depended on the total number of visits the participant attended.

Hence, the total payoff for participants in the control group (CG) was:

$$Y_T^{GC} = 20.t, \qquad for\ t = \{1, \dots, T\}$$

Monetary reward for abstinence was given by vouchers (Kadeos http://www.edenred.fr/besoin/avantages-aux-salaries/produit/ticket-kadeos/) that could be redeemed in many shops and superstores; they did not allow for buying tobacco or alcohol products. The value of each voucher was €20. Participants in both the financial incentive and control groups received a €20 voucher as a show-up fee for completing the visit.

Outcome measures

Biochemical verification of self-reported smoking abstinence

Expired air carbon monoxide (eCO) ≤ 8 ppm was used as a cutoff point to distinguish abstinent from nonabstinent smokers. This cutoff was proposed by the Society for Research on Nicotine and Tobacco Subcomittee on Biochemical Verification[4]. Since then, eCO cutpoints have been proposed to be reduced (< 6 ppm)[5] and in pregnant smokers who participated in studies assessing financial incentives (n=131), Higgins et al.[6] reported poor agreement with urinary cotinine and the highest sensitivity and specificity at eCO < 4 ppm. Moreover, in our previous study, we used the cutoff point ≤ 8 ppm. In fact, the update of biochemical verification of smoking abstinence suggests that investigators should select an appropriate cutoff point ranging from 4 to 10 ppm[5].

Power and sample size calculations

The power calculation was based on the main outcome measure. A previous study[7] that compared nicotine patches to placebo patches in pregnant smokers showed a continuous

abstinence rate of 5.5% in the nicotine *versus* 5.1% in the placebo group. We hypothesized a 10% continuous abstinence rate, double of the previously observed continuous abstinence rate[8] in the control group presuming the show-up fee might increase the abstinence rate by itself. Assuming a 20% continuous abstinence rate in the financial incentives group, with an $\alpha=0.05$ and $1-\beta= 0.80$, we planned to randomise at least 199 women to each group[8]. The targeted sample size was 420; the randomization of 460 to 480 women was planned hypothesising a dropout rate of 9% to 12% (40 to 60 participants).

Statistical Analyses

We used the log-rank test to compare the time to relapse. We compared point prevalence abstinence rate, past 30-day NRT use using mixed logistic models and craving for tobacco (FTCQ-12) with a mixed linear model.

Sensitivity analyses of the primary outcome

Several sensitivity analyses were performed to assess the robustness of the results using alternative definitions of continuous abstinence and the smoking status of participants who did not show up.

Sensitivity analysis 1

Because some participants may have given birth before the planned 6th visit the first alternative outcome was continuous abstinence at each visit from quit date to delivery. We assumed that if delivery occurred within 30 days of visit n, then visit n+1 could not occur. Therefore, continuous abstinence was measured between the quit date and visit n.

Sensitivity analysis 2

The second alternative definition of the primary outcome stated that the participant was considered continuously abstinent if she was abstinent at each visit or if she was not abstinent only once because she did not show up.

Sensitivity analysis 3

The third sensitivity analysis used the imputed dataset. This dataset included participants who did not show up, and observations were therefore missing. Missing observations were assumed to be missing at random (MAR) or missing completely at random (MCAR). We used a univariate imputation sampling method to impute missing values of the abstinence rate due to no-show-up. At each visit, we imputed the abstinence status from a set of characteristics measured at baseline (age, number of cigarettes smoked per day, partner's smoking status, Fagerström Test for Cigarette Dependence total score[9], French Tobacco Craving Questionnaire 12 items total score[10], age at first cigarette smoked, twin pregnancy, centres, motivation to quit and income) according to the algorithm proposed by van Buuren et al.[11]. We first estimated the vector of coefficients and the residual variance by regressing the non-missing values of the abstinence status on the completed version of the explanatory variable measured at baseline. Then, we predicted the fitted values at the non-missing observation of the abstinence status. We drew a random value from the posterior distribution of the residual standard deviation and the estimate, beta (conditional on the standard deviation, sigma), thus allowing for uncertainty in the beta estimate. We used the beta estimate to predict the fitted values at the missing observations of abstinence status. Finally, the imputed values were predicted directly from the beta, sigma, and covariates.

We acknowledge that compared to multiple imputation techniques, this imputation method decreases variability. In addition, this method cannot distinguish between observed and imputed values and therefore do no incorporate into the model the uncertainty associated with that imputed value. We could not use multiple imputation techniques in our setting because the main outcome is a combination of point abstinence. The multiple imputation techniques could have only be used for each point prevalence abstinence, but not for the main outcome.

Sensitivity analysis 4

This sensitivity analysis was a per protocol analysis that restricted the sample to participants who attended each visit.

Secondary outcomes for mothers

The exact date of relapse after quitting was not collected because of the uncertainty of recall and the lack of biochemical measures (eCO) at the moment of lapse/relapse. The date of lapse or relapse was defined as the date of the visit at which non-abstinence was first ascertained.

Time to relapse was the difference (in days) between the first date of the visit at which the women reported smoking and the set quit date. Among those who never quit smoking, the relapse date was the date of the second visit where the woman reported smoking. A special case was when the participant did not show-up at the visit and was considered as non-abstinent. In this case, we did not have a date for the date of relapse. Hence, we used the date of the last visit of the confirmed abstinence.

The FTCQ-12 score comprises 12 items rated on a 1 to 7 scale[9] the MNWS 8 items rated on a 1 to 4 scale[12]. For both questionnaires, the items were summed to yield a total score. The FTCQ-12 and MNWS were measured at each visit.

We calculated the total number of cigarettes smoked by multiplying the number of daily cigarettes smoked (number of cigarettes smoked in the past 7 days measured at each visit divided by 7) by the number of days between each visit. This outcome included only participants who completed all visits to avoid downward bias. We tested whether the total number of cigarettes smoked was different between groups using an unadjusted linear probability model. Analysis of these latter outcomes was subject to bias because they were only measured among those who attended the visits.

We specifically analysed three longitudinal variables of interest collected at each visit and for which correlation between repeated measures may matter: point prevalent abstinence, past 30-day NRT use and craving for tobacco (FTCQ-12 score). Point prevalence abstinence and NRT

use at each visit is compared by a mixed-effect logistic model for which we report OR, 95% CI and P-values. Mixed-effects linear model is used for craving for tobacco for which we report linear coefficient, 95% CI and P-value. The models allow to take into account correlation between repeated measures. We also report the visit*group interaction by mixed-effects linear model to evaluate the time-group interaction.

Secondary outcomes for newborns

Birthweight and other birth characteristics were collected from hospital charts or, if not available, from the child's health record booklet, a national, mandatory follow-up booklet for children born in France. All differences were first tested by unadjusted logit models. We calculated gestational age in days using the recorded start of pregnancy and the delivery date. The research protocol did not include the analysis of birthweight dichotomized at 2500 g. However, current recommendations suggest that birthweight should be analysed on a dichotomized manner, low birthweight being defined as birthweight less than 2500 g[13]. Because analyses of dichotomised birthweight was not included in the protocol, all results on dichotomised birthweight should be considered more as hypothesis generating than confirmatory.

Unexpectedly, despite the randomisation of the mothers, there were fewer girls in the control than in the financial incentives group. Since girls have smaller birthweights than boys, we also analyzed the effect of financial incentives on the probability of the newborns' weight being ≥2500 g while controlling for sex. As a second step, we added a control for preterm birth[14]. Finally, we added an interaction term between the group and preterm birth.

Analyses of no-show-up and drop-out.

Because women who did not show up at a visit were considered smokers, having been randomised to the control group (i.e., no financial reward of abstinence) could favor no-show-ups, which could lead to falsely increasing the efficacy of financial incentives. We made a

distinction between drop-out and no-show-up. Drop-out for any reason was defined as no-show-up at visit V_n and no-show-up at any further visit among those who had not yet dropped out. We tested whether dropping out differed by group using an unadjusted logistic model.

We examined whether the probability of no-show-up or drop-out was predicted by abstinence status in the preceding visit using unadjusted logistic models. In addition, we tested whether this association differed by being in the control or financial incentives group.

As per protocol (https://clinicaltrials.gov/ct2/show/NCT02606227), the researcher who carried out the statistical analysis used a blinded dummy variable indicating if the participant was in the control or financial incentives group.

For all analyses, a two-tailed P-value ≤0.05 was considered significant. Statistical analyses were performed using STATA SE 15 (Statacorp).

Results

The first participant was randomised on April 8, 2016, the last participant was assessed on July 2, 2019.

Primary outcome

Sensitivity analyses

Supplementary Table 2 shows the sensitivity analyses. To ease the comparison with the main result, we reproduced it in the first row. Sensitivity analyses confirmed the robustness of the main analysis of the primary outcome.

Secondary Outcomes

Mothers

The point prevalence abstinence rate was higher at all visits in the financial incentives than in the control group the odds ratios ranged from 2.22, 95% CI: 1.37 to 3.61 to 3.12, 95% CI: 2.0 to 4.87 (all P-values <0.01). The robust overall difference in point prevalence abstinence rate was confirmed by the mixed effect logistic model. The odd ratio increases to 4.61, 95% CI:

1.41 to 15.01 (p=0.011) and the interaction term between visit and group ranges between 0.12 and 0.21 (all P-values <0.001) (**Supplementary Table 3a**).

Concomitant NRT use

Supplementary Table 4 shows that past 30 days NRT use is significantly higher in the control group than in the financial incentive group at Visit 4.. This result is confirmed in the mixed effect logistic model in which the interaction term between Visit 4 * group as well as Visit 5 * group is negative and significant (p-value 0.001 and 0.023 respectively (**Supplementary Table 3b**). However, the mixed effect linear model showed no overall difference between the two groups (**Supplementary Table 3a**).

Tobacco craving (FTCQ-12)

The negative effect of the intervention on tobacco craving, i.e. the reduction of craving for tobacco is confirmed by the mixed effect linear model (**Supplementary Table 3a**). The marginal effects of the interaction term between visit and group for each visit range between -3.61 and -4.98 (all P-values ≤ 0.001) (**Supplementary Table 3b**).

Self-report of no smoking and biochemical verification of no smoking.

Of the 599 simultaneously recorded self-reports of no smoking during the last 7 days and eCO measures, only 6 measures of eCO were >8 ppm (1 in the financial incentives and 5 in the control group).

Postdelivery assessment

Only 262/460 (56%) participants could be reached at the 6 months postdelivery phone calls: 133 in the financial incentives and 129 in the control group. Thirty-six (27.1%) in the financial incentives and 26 (20.2%) in the control group reported being abstinent in the last 7 days; the respective numbers among all randomized participants were 15.58% and 11.35%.

No-show-up and drop-out

No-show-up increased with time in both groups: financial incentives group: 13.99%, 22.51%, 26.84%, 34.2%, and 48.48%, and control group: 16.16%, 26.20%, 34.06%, 41.92%, and 55.02%, at visit 2, 3, 4, 5 and 6, respectively. No-show-ups were not associated with being in the financial incentives or in the control group (for visits 2 to 6, all p-values >0.05 from **Supplementary Table 5**). Tobacco non-abstinence at the previous visit predicted a next visit no-show-up (all P-values <0.05); however, this effect of previous visit non-abstinence did not differ by group (p-values ranging from 0.255 to 0.827). The drop-out rates were as follows in the financial incentives group: 12.55%, 9.41%, 5.46%, and 9.83%, and in the control group: 14.8%, 11.79%, 8.72%, and 12.10% at visit 2, 3, 4, and 5, respectively. The global dropout rate was 40 % in the control and 32% in the financial incentives group. This difference was not statistically significant (P= 0.105). To note that the total dropout rate is not the sum of the dropout rates at each visit because the dropout rate at each visit was calculated among participants that have not yet dropped out of the sample.

The drop-out rate was not associated with being randomized to the financial incentives or control group (p-values ranging from 0.166 to 0.529). The drop-out rate was significantly associated with non-abstinence, i.e., non-abstinence at each visit predicted drop-out at the next visit (P-values ranging from 0.001 to 0.015). This association was not influenced by being in the financial incentives or control group (p-values ranging from 0.297 to 0.494).

Newborns

Supplementary Table 6 shows the number of poor neonatal outcomes. Four newborns had 4 poor neonatal outcomes in the financial incentive group. Eighteen newborns had 19 neonatal outcomes in the control group (one newborn had two poor neonatal outcomes).

Supplementary Table 7 shows the results of post-hoc analysis of dichotomised birthweight.

Costs

The total cost for the control group was €19,520 and the total cost for the financial incentives group was €49,040 among which €28,040 correspond to financial incentives conditional on abstinence. There were 21 more continuously successful quitters in the financial incentives (N=38) than in the control group (N=17). The total cost per successful continuously abstinent quitter in the control group is €1,148. The total cost per successful quitter in the incentive group is €1,291. The cost of incentives (without show-up fees) per additional successful quitter is €1,335 (28040/(38-17)).

Discussion

Comparison with existing studies

In a pilot study (contingent group, n=30, noncontingent group, n=23) Higgins et al. (2004)[15] reported higher biochemically verified end of pregnancy 7-day point prevalence abstinence (11/30 *versus* 2/23) in the contingent group. In the control group show-up voucher values were $15 per visit (antepartum); in the contingent voucher condition vouchers were delivered contingent on eCO ≤ 6 ppm or urinary cotinine concentration ≤ 80 ng/ml and was independent on self-report. Negative urine results were rewarded by $1.25 up to a maximum of $45. Positive biochemical test results reset the voucher value back to the original low value, but two consecutive negative tests restored the value to the pre-reset level.

In Heil et al.[16], the contingent (n=40) and non-contingent (n=42) voucher conditions were similar than in Higgins et al. (2004)[15]. Contingent vouchers increased point prevalence abstinence at the end of pregnancy (41% *versus* 10%) and the number of weeks during which women were continuously abstinent was higher in the voucher than in the control group (9.7 weeks *versus* 2 weeks).

In Higgins et al. (2010)[17] 7-day late pregnancy point prevalence abstinence rate (31.1 vs 7.4%), birthweight and percent of newborns with low birthweight were higher in the contingent than in the non-contingent group. Increased reward of abstinence during the early phase of

quitting compared to rewarding all smoking abstinences while keeping the amount of reward similar provided similar results[18].

The Tappin et al. study[19] is the closest to ours in terms of design, sample size and amount of reward. Participants in the intervention group could receive vouchers up to £400 for engaging with stop smoking services or for quitting, or both. Participants received vouchers of £50 if attended the face to face visit and set a quit date. Confirmed quitters (eCO<10 ppm) received a £50 voucher. Abstinent participants at week 12 received £100 vouchers. Self-reportedly abstinent women with eCO <10 ppm between 34 to 38 weeks' gestation received vouchers of £200. The main outcome was end of pregnancy point prevalence and not continuous abstinence rate. The point prevalence abstinence rate at 34 to 38 weeks gestation was 22.5% in the intervention and 8.6% in the usual care group. No difference in birthweight was observed.

Comparison of the incentives design

In the Higgins group's studies[15--18] incentives increased with continuous abstinence but incentives were reset in case of positive biochemical measure of tobacco intake. But if the biochemical control showed two consecutive negative results the voucher value was restored to pre-reset level. Tappin et al.[19] 2015 was based on an incentive system which did not reward successive abstinences and did not progressively increase incentives based on previous abstinence at each visit. In the current study incentives were also increased conditional on smoking abstinence but were not reset if no abstinence occurred.

The initial amount was $6.25 and escalated by $1.25 with a maximum of $45[15-18] or the amount was doubled at each visit at which the incentives were implemented[14]. In the current study the base amount was €20 incremented progressively to promote continuous abstinence. The frequency of antepartum visits was 8 or more[15-18] or fixed to 3[19] while in the present study monthly visits were planned from quit date up to Visit 6.

No-show-up and drop-out rates

One could hypothesise that the no-show-up or the drop-out rate would be higher in the control than in the financial incentives group. However, the comparison of no-show-up or drop-out rates did not result in significant differences between the groups. It is conceivable that the show-up fee provided also in the control group reduced the risk of no-show-up or drop-out in the control group.

As could be expected, no-show-up was predicted by no abstinence at the previous visit but this was independent of being in the intervention or in the control group.

The drop-out rate was 12.55%, 9.41%, 5.46%, and 9.83% in the financial incentives and 14.8%, 11.79%, 8.72%, and 12.10% in the control group at visit 2, 3, 4, and 5, respectively. This is consistent with studies closest to ours if we compare single-assessment drop-out. In Heil et al.[14] the drop-out rate at each assessment ranges between 5% and 13%. In Tappin et al.[17] the dropout-rate at the end of pregnancy assessment was 15% in the financial incentives and 14% in the control group. Our global drop-out rate was statistically similar in the financial incentives and the control groups. By lack of previous reports on overall drop-out rates, comparison with other studies cannot be made.

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Supplementary Table 1. Four examples of the financial incentives in euros according to the abstinence (A)/nonabstinence (Ā) of pregnant women at study visits (V_n). R= randomisation visit, V1.

Scenario for 6 visits	R= V1 (€)	V2	V3	V4	V5	V6	Total payoff
1. RAAAAA	20	A $I_2^A = 1,$ $N_2^A = 1$ $40.1.1 + 20 = 60$	A $I_3^A = 1,$ $N_3^A = 2$ $20.(2+1).1 + 2 = 80$	A $I_4^A = 1,$ $N_4^A = 3$ $(20.(3+1).1 + 20) = 100$	A $I_5^A = 1,$ $N_5^A = 4$ $(20.(4+1).1 + 20) = 120$	A $I_6^A = 1,$ $N_6^A = 5$ $(20.(5+1).1 + 20) = 140$	500
2. RAAĀĀĀ	20	A $I_2^A = 1,$ $N_2^A = 1$ $40.1.1 + 20 = 60$	A $I_3^A = 1,$ $N_3^A = 2$ $20.(2+1).1 + 2 = 80$	Ā $I_4^A = 0,$ $N_4^A = 2$ $(20.(2+1).0 + 20) = 20$	Ā $I_5^A = 0,$ $N_5^A = 2$ $(20.(2+1).0 + 20) = 20$	Ā $I_6^A = 0,$ $N_6^A = 2$ $(20.(2+1).0 + 20) = 20$	220
3. RAĀAĀA	20	A $I_2^A = 1,$ $N_2^A = 1$ $40.1.1 + 20 = 60$	Ā $I_3^A = 0,$ $N_3^A = 1$ $(20.(1+1).0 + 20) = 20$	A $I_4^A = 1,$ $N_4^A = 1$ $20.(1+1).1 + 20 = 60$	Ā $I_5^A = 0,$ $N_5^A = 1$ $(20.(1+1).0 + 20) = 20$	A $I_6^A = 1,$ $N_5^A = 1$ $(20.(1+1).1 + 20) = 60$	240
4. RĀAAĀĀ	20	Ā $I_2^A = 0,$ $N_2^A = 1$ $40.1.0 + 20 = 20$	A $I_3^A = 1,$ $N_3^A = 1$ $(20.(1+1).1 + 20) = 60$	A $I_4^A = 1,$ $N_4^A = 2$ $20.(2+1).1 + 2 = 80$	Ā $I_5^A = 0,$ $N_5^A = 2$ $(20.(2+1).0 + 20) = 20$	Ā $I_6^A = 0,$ $N_6^A = 2$ $(20.(2+0).0 + 20) = 20$	220

Supplementary Table 2. Sensitivity analyses of the primary outcome: continuous abstinence rate.

	OR	95% confidence interval	P-value
Main result			
Primary outcome: continuous abstinence rate up to visit 6: Show-up and biochemically confirmed abstinence at each visit	2.45	1.34 to 4.49	0.004
Sensitivity analyses			
1. Show-up and biochemically confirmed abstinence at each visit up to delivery	2.25	1.27 to 3.98	0.005
2. Show-up and biochemically confirmed abstinence at each visit bracketing the no-show-up visit.	2.34	1.36 to 4.04	0.002
3. Biochemically confirmed abstinence at each visit and imputation for the no-show-up visit	2.18	1.28 to 2.71	0.004
4. Per protocol analysis: Restricting the sample to participants who attended each visit	2.32	1.21 to 4.45	0.011

Supplementary Table 3a. Effect of the intervention on point prevalence abstinence, NRT use and craving for tobacco (French Tobacco Craving Questionnaire 12 items, FTCQ-12)

Outcomes		95% confidence interval	P-value
Point prevalence abstinence (OR)	4.61	1.41 to 15.01	0.011
NRT use (OR)	0.88	0.62 to 1.24	0.462
Craving for tobacco (FTCQ-12) (linear coefficient β)	-1.82	-3.55 to -0.08	0.040

Supplementary Table 3b Effect of time*group interaction on point prevalence abstinence, NRT use and craving for tobacco.

Point prevalence abstinence	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Marginal effect	0.12	0.21	0.19	0.18	0.14
95% CI	0.05 to 0.19	0.14 to 0.28	0.12 to 0.26	0.12 to 0.25	0.07 to 0.21
P value	0.000	0.000	0.000	0.000	0.000
NRT use	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Marginal effect	-0.02	-0.07	-0.18	-0.13	-0.06
95% CI	-0.12 to 0.08	-0.17 to 0.03	-0.29 to -0.08	-0.24 to -0.02	-0.18 to 0.06
P value	0.730	0.151	0.001	0.023	0.301
Craving for tobacco (FTCQ-12)	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Linear coefficient β	-4.11	-3.61	-3.99	-4.33	-4.98
95% CI	-6.22 to -2.01	-5.80 to -1.41	-6.25 to -1.73	-6.68 to -1.98	-7.54 to -2.41
P value	0.000	0.001	0.001	0.000	0.000

Note: Each marginal effect represents the % change of being in the financial incentive group compared to the control group at each visit compared to the visit 1 (interaction term Visit * Financial incentive). Visit 1 is the reference category.

Supplementary Table 4. Effect of the intervention on the probability of having used NRT in the past 30 days and intervention by NRT use interaction.

	Visit 2	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
Effect of the intervention on the probability of having used NRT					
OR	1.13	0.81	0.55	0.66	0.85
95% CI	0.73 to 1.75	0.52 to 1.27	0.35 to 0.86	0.41 to -1.05	0.50 to 1.46
P value	0.589	0.361	0.008	0.079	0.562
Intervention by NRT use interaction					
OR	1.12	2.29	1.60	0.96	0.57
95% CI	0.37 to 3.35	0.87 to 6.04	0.62 to 4.12	0.35 to 2.60	0.17 to 1.94
P-value	0.843	0.093	0.333	0.930	0.371
N	392	347	320	285	222

Supplementary Table 5. No-show-up by groups.

Financial incentives vs. control group	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
OR	0.775	0.818	0.710	0.720	0.769
95% CI	0.46 to 1.30	0.53 to 1.25	0.48 to 1.06	0.50 to 1.05	0.53 to 1.11
P-value	0.336	0.357	0.093	0.088	0.161

Supplementary Table 6. Number of poor neonatal outcomes.

Poor neonatal outcomes	Financial Incentive (N=202)	Control (N=209)
Transfer to neonatal unit	2	12
Congenital malformation	2	4
Convulsions	0	0
Perinatal death	0	3

Supplementary Table 7.Unadjusted and adjusted analyses of the probability of having a newborn with a birthweight ≥2500 g.

	(1) Unadjusted	(2) Adjusted for newborn's sex	(3) Adjusted for sex and prematurity
Financial incentives vs. control			
OR	1.95	2.05	2.06
SE	(0.68)	(0.72)	(0.87)
95% CI	0.99 to 3.85	1.03 to 4.10	0.90 to 4.71
P-value	0.055	0.041	0.086

Notes: Prematurity is defined as being born before 37 weeks of gestational age[22]. The odds ratios (95% confidence intervals) for sex are 1.39 (0.71 to 2.69) and 1.30 (0.58 to 2.89) for models 2 and 3 respectively. The odds ratio (95% confidence intervals) for prematurity is 0.03 (0.01 to 0.07) for the model 3.

Supplementary Table 8. List of serious adverse events as declared by the investigators and recorded by the trial's pharmacovigilance system.

Serious adverse events	**Financial Incentives N=231**	**Control N=229**
Number of serious adverse events	29	26
Miscarriage	3	2
Placenta praevia		1
Preterm rupture of membranes	3	1
Chest pain	1	
Metrorrhagia with stitching		1
Threat of preterm delivery with hospital stay	5	7
Hellp syndrome		1
Deletion of the long arm of chromosome 12		1
Trisomy 21		1
Reduced fetal movements	2	
Headache/migraine		2
Chorioamniotitis	1	
Stillbirth		2
Preeclampsia	2	
Urinary infection	1	
Medical abortion because of Trisomy 21	1	
Uterine atony	1	
Birth at 22 weeks of amenorrhea	1	
Proteinuria (isolated)		2
Medical abortion	1	
Annexectomy		1
Perforated appendicitis	1	
Type 1 diabetes with nephrotic syndrome and fetal growth restriction		1

Fetal growth restriction	2	
Fetal compression by maternal kidney		1
Fetal malformation		1
Congenital ear malformation	1	1
Emergency C section	1	
Pyelonephritis	1	
Infection syndrome with preterm birth	1	